DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9929]

RIN 1545–BP47

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB93

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147 and 158

[CMS–9915–F]

RIN 0938–AU04

Transparency in Coverage

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The final rules set forth requirements for group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request to a participant, beneficiary, or enrollee (or his or her authorized representative), including an estimate of the individual's cost-sharing liability for covered items or services furnished by a particular provider. Under the final rules, plans and issuers are required to make this information available on an internet website and, if requested, in paper form, thereby allowing a participant, beneficiary, or enrollee (or his or her authorized representative) to obtain an estimate and understanding of the individual's out-of-pocket expenses and effectively shop for items and services. The final rules also require plans and issuers to disclose in-network provider negotiated rates, historical out-of-network allowed amounts, and drug pricing information through three machine-readable files posted on an internet website, thereby allowing the public to have access to health coverage information that can be used to understand health care pricing and potentially dampen the rise in health care spending. The Department of Health and Human Services (HHS) also finalizes amendments to its medical loss ratio (MLR) program rules to allow issuers offering group or individual health insurance coverage to receive credit in their MLR calculations for savings they share with enrollees that result from the enrollees shopping for, and receiving care from, lower-cost, higher-value providers.

DATES:

Effective date: The final rules are effective on January 11, 2021.

Applicability date: See the **SUPPLEMENTARY INFORMATION** section for information on the applicability dates.

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Customer Service Information: Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1–866–444–EBSA (3272) or visit DOL's website (*http://www.dol.gov/ebsa*). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*) and information on health reform can be found at *http://www.healthcare.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The final rules require group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request, to a participant, beneficiary, or enrollee, which, unless otherwise indicated, for the purpose of the final rules includes an authorized representative, and require plans and issuers to disclose in-network provider rates, historical out-of-network allowed amounts and the associated billed charges, and negotiated rates for prescription drugs in 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 147. HHS also finalizes amendments to its MLR program rules in 45 CFR part 158.

A. Statutory Background and Enactment of PPACA

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010 (collectively, PPACA). As relevant here, PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service (PHS) Act relating to health coverage requirements for group health plans and health insurance issuers in the group and individual markets. The term group health plan includes both insured and self-insured group health plans.

PPACA also added section 715 to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815 to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act, PHS Act sections 2701 through 2728, into ERISA and the Code, making them applicable to group health plans, and health insurance issuers providing coverage in connection with group health plans.

1. Transparency in Coverage

Section 2715A of the PHS Act provides that group health plans and health insurance issuers offering group or individual health insurance coverage must comply with section 1311(e)(3) of PPACA, which addresses transparency in health coverage and imposes certain reporting and disclosure requirements for health plans that are seeking certification as qualified health plans (QHPs) that may be offered on an Exchange. A plan or coverage that is not offered through an Exchange (as defined by section 1311(b)(1) of PPACA) is required to submit the information required to the Secretary of HHS and the relevant state's insurance commissioner, and to make that information available to the public.

Paragraph (A) of section 1311(e)(3) of PPACA requires a plan seeking certification as a QHP to make the following information available to the public and submit it to state insurance regulators, the Secretary of HHS, and the Exchange:

- Claims payment policies and practices,
- periodic financial disclosures,
- data on enrollment,
- data on disenrollment,
- data on the number of claims that are denied,
- data on rating practices,
- information on cost-sharing and payments with respect to any out-of-network coverage, and
- information on enrollee and participant rights under Title I of PPACA.

Paragraph (A) also requires a plan seeking certification as a QHP to submit any ''[o]ther information as determined appropriate by the Secretary.''

Paragraph (C) of section 1311(e)(3) of PPACA requires plans, as a requirement of certification as a QHP, to permit individuals to learn the amount of cost sharing (including deductibles, copayments, and coinsurance) under the individual's coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by an in-network provider in a timely manner upon the request of the individual. Paragraph (C) specifies that, at a minimum, such information must be made available to the individual through an internet website and through other means for individuals without access to the internet.

Together these statutory provisions require the overriding majority of private health plans [1] to disseminate a substantial amount of information to provide transparency in coverage. The portions of the final rules that require plans and issuers to disclose cost-sharing information upon request, to a participant, beneficiary, or enrollee implement paragraph (C) of section 1311(e)(3) of PPACA. The portions of the final rules that require plans and issuers to disclose in-network provider rates, historical out-of-network allowed amounts and the associated billed charges, and negotiated rates for prescription drugs implement paragraph (A) of section 1311(e)(3) of PPACA. The requirements to disclose out-of-network allowed amounts specifically implements the requirement in section 1311(e)(3)(A)(vii) to provide information on ''payments with respect to any out-of-network coverage.'' In addition to payment information on out-of-network charges, the Secretary of HHS determined that payment information on in-network rates and prescription drugs is also appropriate information to require plans and issuers to disclose to provide transparency in coverage under section 1311(e)(3)(A)(ix).

PPACA's transparency in coverage requirements were enacted in coordination with a set of requirements that transformed the regulation of private market health plans and issuers. These requirements for the first time apply a comprehensive framework for regulating private health coverage through Federal law.[2] Prior to PPACA, Federal law relied on states to be the primary regulators of health insurance, but applied only a limited set of Federal requirements to govern private health coverage. Where Federal law regulated private health coverage, there was a substantial variation in how these regulations applied, depending on whether private health coverage was self-insured group coverage, large group insurance coverage, small group insurance coverage, or individual insurance coverage. To establish a comprehensive framework for regulating private health coverage, PPACA first set out a series of requirements on ''Improving Coverage'' that generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage.[3] These requirements ranged from the prohibition on lifetime or annual dollar limits in section 2711 of the PHS Act to the requirement to cover out-of-network emergency services in section 2719A of the PHS Act and include the transparency in coverage requirements in section 2715A of the PHS Act.[4] By including transparency in coverage in this set of requirements that apply to most private coverage, Congress established transparency as a key component to PPACA's comprehensive framework for regulating private health coverage.[5]

On March 27, 2012, HHS issued the Exchange Establishment final rule that implemented sections 1311(e)(3)(A) through (C) of PPACA at 45 CFR 155.1040(a) through (c) and 156.220.[6] The Exchange Establishment final rule created standards for QHP issuers to submit specific information related to transparency in coverage. QHPs are required to post and make data related to transparency in coverage available to the public in plain language and submit this same data to HHS, the Exchange, and the relevant state insurance commissioner. In the preamble to the Exchange Establishment final rule, HHS noted that ''health plan standards set forth under the final rules are, for the most part, strictly related to QHPs certified to be offered through the Exchange and not the entire individual and small group market. Such policies for the entire individual and small and large group markets have been, and will continue to be, addressed in separate rulemaking issued by HHS, and the Departments of Labor and the Treasury.''

2. Medical Loss Ratio

Section 2718(a) of the PHS Act, as added by PPACA, generally requires health insurance issuers offering group or individual health insurance coverage (including a grandfathered health insurance plan) to submit an annual report to the Secretary of HHS that details the percentage of premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under health coverage and on activities that improve health care quality. The proportion of premium revenue spent on clinical services and quality improvement activities is called the MLR. Section 2718(b) of the PHS Act requires an issuer to provide annual rebates to enrollees if its MLR falls below specified standards (generally 80 percent for the individual and small group markets, and 85 percent for the large group market). HHS published an interim final rule to implement the MLR program in the December 1, 2010 **Federal Register** (75 FR 74863). A final rule was published in the December 7, 2011 **Federal Register** (76 FR 76573). The MLR program requirements were amended in final rules published in the December 7, 2011 **Federal Register** (76 FR 76595), the May 16, 2012 **Federal Register** (77 FR 28790), the March 11, 2014 **Federal Register** (79 FR 13743),

[1] As of 2018, private, non-grandfathered health plans that must comply with these statutory provisions covered more than 92 percent of the almost 177 million people covered by private health coverage. The remaining 7.7 percent were covered by grandfathered health plans or were enrolled in short-term limited duration coverage or health care sharing ministries. *See* Kaiser Family Foundation, Health Insurance Coverage of the Total Population in 2018, *https://www.kff.org/other/state-indicator/total-population/?dataView=1&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D*, last accessed October 5, 2020.

[2] *See* Jost, T.S. ''Loopholes in the Affordable Care Act: Regulatory gaps and border crossing techniques and how to address them.'' St. Louis University Journal of Health Law and Policy, Washington & Lee Legal Studies Paper No. 2011–16. August 15, 2011 (explaining that ''[t]he Affordable Care Act was meant to regulate health care plans comprehensively'' and providing further details on the scope of PPACA). Available at: *https://scholarlycommons.law.wlu.edu/wlufac/265/*.

[3] Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119 (2010), section 1001.

[4] In addition to these requirements, PPACA's ''Improving Coverage'' requirements include, among other things: The prohibition on rescissions in section 2712 of the PHS Act; the requirement to cover preventive health services without cost sharing requirements in section 2713 of the PHS Act; the extension of coverage to dependents up to age 26 in section 2714 of the PHS Act; the requirement to provide a summary of benefits and coverage in section 2715 of the PHS Act; quality reporting requirements in section 2717 of the PHS Act; and appeals process requirements in section 2719 of the PHS Act.

[5] Transparency was included as an important and transformative element in other leading comprehensive health reform proposals. *See* Porter, M. and Teisberg, E. *Redefining Health Care.* Harvard Business School Press. Boston, MA. 2006. (''Perhaps the most fundamental role of government in enabling value-based competition is to ensure that universal, high-quality information on provider outcomes and prices for every medical condition is collected and disseminated. This single step will have far-reaching and pervasive effects throughout the system . . . .'').

[6] 77 FR 18310 (Mar. 27, 2012).

the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), the April 25, 2019 **Federal Register** (84 FR 17454), and the February 6, 2020 **Federal Register** (85 FR 7088).

B. Benefits of Transparency in Health Coverage and Past Efforts To Promote Transparency

PPACA's transparency in coverage requirements can help ensure the accurate and timely disclosure of information appropriate to support an efficient and competitive health care market. A well-functioning, competitive market depends on information being available to buyers and sellers.[7] As President Trump's ''Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First'' explains: ''To make fully informed decisions about their health care, patients must know the price and quality of a good or service in advance.'' Yet, as the Executive order then notes, ''patients often lack both access to useful price and quality information and the incentives to find low-cost, high-quality care.'' The lack of this information is widely understood to be one of the root problems causing dysfunction within America's health care system.

The Departments of Labor, HHS, and the Treasury (Departments) are of the view that transparency in health coverage requirements will strengthen America's health care system by giving health care consumers, researchers, regulators, lawmakers, health innovators, and other health care stakeholders the information they need to make, or assist others in making informed decisions about health care purchases. Health care consumers include various persons and entities that finance health care needs through the purchase of insurance. Health care consumers also include uninsured persons without health coverage who must pay out-of-pocket for health care items and services and uninsured persons who may be shopping for health coverage. Employers that sponsor health plans for their employees and government programs that provide health care services and benefits to consumers are also health care consumers.

By requiring the dissemination of price and benefit information directly to consumers and to the public, the transparency in coverage requirements will provide the following consumer benefits:

- Enables consumers to evaluate health care options and to make cost-conscious decisions;
- strengthens the support consumers receive from stakeholders that help protect and engage consumers;
- reduces potential surprises in relation to individual consumers' out-of-pocket costs for health care services;
- creates a competitive dynamic that may narrow price dispersion for the same items and services in the same health care markets; and
- puts downward pressure on prices which, in turn, potentially lowers overall health care costs.

The goal of the final rules is to deliver these benefits to all consumers and health care stakeholders through greater transparency in coverage.

Comments received in response to the proposed rules on transparency in coverage (discussed in more detail later in this preamble) have strengthened the Departments' view that this price transparency effort will equip the public with information to actively and effectively participate in the health care system as consumers.[8] The majority of commenters acknowledged the importance of the availability of health care pricing information and appropriate tools to assist consumers in health care decision-making and managing health care costs. For these reasons and those explained in more detail below in this preamble, the Departments continue to be of the view that price transparency efforts are crucial to providing consumers (individual and institutional) with meaningful and actionable pricing information in an effort to contain the growth of health care costs.

1. Transparency Provides Necessary Information for Consumers To Make More Informed Health Care Spending Decisions

As explained in the report, ''Reforming America's Healthcare System Through Choice and Competition,'' consumers have an important role to play in controlling costs, but consumers must have meaningful information in order to create the market forces necessary to achieve lower health care costs.[9] When consumers seek care, they do not typically know whether they could have received the same service from another provider at lower prices. Third-party payers negotiate prices on the consumer's behalf and reimburse costs directly to health care providers, concealing the actual price from the consumer at the point of care. After receiving care, consumers typically receive an Explanation of Benefits (EOB), which details the price charged by the provider, contracted or negotiated rate, and consumer cost sharing. Often, only after services are rendered is the cost of care disclosed to the consumer.

Historically, there has been little to no incentive for some consumers to consider price and seek lower-cost care.[10] Rapidly rising health care spending in the past 20 years, however, has led to consumers shouldering a greater portion of their health care costs through increases in out-of-pocket expenses.[11]

Since 1970, per capita out-of-pocket expenditures have nearly doubled due to a number of factors.[12] These factors include increased enrollment in high deductible health plans (HDHPs) and accompanying health savings accounts (HSAs), and increased plan and issuer reliance on payments towards deductibles comprising the proportion of total cost-sharing payments.[13] As explained in the preamble to the proposed rules, these shifts in plan design and enrollment are correlated with consumers bearing a greater share of their overall health care costs in the private health insurance market than in previous years.[14] From 2002 to the enactment of PPACA in 2010,

[7] Porter, M. and Teisberg, E. *Redefining Health Care.* Harvard Business School Press. Boston, MA. 2006, pg. 54. (''Information is fundamental to competition in any well-functioning market. It enables buyers to shop for the best value and allows sellers to compare themselves to rivals. Without relevant information, doctors cannot compare their results to best practice and to other providers. And without appropriate information, patient choice has little meaning.'').

[8] 84 FR 65464 (Nov. 27, 2019).

[9] Azar, A.M., Mnuchin, S.T., and Acosta, A. ''Reforming America's Healthcare System Through Choice and Competition.'' United States, Department of Health and Human Services. December 3, 2018. Available at: *https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.*

[10] *Id.*

[11] Claxton, G., Levitt, L., Long M. ''Payments for cost sharing increasing rapidly over time.'' Peterson-Kaiser Health System Tracker. April 2016. Available at: *https://www.healthsystemtracker.org/brief/payments-for-cost-sharing-increasing-rapidly-over-time/.*

[12] ''Out-of-pocket spending.'' Peterson-KFF Health System Tracker. May 2020. Available at: *https://www.healthsystemtracker.org/indicator/access-affordability/out-of-pocket-spending/.*

[13] HDHP as defined in section 223(c)(2) of the Code; *see also* Claxton, G., Levitt, L., Long, M. ''Payments for cost sharing increasing rapidly over time.'' Peterson-KFF Health System Tracker. April 2016. Available at: *https://www.healthsystemtracker.org/brief/payments-for-cost-sharing-increasing-rapidly-over-time/.*

[14] 84 FR 65464, 65465 (Nov. 27, 2019).

nationally, the percentage of private sector employees enrolled in a health plan with a deductible increased from 47.6 percent to 77.5 percent and continued to increase to 86.6 percent in 2019.[15] Average family deductibles for private sector employees grew from $958 in 2002 to $1,975 in 2010, and then to $3,655 in 2019—an 85 percent increase since the enactment of PPACA.[16] These changes represent a substantial increase in the amount that consumers must pay for health care before insurance begins to cover items or services.[17] Deductibles made up 52 percent of cost-sharing spending in 2016, up from 30 percent in 2006, while copays dropped from 43 percent to 17 percent of cost-sharing payments over the same period.[18] The gradual shift away from copayments, which are predictable to the consumer through their set dollar amounts for each covered item or service, to deductibles and coinsurance, has increased the need for consumers to know the negotiated price in order to plan ahead and budget for out-of-pocket costs. Over time, price disclosure can improve consumers' ability to better manage costs of utilized health care for a variety of health care plans. Increased enrollment in HDHPs and the shift to coinsurance across plan and benefit designs means that consumers have a vested interest in learning the costs of care prior to paying for items or services, as they are responsible for paying out-of-pocket expenditures, which are directly dependent on the negotiated or contractual price.

These trends in designing health plans have led to consumers bearing an increased share of their health care costs. The fact that more consumers are bearing greater financial responsibility for the cost of their health care provides an opportunity to establish a more consumer-directed and consumer-driven health care market. Eighty-eight percent of consumers support requirements for providers and issuers to disclose prices prior to care.[19] If consumers have better pricing information and can shop for health care items and services more efficiently, they can increase competition and demand for lower prices.[20] However, consumers generally have little information regarding negotiated rates or out-of-network costs until after services are rendered. There is also wide variability in health care prices for the same service.[21] As a result, it can be difficult for consumers to estimate potential out-of-pocket costs.

2. Transparency Strengthens Stakeholders' Ability To Support Consumers

Making price transparency information publicly available strengthens the work of other health care stakeholders that help provide care or promote access to care to consumers, or otherwise aim to protect consumers and their interests in the health care system. These entities include researchers, regulators, lawmakers, patient and consumer advocates, and businesses that provide consumer support tools and services. A key aspect of transparency in coverage is to make health care pricing information more accessible and useful to consumers by making the information available to persons and entities with the requisite experience and expertise to assist individual consumers and other health care purchasers to make informed health care decisions.

With information on pricing, these other health care stakeholders can better fulfill each of the unique roles they play to improve America's health care system for consumers. For instance, with pricing information researchers could better assess the cost-effectiveness of various treatments; state regulators could better review issuers' proposed rate increases; patient advocates could better help guide patients through care plans; employers could adopt incentives for consumers to choose more cost-effective care; and entrepreneurs could develop tools that help doctors better engage with patients.

3. Transparency Reduces the Potential for Surprise Billing

Making the price of care available to consumers before they receive care can reduce the potential for consumers to be surprised by the price of a health care item or service when they receive the bill after receiving care. However, accessible pricing information holds special value for insured consumers.[22] Surprise billing has become a substantial concern for insured consumers, in particular, consumers who receive a bill from an out-of-network provider when they thought an in-network provider was treating them. While price transparency alone is not a complete solution to this problem, the disclosure of pricing directly to consumers could help mitigate some unexpected health care costs. As just noted, making pricing information public can also strengthen other health care stakeholders' ability to protect consumers. In the case of surprise billing, public information on pricing for in-network and out-of-network services could allow stakeholders to develop better tools to help patients avoid surprises and improve oversight of health insurance issuers, plans, and providers.

4. Transparency Increases Competition and Contains Costs

Without transparency in pricing, market forces cannot drive competition. This lack of competition in many health care markets is demonstrated by significant, unexplained variations in prices for procedures, even within a single region.[23] For example, studies of price variation within California and nationally suggest that there is substantial opportunity for increased transparency to save money by shifting patients from high to lower-cost providers.[24] The Departments are of the

[15] *See* ''Medical Expenditure Panel Survey. Insurance Component National-Level Summary Tables.'' United States Department for Health and Human Services Agency for Healthcare Research and Quality. Available at: *https://www.meps.ahrq.gov/mepsweb/data_stats/quick_tables_search.jsp?component=2&subcomponent=1.*

[16] *Id.*

[17] McCarthy-Alfano, M., et al. ''Measuring the burden of health care costs for working families.'' Health Affairs. April 2, 2019. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20190327.999531/full/.*

[18] Claxton, G. et al. ''Increases in cost-sharing payments continue to outpace wage growth.'' Peterson-KFF Health System Tracker. June 15, 2018. Available at: *https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/.*

[19] ''Harvard CAPS Harris Poll.'' Harvard University. May 2019. Available at: *https://harvardharrispoll.com/wp-content/uploads/2019/06/HHP_May19_vF.pdf?utm_source=hs_email&utm_medium=email&_hsenc=p2ANqtz--NgSdTYggGUP4tWyR2IEQ7i8TCg1s3DcHuQyhErIgkX3KFUi3SFgl9OZKm4-JUOOi9tmMQ.*

[20] Azar, A.M., Mnuchin, S.T., and Acosta, A. ''Reforming America's Healthcare System Through Choice and Competition.'' United States, Department of Health and Human Services. December 3, 2018. Available at: *https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.*

[21] Cooper, Z., et al. ''The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured.'' *The Quarterly Journal of Economics,* Vol. 134. Issue 1. February 2019. September 4, 2018. Available at: *https://academic.oup.com/qje/article/134/1/51/5090426?searchresult=1.*

[22] *See* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Secretary of Health and Human Services' Report on: Addressing Surprise Medical Billing, at p. 3. July 2020. (recognizing that HHS regulatory action to encourage price transparency by insurers ''can serve as the backbone for a more comprehensive surprise billing solution''). Available at *https://aspe.hhs.gov/system/files/pdf/263871/Surprise-Medical-Billing.pdf.*

[23] *Id.*

[24] Boynton, A., Robinson, J. ''Appropriate Use of Reference Pricing Can Increase Value.'' Health Affairs Blog. July 7, 2015. Available at: *https://www.healthaffairs.org/do/10.1377/*

Continued

view that consumers will take advantage of increased transparency to shop for their health care if price transparency is put into place nationwide.[25] Many empirical studies have investigated the impact of price transparency on non-health care markets, with most research showing that ''price transparency leads to lower and more uniform prices, a view consistent with predictions of standard economic theory.'' [26] Studies suggest that consumers want and will use actionable pricing information to shop for more cost-effective care.[27] For example, when automobile prices were presented transparently on the internet, inclusive of the dealer invoice price, the consumers who did not like the traditional bargaining process were able to reduce spending overall by 1.5 percent.[28] Another study demonstrated the public display of life insurance prices for comparison led to a 5 percent decrease in the consumer price.[29] Price transparency also reduced price dispersion across other markets, such as the airline industry, which saw a reduction in price dispersion from 18 percent in 1997 narrowing to 0.3–2.2 percent in 2002 for fares available at multiple travel websites.[30] These lessons from other markets suggest that more thoroughly implementing price transparency across the health care industry could increase competition to provide lower costs and limit price variation.[31]

Despite the general absence of price transparency in the health care sector, there is research showing how price transparency leads to lower and more uniform pricing in health care markets. For instance, as noted in the preamble to the proposed rule, research shows patients saved $7.9 million and issuers saved $36 million on imaging services in New Hampshire after the state launched a website publishing health prices for most consumers with private health insurance.[32] One study found use of a telephone- and email-based tool to search for health care prices reduced the price paid by 10 to 17 percent and reduced the prices paid for care on average by 1.6 percent.[33] Another study of a program that provided health plan participants, beneficiaries, or enrollees with price and quality information to help select high-value imaging services found an increase in the use of lower-cost facilities.[34] This consumer behavior prompted higher-cost facilities to lower their prices, which resulted in a 30 percent reduction in the price variation between low- and high-cost facilities.[35] These studies, as well the numerous studies highlighted in subsequent sections of this rule, offer substantial evidence that price transparency in health care markets will result in consumer benefits similar to those that result from transparency in other markets.

5. The Final Rules Will Fill Gaps Left by State and Private Transparency Efforts

Currently, the information that consumers need to make informed decisions based on the prices of health care services is not readily available or is presented in a manner that makes it challenging to understand. As noted in the preamble to the proposed rules, the 2011 Government Accountability Office (GAO) report, ''Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care,'' found that the lack of transparency in health care prices, coupled with the wide pricing disparities for particular procedures within the same market, can make it difficult for consumers to understand health care prices and to shop effectively based on cost.[36] The report also explored various price transparency initiatives, including tools that consumers could use to generate price estimates before receiving a health care service. The report notes that pricing information displayed by tools varies across initiatives, in large part due to limits reported by the initiatives in their access or authority to collect certain necessary price data. In particular, the report notes the lack of public disclosure of rates negotiated between providers and third-party payers. The GAO report, therefore, recommended that HHS determine the feasibility of, and the next steps for, making estimates of out-of-pocket costs for health care services available to consumers.

States have been at the forefront of transparency initiatives and have adopted a variety of approaches to improve price transparency.[37] More than half of the states have passed legislation establishing price transparency websites or mandating that health plans, hospitals, or physicians make pricing information available to patients.[38] For example, as of September 2020, thirty one states have enacted laws that provide participants, beneficiaries, and enrollees with at least partial protection against the practice of ''balance billing.'' [39] At least eighteen states have All-Payer Claims Databases. However, state transparency requirements are generally not applicable to self-insured group health plans, which cover approximately 58.7

hblog20150707.049155/full/; *see also* Sinaiko, A., Rosenthal, M. ''Examining a Health Care Price Transparency Tool: Who Uses it, and How They Shop for Care.'' 35 Health Affairs 662. April 2016. Available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.0746*.

[25] *See* Gordon, D., et al. ''Health Care Consumer Shopping Behaviors and Sentiment: Qualitative Study.'' Journal of Participatory Medicine. Volume 12. No. 2. 2020. Available at: *https://jopm.jmir.org/2020/2/e13924/* (study demonstrating that consumers already engage in ''behaviors related to seeking, comparing, or knowing the prices of care'' regardless of the presence of price transparency tools).

[26] Austin, D.A., and Gravelle, J.G. ''Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector.'' United States Congress Congressional Research Service. April 29, 2008. Available at: *https://crsreports.congress.gov/product/pdf/RL/RL34101*; *see also* Grennan, M., Swanson, A. ''Transparency and Negotiated Prices: The Value of Information in Hospital-Supplier Bargaining.'' 128 Journal of Political Economy. April 2020 (Citing research in consumer goods showing that information can help decision making when buyers have imperfect information on costs.). Available at: *https://www.nber.org/papers/w22039*; *see also* 84 FR 65464, 65466 (Nov. 27, 2019).

[27] Semigran, H.L., et al. ''Patients' Views on Price Shopping and Price Transparency.'' The American Journal of Managed Care. June 26, 2017. Available at: *https://www.ajmc.com/view/patients-views-on-price-shopping-and-price-transparency*.

[28] Zettlemeyer, F., Morton, F.S., and Silva-Risso, J. ''How the internet Lowers Prices: Evidence from Matched Survey and Automobile Transaction Data.'' Journal of Marketing Research. May 2006. Available at: *https://doi.org/10.1509%2Fjmkr.43.2.168*.

[29] Brown, J., and Goolsbee, A. ''Does the internet Make Markets More Competitive? Evidence from the Life Insurance Industry.'' Journal of Political Economy, vol. 110, June 2002, pp. 481–507.

[30] Clemons, E.K., Hann, I., and Hitt, L. ''Price Dispersion and Differentiation in Online Travel: An Empirical Investigation,'' Management Science, vol. 48, no. 4, 2001, pp. 521–39; *see also* ''Occupational Labor Statistics.'' United States Bureau of Labor Statistics. Available at: *https://www.bls.gov/oes/current/oes_stru.htm*.

[31] 84 FR 65464, 65466 (Nov. 27, 2019).

[32] *Id.*

[33] Lieber, E. ''Does It Pay to Know Prices in Health Care?'' American Economic Journal: Economic Policy. February 2017. Available at *https://pubs.aeaweb.org/doi/pdfplus/10.1257/pol.20150124*.

[34] Wu, S.J. et al. ''Price transparency for MRIs increased use of less costly providers and triggered provider competition.'' Health Affairs. August 2014. Available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0168*.

[35] *Id.*

[36] 84 FR 65464, 65466–65467 (Nov. 27, 2019); *see also* GAO–11–791 at p. 28 (Sep. 2011).

[37] De Brantes, F., et al. ''Price Transparency & Physician Quality Report Card 2017.'' Catalyst for Payment Reform. Available at: *https://www.catalyze.org/product/2017-price-transparency-physician-quality-report-card/*.

[38] Frakt, A., and Mehrotra, A. ''What Type of Price Transparency Do We Need in Health Care?'' Annals of Internal Medicine. April 16, 2019. Available at: *https://www.acpjournals.org/doi/10.7326/M19*.

[39] Kona, M. ''State Balance-Billing Protections.'' The Commonwealth Fund. September 16, 2020. Available at: *https://www.commonwealthfund.org/publications/maps-and-interactives/2020/sep/state-balance-billing-protections*.

percent of private-sector workers.[40] As a result, the data collected under state law does not include data from self-insured plans, and a significant portion of consumers may not have access to information on their plans.

In response to state action and consumer demands for more information on health care pricing, and to align with increased price transparency in other markets, health insurance issuers and self-insured plans have moved to increase price transparency. For example, some plans are using price transparency tools to incentivize employees to make cost-conscious decisions when purchasing health care services. Most large issuers have comparative cost information, which includes rates that plans and issuers have negotiated with in-network providers and suppliers.

However, many existing tools are either insufficient in the amount of detail they provide or the level of accuracy available. In order to expand price transparency to all consumers, Federal action is therefore necessary to establish standards and universal access to this information. In preparation for writing the proposed rules, the Departments met with over 50 stakeholders including plans, issuers, and third-party tool developers. Several stakeholders provided demonstrations of their tools to the Departments. The Departments note that over 90 percent of plans offer some version of a price comparison tool.[41] However, many of the plans and issuers that the Departments met with, who did not have a tool serve large portions of participants, beneficiaries, and enrollees. It is therefore the Departments' understanding that there are still millions of insured Americans that do not have access to any type of health care pricing tool. Also based on these demonstrations, the Departments are of the view that many price transparency tools on the market only offer wide-range estimates or average estimates of pricing that use historical claims data and do not always take into account the accumulated amount a participant, beneficiary, or enrollee has paid toward their deductible or out-of-pocket limit (sometimes referred to as an ''accumulator''). The Departments are of the view that wide-range estimates are of limited value to consumers, given that they may not accurately reflect an individual's plan design and benefits, and that ranges should be replaced by actual estimated out-of-pocket costs, in order to allow the consumer to meaningfully predict costs. In addition, the inclusion of negotiated rates in these tools could help show the changes to a participant's, beneficiary's, or enrollee's costs if they have a future need for the same service, conditioned on the level of fulfillment of any cost-sharing responsibilities. This could help the consumer better understand the full value of the health care they are considering and how the cost may be different in the future when the participant's, beneficiary's, or enrollee's accumulator resets in a new plan year. Information on quality and results are also important for assessing the value of care.[42] Through this increased availability of information and consumer comprehension, transparent pricing can apply pressure on providers to demonstrate and improve quality and health care results. Providers may likely then be in the position of having to justify their costs relative to alternative options.

The Departments are of the view that existing price transparency tools often function in a way that makes them difficult for users to navigate. These tools often display information that makes it difficult to compare one plan against another, understand the scope of services covered and their costs, and interpret the terminology plans and issuers use. Consumers may be discouraged by these difficult user interfaces and may be less likely to make fully informed decisions with their healthcare choices. Research demonstrates that poor or confusing user interfaces will lead users to abandon engagement with the hosting website.[43] The Departments are of the view that it is important to establish a minimum set of standards regarding what is acceptable so that consumers can fully utilize all relevant information. Tools that provide consistent information to every consumer across all markets, and that base cost estimates on accurate and recent information, will be a significant improvement over all or most existing options. Accuracy and consistency are intended to give consumers confidence that the information presented by these tools will not change significantly from the prices they are ultimately charged. Reliability should assure consumers that information in these tools accurately reflects plans' and issuers' best estimates of consumer out-of-pocket costs. The availability of these tools across most private markets will ensure broad access for all participants, beneficiaries, or enrollees to the intended outcomes and potential benefits of the final rules. The Departments anticipate that participants, beneficiaries, and enrollees will become accustomed to having access to this standardized information, no matter what private market plan or coverage they choose, which will make them more comfortable with using this information in health care purchasing decisions. The Departments further anticipate and encourage plans and issuers to include additional functionality and innovation in existing price transparency tools, but a baseline is necessary to give participants, beneficiaries, and enrollees the confidence that, regardless of the tool they use, they can expect the same standard information and functionality.

C. Stakeholder Feedback and Prior Actions in Support of Transparency

In the HHS 2020 Notice of Benefit and Payment Parameters (2020 Payment Notice) proposed rule,[44] HHS sought input on ways to provide consumers with greater transparency regarding their own health care data, QHP offerings on the Federally-facilitated Exchanges (FFEs), and the cost of health care services.[45] Additionally, HHS sought comment on ways to further implement section 1311(e)(3) of PPACA, as implemented by 45 CFR 156.220(d), under which, upon the request of an enrollee, a QHP issuer must make available in a timely manner the amount of enrollee cost sharing under the enrollee's coverage for a specific service furnished by an in-network provider. HHS was particularly interested in what types of data would be most useful to improving consumers' abilities to make informed health care decisions, including decisions related to their coverage specifications and ways to

[40] ''Report to Congress: Self-Insured Health Benefit Plans 2019: Based on Filings through Statistical Year 2016.'' March, 2019. Available at: *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2019.pdf*; *see also* Fronstin, P. ''Self-Insured Health Plans: Recent Trends by Firm Size 1996–2018.'' Employee Benefit Research Institute. No. 488. August 1, 2019. Available at: *https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_488_selfinsur-1aug19.pdf?sfvrsn=bd7e3c2f_6*.

[41] ''Study: Health Plans Implement Price Transparency Tools for Consumers.'' ACA International. April 2016. Available online at: *https://www.expressrecovery.com/file/86c228ef-245f-45cb-abd7-a30edbdec1f3*.

[42] See additional discussion of quality information in section II.C.1 of the preamble.

[43] Georgiou, M. ''User Experience Is the Most Important Metric You Aren't Measuring.'' Entrepreneur. March 1, 2018. Available at: *https://www.entrepreneur.com/article/309161*.

[44] 84 FR 227 (Jan. 24, 2019).

[45] The term ''Exchanges'' means American Health Benefit Exchanges established under section 1311 of PPACA. *See* section 2791(d)(21) of the PHS Act.

improve consumer access to information about health care costs.

Commenters on the 2020 Payment Notice overwhelmingly supported the idea of increased price transparency. Many commenters provided suggestions for defining the scope of price transparency requirements, such as providing costs for both in-network and out-of-network health care, and providing health care cost estimates that include an accounting for consumer-specific benefit information, like progress toward meeting deductibles and annual limitations on cost sharing, as well as remaining visits under visit limits. Commenters expressed support for implementing price transparency requirements across all private markets and for price transparency efforts to be a part of a larger payment reform effort and a provider empowerment and patient engagement strategy. Some commenters advised HHS to carefully consider how such policies should be implemented, warning against Federal duplication of state efforts and requirements that would result in plans and issuers passing along increased administrative costs to consumers and cautioning that the proprietary and competitive nature of payment data should be protected.

In the summer and fall of 2018, HHS hosted listening sessions related to the goal of empowering consumers by ensuring the availability of useable pricing information. The listening sessions included a wide representation of stakeholders including providers, issuers, researchers, and consumer and patient advocacy groups. Attendees noted that currently available pricing tools are underutilized, in part because consumers are often unaware that they exist,[46] and even when used, the tools sometimes convey inconsistent and inaccurate information.

Attendees also commented that tool development could be expensive, especially for smaller health plans, which tend to invest less in technology because of the limited return on investment. Attendees further commented that most tools developed to date do not allow for comparison shopping. Attendees stated that existing tools usually use historical claims data, which results in broad, sometimes regional, estimates, rather than accurate and individualized prices. In a national study, there was alignment among patients, employers, and providers in wanting to know and discuss the cost of care at the point of service.[47] However, attendees noted pricing tools are rarely available when and where consumers are likely to make health care decisions, for example, during interactions with providers. Thus, patients are not able to consider relevant cost issues when discussing referral options or the tradeoffs of various treatment options with referring providers. With access to patient-specific cost estimates for services furnished by particular providers, referring providers and their patients could take pricing information into account when considering clinically appropriate treatment options. Separately, CMS has met with members from several state Departments of Insurance to discuss the limits to state authority to require price transparency in a meaningful way and the benefits and drawbacks of All Payer Claims Databases (APCDs). During these discussions, it became clear that APCDs' reliance on historical claims data that is not necessarily linked to a specific plan or issuer limits the utility of such databases for consumers. These conversations helped clarify the types of price transparency information necessary to empower consumers.

CMS has pursued initiatives in addition to the final rules to improve access to the information necessary to empower consumers to make more informed decisions about their health care costs, including a multi-step effort to implement section 2718(e) of the PHS Act. Section 2718(e) of the PHS Act requires each hospital operating within the United States, for each year, to establish (and update) and make public (in accordance with guidelines developed by the Secretary of HHS) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (SSA). In the Fiscal Year (FY) 2015 Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) proposed and final rules, CMS reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the PHS Act and provided guidelines for its implementation.[48] At that time, CMS required hospitals to either make public a list of their standard charges or their policies for allowing the public to view a list of those charges in response to an inquiry. In addition, CMS stated that it expected hospitals to update the information at least annually, or more often as appropriate, to reflect current charges. CMS also encouraged hospitals to undertake efforts to engage in consumer-friendly communication of their charges to enable consumers to compare charges for similar services across hospitals and to help them understand what their potential financial liability might be for items and services they obtain at the hospital.

In the FY 2019 IPPS/LTCH PPS proposed and final rules, CMS again reminded hospitals of their obligation to comply with section 2718(e) of the PHS Act and announced an update to its guidelines.[49] The updated guidelines, which have been effective since January 1, 2019, require hospitals to make available a list of their current standard charges (whether in the form of a ''chargemaster'' or another form of the hospital's choice) via the internet in a machine-readable format and to update this information at least annually, or more often as appropriate.

In response to stakeholder feedback and in accordance with Executive Order 13877, issued on June 24, 2019,[50] CMS took another important step toward improving health care value and increasing competition in the Calendar Year 2020 Hospital Outpatient Policy Payment System (OPPS) Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates: Price Transparency Requirements for Hospitals to Make Standard Charges Public final rule (Hospital Price Transparency final rule) by codifying regulatory requirements that implement section 2718(e) of the PHS Act, as well as a regulatory scheme under section 2718(b)(3) of the PHS Act that enables CMS to enforce those requirements.[51] The price transparency disclosure requirements that CMS finalized in the Hospital Price Transparency final rule will be effective on January 1, 2021, and they require hospitals to make publicly available, as applicable, their gross charges (as found in the hospital's chargemaster), payer-specific negotiated charges, discounted cash prices, and de-identified minimum and maximum negotiated charges for all items and services they provide through a single online machine-readable file that is updated at least once annually. Additionally, the Hospital Price

[46] Miller, S. ''Healthcare Shopping Tools Often Go Unused.'' Society for Human Resource Management. May 19, 2016. Available at: *https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/health-care-shopping.aspx*.

[47] ''Let's Talk About Money.'' University of Utah Health Home. Available at: *https://uofuhealth.utah.edu/value/lets-talk-about-money.php*.

[48] 79 FR 27978, 28169 (May 15, 2014) and 79 FR 49854, 50146 (Aug. 22, 2014), respectively.

[49] 83 FR 20164, 20548 (May 7, 2018) and 83 FR 41144, 41686 (Aug. 17, 2018), respectively.

[50] 84 FR 30849 (Jun. 27, 2019). The Executive order was issued on June 24, 2019 and was published in the **Federal Register** on June 27, 2019.

[51] 84 FR 65524 (Nov. 27, 2019).

Transparency final rule requires hospitals to display online in a consumer-friendly format, as applicable, the payer-specific negotiated charges, discounted cash prices (or, to the extent one does not exist for a shoppable service, the undiscounted gross charge) and de-identified minimum and maximum negotiated charges for as many of the 70 shoppable services selected by CMS that the hospital provides and as many additional hospital-selected shoppable services as are necessary for a combined total of at least 300 shoppable services (or if the hospital provides fewer than 300 shoppable services, then for as many as the hospital provides). The rule defines a shoppable service as a service that can be scheduled by a health care consumer in advance and further explains that a shoppable service is typically one that is routinely provided in non-urgent situations that does not require immediate action or attention to the patient, thus allowing patients to price shop and schedule such a service at a time that is convenient for them.[52]

In addition to making pricing information available for items and services provided by hospitals, the Administration has also been engaged in increasing transparency of prescription drug pricing and lowering the costs of prescription drugs. Four Executive orders direct CMS and other HHS agencies to develop and issue tools, models, and several regulations to increase competition and lower patients' drug costs.[53] The actions directed in these Executive orders supplement those CMS has already taken to increase drug-pricing transparency and lower drug costs. Through the Drug Spending Dashboard, CMS publishes data on Medicare and Medicaid spending for prescription drugs in an interactive web-based tool so researchers and consumers can easily sort the data to identify trends. Over the past four years, CMS has expanded this dashboard to include reporting on payments for prescription drugs in their first year on the market and information on the drugs' manufacturers.[54] Through the Part D Senior Savings model, beginning January 1, 2021, CMS is testing a change to the Manufacturer Coverage Gap Discount Program (the ''discount program'') to allow Part D sponsors to offer a Part D benefit design that includes predictable copays in the deductible, initial coverage, and coverage gap phases for a broad range of insulins included in the Model by offering supplemental benefits that apply after manufacturers provide a discounted price.[55]

CMS issued regulations addressing prescription drug transparency,[56] including a regulation implementing the statutory prohibition on pharmacist gag clauses,[57] helping to ensure patients have information on lower cost alternatives or that they can save money by paying cash. As part of the Calendar Year (CY) 2018 Medicare Physician Fee Schedule, CMS adopted a policy that all FDA-approved Part B biosimilars would be assigned their own HCPCS codes. Under this revised coding policy, CMS pays for separately payable Part B biosimilars based on its own Average Sales Price (ASP) plus 6 percent of the ASP of its reference product. This policy change was made to promote a stable and robust biosimilars market that drives competition and lowers prices.

In the CY 2019 Medicare Advantage and Part D final rule, CMS adopted a policy to allow for certain low-cost generic drugs to be substituted onto plan formularies at any point during the year, so beneficiaries immediately benefit and have lower cost sharing.[58] The Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses rule[59] finalized in May 2019 requires Part D plans to implement, no later than January 1, 2021, a real-time benefit tool that can be integrated into at least one prescriber's electronic prescribing or EHR system to provide patient-specific formulary and benefit information, including cost sharing.[60] The rule also requires that beginning January 2021, the Explanation of Benefits document that Part D enrollees receive each month must include information on drug price increases and lower-cost therapeutic alternatives. In June 2020, CMS proposed[61] further policy changes that would begin removing barriers to value-based purchasing arrangements between drug manufacturers and payers.[62] Value-based payments for prescription drugs has the potential to increase patient access to new medicines by holding prescription drug manufacturers accountable for outcomes their drug achieves, as well as creating alternatives to traditional cost controls that may impede patient access.[63]

As part of its effort to incentivize states to pursue innovative responses to rising drug prices, CMS approved nine states' (and the District of Columbia's) plan amendment proposals to negotiate supplemental rebate agreements involving value-based purchasing arrangements with drug manufacturers.[64] These supplemental rebate agreements allow states to link payment for prescription drugs to the value delivered to patients. Increasing states' flexibility empowers them to develop policies that are effective and responsive to local conditions and price ''hot spots'' that lower costs, increase

[52] 84 FR 65524, 65564 (Nov. 27, 2019).

[53] ''Trump Administration Announces Historic Action to Lower Drug Prices for Americans.'' United States Department of Health and Human Services. July 24, 2020. Available at: *https://www.hhs.gov/about/news/2020/07/24/trump-administration-announces-historic-action-lower-drug-prices-americans.html*.

[54] ''CMS Releases Enhanced Drug Dashboards Updated with Data for 2018.'' Centers for Medicare & Medicaid Services.'' December 19, 2019. Available at: *https://www.cms.gov/newsroom/press-releases/cms-releases-enhanced-drug-dashboards-updated-data-2018*; *see also* ''CMS Updates Drug Dashboards with Prescription Drug Pricing and Spending Data.'' Centers for Medicare & Medicaid Services. March 14, 2019. Available at: *https://www.cms.gov/newsroom/press-releases/cms-updates-drug-dashboards-prescription-drug-pricing-and-spending-data*.

[55] ''Part D Senior Savings Model.'' Centers for Medicare & Medicaid Services. Available online at: *https://innovation.cms.gov/innovation-models/part-d-savings-model*.

[56] *See* 84 FR 23832 (May 23, 2019) (HHS final rule finalizing policies that aimed to ''increase transparency of drug pricing and drug price increases, giv[e] beneficiaries and prescribers tools to help improve adherence, lower prescription drug costs, and minimize beneficiary out-of-pocket costs''); *see, for example,* 42 CFR 423.128 (requiring additional information in Part D explanations of benefits to increase transparency); 42 CFR 423.160 (requiring adoption of e-prescribing standards to increase transparency).

[57] 42 CFR 423.120(a)(8)(iii); *see also* Verma, S. ''Memorandum to All Part D Plan Sponsors: Unacceptable Pharmacy Gag Clauses.'' Centers for Medicare & Medicaid Services. May 17, 2018. Available at: *https://downloads.cms.gov/files/2018-05-17.pdf*.

[58] ''CMS lowers the cost of prescription drugs for Medicare beneficiaries.'' Centers for Medicare & Medicaid Services. April 2, 2018. Available at: *https://www.cms.gov/newsroom/press-releases/cms-lowers-cost-prescription-drugs-medicare-beneficiaries*.

[59] 84 FR 23832 (May 23, 2019).

[60] ''CMS Takes Action to Lower Prescription Drug Prices and Increase Transparency.'' Centers for Medicare & Medicaid Services. May 16, 2019. Available at: *https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-prescription-drug-prices-and-increase-transparency*.

[61] ''Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS 2482–P) Fact Sheet. Centers for Medicare & Medicaid Services. June 17, 2020. Available at: *https://www.cms.gov/newsroom/fact-sheets/establishing-minimum-standards-medicaid-state-drug-utilization-review-dur-and-supporting-value-based*.

[62] 85 FR 37286 (Jun. 19, 2020).

[63] Verma, S. ''CMS's Proposed Rule On Value-Based Purchasing For Prescription Drugs: New Tools For Negotiating Price For The Next Generation Of Therapies.'' Health Affairs. June 17, 2020. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20200617.728496/full/*.

[64] ''Medicaid State Plan Amendments.'' Centers for Medicare & Medicaid Services. Available online at: *https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html*.

the predictability of expenses, and improve access for patients.

As it currently stands, and despite ongoing Federal efforts to improve price transparency, there continues to be a lack of standardized pricing information to assist consumers in the private market when shopping for health care items and services. While there are several efforts across states, 33 still do not have comprehensive statewide price transparency initiatives,[65] and as noted earlier, sometimes cannot legally require private market plans and issuers to provide real-time, out-of-pocket cost estimates to participants, beneficiaries, and enrollees.

The Departments have concluded that the Hospital Price Transparency final rule and the other efforts described earlier in this section cannot result in enrollees receiving complete price estimates for health care items and services because, as the GAO concluded, complete price estimates require pricing information from both providers and health insurance issuers.[66] In other words, this rule complements existing State, Federal, and private sector price transparency efforts by ensuring that pricing information is available from both hospitals and payers in both the public and private markets and by expanding transparency to pricing information for health care items and services provided outside of a hospital setting. As a result of these rules, regardless of where a consumer seeks information, be it their plan or issuer, or their hospital, they will have guaranteed access to up to date and accurate pricing information. In addition, because section 2718(e) of the PHS Act applies only to items and services provided by hospitals the Hospital Price Transparency final rule does not address price transparency with respect to items and services provided by other health care providers. Accordingly, the Departments have concluded that additional price transparency efforts are necessary and required under the statute to empower a more price-conscious and responsible health care consumer, promote competition in the health care industry, and lower the overall rate of growth in health care spending.[67]

The Departments are of the view that the disclosures required under the final rules are necessary and appropriate to more fully implement section 2715A of the PHS Act and section 1311(e)(3)(C) of PPACA to ensure that consumers have ready access to the information they need to estimate their potential out-of-pocket costs for health care items and services before that service is rendered or that item is delivered. The final rules are also intended to empower consumers by incentivizing market innovators to help consumers understand how their plan or coverage pays for health care and to shop for health care items and services based on price, which is a fundamental factor in any purchasing decision.

D. Executive Order

On June 24, 2019, President Trump issued Executive Order 13877, ''Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First.'' Section 3(b) of Executive Order 13877 directed the Secretaries of the Departments to issue an advance notice of proposed rulemaking (ANPRM), consistent with applicable law, soliciting comment on a proposal to require health care providers, health insurance issuers, and self-insured group health plans to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care. The Departments considered the issue, including by consulting with stakeholders, and determined that an NPRM, rather than an ANPRM, would allow for more specific and useful feedback from commenters, who would be able to respond to specific proposals.

E. Proposed Rules

In response to Executive Order 13877 and to also implement legislative mandates under sections 1311(e)(3) of PPACA and section 2715A of the PHS Act, the Departments published an NPRM entitled ''Transparency in Coverage'' on November 27, 2019 (to be codified at 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 147) (the proposed rules) with comments requested by January 14, 2020.[68] In response to requests from stakeholders, the Departments extended the comment period 15 days, to January 29, 2020.[69] The proposed rules set forth proposed requirements for group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request to a participant, beneficiary, or enrollee, including an estimate of an individual's cost-sharing liability for covered items or services furnished by a particular provider. The Departments proposed that plans and issuers be required to make such information available on an internet website and, if requested, through non-internet means, thereby allowing a participant, beneficiary, or enrollee to obtain an estimate and understanding of the individual's out-of-pocket expenses and effectively shop for items and services. The proposed rules also included proposals to require plans and issuers to disclose in-network provider negotiated rates, and historical out-of-network allowed amounts through two machine-readable files posted on an internet website, thereby allowing the public to have access to health coverage information that can be used to understand health care pricing and potentially dampen the rise in health care spending.

The proposed rules also included requests for information (RFIs) on topics closely related to the rulemaking. Due to the design and capability differences among the information technology (IT) systems of plans and issuers, as well as difficulties consumers experience in deciphering information relevant to health care and health insurance, the Departments sought comment on additional price transparency requirements that could supplement the proposed requirements for disclosing cost-sharing information to participants, beneficiaries, or enrollees and the proposed requirements for public disclosure of negotiated rates and historical allowed amount data for covered items and services from out-of-network providers. Specifically, the Departments sought comment on whether plans and issuers should be required to disclose information necessary to calculate a participant's, beneficiary's, or enrollee's cost-sharing liability through a publicly-available, standards-based application programming interface (API).

Such a requirement would build off a final rule, ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare

[65] LaPointe, J. ''Few States Have Robust Healthcare Transparency Laws.'' RevCycle Intelligence. May 11, 2020. Available at: *https://revcycleintelligence.com/news/few-states-have-robust-healthcare-price-transparency-laws*.

[66] GAO–11–791 (Sep. 2011).

[67] This view is consistent with the legislative history of PPACA. As initially introduced in the Senate on November 19, 2009, PPACA included only the requirement on hospitals to disclose standard charges included in section 2718. On December 1, 2009, in comments supporting the hospital transparency requirement, Sen. Max Baucus noted, ''I think the same should also apply to physicians so people have a better idea what they will pay or their insurance company will pay for these procedures.'' *https://www.congress.gov/111/crec/2009/12/08/CREC-2009-12-08.pdf*. Sections 2715A and 1311(e)(3)(C) were then amended to PPACA on December 19 in the final managers amendment before passage in the Senate. Available at: *https://www.congress.gov/111/crec/2009/12/19/CREC-2009-12-19.pdf*.

[68] 84 FR 65464 (Nov. 27, 2019).

[69] 85 FR 276 (Jan. 3, 2020).

Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and Chip Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers'' (CMS Interoperability & Patient Access final rule), that CMS published on May 1, 2020.[70] That rule requires Medicare Advantage organizations, Medicaid and CHIP Fee-for-Service programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in the FFEs to provide enrollees with access to select data, including claims data, through a standards-based API that conforms to the technical standards adopted in the Office of the National Coordinator for Health Information Technology (ONC) 21st Century Cures Act final rule at 45 CFR 170.215. The CMS Interoperability & Patient Access final rule requires certain entities, such as FFE QHP issuers, to provide certain data through a standards-based API. The Departments appreciate the comments received in response to the API RFI and will use the comments to inform the need for future rulemaking regarding whether plans and issuers should be required to disclose information necessary to calculate cost-sharing liability through a publicly-available, standards-based API. HHS will also monitor the implementation of the CMS Interoperability & Patient Access final rule to inform any such future rulemaking.

The proposed rule also included RFIs on how provider quality measurements and reporting in the private health insurance market may be used to complement cost-sharing information for plans and issuers in the private health insurance market. The Departments sought comment on how existing quality data on health care provider items and services could be leveraged to complement the proposals in the proposed rules. The primary goal of the proposed and final rules is making information available to address the absence of price transparency in the health care market; the final rules do not address health care quality at this time.

HHS also proposed to amend its MLR program rules using the authority under section 2718(c) of the PHS Act, under which the standardized methodologies for calculating measures of the activities reported under section 2718(a) of the PHS Act shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans. Specifically, HHS proposed to recognize the special circumstances of a different and newer type of plan for purposes of MLR reporting and calculations for plans that share savings with consumers who choose lower-cost, higher-value providers. HHS proposed to amend 45 CFR 158.221 to add a new paragraph (b)(9) to allow any such ''shared savings'' payments made by an issuer to an enrollee as a result of the enrollee choosing to obtain health care from a lower-cost, higher-value provider, to be factored into an issuer's MLR numerator, beginning with the 2020 MLR reporting year (for reports filed by July 31, 2021).

The Departments requested comments on all aspects of the proposed rules, as well as a number of specific issues. The Departments received over 25,000 comments in response to the proposed rules from a range of stakeholders, including plans and issuers, health care providers, prescription drug companies, employers, state regulators, health IT companies, health care policy organizations and think tanks, and individuals. No requests for a public hearing were received. The Departments received a number of comments and suggestions that were outside the scope of the proposed rules that are not addressed in the final rules (for example, regarding hospital prices, other methods for reducing health care and prescription drug costs, consumer education and provider directories). After careful consideration of the comments, the Departments are finalizing the proposed rules with certain modifications made in response to comments. These modifications are discussed later in this preamble.

F. Legal Authority

Several commenters questioned the Departments' legal authority regarding various aspects of the proposed rules. The Departments are of the view that the legal authorities identified earlier in this preamble are sufficient to support the final rules.

1. Statutory Authority Under Section 1311(e)(3) of PPACA

Several commenters contended that section 1311(e)(3)(A)(ix) of PPACA does not give the Departments statutory authority to require that plans and issuers make the rates they have negotiated with providers and out-of-network allowed amounts publicly available. The commenters noted that section 1311(e)(3)(A) of PPACA enumerates eight specific categories of information subject to the transparency in coverage mandate followed by a ninth ''catchall'' category consisting of ''other information as determined appropriate by the Secretary.'' [71] These commenters maintained that the Secretary of HHS's authority under section 1311(e)(3)(A)(ix) of PPACA is insufficient to support a requirement to publicize negotiated rates because they are not sufficiently similar to the other categories of information identified under section 1311(e)(3)(A) of PPACA.

The Departments disagree with these comments and are of the view that the information required to be disclosed under this rule fits squarely within the scope of information that plans and issuers may be required to disclose under section 1311(e)(3)(A)(ix) of PPACA and section 2715A of the PHS Act. Section 1311(e)(3)(A)(i) to (viii) of PPACA outlines specific information and data that must be submitted to the Exchange, the Secretary of HHS, the relevant State insurance commissioner, and the public on an accurate and timely basis. In addition, section 1311(e)(3)(A)(ix) of PPACA requires health plans to submit ''other information as determined appropriate by the Secretary.'' Under established principles of statutory construction, when a general term follows a list of specific terms in a statute, the general term is construed to encompass subjects of a similar character to the specific terms. The principle of *ejusdem generis* guides courts in evaluating a catch-all at the end of a list. Therefore, when a statute allows an implementing agency to exercise its discretion by adding additional items to a list, the implementing agency is empowered to add additional items as long as those items are of similar character to the items enumerated in the statute.[72] In this case, the statutory list includes information and data useful to evaluate the coverage offered by plans and issuers with an emphasis on business practices, financial stability, and consumer experience. The list also includes information useful to regulators and the public in general to evaluate plans' and issuers' business practices and activity in the market. Given that the list includes some disclosures that are more immediately useful to individual consumers and others that are more immediately useful to regulators, the catchall provision is reasonably and best read as Congress' recognition that the Secretary of HHS (and, therefore, the Departments, by virtue of their joint authority under section 2715A of the PHS Act) would need broad flexibility to require the

[70] 85 FR 25510 (May 1, 2020).

[71] *See* section 1311(e)(3)(A)(i) through (viii) of PPACA.

[72] *See Norfolk & Western R. Co.* v. *Train Dispatchers,* 499 U.S. 117, 128–29 (1991).

disclosure of information as appropriate to deliver the transparency necessary for consumers to understand their coverage options and for regulators to hold plans and issuers accountable.

It is important to note that Congress considered one amendment that would have only required public disclosure at least annually of in-network allowed charges and expected allowed charges for out of network without allowing the Secretary discretion to add to the content of the required disclosure.[73] Instead of adopting this prescriptive approach, Congress required public disclosure of a broader set of information that similarly included payments for out-of-network services, as well as providing the Secretary discretion to require disclosure of other information. While Congress did not specifically include in-network allowed charges in the provision enacted, the discretion they provided suggests they understood that the Secretary might later find that requiring the disclosure of additional information, including information considered by Congress, might be useful and appropriate. That Congress considered and rejected a more prescriptive approach strongly suggests Congress intended that the Secretary have the ability to mandate more particularized disclosures in the future, including the disclosure of in-network negotiated rates.[74]

A plan's or issuer's negotiated rates provide important information to help consumers both evaluate their options before buying coverage and, after choosing coverage, evaluate how to use their coverage when they need care. Those shopping for coverage will benefit from knowing how effectively a plan or issuer negotiates rates; for example, by comparing the rates one plan or issuer pays a provider for a particular item or service that this consumer knows they, or their family, will need in the future, which can then allow them to shop and compare which plans and issuers offer the most value. Once coverage is obtained, knowing negotiated rates upfront will ensure consumers covered under a variety of plan designs and coverage options to, in each case, have access to the information they need to obtain health care services in an efficient, cost-effective manner, when considering available options for a shoppable service. As discussed earlier in this preamble, making negotiated rates public also strengthens other health care stakeholders' ability to support consumers. Because negotiated rates provide important information to help people—including consumers, regulators and the general public—evaluate the coverage offered by a plan or issuer, it clearly falls within the scope of information already required under section 1311(e)(3)(A) of PPACA. As discussed in more detail later in this section, out-of-network allowed amounts likewise provide vital information to help evaluate coverage.

Out-of-network allowed charges also provide consumers with important information. Consumers may opt for out-of-network services for numerous reasons, such as the unavailability of an in-network provider who can meet certain medical needs, an existing relationship with an out-of-network provider, the recommendation of another provider, or personal convenience. Disclosure of estimates of out-of-network allowed amounts is essential to the ability of consumers considering out-of-network services to form an estimate of their potential liability. Limiting transparency in pricing requirements to only providers under contract with a carrier would prevent transparency for all such services, contrary to the plain language of the statute.[75] Indeed, the language of the statute (for example, the requirement of section 1311(e)(3)(B) of PPACA that the intended audience, including individuals with limited English proficiency, can readily understand and use because that language is concise, well-organized, and follows other best practices of plain language writing) indicates an intention to assist consumers by enhancing their ability to make cost-conscious decisions; this is an essential component of establishing and maintaining robust market competition with costs that are reasonable and plausibly tethered to standard market discipline. As the preamble to the proposed rules observed, there is substantial evidence that increased price transparency provides consumers and the public at large with the information that is necessary to improve market efficiency.[76] For these reasons, the Departments are of the view that requiring disclosure of estimates of out-of-network allowed amounts, which reflect out-of-network benefits under a plan, is well within both the text and spirit of the statute and its aims to assist consumers in selecting providers, evaluating market options, increasing competition, and reducing market disparities. The Departments have identified these requirements as beneficial to the ongoing efforts of employers and regulators to aid consumers, and as consistent with the goals of the statute; thus, the Departments reject the assertion of commenters that these purposes are beyond the scope of the statute.

Several commenters asserted that the specific justifications the Departments cite as support for mandating the disclosure of negotiated rates are unrelated to the purposes authorized by statute. They asserted that those purposes—assisting consumers in selecting health care providers, assisting consumers in evaluating options in the market, increasing competition and reducing disparities in the market, assisting employers, and assisting state regulators—have no relationship to the statutory purpose of providing transparency in coverage for consumers. Moreover, commenters stated that the statute does not authorize the use of price transparency mechanisms to affect issuer and provider rate negotiations or health care costs generally, to assist employers in negotiations, or to aid state regulators in their duties. The Departments, however, find ample support in PPACA evidencing the relationship between the purposes intended to be served by this final rule, the overall purposes of PPACA, and the PPACA's price transparency measures, including section 1311(e)(3).

The purposes underlying the final rule's requirement to disclose negotiated rates are directly tied to providing transparency in coverage to consumers. The negotiated rate information that the final rules require to be disclosed pursuant to the Departments' authority under section 1311(e)(3)(A)(ix) of PPACA, and section 2715A of the PHS Act, is directly relevant to providing consumers with transparent pricing information sufficient to allow them to assess, in advance of receiving services, their liability under a health plan or

[73] Congressional Record 155: 183 (December 8, 2009) p. S12716. Available at: *https://www.congress.gov/111/crec/2009/12/08/CREC-2009-12-08-senate.pdf.*

[74] *See, for example, Lehman* v. *Nakshian,* 453 U.S. 156, 167–8 (1981) (citing a rejected amendment to a Federal statute as evidence of Congressional intent).

[75] Section 1311(e)(3)(A)(vii) of PPACA.

[76] 84 FR 65464, 65489, 65495 (Nov. 27, 2019); *see also* Austin, D.A., and Gravelle, J.G. ''Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' United States Congress Congressional Research Service. July 24, 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf; see also* Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. Econ. & Stat. 1 (2018). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf; see also* Enthoven, A. Market Forces and Efficient Health Care Systems. Health Affairs, Vol. 23, No. 2. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.23.2.25.*

health coverage in the numerous instances in the course of any plan year in which the negotiated rate will determine all or a portion of a consumer's liability. This is important information that helps consumers under a wide variety of plan designs and cost-sharing arrangements in both choosing and using coverage. The Departments are requiring the disclosure of cost information to further the goal of price transparency and are doing so under the authority of section 1311(e)(3) of PPACA.

Two commenters suggested that the proposal to require the release of negotiated rates in machine-readable format is not authorized under the statute. The statute mandates that transparency in coverage information ''shall be provided in plain language . . . that the intended audience, including individuals with limited English proficiency, can readily understand and use because it is concise, well-organized, and follows best practices of plain writing.'' [77] These commenters contended that machine-readable information is not plain language that is accessible or understandable to the typical consumer, and is therefore not within the scope of information authorized for public disclosure under section 1311(e)(3)(B) of PPACA.

The Departments disagree with this assertion. Consistent with the statute, the final rules require the machine-readable files to include a plain language description for each billing code. The proposed requirement that two data files be provided in ''machine-readable format''—one containing negotiated rates and the other containing out-of-network allowed amounts—is a purely operational consideration intended to ensure that the file data can be imported or read by a computer system directly, without altering the data, and without reliance on proprietary software.[78] Under section 1311(e)(3)(B) of PPACA, the ''plain language'' requirement concerns information to be made available to the public, the ''intended audience,'' per the statute. The Departments require the publication of data in machine-readable files so that the required information may be presented to all members of the intended audience in a concise, well-organized manner that follows best practices of plain writing relevant to the intended audience.

The Departments explain elsewhere in the preamble that the intended audience for the information required to be published under the final rules includes all consumers and purchasers of health care items and services, including individual consumers, employers, and government health care programs. The intended audience also includes health care stakeholders such as researchers, legislators, and regulators, as well as application developers who could make the information usable and easily understood by laypersons. Accordingly, application developers will be able to access the data in a format that is easily used and understood using skills common to application developers. This same expertise allows such innovators to incorporate large data sets into easy-to-use internet-based tools and mobile applications that will present information to laypersons in easy-to-understand, plain language that is sufficiently concise and well-organized. The Departments are of the view that providing the files in machine-readable format is an effective and necessary mechanism to ensure that price transparency information be made available to all members of the intended audience in a consistent, understandable, plain language format, as the statute requires.

One commenter suggested that the disclosures to the public required under section 1311(e)(3)(A) of PPACA consist of aggregated data only and do not contemplate or allow public disclosure of specific rate and price information. The Departments disagree. While it is true that several of the data elements listed under section 1311(e)(3)(A) of PPACA are general in nature, such as financial disclosures and enrollment data, this fact does not compel the conclusion that all elements listed must be construed as requiring aggregated information. As noted above, the list encompasses information and data useful to the evaluation of plans and issuers by all varieties of health care consumer, including individuals, employers, and government programs. Certain elements provide information specific to the benefits and protections a plan or issuer's coverage provides to an individual, including claims payment policies and information on enrollee rights under the law. In particular, the data element listed at section 1311(e)(3)(A)(vii) of PPACA encompasses ''information on cost sharing and payments with respect to any out-of-network coverage,'' which, by its plain terms, does not contemplate general or cumulative information.

The final rules specify the nature of the information that must be made available pursuant to sections 1311(e)(3)(A)(vii) and (ix) of PPACA, and the manner in which it is to be made available to fully implement the goals and purposes of the statute. Section 1311(e)(3)(C) of PPACA concerns disclosures to participants, beneficiaries, and enrollees receiving services from participating providers only, whereas section 1311(e)(3)(A) of PPACA concerns disclosures to the public generally and incorporates out-of-network payment information as well. Taken together, and as implemented under the final rules, the statute and regulatory schemes cover all persons seeking health pricing information in a given market, and advance the purposes of enhancing competition, reducing price disparities, and ultimately lowering costs through transparency in coverage.

Ultimately, by adding section 2715A of the PHS Act and section 1311(e)(3) of PPACA through the manager's amendment prior to passing PPACA in the Senate, Congress made transparency a key component of the PPACA's comprehensive framework for regulating private health coverage through Federal law. Notably, in contrast to the amendment rejected by Congress discussed earlier in this preamble, the transparency in coverage provisions signed into law provide a far more comprehensive and expansive approach toward providing transparency. The law covers nearly all private health plans, requires disclosure by plans through an internet website, requires disclosures to more entities, requires a broader set of information disclosures, and provides additional discretion to expand information disclosures. By taking this approach, Congress recognized both the importance and the complexity of requiring transparency. The discretion provided under the statute ensures that the Departments can accommodate changes in technology and health care markets, as well as build on the information disclosures specifically itemized in the statute.

A commenter also contended that the proposal to require issuers to make estimates of out-of-network allowed amounts available through the internet-based self-service tool is not authorized by the statute. This commenter asserted that section 1311(e)(3)(C) of PPACA only authorizes a requirement that payers make available information concerning cost-sharing obligations with respect to items or services furnished by a participating provider, not by out-of-network providers.

The Departments disagree and are of the view that the statute fully supports a requirement that plans and issuers make available information concerning cost-sharing obligations with respect to

[77] Section 1311(e)(3)(B) of PPACA.

[78] 84 FR 65464, 65481 (Nov 27. 2019).

items or services furnished by out-of-network providers. The information to be made available under section 1311(e)(3) specifically includes ''[i]nformation on cost sharing and payments with respect to any out-of-network coverage,'' as well as ''[o]ther information as determined appropriate by the Secretary.'' [79] While section 1311(e)(3)(C) of PPACA focuses primarily on providing information to enrollees, section 1311(e)(3)(A) of PPACA authorizes the Departments to make certain out-of-network information available to the public, which includes participants, beneficiaries, and enrollees. Thus the Departments reasonably determined that section 1311(e)(3)(A) and (C), together, authorize the requirement that plans and issuers provide cost estimates for covered items and services provided by out-of-network providers.

2. Constitutional Concerns

Several commenters asserted that requiring issuers to make rates they have negotiated with providers available to the public constitutes compelled commercial speech in violation of the First Amendment to the Constitution, and an unlawful taking of trade secrets without just compensation in violation of the Fifth Amendment. Commenters cited various reasons for their belief that the requirement in the proposed rules to disclose negotiated rates to the public could not survive constitutional scrutiny.

Several commenters contended that the proposed requirement constituted compelled commercial speech, and that the rationale the Departments articulated to justify the proposed requirement failed to meet the legal standard necessary to justify such action. One commenter asserted that a standard of constitutional scrutiny higher than that relevant to compelled commercial speech applies to the requirement to publish negotiated rates because, the commenter contended, the disclosure of negotiated rates does not propose a future commercial transaction. Some commenters challenged the proposed rules on the basis that negotiated rates have little or no relevance or value to consumers attempting to ascertain their potential liability for a particular service at a given point in time in the future because negotiated rates do not reflect the terms of different plan designs or the status of the individual consumer at a given point in time in relation to cost-sharing obligations, in particular any annual deductible.

Two commenters asserted that the requirement to publicly disclose negotiated rates would go well beyond the stated goal of providing notice to participants, beneficiaries, and enrollees of cost-sharing liability for covered services because it calls for negotiated rates to be available to the public generally, not just to enrolled consumers inquiring about their coverage. They also claimed that disclosure of negotiated rates would be extremely burdensome because fulfilling the mandate would require the disclosure of millions, or even billions, of data points. One commenter asserted that because the requirement to publish negotiated rates would not be useful to consumers in all situations, the requirements in the proposed rules were not narrowly tailored enough to survive constitutional scrutiny.

Some commenters also contended that the Departments' other stated interests in mandating the publication of negotiated rates, including lowering prices, increasing competition, and informing decision-making in the market generally, are not authorized under relevant statute; therefore, the breadth of these requirements is overly burdensome and inclusive of information not necessary to advance the goals of the statute. These commenters concluded that, to the extent the mandated publication of negotiated rates is calculated to advance those purposes, they are not sufficiently tailored to statutory goals to survive constitutional scrutiny.

a. First Amendment Compelled Speech

The Departments disagree that the proposed rules and the final rules run afoul of the First Amendment and would not survive constitutional scrutiny. As the United States Supreme Court recognized in *Zauderer* v. *Office of Disciplinary Counsel,* 471 U.S. 626 (1985) and recently confirmed in *National Institute of Family and Life Advocates* v. *Becerra,* 138 S. Ct. 2361, 2372, 2376 (2018) (''*NIFLA*''), required disclosures of factual, uncontroversial information in commercial speech are subject to more deferential First Amendment scrutiny. Under the approach articulated in *Zauderer,* courts have upheld required disclosures of factual information in the realm of commercial speech where the disclosure requirement reasonably relates to a government interest and is not unjustified or unduly burdensome such that it would chill protected speech. *See, e.g., Am. Meat Inst.* v. *U.S. Dept. of Agric.,* 760 F.3d 18, 27 (D.C. Cir. 2014); *Mass. Ass'n of Private Career Sch.* v. *Healey,* 159 F. Supp. 3d 173, 201 (D. Mass. 2016).

The Departments articulated substantial governmental interests in proposing these requirements: Assisting consumers of health care services in understanding the costs for which they will be liable for covered services prior to the delivery of the services; assisting other consumers of health care, such as employers and government health benefits programs, in evaluating and negotiating coverage options and obtaining the most value for health care dollars; and supporting a market-driven health care economy that is sustainable. The preamble to the proposed rules also explained how the information required to be disclosed under the proposed rules is of substantial value to consumers, including health plan participants, beneficiaries, and enrollees who have and have not satisfied their annual deductible or reached their maximum out-of-pocket limit, and that remains true under the final rules. For such consumers who have not met their deductibles, knowledge of negotiated rates is necessary for estimating their out-of-pocket costs because these consumers generally will be responsible for paying the full negotiated rate for health care items and services until they reach their deductible (or the maximum annual limit on cost sharing).

As the Departments noted earlier in the preamble, between the enactment of PPACA and 2019, average family deductibles for private sector employees increased by 85 percent, up to $3,655 in 2019.[80] Consumers in the private health insurance market are increasingly responsible for a greater share of their health care costs through higher deductibles and shifts from copayments to coinsurance.[81] The final rules will give health care consumers and stakeholders information vital to their roles in creating and supporting a sustainable market-driven health care economy.

[79] Section 1311(e)(3)(A) of PPACA; *see also* Section 1311(e)(3)(A)(vii) and (ix) of PPACA.

[80] *See* ''Medical Expenditure Panel Survey. Insurance Component National-Level Summary Tables.'' United States Department for Health and Human Services Agency for Healthcare Research and Quality. Available at: *https://www.meps.ahrq.gov/mepsweb/data_stats/quick_tables_search.jsp?component=2&subcomponent=1.*

[81] The preamble to the proposed rules contains a detailed discussion regarding increases in deductibles. *See* 84 FR 65464, 65465 (Nov. 27, 2019) (citing Ray, M., Copeland, R., Cox, C. ''Tracking the rise in premium contributions and cost-sharing for families with large employer coverage,'' Peterson-Kaiser Health System Tracker. August 14, 2019. Available at: *https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributionsand-cost-sharing-for-families-with-large-employercoverage/.*).

The final rules also will provide critical information to consumers who have satisfied their deductibles or reached their out-of-pocket limit. These consumers may wish to base their health care spending decisions on underlying prices to avoid excess spending by their issuer or employer that could lead to premium increases, increased out-of-pocket obligations, or lower employer contributions toward employer-sponsored coverage. Knowing the rates negotiated by other issuers in their geographic market will assist consumers during open enrollment, as they search for a plan that may lower their out-of-pocket costs in the coming year.

The government also has a substantial interest in assisting other health care spenders, such as employers and government benefits programs, to make coverage choices that drive value for the public. Given the size and scope of the country's health care market and the fact that choices made by employers and benefits programs operate at scale to direct health care spending, the government can increase the value of health care expenditures by ensuring those entities have access to accurate information. Providing employers and government benefit programs with actionable data may also help drive down total health care spending, as issuers compete to offer higher-value programs.

The government's interest in promoting a sustainable health care economy driven by market forces is substantial, as reflected in section 1311(e) of PPACA. As of 2018, U.S. health care spending had reached $3.6 trillion, or $11,172 per person and accounted for 17.7 percent of the nation's Gross Domestic Product.[82] Given the scope of the market and the earlier-discussed data suggesting that price transparency and market forces can drive down health care costs, the government's interest in increasing price transparency is substantial.

Each of the three interests identified above is furthered by the final rules. For individuals, the data provided will permit them to compare prices for health care items and services and allocate their funds accordingly. For benefit plans and employers, the information provided will guide decision-making about which coverage options to offer, and which providers or third parties, like pharmacy benefit managers (PBMs), to contract with. For the health care economy as a whole, the Departments are of the view (based on available data) that transparency and market forces will drive savings and reduce expenditures. Accordingly, the Departments continue to hold the view that the final rules serve substantial government interests.

Furthermore, the requirement to provide these disclosures does not unduly burden plan or issuer speech because nothing in the final rules would ''drown out [a plans' or issuers'] own message'' or ''effectively rule out'' any mode of communication. *See NIFLA,* 138 S. Ct. at 2378. Plans and issuers remain free to communicate with consumers using methods and media they have always used or may choose to use in the future.

The Departments further disagree that the final rules would be subject to a standard of constitutional scrutiny higher than that applied to compelled commercial speech. For First Amendment purposes, commercial speech is speech ''related solely to the economic interests of the speaker and its audience.'' *Cent. Hudson Gas & Electric Corp.* v. *Pub. Serv. Comm'n of N.Y.,* 447 U.S. 557, 561 (1980). Price information concerning the cost of health services is related solely to the economic interests of providers and the consumers who seek their services. The speech in question here, therefore, is commercial speech.

Furthermore, the disclosure of negotiated rates is one concerning ''purely factual and uncontroversial information about the terms [*i.e.,* the price] under which services are available.'' *See Zauderer,* 471 U.S. at 651; *see also Am. Meat Inst.* v. *U.S. Dept. of Agric.,* 760 F.3d 18, 27 (D.C. Cir. 2014). Therefore, the imposition on commercial speech by the final rules need only be ''reasonably related'' to the government's stated interest. For the reasons discussed above, the Departments are of the view that making available negotiated rates to consumers is reasonably related to the government's stated interests in providing greater cost information to consumers and benefit plans, as well as increasing price transparency in the health care market more broadly. While the Departments disagree that the stricter constitutional scrutiny under *Central Hudson* would apply to the final rules for the reasons discussed above, the Departments also are of the view that the government interests described above are ''substantial,'' and the regulations, for the reasons described above, directly advance that governmental interest and are not more extensive than necessary to serve that interest. None of the alternatives considered by the Departments would provide the full panoply of information necessary to achieve the identified interests. Specifically, the only way to provide information concerning a consumer's personal liability for health care services when the negotiated rate is all or any portion of that liability is by disclosing those rates.

The Departments disagree that the rules are excessively burdensome and are invalid because they purportedly exceed the statute's goal of providing notice of cost-sharing liability. The Departments are of the view that, in addition to providing participants, beneficiaries, and enrollees with notice of cost-sharing liability, the final rules are intended to advance a number of concurrent goals, as described earlier in this preamble. These goals are consistent with the full text of section 1311(e)(3) of PPACA and section 2715A of the PHS Act. They include the overarching goal of facilitating a market-driven heath care system by giving consumers of health care services data that will enable consumers to make fully informed, cost-conscious decisions when choosing health care. These transparency requirements will support the creation of a competitive dynamic in health care markets that leads to narrower price differentials for the same services, fosters innovation, and potentially lowers overall health care costs over time.[83] These goals are consistent with the statutory mandate to promote transparency in coverage by making available to the public accurate and timely health care information, including cost-sharing information, and other information as deemed appropriate by the Departments.

The Departments also disagree with any notion that, because published negotiated rates would not be useful to all consumers in all situations, the final rules are not sufficiently tailored to survive constitutional scrutiny. Consumers seeking in-network items or services must have access to negotiated rate information to calculate out-of-pocket costs under the majority of health care payment models. These negotiated rates determine the price they will be obliged to pay, up to the applicable out-of-pocket limit. Thus, disclosing the negotiated rate is important to the consumer's ability to reasonably estimate his or her personal financial liability in advance of receiving services. In particular, and as explained earlier in this preamble, annual deductibles for plans and issuers

[82] ''Historical National Health Expenditure Data.'' Centers for Medicare and Medicare Services. Available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.*

[83] 84 FR 65465 (Nov. 27, 2019).

now routinely obligate consumers to pay several thousand dollars before the plan or issuer pays any benefits. The requirement to disclose negotiated rates to consumers is, therefore, crucial to providing meaningful transparency in health care markets.

b. Fifth Amendment Taking

The Departments also disagree that the requirement to disclose negotiated rates in the final rules constitutes an unlawful taking without just compensation under the Fifth Amendment. As an initial matter, the subject of any ''taking'' is a cognizable property interest. Commenters asserted that their negotiated rates constitute property because they are trade secrets. The Departments disagree. In order for a piece of information to qualify as a trade secret, it must be the subject of efforts to maintain its secrecy that are reasonable under the circumstances. Under most circumstances, if a piece of information is disclosed to third parties who have no obligation to keep it a secret, it does not qualify for trade secrets protection. Negotiated rates for health care items and services are routinely disclosed in EOBs provided to participants, beneficiaries, and enrollees. Participants, beneficiaries, and enrollees have no obligation to keep the information contained in their EOBs secret; some patients provide them to journalists or upload them to crowd-sourcing websites.[84] The Departments are of the view that this routine disclosure of negotiated rate information is sufficient to defeat any asserted trade-secret protection, and, therefore, the issuers have no proprietary interest in the negotiated rates that could be the subject of a constitutional ''taking.''

Moreover, plans' and issuers' expectations of confidentiality in information provided as a condition of participation in a highly regulated industry (for example, health insurance) are substantially diminished by the highly regulated nature of the industry. *See, e.g., Ruckelshaus* v. *Monsanto Co.,* 467 U.S. 986, 1007 (1984) (noting that expectations are necessarily adjusted in areas that ''ha[ve] long been the source of public concern and the subject of government regulation''); *Me. Educ. Ass'n Benefits Trust* v. *Cioppa,* 695 F.3d 145 (1st Cir. 2012) (discussing a Maine law requiring health issuers to disclose loss information); *Franklin Mem'l Hosp.* v. *Harvey,* 575 F.3d 121, 128 (1st Cir. 2009) (holding that a claimant's investment-backed expectations were ''tempered by the fact that it operate[d] in the highly regulated hospital industry'').[85] Plans and issuers are already subject to extensive regulation under Federal and state law. As noted by the 1st Circuit in *Pharmacy Care* v. *Rowe:*

> If [regulated parties] truly assumed that they would be free from disclosure requirements . . . this would be more wishful thinking than reasonable expectation. Whether or not the law strikes the right economic balance between competing producer and consumer interests, it is no more a taking than the requirement that public corporations disclose private corporate information about financial prospects to the public through regular SEC filings.

Pharm. Care Mgmt. Ass'n v. *Rowe,* 429 F.3d 294, 316 (1st Cir. 2005) (joint concurring opinion representing the opinion of the court). The Court further stated: ''Given the absence of a full-scale taking and the presence of a traditional regulatory interest, it is enough to defeat the takings claim that no reasonable investment-backed expectation is present at all.'' *Id.* at 315; *see also Good* v. *United States,* 189 F.3d 1355, 1363 (Fed. Cir. 1999) (''We have previously held that the government is entitled to summary judgment on a regulatory takings claim where the plaintiffs lacked reasonable, investment-backed expectations. . . .'').

Even if there were some property interest in negotiated rates, the Departments are of the view that this regulation is not a taking. The Supreme Court ''has identified several factors that should be taken into account when determining whether a governmental action has gone beyond 'regulation' and effects a 'taking.' '' *Monsanto,* 467 U.S. at 1005. Among those factors are ''the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations.'' *Id.* (citing *PruneYard Shopping Ctr.* v. *Robins,* 447 U.S. 74, 83 (1980)); *see also Kaiser Aetna* v. *United States,* 444 U.S. 164, 175 (1979); *Penn Cent. Transp. Co.* v. *City of N.Y.,* 438 U.S. 104, 124 (1978).

In requiring disclosure under the final rules, the government does not do so with the intention that the information is primarily and explicitly for the government's own use, or that any such potential impact is the purpose for requiring the disclosure. Instead, the final rules are intended to, and will, enable consumers to access information needed to make informed decisions on health care services. Under *Penn Central,* ''[a] 'taking' may more readily be found when the interference with property can be characterized as a physical invasion by government than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good.'' *Penn Central,* 438 U.S. at 124 (citation omitted). The final rules clearly fall on the other end of the spectrum, arising from statutory provisions, section 1311(e)(3) of PPACA and section 2175A of the PHS Act, that ''adjust[t] the benefits and burdens of economic life to promote the common good.'' *Connolly* v. *Pension Benefit Guar. Corp.,* 475 U.S. 211, 212 (1986).

3. Protections for Proprietary, Confidential Business Information, and Trade Secrets

Several commenters objected to the proposed rules on grounds that the requirement that issuers make public negotiated rates with providers would require the disclosure of allegedly confidential, proprietary business information, and trade secrets that are expressly protected from disclosure by a variety of Federal and state laws, and the statute does not in any way purport to abrogate those protections. Several commenters pointed to the Defend Trade Secrets Act (DTSA), which protects the property rights of trade secret holders,[86] and the Freedom of Information Act (FOIA),[87] which protects confidential, proprietary business information, and trade secrets from public disclosure, as examples of Congress' intent that such information be protected.

The Departments disagree. As discussed above, the Departments are of the view that the routine disclosure of negotiated rate information to third parties via EOBs means that the rate information is not a trade secret, and the DTSA, therefore, does not apply. Even if it did, there can be no meaningful sense in which the disclosure of this information pursuant to the final rules would constitute a misappropriation by

[84] Kliff, S. ''Why I'm Obsessed With Patients' Medical Bills, New York Times. August 7, 2020. Available at *https://www.nytimes.com/2020/08/07/insider/coronavirus-medical-bills.html*; *see also* Cerullo, M. ''As medical costs soar, more Americans turn to crowdfunding.'' CBS News. February 21, 2020. Available at: *https://www.cbsnews.com/news/health-care-costs-crowdfunding-medical-bills/.*

[85] PBMs serve as intermediaries between pharmacies and health benefit plans, including plans covered by ERISA. PBMs contract with pharmacies to establish pharmacy networks and contract with health benefit plans to provide access to those pharmacy networks. When a participant in a health benefit plan fills a drug prescription at a network pharmacy, the PBM pays the pharmacy at the rate negotiated in the contract between the PBM and the pharmacy (less any copayment by the participant), and the health benefit plan then reimburses the PBM at the rate negotiated in the contract between the PBM and the health benefit plan.

[86] 18 U.S.C. 1836(b).

[87] 5 U.S.C. 552.

improper means prohibited by the DTSA. The disclosures in question would be made pursuant to a regulatory mandate authorized by law, to effectuate policy priorities enacted by Congress: Namely, transparency in health care. These disclosures cannot reasonably be construed as ''theft, bribery, or misrepresentation.'' [88]

The disclosures required under the final rules would also not constitute a breach or inducement of a breach of a duty to maintain secrecy, as the final rules apply prospectively in a regulatory environment in which all parties to provider agreements, and all affected plans and issuers, are being placed on notice and should be aware in advance of the requirements of the final rules. All parties to these contracts are therefore positioned to modify contractual arrangements, or similar policies, practices, or expectations relating to privacy or trade secrets to conform to the final rules. Otherwise, the final rules will supersede these arrangements to the extent necessary to implement these rules.

FOIA is also not relevant to the disclosure that would be required by the final rules.[89] FOIA is a public information law that applies to Federal agencies, and generally enables the public to obtain records in possession of an agency.[90] Under the final rules, by contrast, negotiated rate information and out-of-network allowed amount information would be made available for the express purpose of making the information broadly available to the public, consistent with the authority Congress vested in the Departments. FOIA does not apply to disclosures by private entities such as the plans and issuers that would be subject to the disclosure requirements in the final rules. The exemptions found in the FOIA statute apply to disclosures by the government; that a piece of information might be subject to a FOIA exemption does not mean it is entitled to a heightened protection from disclosure when held by a private party.

Neither does FOIA apply to information maintained by private entities and not by an agency or government contractor, as that information would not constitute an agency record. To be an agency record subject to FOIA, an agency must have created or obtained the materials and must be in control of the materials. *U.S. Dep't of Justice* v. *Tax Analysts,* 492 U.S. 136, 145 (1989). Regardless of whether the negotiated rates and allowed amounts would constitute trade secrets or commercial information under FOIA, a requirement that private entities make certain information public does not implicate FOIA.

One commenter contended that the proposed disclosure of negotiated rates does not concern trade secrets, and is therefore not prohibited for that reason. The commenter asserted that the proposed disclosures concern end prices, which are comparable to the ''sticker price'' of a medical service or device. The commenter stated that those prices are not themselves trade secrets, which the commenter contended consist of negotiating tactics which the proposed rules would not require issuers to make available to the public. As indicated above in relation to the DTSA, the Departments agree that the final rules do not implicate trade secrets.

In support of the proposition that Congress could not have intended to undermine existing protections for confidential or proprietary business information and trade secrets when it enacted section 1311(e)(3) of PPACA, one commenter noted that elsewhere in PPACA, where Congress mandated pricing-related disclosures, it included language or arrangements that protected individual negotiated rates and pricing information from disclosure. A provision relating to the disclosure of drug cost information mandates release of only aggregated information and includes a specific designation of the information as confidential and protected from publication except in specific formats and for limited purposes that protect the identity of the parties to particular pricing arrangements.[91] Another provision mandates that hospitals make public a list of standard charges for items and services, not negotiated rates, on an annual basis only.[92] Both of these provisions, the commenter suggested, indicate Congressional intent to protect proprietary business information that is contrary to the requirements of the proposed rule.

The Departments are aware that Congress included provisions preventing or limiting disclosures of health care information in other sections of PPACA but note that Congress did not include such provisions in section 1311(e)(3)(A) of PPACA, indicating no intention that such restrictions apply in this context.[93]

Several commenters also pointed to the Sherman Antitrust Act, and specific applications of antitrust principles relating to the disclosure of trade secrets, including negotiated rates between issuers and providers in the health care context. They contend that Congress could not have intended to indirectly undermine these long-standing standards and policies when it enacted section 1311(e)(3) of PPACA. Several commenters also cited interpretive communications and similar guidance from the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice for the proposition that public disclosure of negotiated prices can have anticompetitive effects and harm consumers, contrary to long standing principles of antitrust law. One commenter recommended that any plan to make public privately negotiated rates should include requirements to aggregate information to ensure that arrangements of specific market participants remain confidential, and that a time lag also should be applied to any released data to ensure current information is not compromised.

The Departments disagree with the notion that the final rules will lead to anticompetitive behavior by plans, issuers, and providers. The Sherman Antitrust Act prohibits any contract, combination, or conspiracy in restraint of trade or commerce.[94] Specifically, the law prohibits any ''person'' from entering into any such contract, trust, or similar arrangement.[95] ''The primary purpose of the antitrust laws is to protect interbrand competition.'' *State Oil Co.* v. *Khan,* 522 U.S. 3, 15 (1997) (citing *Bus. Elec. Corp.* v. *Sharp Elec. Corp.,* 485 U.S. 717, 726 (1988)). The Departments are not of the view that publication of plans' and issuers' negotiated rates with providers is likely to spur plans and issuers (''persons'') to violate the law by colluding to fix their prices in a manner that restrains trade. Rather, while the publication of price information sometimes facilitates tacit collusion, based on public comments and the many empirical studies that have investigated the impact of price transparency on other, non-health care markets, the Departments are of the

[88] 18 U.S.C. 1839(5)–(6).

[89] 5 U.S.C. 552.

[90] 5 U.S.C. 552(b)(4).

[91] 42 U.S.C. 1320b–23(c).

[92] 42 U.S.C. 300gg(18)(e).

[93] *See, for example, Keene Corp.* v. *United States,* 508 U.S. 200, 208 (1993) (''[W]here Congress includes particular language in one section of a statute but omits it in another . . . it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'').

[94] 15 U.S.C. 1.

[95] *Id.* ''Person'' or ''persons'' are defined at 15 U.S.C. 12(a) (''[P]erson'' or ''persons'' wherever used in this Act shall be deemed to include corporations and associations existing under or authorized by the laws of either the United States, the laws of any of the Territories, the laws of any State, or the laws of any foreign country'').

view that transparency of negotiated rates will likely motivate plans, issuers, and providers to reassess the competitiveness of their prices in order to continue to successfully compete with lower premiums, deductibles, and other cost-sharing responsibilities, and lower priced health care items and services. As stated in the preamble of the Hospital Price Transparency Final Rule, many empirical studies have investigated the impact of price transparency on markets, with most research, consistent with predictions of standard economic theory, showing that price transparency leads to lower and more uniform prices.[96] Traditional economic analysis suggests that if consumers were to have better pricing information for health care services, providers would face pressure to lower prices and provide better quality care. Falling prices may, in turn, expand consumers' access to health care.[97]

By disclosing negotiated rates, the Departments are of the view that the public (including patients, employers, clinicians, and other third parties) will have the information necessary to make more informed decisions about their care. The Departments expect that the impact of more expansive transparency in pricing information will increase market competition and may ultimately drive down the cost of health care services, making care more affordable for all consumers.

Although the Departments appreciate that regulated entities could seek to engage in unlawful behavior in restraint of trade, antitrust law does not proscribe or limit action by the Federal Government to address chronic issues in the nation's health care markets. Such actions include new, innovative measures that, based on evidence and research, are likely to improve competition and lower costs to consumers. The Departments also are of the view that the statute and the final rules do not constitute an abrogation of antitrust law. Nothing under the final rules creates, compels, or endorses agreements or conspiracies between or among persons to form illegal arrangements or trusts in restraint of trade or commerce. To the contrary, antitrust law enforcement remains an important tool to protect these markets from anticompetitive behavior.

The Departments are of the view that the disclosure of negotiated rates would serve a greater public interest and that ''concealing negotiated price information serves little purpose other than protecting dominant providers' ability to charge above-market prices. . . .'' [98] For example, in Maine, one state official indicated that ''to date, there is no evidence that the release of [Maine Health Data Organization] claims data has resulted in an anticompetitive market. Similarly, disclosure of claims data in New Hampshire has resulted increased competition and reduced prices for health care.[99]

For the reasons set forth in this preamble, the Departments are of the view that the final rules will enhance competition, improve markets, and benefit all consumers of health care, including individuals, employers, and government health care programs. Under the final rules, disclosure of the negotiated rate is critical to the ability of consumers, including those who have not met their annual deductible obligation, to be able to reasonably estimate in advance their personal liability for covered services from participating providers. It is also critical in estimating coinsurance liabilities that are calculated as a percentage of provider charges. In addition, the Departments are of the view that accessible pricing information improves market efficiency.[100]

4. Administrative Procedure Act (APA) and Arbitrary and Capricious Agency Action

Some commenters asserted that the proposed rules were arbitrary and capricious and thus violate the APA. Two commenters contended that the Departments' rationale is entirely speculative. They also contended that the Departments have not quantified in a reliable way the costs or anticipated benefits of the proposed rules, examined relevant data, or articulated a satisfactory explanation for the proposed rules. One commenter held the opposite position and asserted that the proposed rules were fully consonant with APA requirements. The commenter believed the Departments are implementing PPACA appropriately, and that the interpretation of the authorities underlying the proposed rules was reasonable and rationally explained by the Departments.

The Departments are also of the view that the final rules are consistent with the APA. Section 1311(e)(3) of PPACA and section 2715A of the PHS Act are designed to assist consumers by enhancing their ability to make cost-conscious decisions, which is essential to establish and maintain the level of market competition necessary to ensure that health care costs are rational, reasonable, and governed by standard market discipline. As the preamble to the proposed rules observed, there is substantial evidence that increased price transparency improves market efficiency.[101] For these reasons, it is within the scope of the statute to assist consumers with selecting providers, evaluating market options, increasing competition, and reducing market disparities. The carefully targeted information is essential to the goals of price transparency, and there is no other means of making cost-sharing liability information available to consumers whose personal liability is determined in whole or in part by reference to negotiated rates or allowed amounts. The Departments further hold the view that the Departments have made reasonable efforts to quantify all aspects of the final rules, and their potential effects, for which data is available. The Departments also note that efforts have been made to qualitatively address those areas where the Departments are unable to adequately derive quantitative assessments. Responses to additional comments are discussed later in the Regulatory Impact Analysis (RIA) and Regulatory Alternatives Considered sections of this preamble.

This preamble (as well as the preamble to the proposed rules) cites substantial research indicating that increased price transparency increases competition and lowers costs, leads to

[96] 84 FR 65464, 65524 (Nov. 27, 2019).

[97] Austin, A. D., and Gravelle, J. G. ''Congressional Research Service Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector''. April 29, 2008. Available at: *https://crsreports.congress.gov/product/pdf/RL/RL34101.*

[98] Catalyst for Payment Reform. ''Report Card on State Price Transparency Laws.'' July 2015. Available at: *https://www.catalyze.org/wp-content/uploads/woocommerce_uploads/2017/04/2015-Report-Card-on-State-Price-Transparency-Laws.pdf.*

[99] Brown Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 101 Rev. of Econ. & Stat. 699 (2019). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.*

[100] Austin, D.A., and Gravelle, J.G. ''CRS Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' July 24, 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf.*

[101] 84 FR 65464, 65489; 65495 (Nov. 27, 2019); *see also* Austin, A.D., and Gravelle, J.G. ''Congressional Research Service Report to Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' July 24, 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf; see also* Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. Econ. & Stat. 1. Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf*; *see also* Enthoven, A. ''Market Forces and Efficient Health Care Systems.'' Health Affairs, Vol. 23, No. 2. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.23.2.25.*

more uniform pricing within markets, and increases overall market efficiency.[102] This preamble also cites an abundance of evidence indicating that industry and other stakeholders believe that increased price transparency will enhance competition and benefit consumers. As stated earlier in this preamble in relation to comments regarding the First Amendment, the information the final rules require to be disclosed is clearly identified and has a direct nexus to the government's legitimate and substantial interest in ensuring that consumers have sufficient information to calculate out of pocket costs for health care items and services and ultimately assess whether the payment terms of plans and coverages are fair, reasonable, or advantageous to the consumer. Furthermore, in the Impact Estimates of the Transparency in Coverage Provisions and Accounting Table section later in this preamble, the Departments identify ranges of relevant factors and categories of information that the Departments have attempted to quantify, as well as those factors and categories that the Departments cannot quantify at this time. Nevertheless, the Departments are of the view that those determinations are reasonable and sufficiently thorough, and that the Departments' expectations regarding the impacts of the final rules are not speculative.

5. Other Legal Concerns

Several commenters asserted that requiring issuers to make negotiated prices public could violate various state laws, principles of common law, and tort laws concerned with the protection of trade secrets and proprietary business information. Several commenters specifically stated that the proposal would violate the Uniform Trade Secrets Act (UTSA) [103] as adopted by several states.

The Departments understand these concerns and appreciate that States have passed laws and regulations that may address the same or similar information the final rules require to be publicly disclosed, or disclosed to participants, beneficiaries, or enrollees. The final rules will preempt these laws, to the extent they conflict with Federal law and would prevent application of Federal requirements, as required under section 1321(d) of PPACA and section 2724(a) of the PHS Act. The Departments discuss this issue in more detail later in this preamble in the context of addressing federalism considerations.

Moreover, the Departments are also of the view that negotiated rates do not constitute trade secrets as defined under the UTSA and under principles of tort law. A trade secret under the UTSA is ''information, including a formula, pattern, compilation, program, device, method, technique, or process'' that ''derives independent economic value. . . . from not being generally known [or] readily ascertainable by proper means by . . . other persons who can obtain economic value from its disclosure [and] is the subject of efforts to . . . maintain its secrecy.'' [104] Critically, and as discussed earlier, negotiated rates are routinely disclosed to beneficiaries in EOBs.

To the extent the final rules require disclosure of trade secrets, the activity that supports a cause of action under tort law includes obtaining the information by improper means or a breach of confidence.[105] No such scenario is implicated where the disclosure is made pursuant to a regulatory mandate authorized by statute. In this context, the disclosure is a legal obligation, and so the disclosure is by definition proper and made in the absence of any duty of confidence.

Finally, even if negotiated rates could constitute trade secrets under a state's law, state law cannot invalidate the authority Congress granted to the Departments under section 1311(e)(3) of PPACA to require disclosure of negotiated rates and other information that the Departments determine appropriate to create a level of transparency in coverage sufficient to address chronic issues in American health care markets, including rising health care prices.

Several commenters asserted that making negotiated rates public would violate contractual arrangements between virtually all issuers and providers, in particular contractual provisions that prohibit disclosure of negotiated rates. One commenter noted that this would, at a minimum, require a considerable effort to amend many existing contracts.

The Departments understand that changes in applicable laws and regulations may necessitate changes to certain business and contractual relationships over time. The Departments are of the view, however, that the final rules are necessary to advance the interests of consumers and to fulfill the goals of the relevant statutes. The Departments also anticipate that in most cases, affected contracts include clauses that specifically anticipate the possibility of future changes to applicable law or regulations. Additionally, even if a contract between a provider and a payer includes a provision prohibiting the public disclosure of its terms, it is the Departments' understanding that such contracts typically include exceptions if a particular disclosure is required by Federal law. Finally, as the Supreme Court has found, ''[c]ontracts, however express, cannot fetter the constitutional authority of Congress. Contracts may create rights of property, but when contracts deal with a subject matter which lies within the control of Congress, they have a congenital infirmity. Parties cannot remove their transactions from the reach of dominant constitutional power by making contracts about them.'' *Norman* v. *Balt. & Ohio R.R. Co.,* 294 U.S. 240, 307–08 (1935) (''If the regulatory statute is otherwise within the powers of Congress . . . its application may not be defeated by private contractual provisions.''); *see also Connolly,* 475 U.S. at 224.

Several commenters contended that the proposed rules would be inconsistent with certain Executive orders. One commenter contended that Executive Order 13877, which the Departments cited as the impetus for the proposed rules, directs the agencies to ''require . . . health insurance issuers . . . to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care.'' The commenter asserted that this directive does not rationally encompass a requirement that issuers make public all negotiated rates and allowed amounts.

[102] 84 FR 65464, 65466–67 (Nov. 27, 2019).

[103] The Uniform Trade Secrets Act is a model statute that a majority of states have adopted in some form. The UTSA is promulgated by the Uniform Law Commission. S*ee generally,* Uniform Trade Secrets Act with 1985 Amendments, Nat'l Conference of Commissioners on Uniform State Laws, August 1985. UTSA has been adopted in some form by 48 states. New York and North Carolina are the exceptions. *See* ''Trade Secrets Act.'' Uniform Laws Commission. Available at: *https://www.uniformlaws.org/committees/community-home?CommunityKey=3a2538fb-e030-4e2d-a9e2-90373dc05792.*

[104] *See* Uniform Trade Secrets Act with 1985 Amendments, Nat'l Conference of Commissioners on Uniform State Laws, August, 1985; Restatement (First) of Torts section 757 (1939).

[105] Restatement (First) of Torts section 757 (1939) (''*GENERAL PRINCIPLE.* One who discloses or uses another's trade secret, without a privilege to do so, is liable to the other if (a) he discovered the secret by improper means, or (b) his disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him, or (c) he learned the secret from a third person with notice of the facts that it was a secret and that the third person discovered it by improper means or that the third person's disclosure of it was otherwise a breach of his duty to the other, or (d) he learned the secret with notice of the facts that it was a secret and that its disclosure was made to him by mistake.'').

The commenter also asserted that the proposed rules are incompatible with section 3(b) of Executive Order 13877, which provides that any rulemaking be ''consistent with applicable law,'' in that the proposed rules run contrary to antitrust law as well as prohibitions against disclosing trade secrets.

The Departments disagree with these comments. First, Executive Order 13877 clearly states that it is ''not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.'' Executive Order 13877, Sec. 8(c). Thus, an Executive order cannot form the basis of a challenge to a rulemaking. Second, for all the reasons detailed earlier in this preamble, the Departments are of the view that the final rules are necessary and appropriate measures that are sufficiently narrowly tailored to meet the stated goals of the Executive order. Making public the negotiated rates and out-of-network allowed amounts is essential for consumers to obtain useful information about out-of-pocket costs they are likely to incur before receiving services. Due to the prevalence of high deductibles throughout markets nationwide, this information will be crucial for a significant cohort of persons enrolled in health plans to be able to anticipate costs in advance of each plan year. For the public, access to information concerning allowed amounts is essential to obtain reliable advance estimates of personal liability to facilitate cost-conscious choices that enhance competition and lower overall costs. Finally, as described later in this preamble, the Departments considered many alternatives to the proposed and final rules. The Departments are of the view that the final rules are a straightforward implementation of the mandate of section 1311(e)(3) of PPACA, and that the choices taken in particular instances are well calculated to effectively and fully implement the goals of the authorizing statutes. Moreover, the regulations provide tools and information to consumers that are critical to their ability to access meaningful price information, including the personal liability associated with a substantial portion of health care services. This directly facilitates the meaningful engagement of consumers with their own health care and protects patients from the likelihood of unanticipated health care costs. As such, the regulations fulfill the mandate of Executive Order 13877.

For the foregoing reasons, the final rules adopt the majority of the provisions in the proposed rules, with certain modifications, as described in detail in the following sections of this preamble.

II. Overview of the Final Rules Regarding Transparency—the Departments of the Treasury, Labor, and Health and Human Services

The Departments are finalizing price transparency requirements set forth in the final rules in 26 CFR 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3, 29 CFR 2590.715–2715A1, 2590.715–2715A2, and 2590.715–2715A3, and 45 CFR 147.210, 147.211, and 147.212. The final rules separate the proposed regulations all contained in 26 CFR 54.9815–2715A, 29 CFR 2590.715–2715A, and 45 CFR 147.210, into three separate regulations for each of the Departments. The regulations set forth the scope and relevant definitions in 26 CFR 54.9815–2715A1, 29 CFR 2590.715–2715A1, and 45 CFR 147.210 (which correspond with paragraph (a) of the proposed regulations). The regulations at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and, 45 CFR 147.211 (which correspond with paragraph (b) of the proposed regulations) include: (1) A requirement that group health plans and health insurance issuers in the individual and group markets disclose to participants, beneficiaries, or enrollees upon request, through a self-service tool made available by the plan or issuer on an internet website, cost-sharing information for a covered item or service from a particular provider or providers, and (2) a requirement that plans and issuers make such information available in paper form, upon request. As explained in more detail later in this preamble, the final rules adopt a three-year, phased-in approach with respect to the scope of the requirement to disclose cost-sharing information. Plans and issuers must make cost-sharing information available for 500 items and services identified by the Departments for plan years (in the individual market, for policy years) beginning on or after January 1, 2023, and must make cost-sharing information available for all items and services for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

The regulations at 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 (at paragraph (c) of the proposed regulations) require that plans and issuers disclose pricing information to the public through three machine-readable files. One file requires disclosure of payment rates negotiated between plans or issuers and providers for all covered items and services. The second file will disclose the unique amounts a plan or issuer allowed, as well as associated billed charges, for covered items or services furnished by out-of-network providers during a specified time period. To reduce the complexity and burden of including prescription drug information in the negotiated rate machine-readable file, the final rules require a third file that will include pricing information for prescription drugs. The final rules modify the applicability date for these provisions to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

The provisions proposed at paragraph (d) of the proposed regulations are finalized in 26 CFR 54.9815–2715A2 and 54.9815–2715A3, 29 CFR 2590.715–2715A2 and 2590.715–2715A3, and 45 CFR 147.211 and 147.212 with non-substantive editorial changes for increased readability, and with effective dates reflecting the phased approach to implementation mentioned earlier and discussed in more detail later in this preamble.

In addition to splitting the final rules into three separate regulations for each Department, the Departments have added severability clauses to the final rules to emphasize the Departments' intent that, to the extent a reviewing court holds that any provision of the final rules is unlawful, the remaining rules should take effect and be given the maximum effect permitted by law. The final rules provide that any provision held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from the relevant section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

To streamline the final rules, the Departments have removed definitions of terms that are defined in the applicable statute or elsewhere in such statutes' implementing regulations and have revised certain definitions to provide more clarity. Finally, based on comments received, the Departments have reassessed the associated burden estimates in the Economic Impact Analysis and Paperwork Burden section of this preamble.

A. Definitions

The final regulations at 26 CFR 54.9815–2715A1(a), 29 CFR 2590.715–2715A1(a), and 45 CFR 147.210(a) (paragraph (a) of the proposed regulations) set forth definitions that are applicable to the regulations at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–

2715A2, and 45 CFR 147.211 (paragraph (b) of the proposed regulations) and 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, 45 CFR 147.212 (paragraph (c) of the proposed regulations). The Departments have revised the proposed definitions of some terms and included new defined terms in order to clarify the final requirements of 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211, and 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212. Comments on the definitions in the proposed rule focused on concerns regarding consistency of definitions across related government programs, the general need for increased clarity in relation to some proposed definitions, and the need for resolution of perceived ambiguities in the proposed definitions. In response to these comments, the Departments are not finalizing certain proposed definitions that are already defined in existing, pertinent regulations. The Departments are finalizing revised versions of other proposed definitions to clarify their meaning, as well as the policies and requirements adopted in the final rules.

Commenters recommended aligning definitions in the proposed regulations with those in other existing regulations to avoid conflicts. In light of these recommendations, the Departments are not finalizing the proposed definition of ''participant'' under 26 CFR 54.9815–2715A1, 29 CFR 2590.715–2715A1, or 45 CFR 147.210 because the term is already defined in the Departments' regulations at 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103. Likewise, the Departments are not finalizing the proposed definition of ''beneficiary'' under proposed 45 CFR 145.210 and 29 CFR 2590.715–2715A1, because the term is already defined under HHS regulation at 45 CFR 144.103 and in statute at ERISA section 3(8). The Departments, however, are finalizing the definition of ''beneficiary'' proposed under 26 CFR 54.9815–2715A(a) (now at 26 CFR 54.9815–2715A1), because the term is not otherwise defined in Treasury Regulations or the Code. Finally, the Departments are not finalizing the proposed definition for ''qualified health plan'' at 45 CFR 145.210 since the term is not used in the regulation text.

Some commenters requested clarification of the terms ''participants'' and ''beneficiaries'' because the proposed rules' definitions of these terms included individuals who may become eligible for a plan or coverage, and as the proposed rules envisioned personalized feedback to ''participants'' and ''enrollees'' it would be impossible to provide such information to an individual not currently enrolled in a plan or coverage. The Departments agree. However, instead of modifying existing, applicable definitions for ''participants'' and ''beneficiaries,'' the final rules, at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211, and this preamble below clarify to whom these disclosures are required.

One commenter recommended the Departments define the term ''in-network provider'' in the final rules to clearly exclude device suppliers and manufacturers that, the commenter suggested, have not traditionally been considered in-network providers and whose price information is of limited value to consumers. The Departments do not agree that device suppliers and manufacturers should be excluded. Based on the numerous public comments from individuals who support broad price transparency for all covered items and services, the Departments are of the view that pricing information for all covered items and services should be available, including pricing for durable medical equipment (DME) or other medical devices that are supplied to a participant, beneficiary, or enrollee by a provider under a contract with a plan or issuer. To clarify, the final rules define in-network provider to mean any provider of items and services with which the plan or issuer, or a third-party for a plan or issuer, has a contract setting forth the terms under which a covered item or service may be provided to a participant, beneficiary, or enrollee. The Departments broadened this definition to clarify that even where a provider and a plan or issuer have a limited rate agreement of some kind, or a rate agreement covering DME, those providers should be considered in-network providers for purposes of the final rules. Additionally, if a plan or issuer enters into a contract or has such payment arrangements, then the pricing information for the specific covered items or services subject to that contract or payment arrangement are required to be disclosed as part of the internet self-service tool and machine-readable files.

The proposed regulations included a definition for ''negotiated rate'' to mean the amount a group health plan or health insurance issuer, or a third party on behalf of a plan or issuer, has contractually agreed to pay an in-network provider for covered items and services, pursuant to the terms of an agreement between the provider and the plan or issuer, or a third-party on behalf of a plan or issuer. Consistent with the proposed and final definitions of ''items and services,'' plans and issuers are required to disclose ''negotiated rates'' for encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees) to participants, beneficiaries, and enrollees through the internet-based self-service tool (and in paper form) as well as to the public through a machine-readable file. One commenter requested the Departments clarify the meaning of ''negotiated rate'' for prescription drugs, noting that they assumed the Departments expected plans and issuers to provide the drug price negotiated by a PBM on behalf of the plan. Another commenter asserted that the ''negotiated rate'' of prescription drugs for disclosure should be the price patients will see at the point-of-sale, meaning the undiscounted price of the drug, plus dispensing fees. Conversely, another commenter stated that dispensing fees are not paid by enrollees or used in determining cost-sharing liability. Other commenters suggested that the Departments grant plans and issuers flexibility in determining the appropriate rate for disclosure, as plans and issuers use a variety of different benchmarks, such as the Average Wholesale Price (AWP), or Wholesale Acquisition Cost (WAC) which may be considered as the ''negotiated rate'' for the purpose of determining cost-sharing liability under the plan or coverage.

In the final rules, the Departments have revised the definition of ''negotiated rate'' to mean the amount a plan or issuer has contractually agreed to pay for a covered item or service, whether directly or indirectly through a third party administrator (TPA) or PBM, to an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items or services. The final rules adopt the proposed definition with two key modifications. First, the term ''third party'' from the proposed definition is expanded in the final rules to explicitly refer to ''third-party administrator or pharmacy benefit manager.'' Second, the final definition of ''negotiated rate'' specifically notes that the term in-network provider includes an in-network pharmacy or other prescription drug dispenser. The purpose of these modifications is to confirm the commenter's inference that in the case of prescription drugs, the plan or issuer should include the price negotiated for that plan or issuer by a PBM. Furthermore, the ''negotiated rate'' in the final rules is intended to be broad enough to account for different plan

designs and benchmarks for determining negotiated rates.

The final rules also add definitions for the following terms that were not included in the proposed regulations: ''billed charge,'' ''copayment assistance,'' ''derived amount,'' ''historic net price,'' ''national drug code,'' and ''underlying fee schedule.'' The addition of these definitions is discussed later in this preamble.

One commenter noted that the Departments have proposed definitions for ''accumulated amounts,'' ''cost-sharing liability,'' and ''cost-sharing information'' that are unique to the proposed rules and, in some cases, differ from definitions of similar terms used in other related regulations. In particular, this commenter recommended that all definitions should explicitly recognize that cost sharing can be paid by or on behalf of an enrollee, participant, or beneficiary, since that is how cost sharing is defined by HHS regulation. The commenter also requested that the Departments clarify the proposed definition of ''accumulated amounts'' and suggested revising the definition to state clearly that accumulated amounts are the ''amount of financial responsibility a participant, beneficiary, or enrollee has incurred, whether satisfied by or on behalf of the participant, beneficiary, or enrollee. . . .''

The Departments recognize that cost sharing may be paid by a third-party on behalf of an enrollee, participant, or beneficiary. However, the Departments are of the view that some plans and issuers do not count cost-sharing liability payments made by a third-party towards a participant's, beneficiary's, or enrollee's accumulated amounts, and modifying the definitions as suggested by the commenter could cause confusion in the context of the final rules.

The Departments have added disclosure requirements that are discussed in detail elsewhere in this preamble to address this concern. The definitions being finalized also include non-substantive editorial changes from the proposed regulations for readability to the following terms; ''accumulated amounts,'' ''billing code,'' ''bundled payment arrangement,'' ''cost-sharing liability,'' ''cost-sharing information,'' ''covered items or services,'' ''item or services,'' and ''out-of-network allowed amount.''

The definitions identified as new or substantively modified in this section, as well as those that are being finalized as proposed, are discussed further in relation to the requirements of 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 and 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 throughout this preamble.

B. Requirements for Disclosing Cost-Sharing Information to Participants, Beneficiaries, and Enrollees

The final rules are intended to enable participants, beneficiaries, and enrollees to obtain an estimate of their potential cost-sharing liability for covered items and services they might receive from a particular health care provider, consistent with the requirements of section 2715A of the PHS Act and section 1311(e)(3)(C) of PPACA. Accordingly, the Departments proposed in paragraph (b) of the proposed regulations to require group health plans and health insurance issuers to disclose certain information relevant to a determination of a consumer's out-of-pocket costs for a particular health care item or service in accordance with specific method and format requirements, upon the request of a participant, beneficiary, or enrollee.

A majority of commenters supported the Departments' proposal and urged the Departments to finalize this section of the proposed rules. Many commenters were supportive of being able to know their costs before receiving care in order to make informed shopping decisions. Some commenters agreed that consumers should have access to cost information in advance of receiving care, but suggested modifications to the proposed requirements. The final rules adopt the requirement that plans and issuers disclose certain cost-sharing information for a particular health care item or service, generally as set forth in the proposed rules, but with certain modifications and clarifications explained later in this section of this preamble.

1. Information Required To Be Disclosed to Participants, Beneficiaries, or Enrollees

Based on significant research and review of public comments, the Departments concluded that requiring group health plans and health insurance issuers to disclose to participants, beneficiaries, or enrollees cost-sharing information in the manner most familiar to them is the best means to empower individuals to understand their potential cost-sharing liability for covered items and services furnished by particular providers. The Departments, therefore, modeled the proposed price transparency requirements on existing notice requirements.

Specifically, section 2719 of the PHS Act (incorporated into the Code by section 9815 of the Code and into ERISA by section 715 of ERISA) requires non-grandfathered plans and issuers offering non-grandfathered coverage in the individual or group markets to provide a notice of adverse benefit determination (typically satisfied by the EOB) to participants, beneficiaries, or enrollees after health care items or services are furnished and claims for benefits are adjudicated. EOBs typically include the amount billed by a provider for items and services, negotiated rates or underlying fee schedules with in-network providers or allowed amounts for out-of-network providers, the amount the plan paid to the provider, and the individual's obligation for deductibles, copayments, coinsurance, and any other balance under the provider's bill. Consumers are accustomed to seeing cost-sharing information as it is presented in an EOB. The proposed rules were intended to similarly require plans and issuers to provide the specific price and benefit information on which an individual's cost-sharing liability is based. Based on comments, the Departments are of the view that participants, beneficiaries, and enrollees would also benefit from understanding the price of items and services, even in circumstances when their cost-sharing liability is not based upon a negotiated rate or underlying fee schedule rate. Given this primary goal of overall price transparency, the Departments are requiring disclosure of the negotiated rate, even if it is not the amount used as the basis for cost-sharing liability.

The proposed rules set forth seven content elements that a plan or issuer must disclose, upon request, to a participant, beneficiary, or enrollee for a covered item or service: estimated cost-sharing liability, accumulated amounts, negotiated rates, out-of-network allowed amounts, a list of items and services subject to bundled payment arrangements, a notice of prerequisites, if applicable, and a disclosure notice. These seven content elements generally reflect the same information that is included in an EOB after health care services are provided. The Departments determined that each of the seven content elements, as well as two additional content elements, are necessary and appropriate to implement the mandates of section 2715A of the PHS Act and section 1311(e)(3)(C) of PPACA by permitting individuals to learn the amount of their cost-sharing liability and understand the price for specific items or services under a plan

or coverage from a particular provider. The final rules adopt the requirement that plans and issuers must satisfy these elements through disclosure of actual data relevant to an individual's cost-sharing liability that is accurate at the time the request is made. The Departments acknowledge that plans and issuers may not have processed all of an individual's outstanding claims when the individual requests the information; therefore, plans and issuers would not be required to account for outstanding claims that have not yet been fully processed. As set forth in 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 this cost-sharing information must be disclosed upon request in two ways: (1) Through a self-service tool that meets certain standards and is available on an internet website, and (2) in paper form, if requested by the participant, beneficiary, or enrollee.

Furthermore, under the final rules, the cost-sharing information must be disclosed to the participant, beneficiary, or enrollee in plain language. The final rules define ''plain language'' to mean written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee. Determining whether this standard has been satisfied requires an exercise of considered judgment and discretion, taking into account such factors as the level of comprehension and education of typical participants, beneficiaries, or enrollees in the plan or coverage and the complexity of the terms of the plan or coverage. Accounting for these factors would likely require limiting or eliminating the use of technical jargon and long, complex sentences, so that the information provided will not have the effect of misleading, misinforming, or failing to inform participants, beneficiaries, or enrollees.

Several commenters agreed that the information found in an EOB is a good basis for informing individuals of their cost-sharing liability and will effectively further coverage transparency efforts. One commenter stated that information found in an advance EOB is neither a trade secret, nor proprietary, as it is routinely disclosed following care. Other commenters expressed concern about this concept of an advance EOB, stating that most plans and issuers do not have access to all the information necessary to provide beneficiaries with an upfront adjudication of the beneficiary's claim, and that the vast majority of data provided via online tools now rely on estimated costs drawn from publicly available sources rather than personal information and circumstances.

Many commenters expressed concerns that the elements and methods of disclosure proposed by the Departments are overly prescriptive, hindering health plan innovation and requiring potentially significant reworking of existing transparency tools, as well as requiring massive IT and resource investments by all commercial plans and issuers to develop, build or modify, test, and implement tools that meet the new standards. Several commenters recommended providing plans and issuers with flexibility to build upon current systems. Another commenter urged the Departments to evaluate the individualized tools currently available, and that if requirements for cost-estimator tools are adopted, they should give carriers and TPAs maximum flexibility in designing their tools. One commenter felt a better approach would be to educate consumers about the online tools that are currently available and assist employers to encourage their use. Several commenters opposed the requirement to provide the tool and suggested the Departments remove this requirement from the final rules altogether. These commenters stated that price estimator tools should not be required, citing studies showing low tool utilization by consumers and plan participants, beneficiaries, or enrollees. These commenters stated that the administration should instead focus on educating consumers about the online tools that are currently available and assisting employers and plans in encouraging their use.

The Departments are of the view that modeling the pricing disclosures on the elements provided within an EOB is both reasonable and appropriate. The Departments acknowledge the potential burden of updating existing tools to comply with the final rules, but the Departments think that the potential burden is outweighed by the importance of all enrollees, beneficiaries, and participants having access to self-service tools that provide a baseline of accurate pricing elements. The Departments also acknowledge that, historically, there has been low utilization of existing tools; however, the Departments are of the view that by creating minimum uniform standards, consumers will have access to more reliable, personalized estimates and will be more likely to use the tools.

As described earlier in this preamble, through independent examination and engagement with stakeholders, the Departments are of the view that existing tools vary widely in usability and reliability due to the lack of minimum standards.[106] The Departments received thousands of supportive comments from individuals eager for access to transparent pricing information, indicating that the current tools available are inadequate in practice. Furthermore, as discussed in great detail throughout this preamble, as consumers increasingly become financially responsible for a greater proportion of the cost of their care (through deductible and coinsurance requirements, for example) they have a vested interest in comparing prices of potential providers and such items as prescription drugs. As such, it is likely in the best interest of plans, issuers, and providers to promote and educate their consumers on the benefits of these shopping tools, and the Departments encourage them to do so. The Departments do not agree with the commenter who stated that educating consumers regarding existing tools and encouraging their use would be a better approach than requiring the self-service tool as proposed. While the Departments agree that educating consumers on existing self-service tools is important, it does not replace the benefits of making reliable self-service tools available to most participants, beneficiaries, and enrollees in private market plans and coverages. The Departments are of the view that minimum consistent requirements for all plans and issuers may lead to an increase in health literacy and drive consumerism as participants, beneficiaries, and enrollees become more familiar with how plans and issuers calculate cost-sharing liability. Furthermore, the final rules adopt a phased implementation approach to these requirements as a mechanism to help mitigate the associated implementation burdens.

Some commenters requested that the Departments confirm that the intent of the proposed rules is that only participants and beneficiaries enrolled in the plan would have access to the tool, noting that the proposed regulations used the ERISA definitions of ''participant'' and ''beneficiary,''

[106] ''Are healthcare's cost estimate tools making matters worse for patients?'' Becker's Hospital CFO Report, November 2015. Available at: *https://www.beckershospitalreview.com/finance/are-healthcare-s-cost-estimate-tools-making-matters-worse-for-patients.html. Citing* Gordon, E. ''Patients Want to Price-Shop For Care, But Online Tools Unreliable.'' NPR. November 30, 2015, Available at *https://www.npr.org/sections/health-shots/2015/11/30/453087857/patients-want-to-price-shop-for-care-but-online-tools-unreliable.* (''Some estimators reflect a combined range of possible costs, while others are based off historical pricing or claims data from various sources. Many online estimate tools are restricted in the types of procedures they include. . .'').

which include individuals who may become eligible for the plan. Many commenters encouraged the Departments to also require that plans and issuers make cost-sharing information easily accessible to authorized representatives—which may include health care providers—so that they can better respond to patient inquiries. These commenters suggested that patients reasonably turn to providers for this information when contemplating or scheduling health care services, but providers often face barriers in accessing the necessary details from issuers to provide a timely, accurate estimate. Commenters suggested that plans and issuers should be required to give providers access to their patients' specific benefit information via a secure website, subject to patient consent. One commenter recommended that the tool be made applicable for the public while they are in the shopping and plan selection phase, not just after someone is enrolled in a plan. This commenter suggested that true cost transparency would not be possible if this information was not made available in advance.

The final rules clarify that disclosures of cost-sharing information are only required to individuals who are enrolled in the plan or coverage; no disclosures are required to be made to a ''participant'' or ''beneficiary'' solely because they might become eligible for the plan in the future. This is reflected by a revision to the proposed language being finalized at 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b) to refer to plans and issuers providing cost-sharing information to a participant, beneficiary, or enrollee who is enrolled in a plan or coverage. The Departments understand the value in provider access to cost-sharing information required under the final rules. However, this rulemaking focuses on implementing the statutory obligation for plans to make this information available to participants, beneficiaries, and enrollees. A participant, beneficiary, or enrollee may choose to share information regarding their personal cost-sharing liability with a provider for the purposes of making health care decisions. The final rules also require that this information must be provided to a participant's, beneficiary's, or enrollee's authorized representative. Under other applicable regulations, participants, beneficiaries, or enrollees may appoint a health care provider as their authorized representative.[107]

Regarding whether other types of information should be required to be disclosed in the self-service tool, several commenters expressed concern that information regarding cost without accompanying provider quality information could have a detrimental effect on overall health care cost and delivery of value-based care. One commenter stated that shifting care to a lower-cost provider could have unintended consequences of higher costs associated with unnecessary or improper care. Commenters recommended that a quality metric be included and that quality information be allowed to be included alongside price.

As discussed in the background section of this preamble and later in this preamble, the Departments acknowledge that quality information could be a valuable addition to a self-service tool. However, the Departments did not propose to require disclosure of quality information. Rather, the Departments sought comments regarding quality information in the proposed rules and plan to take those comments into consideration for future action. The Departments encourage plans and issuers to further innovate around the baseline standards outlined above and include quality information and other metrics not required by the final rules that would assist in consumer decision-making.

Several commenters suggested that plans and issuers should be required to disclose information not directly related to cost sharing. One commenter urged the Departments to include an additional requirement in the final rules for plans and issuers to provide consumers with information they need to fully understand their cost-sharing obligations for emergency services at the time they obtain their coverage, and recommended plans and issuers also update this information on an annual basis or when major changes occur that would impact their access to, and overall cost of, emergency care, such as changes to their provider. Another commenter recommended that when consumers enter a search for a primary service or treatment, that they also be provided with an ''alert'' that additional services, such as anesthesia, pathology, or laboratory tests, likely will be involved and will entail additional costs, which should also be disclosed. Another commenter requested that the Departments add the ''type of plan'' (for example, ERISA-covered group health plan, a QHP, a Medicare Advantage plan, a Medicaid MCO plan, an individual health plan, or a plan that is grandfathered from PPACA requirements) and in what state the plan is providing coverage as disclosure content elements that health plans would be required to post on the proposed internet-based self-service tool, so that the information is readily available.

The Departments recognize the benefit of providing information for emergency services at the time consumers obtain their coverage. The Departments are of the view, however, that existing rules governing summaries of benefits and coverage are designed to provide such information to consumers at the time they obtain coverage. As such, the Departments are not inclined to duplicate existing requirements in the final rules. The Departments also acknowledge that alerting consumers to additional services associated with a service or treatment for which they searched could be beneficial. For this reason, the final rules provide plans and issuers flexibility to give disclaimers that can address the likelihood that services in addition to the one for which a consumer searched will be necessary. The final rules also require that plans and issuers outline individual services when a consumer requests an estimate for a service that, per the agreement between a payer and a provider, will be provided and billed as a bundle. Plans and issuers are also free to provide such information in any way they so choose, including through an alert. The Departments are also of the view that participants, beneficiaries, and enrollees are generally aware of the type of plan they are enrolled in or can reasonably access this information by contacting their plan or issuer and therefore decline to require this information as part of the final rules.

Scope of Items and Services

Many commenters stated that the requirement to disclose the price of all covered items and services was overly broad and overly burdensome, and instead suggested the Departments limit disclosure to a core set of ''shoppable services'' that are commonly searched for in existing cost-estimator tools. Many commenters referenced the recently finalized definition of a shoppable service that was included in the Hospital Price Transparency final rule as ''a service that can be scheduled by a health care consumer in

[107] 29 CFR 2560.503–1(b)(4); *see also* 26 CFR 54.9815–2719(b)(2)(i), 29 CFR 2590.715–2719(b)(2)(ii), and 45 CFR 147.136(b)(2)(ii).

advance.''[108] Two commenters recommended no more than 300 shoppable items and services, while another suggested a limit of 200. As a way to reduce the cost burden, one commenter suggested that the requirements under the rules be limited to services that are priced above a certain threshold and provided $5,000 as an example. One commenter said the Departments should permit health plans and issuers to tailor their tools to best meet their enrollees' and providers' demonstrated needs and priorities, including selection of the items and services for which estimates are most useful and meaningful for participants, beneficiaries, and enrollees. Another commenter recommended that the cost-sharing requirement be limited to items and services where the estimated out-of-pocket price is frequently the same as the final price. Another recommended the tool not require data on those items/services with volatile prices or low volume.

One commenter, representing many plans and issuers, provided a list of 421 items and services that they recommended including under this disclosure requirement. The recommended list of 421 items and services are a result of an analysis the commenter performed which compared member feedback, claims frequency, operational feasibility, and state mandates and regulations, as well as variability of cost and search frequency. All 421 items and services were included by, at the minimum, a subset of issuers, indicating confidence that the covered items and services were shoppable. This commenter also noted that their survey of existing tools found a median of 526 services available to consumers enrolled in commercial coverage.

A few commenters recommended that the Departments limit the list of items and services to only major medical services. One commenter recommended the Departments not include cost sharing for DME. Several commenters suggested that a Technical Expert Panel (TEP) was needed to review data and input from stakeholders, advise on research the Departments should undertake, and determine which items and services and functional requirements would be suitable to include in the future.

Many individual commenters expressed their desire for dental, vision, and other excepted benefits to be included under the requirements of the final rules or in the near future. Further, a majority of individual commenters encouraged the Departments to require the inclusion of all items and services, stating that consumers have a right to know this information for all items and services in advance. Several commenters recommended that the rules be implemented in a more gradual phased-in timeline, by requiring the tool to cover a narrower data set of the most common shoppable services first and then broadened to eventually include all items and services. Another commenter stated that to the extent that the services include non-medical estimates like pharmacy and dental costs, those costs could likely only be included by allowing third parties that fulfill those benefits to provide separate transparency tools that integrate with a plan's tool.

The Departments agree with commenters who stated that consumers should be given price estimates in advance, and the Departments understand that what is considered useful and meaningful pricing information is likely to be unique to an individual's circumstances. For these reasons, and the rationale for this rulemaking described throughout this preamble, the Departments decline to accept suggestions related to limiting the number or types of items and services included under this requirement. However, the Departments acknowledge the potential burden of incorporating all items and services into a self-service tool immediately and are therefore finalizing a phased-in implementation timeline. Under the final rules, plans and issuers are required to provide estimates for the 500 items and services identified in Table 1 for plan years (in the individual market, for policy years) beginning on or after January 1, 2023. However, plans and issuers will be required to disclose pricing information with respect to all items and services for plan years (in the individual market, for policy years) beginning on or after January 1, 2024. Given that pricing estimates for all items and services will ultimately be required, the Departments do not find it necessary to convene a TEP to determine which items and services and functional requirements would be suitable to include in the future.

Further, in finalizing the provision that plans and issuers disclose cost-sharing liability information for all covered items and services, the Departments are clarifying that cost-sharing information must also be provided for covered prescription drugs and DME. As discussed later in this preamble, a plan or issuer will be considered compliant with this requirement if it offers its participants, beneficiaries, or enrollees access to the pricing information that is required under 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211, through a third-party tool, such as a PBM tool. As discussed elsewhere in this preamble, the Departments clarify that excepted benefits, such as limited-scope dental benefits offered under a separate policy, certificate, or contract of insurance that are not an integral part of a group health plan or health insurance coverage, are not subject to the requirements established under the final rules.

In developing the list of 500 items and services that are required to be included in the self-service tool during the first year of implementation, the Departments considered the recommendations made by the commenters to include shoppable items and services that are commonly used in existing tools. As mentioned above, in a survey of existing price transparency tools currently in use, one commenter found that the median number of items and services in existing tools is 526. Table 1 lists 500 items and services that will be required to be included in the first phase of implementation of the internet-based self-service tool. The Departments will publish a copy of this list on a publicly available website. The majority of these items and services (416) are based on the recommendation of several stakeholders. The Departments have determined not to include five of the recommended codes because they have since been retired. The Departments augmented the list with 84 additional services. These 84 services reflect some of the most frequently found services in External Data Gathering Environment (EDGE) [109] data, which are representative of services commonly provided in the individual and small group (or merged) markets. The Departments also examined the aggregate claims costs associated with these services nationally and concluded that these services could

[108] 84 FR 65524 (Nov. 27, 2019) (codified at 45 CFR 180.20).

[109] CMS began collecting enrollee-level data from issuers' EDGE servers beginning with the 2016 benefit year. See the HHS Notice of Benefit and Payment Parameters for 2018; Final Rule, 81 FR 94058, 94101–94103 (Dec. 22, 2016). The enrollee-level EDGE data collected by CMS includes an enrollment file, a medical claims file, a pharmacy claims file, and a supplemental diagnosis file for risk adjustment-covered plans in the states where HHS operates the risk adjustment program. CMS does not collect enrollee-identifiable elements to safeguard enrollee privacy and issuers' proprietary information. *See,* for example, 45 CFR 153.720.

have significant cost variability, ranging from the 25th percentile to the 75th percentile of costs, depending on service.

TABLE 1—500 ITEMS AND SERVICES LIST

Code	Description	Plain language description
J0702	BETAMETHASONE ACET&SOD PHOSP	Injection to treat reaction to a drug.
J1745	INFLIXIMAB NOT BIOSIMIL 10MG	A biologic medication.
G0102 ...	Prostate cancer screening; digital rectal examination	
G0103 ...	Prostate cancer screening; prostate specific antigen test (psa).	
G2061 ...	Qualified non physician healthcare professional online assessment; 5–10 minutes.	Qualified non physician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes.
G2062 ...	Qualified non physician healthcare professional online assessment service; 11–20 minutes.	Qualified non physician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes.
G2063 ...	Qualified non physician qualified healthcare professional assessment service; 21+ minutes.	Qualified non physician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes.
G0206 ...	Diagnostic mammography, including computer-aided detection (cad) when performed; unilateral.	
G0204 ...	Diagnostic mammography, including computer-aided detection (cad) when performed; bilateral.	
G0121 ...	Colon ca scrn; not hi risk ind	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk.
G0105 ...	Colorectal ca scrn; hi risk ind	Colorectal cancer screening; colonoscopy on individual at high risk.
S0285	Cnslt before screen colonosc	Colonoscopy consultation performed prior to a screening colonoscopy procedure.
G0289 ...	Arthro, loose body + chondro	Arthroscopy, knee, surgical, for removal of loose body, foreign body, debridement/shaving of articular cartilage (chondroplasty) at the time of other surgical knee arthroscopy in a different compartment of the same knee.
G0120 ...	Colon ca scrn; barium enema	Colorectal cancer screening; alternative to g0105, screening colonoscopy, barium enema.
460	SPINAL FUSION (POSTERIOR)	Spinal fusion except cervical.
470	KNEE REPLACEMENT	Major joint replacement or reattachment of lower extremity.
473	SPINAL FUSION (ANTERIOR)	Cervical spinal fusion.
743	HYSTERECTOMY	Uterine and adnexa procedures for non-malignancy.
1960	Anesthesia for vaginal delivery	
1961	Anesthesia for cesarean delivery	
1967	Anesthesia for labor during planned vaginal delivery	
1968	Anesthesia for cesarean delivery following labor	
10005	FNA W IMAGE	Fine needle aspiration biopsy, including ultrasound guidance; first lesion.
10021	FNA W/O IMAGE	Fine Needle Aspiration Biopsy without imaging.
10040	ACNE SURGERY	Incision and Drainage Procedures on the Skin, Subcutaneous and Accessory Structures.
10060	DRAINAGE OF SKIN ABSCESS	Incision and drainage of abscess; simple or single and complex or multiple.
10140	DRAINAGE OF HEMATOMA/FLUID	Incision and drainage of hematoma, seroma or fluid collection.
10160	PUNCTURE DRAINAGE OF LESION	Puncture aspiration of abscess, hematoma, bulla, or cyst.
11000	DEBRIDE INFECTED SKIN	Removal of infected skin.
11056	TRIM SKIN LESIONS 2 TO 4	Paring or cutting of benign hyperkeratotic lesion.
11102	BIOPSY SKIN LESION	Tangential biopsy of skin (for example, shave, scoop, saucerize, curette); single lesion.
11103	BIOPSY SKIN ADD–ON	Tangential biopsy of skin (for example, shave, scoop, saucerize, curette); each separate/additional lesion.
11200	REMOVAL OF SKIN TAGS <W/15	Removal of skin tags, multiple fibrocutaneous tags, any area.
11401	EXC TR–EXT B9+MARG 0.6–1 CM	Under Excision-Benign Lesions Procedures on the Skin 0.6–1 CM.
11422	EXC H–F–NK–SP B9+MARG 1.1–2	Under Excision-Benign Lesions Procedures on the Skin 1.1–2 CM.
11602	EXC TR–EXT MAL+MARG 1.1–2 CM	Excision-Malignant Lesions.
11721	DEBRIDE NAIL 6 OR MORE	Removal of 6 or more nails.
11730	REMOVAL OF NAIL PLATE	Separation and removal of the entire nail plate or a portion of nail plate.
11900	INJECT SKIN LESIONS </W7	Injections to remove up to 7 lesions on the skin.
12001	RPR S/N/AX/GEN/TRNK 2.5CM/<	Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities.
12011	RPR F/E/E/N/L/M 2.5 CM/<	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes.
17000	DESTRUCT PREMALG LESION	Destruction of pre-cancerous lesion.
17003	DESTRUCT PREMALG LES 2–14	Destruction of 2–14 pre-cancerous lesions.
17110	DESTRUCT B9 LESION 1–14	Destruction of 1–14 common or plantar warts.
17111	DESTRUCT LESION 15 OR MORE	Destruction of >15 common or plantar warts.
17250	CHEM CAUT OF GRANLTJ TISSUE	Chemical destruction of pre-cancerous lesions of the skin.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
17311	MOHS 1 STAGE H/N/HF/G	Micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens.
19120	REMOVAL OF BREAST LESION	
20550	INJ TENDON SHEATH/LIGAMENT	Injection of medication into a tendon or ligament.
20551	INJ TENDON ORIGIN/INSERTION	Injection of medication into the tendon/ligament origin.
20553	INJECT TRIGGER POINTS 3/>	Injection of medication into an area that triggers pain.
20600	DRAIN/INJ JOINT/BURSA W/O US	Draining or injecting medication into a small joint/bursa without ultrasound.
20605	DRAIN/INJ JOINT/BURSA W/O US	Draining or injecting medication into a large joint/bursa without ultrasound.
20610	DRAIN/INJ JOINT/BURSA W/O US	Draining or injecting medication into a major joint/bursa without ultrasound.
20612	ASPIRATE/INJ GANGLION CYST	Removal of fluid or injection of medication into a ganglion cyst.
27440	Revision of knee joint	Repair of knee joint.
27441	Revision of knee joint	Repair of knee joint.
27442	Revision of knee joint	Repair of knee joint.
27443	Revision of knee joint	Repair of knee joint.
27445	Revision of knee joint	Repair of knee joint with hinged prosthesis.
27446	Revision of knee joint	Repair of knee joint.
28296	CORRECTION HALLUX VALGUS	Under Repair, Revision, and/or Reconstruction Procedures on the Foot and Toes.
29826	Subacromial Decompression	Shaving of shoulder bone using an endoscope.
29848	WRIST ENDOSCOPY/SURGERY	Carpal tunnel release.
29880	KNEE ARTHROSCOPY/SURGERY	Surgery to remove of all or part of a torn meniscus in both medial and lateral compartments.
29881	KNEE ARTHROSCOPY/SURGERY	Surgery to remove of all or part of a torn meniscus in one compartment.
29888	KNEE ARTHROSCOPY/SURGERY	ACL reconstruction.
30520	REPAIR OF NASAL SEPTUM	Repair procedures of the nose.
31231	NASAL ENDOSCOPY DX	Nasal endoscopy, diagnostic, unilateral or bilateral.
31237	NASAL/SINUS ENDOSCOPY SURG	Surgical nasal/sinus endoscopy with biopsy, polypectomy or debridement.
31575	DIAGNOSTIC LARYNGOSCOPY	Flexible, fiberoptic diagnostic laryngoscopy.
36415	ROUTINE VENIPUNCTURE	Collection of venous blood by venipuncture.
36471	NJX SCLRSNT MLT INCMPTNT VN	Injections to remove spider veins on the limbs or trunk.
36475	ENDOVENOUS RF 1ST VEIN	Ablation of incompetent vein.
36478	ENDOVENOUS LASER 1ST VEIN	Laser removal of incompetent vein.
42820	REMOVE TONSILS AND ADENOIDS	Removal of tonsils and adenoid glands patient younger than age 12.
42826	REMOVAL OF TONSILS	Primary or secondary removal of tonsils.
42830	REMOVAL OF ADENOIDS	Primary removal of the adenoids.
43235	EGD DIAGNOSTIC BRUSH WASH	Diagnostic examination of esophagus, stomach, and/or upper small bowel using an endoscope.
43239	EGD BIOPSY SINGLE/MULTIPLE	Biopsy of the esophagus, stomach, and/or upper small bowel using an endoscope.
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption.	Surgical procedure used for weight loss resulting in a partial removal of stomach.
44388	Colonoscopy thru stoma spx	Diagnostic examination of large bowel using an endoscope which is inserted through abdominal opening.
44389	Colonoscopy with biopsy	Biopsies of large bowel using an endoscope which is inserted through abdominal opening.
44394	Colonoscopy w/snare	Removal of large bowel polyps or growths using an endoscope.
45378	DIAGNOSTIC COLONOSCOPY	Diagnostic examination of large bowel using an endoscope.
45379	Colonoscopy w/fb removal	Removal of foreign bodies in large bowel using an endoscope.
45380	COLONOSCOPY AND BIOPSY	Biopsy of large bowel using an endoscope.
45381	Colonoscopy submucous njx	Injections of large bowel using an endoscope.
45382	Colonoscopy w/control bleed	Control of bleeding in large bowel using an endoscope.
45384	Colonoscopy w/lesion removal	Removal of polyps or growths in large bowel using an endoscope.
45385	COLONOSCOPY W/LESION REMOVAL	Removal of polyps or growths of large bowel using an endoscope.
45386	Colonoscopy w/balloon dilat	Balloon dilation of large bowel using an endoscope.
45388	Colonoscopy w/ablation	Destruction of large bowel growths using an endoscope.
45390	Colonoscopy w/resection	Removal of large bowel tissue using an endoscope.
45391	Colonoscopy w/endoscope us	Ultrasound examination of lower large bowel using an endoscope.
45392	Colonoscopy w/endoscopic fnb	Ultrasound guided needle aspiration or biopsy of lower large bowel using an endoscope.
45398	Colonoscopy w/band ligation	Tying of large bowel using an endoscope.
47562	LAPAROSCOPIC CHOLECYSTECTOMY	Removal of gallbladder using an endoscope.
47563	LAPARO CHOLECYSTECTOMY/GRAPH	Gallbladder removal with use of an x-ray exam of the bile ducts.
49505	PRP I/HERN INIT REDUC >5 YR	Repair of groin hernia patient age 5 years or older.
49585	RPR UMBIL HERN REDUC > 5 YR	Repair of umbilical hernia in patients over 5 years old.
49650	LAP ING HERNIA REPAIR INIT	Inguinal hernia repair done by laparoscope.
50590	FRAGMENTING OF KIDNEY STONE	Surgical procedures on the kidney to break up and remove kidney stones.
51741	ELECTRO–UROFLOWMETRY FIRST	A diagnostic test used to measure the flow of urine.
51798	US URINE CAPACITY MEASURE	Ultrasound of bladder to measure urine capacity.
52000	CYSTOSCOPY	Procedure on the bladder.
52310	CYSTOSCOPY AND TREATMENT	Removing an indwelling ureteral stent by cystoscopy.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
52332	CYSTOSCOPY AND TREATMENT	Ureteral stents inserted internally between the bladder and the kidney and will remain within the patient for a defined period of time.
55250	EXCISION PROCEDURES ON THE VAS DEFERENS	Removal of sperm duct(s).
55700	Prostate biopsy	Biopsy of prostate gland.
55866	Surgical Procedures on the Prostate	Surgical removal of prostate and surrounding lymph nodes using an endoscope.
57022	Incision and drainage of vaginal blood accumulation following delivery.	
57288	REPAIR BLADDER DEFECT	Replacement of sling to support the bladder.
57454	BX/CURETT OF CERVIX W/SCOPE	Biopsy of cervix or uterus.
58100	EXCISION PROCEDURES ON THE CORPUS UTERI	Biopsy of the lining of the uterus.
58558	HYSTEROSCOPY BIOPSY	Surgical hysteroscopy with biopsy.
58563	HYSTEROSCOPY ABLATION	Surgical procedure used to treat premenopausal abnormal uterine bleeding.
58565	HYSTEROSCOPY STERILIZATION	Laparoscopic/Hysteroscopic Procedures on the uterus.
58571	TLH W/T/O 250 G OR LESS	Laparoscopic hysterectomy.
58661	LAPAROSCOPY REMOVE ADNEXA	Removal of either benign or malignant tissue from the uterus, ovaries, fallopian tubes, or any of the surrounding tissues using a laparoscope.
58662	LAPAROSCOPY EXCISE LESIONS	Removal of lesions of the ovary, pelvic viscera, or peritoneal surface.
58671	LAPAROSCOPY TUBAL BLOCK	Laparoscopic tubal sterilization is surgery to block the fallopian tubes to prevent pregnancy.
59000	AMNIOCENTESIS DIAGNOSTIC	Removal of amniotic fluid from the uterus for diagnostic purposes.
59025	FETAL NON–STRESS TEST	A common prenatal test used to check on a baby's health.
59400	OBSTETRICAL CARE	Obstetrical pre- and postpartum care and vaginal delivery.
59409	Vaginal delivery	
59410	Vaginal delivery with post-delivery care	
59414	Vaginal delivery of placenta	
59425	Pre-delivery care 4–6 visits	
59426	Pre-delivery care 7 or more visits	
59510	CESAREAN DELIVERY	Cesarean delivery with pre- and post-delivery care.
59514	Cesarean delivery	
59515	Cesarean delivery with post-delivery care	
59610	VBAC DELIVERY	Vaginal delivery after prior cesarean delivery.
59612	Vaginal delivery after prior cesarean delivery	
59614	Vaginal delivery after prior cesarean delivery with post-delivery care.	
62322	SPINAL INJECTION FOR PAIN MANAGEMENT	Injection of substance into spinal canal of lower back or sacrum using imaging guidance.
62323	Injection of substance into spinal canal of lower back or sacrum using imaging guidance.	
63030	LOW BACK DISK SURGERY	Surgical procedure to decompress a herniated vertebra.
64483	Transforaminal Epidural Injection	Injections of anesthetic and/or steroid drug into lower or sacral spine nerve root using imaging guidance.
64493	INJ PARAVERT F JNT L/S 1 LEV	Injection into lower back of nerve block using imaging guidance.
64721	CARPAL TUNNEL SURGERY	Release of the transverse carpal ligament.
66821	YAG capusulotomy surgery	Removal of recurring cataract in lens capsule using laser.
66984	CATARACT SURG W/IOL 1 STAGE	Removal of cataract with insertion of lens.
67028	INJECTION EYE DRUG	Injection of a pharmaceutical agent into the eye.
69210	REMOVE IMPACTED EAR WAX	Removal of ear wax from one or both ears.
69436	CREATE EARDRUM OPENING	Insertion of tubes into one or both ears.
70450	CT HEAD/BRAIN W/O DYE	CT scan head or brain without dye.
70486	CT MAXILLOFACIAL W/O DYE	CT Scan of the face and jaw without dye.
70491	CT SOFT TISSUE NECK W/DYE	CT scan of neck with dye.
70551	MRI BRAIN STEM W/O DYE	MRI of brain stem without dye.
70553	MRI BRAIN STEM W/O & W/DYE	MRI scan of brain before and after contrast.
71045	CHEST X–RAY	Single view.
71046	CHEST X–RAY	2 views, front and back.
71047	CHEST X–RAY	3 views.
71048	CHEST X–RAY	4 or more views.
71101	X–RAY EXAM UNILAT RIBS/CHEST	Radiologic examination of one side of the chest/ribs.
71250	CT THORAX W/O DYE	CT scan of the thorax without dye.
71260	CT THORAX W/DYE	CT scan of the thorax with dye.
71275	CT ANGIOGRAPHY CHEST	Diagnostic Radiology (Diagnostic Imaging) Procedures of the Chest.
72040	X–RAY EXAM NECK SPINE 2–3 VW	Radiologic examination of the neck/spine, 2–3 views.
72050	X–RAY EXAM NECK SPINE 4/5VWS	Radiologic examination of the neck/spine, 4–5 views.
72070	X–RAY EXAM THORAC SPINE 2VWS	Radiologic examination of the middle spine, 2 views.
72072	X–RAY EXAM THORAC SPINE 3VWS	Radiologic examination of the middle spine, 3 views.
72100	X–RAY EXAM L–S SPINE 2/3 VWS	X-ray of the lower spine 2–3 views.
72110	X–RAY EXAM L–2 SPINE 4/>VWS	X-ray of lower and sacral spine, minimum of 4 views.
72131	CT LUMBAR SPINE W/O DYE	CT scan of lower spine without dye.
72141	MRI NECK SPINE W/O DYE	MRI of the neck or spine without dye.
72146	MRI CHEST SPINE W/O DYE	MRI of chest and spine without dye.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
72148	MRI LUMBAR SPINE W/O DYE	MRI scan of lower spinal canal.
72156	MRI NECK SPINE W/O & W/DYE	MRI of neck/spine with and without dye.
72157	MRI CHEST SPINE W/O & W/DYE	MRI of chest and spine with and without dye.
72158	MRI LUMBAR SPINE W/O & W/DYE	MRI of lower back with and without dye.
72170	X–RAY EXAM OF PELVIS	Radiologic examination of the pelvis.
72192	CT PELVIS W/O DYE	CT of pelvis without dye.
72193	CT PELVIS W/DYE	CT scan, pelvis, with contrast.
72195	MRI PELVIS W/O DYE	MRI of pelvis without dye.
72197	MRI PELVIS W/O & W/DYE	MRI of pelvis before and after dye.
73000	X–RAY EXAM OF COLLAR BONE	Radiologic examination of the collar bone.
73030	X–RAY EXAM OF SHOULDER	Radiologic examination of the shoulder.
73070	X–RAY EXAM OF ELBOW	Radiologic examination, elbow; 2 views.
73080	X–RAY EXAM OF ELBOW	Radiologic examination, elbow; 3 or more views.
73090	X–RAY EXAM OF FOREARM	Radiologic examination of the forearm.
73100	X–RAY EXAM OF WRIST	3 or more views.
73110	X–RAY EXAM OF WRIST	Up to 3 views.
73120	X–RAY EXAM OF HAND	X-ray of the hand with 2 views.
73130	X–RAY EXAM OF HAND	X-ray of the hand with 3 or more views.
73140	X–RAY EXAM OF FINGER(S)	Radiologic examination of the finger(s).
73221	MRI JOINT UPR EXTREM W/O DYE	MRI of upper extremity without dye.
73560	X–RAY EXAM OF KNEE 1 OR 2	Radiologic examination of the knee with 1 or 2 views.
73562	X–RAY EXAM OF KNEE 3	Radiologic examination of the knee with 3 views.
73564	X–RAY EXAM KNEE 4 OR MORE	Radiologic examination of the knee with 4 or more views.
73565	X–RAY EXAM OF KNEES	Radiologic examination of both knees.
73590	X–RAY EXAM OF LOWER LEG	Radiologic examination of the lower leg.
73600	X–RAY EXAM OF ANKLE	Radiologic examination of the ankle with 2 views.
73610	X–RAY EXAM OF ANKLE	Radiologic examination of the ankle with 3 views.
73620	X–RAY EXAM OF FOOT	Radiologic examination, foot; 2 views.
73630	X–RAY EXAM OF FOOT	Radiologic examination of the foot with 3 or more views.
73650	X–RAY EXAM OF HEEL	Radiologic examination of the heel.
73660	X–RAY EXAM OF TOE(S)	Radiologic examination of the toe(s).
73700	CT LOWER EXTREMITY W/O DYE	CT scan of leg without dye.
73718	MRI LOWER EXTREMITY W/O DYE	MRI of leg without dye.
73721	MRI JNT OF LWR EXTRE W/O DYE	MRI of lower extremity joint (knee/ankle) without dye.
73722	MRI JOINT OF LWR EXTR W/DYE	MRI of lower extremity joint (knee/ankle) with dye.
73723	MRI JOINT LWR EXTR W/O&W/DYE	MRI of lower extremity joint (knee/ankle) with and without dye.
74022	X–RAY EXAM SERIES ABDOMEN	Serial radiologic examination of the abdomen.
74150	CT ABDOMEN W/O DYE	CT of abdomen without dye.
74160	CT ABDOMEN W/DYE	CT of abdomen with dye.
74170	CT ABDOMEN W/O & W/DYE	CT of abdomen with and without dye.
74176	CT ABD & PELVIS W/O CONTRAST	CT of abdomen and pelvis without dye.
74177	CT ABD & PELV W/CONTRAST	CT scan of abdomen and pelvis with contrast.
74178	CT ABD & PELV 1/> REGNS	Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions.
74181	MRI ABDOMEN W/O DYE	MRI of abdomen without dye.
74183	MRI ABDOMEN W/O & W/DYE	MRI of abdomen without and with dye.
76000	CHEST X–RAY	Flouroscopy, or x-ray "movie" that takes less than an hour.
76001	CHEST X–RAY	Flouroscopy, or x-ray "movie" that takes more than an hour.
76512	OPHTH US B W/NON–QUANT A	Ultrasound of the eye.
76514	ECHO EXAM OF EYE THICKNESS	A diagnostic procedure that allows a provider to see the organs and other structures in the abdomen.
76536	US EXAM OF HEAD AND NECK	Ultrasound of head and neck.
76642	ULTRASOUND BREAST LIMITED	Limited ultrasound of the breast.
76700	US EXAM ABDOM COMPLETE	Ultrasound of abdomen with all areas scanned.
76705	ECHO EXAM OF ABDOMEN	A diagnostic procedure that allows a provider to see the organs and other structures in the abdomen.
76770	US EXAM ABDO BACK WALL COMP	Ultrasound of back wall of the abdomen with all areas viewed.
76775	US EXAM ABDO BACK WALL LIM	Ultrasound of back wall of the abdomen with limited areas viewed.
76801	OB US < 14 WKS SINGLE FETUS	Abdominal ultrasound of pregnant uterus (less than 14 weeks) single or first fetus.
76805	OB US >/= 14 WKS SNGL FETUS	Abdominal ultrasound of pregnant uterus (greater or equal to 14 weeks 0 days) single or first fetus.
76811	OB US DETAILED SNGL FETUS	Ultrasound of single fetus.
76813	OB US NUCHAL MEAS 1 GEST	Evaluation through measurement of fetal nuchal translucency.
76815	OB US LIMITED FETUS(S)	Ultrasound of fetus with limited views.
76817	TRANSVAGINAL US OBSTETRIC	Transvaginal ultrasound of uterus.
76818	FETAL BIOPHYS PROFILE W/NST	Fetal biophysical profile with non-stress test.
76819	FETAL BIOPHYS PROFIL W/O NST	Fetal biophysical profile without non-stress test.
76830	TRANSVAGINAL US NON–OB	Ultrasound of the pelvis through vagina.
76831	ECHO EXAM UTERUS	A diagnostic procedure that allows a provider to see the uterus.
76856	US EXAM PELVIC COMPLETE	Complete ultrasound of the pelvis.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
76857	US EXAM PELVIC LIMITED	Limited ultrasound of the pelvis.
76870	US EXAM SCROTUM	Ultrasound of the scrotum.
76872	US TRANSRECTAL	Transrectal ultrasound.
76882	US LMTD JT/NONVASC XTR STRUX	Diagnostic ultrasound of an extremity excluding the bone, joints or vessels.
77047	MRI BOTH BREASTS	Magnetic resonance imaging, breasts, without contrast material; bilateral.
77065	DX MAMMO INCL CAD UNI	Mammography of one breast.
77066	DX MAMMO INCL CAD BI	Mammography of both breasts.
77067	SCR MAMMO BI INCL CAD	Mammography of both breasts-2 or more views.
77080	BONE DENSITY STUDY OF SPINE OR PELVIS	Scan to measure bone mineral density (BMD) at the spine and hip.
77385	Ntsty modul rad tx dlvr smpl	Radiation therapy delivery.
77386	Ntsty modul rad tx dlvr cplx	Radiation therapy delivery.
77387	Guidance for radia tx dlvr	Guidance for localization of target delivery of radiation treatment delivery.
77412	Radiation treatment delivery	Radiation treatment delivery.
78014	THYROID IMAGING W/BLOOD FLOW	Scan using a radioactive medication (radiopharmaceutical) to take pictures or images of the thyroid gland.
78306	BONE IMAGING WHOLE BODY	A procedure most commonly ordered to detect areas of abnormal bone growth due to fractures, tumors, infection, or other bone issues.
78452	HT MUSCLE IMAGE SPECT MULT	Image of the heart to assess perfusion.
78815	PET IMAGE W/CT SKULL–THIGH	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization.
80048	METABOLIC PANEL TOTAL CA	Basic metabolic panel.
80050	GENERAL HEALTH PANEL	General health panel.
80051	Blood test panel for electrolytes (sodium potassium, chloride, carbon dioxide).	.
80053	COMPREHEN METABOLIC PANEL	Blood test, comprehensive group of blood chemicals.
80055	OBSTETRIC PANEL	Obstetric blood test panel.
80061	LIPID PANEL	Blood test, lipids (cholesterol and triglycerides).
80069	RENAL FUNCTION PANEL	Kidney function panel test.
80074	ACUTE HEPATITIS PANEL	Acute hepatitis panel.
80076	HEPATIC FUNCTION PANEL	Liver function blood test panel.
80081	Blood test panel for obstetrics (cbc, differential wbc count, hepatitis b, hiv, rubella, syphilis, antibody screening, rbc, blood typing).	.
80197	ASSAY OF TACROLIMUS	Test is used to measure the amount of the drug in the blood to determine whether the concentration has reached a therapeutic level and is below the toxic level.
80307	Drug test prsmv chem anlyzr	Testing for presence of drug.
81000	URINALYSIS NONAUTO W/SCOPE	Manual urinalysis test with examination using microscope.
81001	URINALYSIS; MANUAL OR AUTO WITH OR WITHOUT MICROSCOPY.	Manual urinalysis test with examination with or without using microscope.
81002	URINALYSIS NONAUTO W/O SCOPE	Manual urinalysis test with examination without using microscope.
81003	URINALYSIS; MANUAL OR AUTO WITH OR WITHOUT MICROSCOPY.	Automated urinalysis test.
81025	URINE PREGNANCY TEST	Urine pregnancy test.
82043	UR ALBUMIN QUANTITATIVE	Urine test to measure albumin.
82044	UR ALBUMIN SEMIQUANTITATIVE	Urine test to measure albumin-semiquantitative.
82248	BILIRUBIN DIRECT	Measurement of direct bilirubin.
82306	VITAMIN D 25 HYDROXY	Blood test to monitor vitamin D levels.
82553	CREATINE MB FRACTION	Blood test to detect heart enzymes.
82570	ASSAY OF URINE CREATININE	Test to measure creatinine in the urine.
82607	VITAMIN B–12	Blood test to measure B–12.
82627	DEHYDROEPIANDROSTERONE	Blood test to measure an enzyme in the blood.
82670	ASSAY OF ESTRADIOL	Blood test to measure a type of estrogen in the blood.
82728	ASSAY OF FERRITIN	Test to determine level of iron in the blood.
82784	ASSAY IGA/IGD/IGG/IGM EACH	Test to determine levels of immunoglobulins in the blood.
82803	BLOOD GASES ANY COMBINATION	Test to measure arterial blood gases.
82947	ASSAY GLUCOSE BLOOD QUANT	Quantitative measure of glucose build up in the blood over time.
82950	GLUCOSE TEST	Test of glucose level in the blood.
82951	GLUCOSE TOLERANCE TEST	Test to predict likelihood of gestational diabetes.
83001	ASSAY OF GONADOTROPIN (FSH)	Test of hormone in the blood.
83002	ASSAY OF GONADOTROPIN (LH)	Test of hormone in the blood.
83013	H PYLORI (C–13) BREATH	Test of breath for a stomach bacterium.
83036	GLYCOSYLATED HEMOGLOBIN TEST	Blood test to measure average blood glucose levels for past 2–3 months.
83516	IMMUNOASSAY NONANTIBODY	Chemical test of the blood to measure presence or concentration of a substance in the blood.
83540	ASSAY OF IRON	Blood test to measure the amount of iron that is in transit in the body.
83550	IRON BINDING TEST	Blood test that measures the amount of iron carried in the blood.
83655	ASSAY OF LEAD	Blood test to determine the concentration of lead in the blood.
83718	ASSAY OF LIPOPROTEIN	Blood test to measure the level of lipoproteins in the blood.
83880	ASSAY OF NATRIURETIC PEPTIDE	Blood test used to diagnose heart failure.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
84134	ASSAY OF PREALBUMIN	Blood test to measure level of prealbumin.
84153	ASSAY OF PSA TOTAL	PSA (prostate specific antigen).
84154	PSA (prostate specific antigen) measurement	.
84436	ASSAY OF TOTAL THYROXINE	Blood test to measure a type of thyroid hormone.
84439	ASSAY OF FREE THYROXINE	Blood test to evaluate thyroid function.
84443	ASSAY THYROID STIM HORMONE	Blood test, thyroid stimulating hormone (TSH).
84460	ALANINE AMINO (ALT) (SGPT)	Blood test to evaluate liver function.
84480	ASSAY TRIIODOTHYRONINE (T3)	Blood test to evaluate thyroid function.
84484	ASSAY OF TROPONIN QUANT	Blood test to measure a certain protein in the blood to determine heart muscle damage.
84703	CHORIONIC GONADOTROPIN ASSAY	Blood test to assess for pregnancy.
85007	BL SMEAR W/DIFF WBC COUNT	Blood test to assess for infection.
85018	HEMOGLOBIN	Blood test to measure levels of hemoglobin.
85025	COMPLETE CBC W/AUTO DIFF WBC	Complete blood cell count, with differential white blood cells, automated.
85027	COMPLETE CBC AUTOMATED	Complete blood count, automated.
85610	PROTHROMBIN TIME	Blood test, clotting time.
85730	THROMBOPLASTIN TIME PARTIAL	Coagulation assessment blood test.
86039	ANTINUCLEAR ANTIBODIES (ANA)	Blood test to determine autoimmune disorders.
86147	CARDIOLIPIN ANTIBODY EA IG	Blood test to determine cause of inappropriate blood clot formation.
86200	CCP ANTIBODY	Blood test to diagnose rheumatoid arthritis.
86300	IMMUNOASSAY TUMOR CA 15–3	Blood test to monitor breast cancer.
86304	IMMUNOASSAY TUMOR CA 125	Blood test to monitor for cancer.
86336	INHIBIN A	Blood test to monitor for cancer in the ovaries or testis.
86592	SYPHILIS TEST NON–TREP QUAL	Blood test to screen for syphilis.
86644	CMV ANTIBODY	Blood test to monitor for cytomegalovirus.
86665	EPSTEIN–BARR CAPSID VCA	Blood test to diagnose mononucleosis.
86677	HELICOBACTER PYLORI ANTIBODY	Blood test to if peptic ulcers are caused by a certain bacterium.
86703	HIV–1/HIV–2 1 RESULT ANTBDY	Blood test to diagnose HIV.
86704	HEP B CORE ANTIBODY TOTAL	Blood test indicating infection with Hepatitis B.
86708	HEPATITIS A ANTIBODY	Blood test indicating infection with Hepatitis A.
86762	RUBELLA ANTIBODY	Blood test to determine if antibodies exist for rubella.
86765	RUBEOLA ANTIBODY	Blood test to determine if antibodies exist for measles.
86780	TREPONEMA PALLIDUM	Blood test to determine existence of certain bacterium that causes syphilis.
86803	HEPATITIS C AB TEST	Blood test to determine infection with Hepatitis C.
86850	RBC ANTIBODY SCREEN	Blood test to screen for antibodies that could harm red blood cells.
87040	BLOOD CULTURE FOR BACTERIA	Blood test to screen for bacteria in the blood.
87046	STOOL CULTR AEROBIC BACT EA	Blood test to identify bacteria that may be contributing to symptoms in the gastrointestinal tract.
87070	CULTURE OTHR SPECIMN AEROBIC	Test of body fluid other than blood to assess for bacteria.
87077	CULTURE AEROBIC IDENTIFY	Test of a wound for type of bacterial infection.
87081	CULTURE SCREEN ONLY	Medical test to find an infection.
87086	URINE CULTURE/COLONY COUNT	Culture of the urine to determine number of bacteria.
87088	URINE BACTERIA CULTURE	Culture of the urine to determine bacterial infection.
87101	SKIN FUNGI CULTURE	A procedure used to determine if fungi are present in an area of the body.
87186	MICROBE SUSCEPTIBLE MIC	A test used to determine which medications work on bacteria for fungi.
87205	SMEAR GRAM STAIN	A lab test used to detect bacteria or fungi in a sample taken from the site of a suspected infection.
87210	SMEAR WET MOUNT SALINE/INK	A lab test to screen for evidence of vaginal infection.
87324	CLOSTRIDIUM AG IA	A test of the stool to diagnose Clostridium difficile (C. diff) infection.
87389	HIV–1 AG W/HIV–1 & HIV–2 AB	Test for HIV.
87491	CHYLMD TRACH DNA AMP PROBE	Test that detects Chlamydia.
87510	GARDNER VAG DNA DIR PROBE	Blood test for vaginitis.
87591	N.GONORRHOEAE DNA AMP PROB	Blood test for an STD.
87624	Hpv high-risk types	Detection test for human papillomavirus (hpv).
87653	STREP B DNA AMP PROBE	Blood test for strep infection.
87661	TRICHOMONAS VAGINALIS AMPLIF	Blood test for an STD.
87801	DETECT AGNT MULT DNA AMPLI	Blood test to determine genetic material of certain infectious agents.
87804	INFLUENZA ASSAY W/OPTIC	Flu test.
87807	RSV ASSAY W/OPTIC	Test for RSV.
87880	STREP A ASSAY W/OPTIC	Test for strep A.
88112	CYTOPATH CELL ENHANCE TECH	Urine test.
88141	CYTOPATH C/V INTERPRET	Cervical cancer screening test with interpretation.
88142	CYTOPATH C/V THIN LAYER	PAP smear.
88150	CYTOPATH C/V MANUAL	Cervical cancer screening test done manually.
88175	CYTOPATH C/V AUTO FLUID REDO	PAP smear.
88305	TISSUE EXAM BY PATHOLOGIST	Test of tissues for diagnosis of abnormalities.
88312	SPECIAL STAINS GROUP 1	Blood test to assist with diagnosis.
88313	SPECIAL STAINS GROUP 2	Blood test to assist with diagnosis.
88342	IMMUNOHISTO ANTB 1ST STAIN	Pathology test.
90460	IM ADMIN 1ST/ONLY COMPONENT	Immunization administration in children <18.
90471	IMMUNIZATION ADMIN	Immunization administration by a medical assistant or nurse.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
90474	IMMUNE ADMIN ORAL/NASAL ADDL	Immunization administered orally or nasally.
90632	HEPA VACCINE ADULT IM	Hepatitis A vaccination for adults.
90633	HEPA VACC PED/ADOL 2 DOSE IM	Hepatitis A vaccination for adolescents and children.
90649	4VHPV VACCINE 3 DOSE IM	3-dose HPV vaccination.
90656	IIV3 VACC NO PRSV 0.5 ML IM	Flu shot-high dose for 2019–2020 flu season given by injection.
90658	IIV3 VACCINE SPLT 0.5 ML IM	Preservative free flu vaccine.
90672	LAIV4 VACCINE INTRANASAL	Nasal flu vaccine.
90681	RV1 VACC 2 DOSE LIVE ORAL	Rotavirus vaccination.
90686	IIV4 VACC NO PRSV 0.5 ML IM	Flu shot-high dose for 2019–2020 flu season given by injection for people >65.
90707	MMR VACCINE SC	Measles, mumps, and rubella vaccine.
90710	MMRV VACCINE SC	Measles, mumps, rubella, and varicella vaccine.
90715	TDAP VACCINE 7 YRS/> IM	Diphtheria, tetanus acellular, and pertussis vaccine for adults.
90716	VAR VACCINE LIVE SUBQ	Varicella vaccine.
90732	PPSV23 VACC 2 YRS+ SUBQ/IM	pneumococcal vaccine.
90734	MENACWYD/MENACWYCRM VACC IM	meningococcal conjugate vaccine.
90736	HZV VACCINE LIVE SUBQ	Shingles vaccine.
90746	HEPB VACCINE 3 DOSE ADULT IM	Hepatitis B vaccine.
90791	PSYCH DIAGNOSTIC EVALUATION	A diagnostic tool employed by a psychiatrist to diagnose problems with memory, thought processes, and behaviors.
90792	PSYCH DIAG EVAL W/MED SRVCS	A diagnostic tool employed by a psychiatrist to determine if medications are needed.
90832	PSYTX W PT 30 MINUTES	Psychotherapy, 30 min.
90833	PSYTX W PT W E/M 30 MIN	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service.
90834	PSYTX W PT 45 MINUTES	Psychotherapy, 45 min.
90836	PSYTX W PT W E/M 45 MIN	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service.
90837	PSYTX W PT 60 MINUTES	Psychotherapy, 60 min.
90838	Psychotherapy, 60 minutes	
90839	Psychotherapy for crisis, first 60 minutes	
90840	Psychotherapy for crisis	
90846	Family psychotherapy, 50 minutes	Family psychotherapy, not including patient, 50 min.
90847	FAMILY PSYTX W/PT 50 MIN	Family psychotherapy, including patient, 50 min.
90853	GROUP PSYCHOTHERAPY	Group psychotherapy.
92002	EYE EXAM NEW PATIENT	Intermediate exam.
92004	EYE EXAM NEW PATIENT	Complete exam.
92012	EYE EXAM ESTABLISH PATIENT	Eye exam on an established patient.
92014	EYE EXAM&TX ESTAB PT 1/>VST	Eye exam and treatment for established patient.
92083	VISUAL FIELD EXAMINATION(S)	An eye examination that can detect dysfunction in central and peripheral vision.
92133	CMPTR OPHTH IMG OPTIC NERVE	Optic nerve imaging.
92507	SPEECH/HEARING THERAPY	Therapy for speech or hearing.
92523	SPEECH SOUND LANG COMPREHEN	Evaluation of speech sound production with evaluation of language comprehension.
92552	PURE TONE AUDIOMETRY AIR	Type of hearing test.
93000	ELECTROCARDIOGRAM COMPLETE	Routine EKG using at least 12 leads including interpretation and report.
93015	CARDIOVASCULAR STRESS TEST	Test to determine heart abnormalities.
93303	ECHO TRANSTHORACIC	Test to screen the heart for abnormalities.
93306	Tte w/doppler complete	Ultrasound examination of heart including color-depicted blood flow rate, direction, and valve function.
93307	TTE W/O DOPPLER COMPLETE	Echo without doppler study.
93320	DOPPLER ECHO EXAM HEART	Echo with doppler.
93350	STRESS TTE ONLY	Stress test with echocardiogram.
93452	Cardiac Catheterization	Insertion of catheter into left heart for diagnosis.
93798	CARDIAC REHAB/MONITOR	Use of EKG to monitor cardiac rehabilitation.
93880	EXTRACRANIAL BILAT STUDY	Study of vessels on both sides of the head and neck.
93922	UPR/L XTREMITY ART 2 LEVELS	Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries.
93970	EXTREMITY STUDY	Complete bilateral study of the extremities.
93971	EXTREMITY STUDY	One sided or limited bilateral study.
94010	BREATHING CAPACITY TEST	Test to determine how well oxygen moves from the lungs to the blood stream.
94060	EVALUATION OF WHEEZING	Test to determine if wheezing is present.
94375	RESPIRATORY FLOW VOLUME LOOP	Graphical representation of inspiration and expiration.
94726	PULM FUNCT TST PLETHYSMOGRAP	Measures how much air is in the lungs after taking a deep breath.
94727	PULM FUNCTION TEST BY GAS	Measure of lung function and gas exchange.
94729	CO/MEMBANE DIFFUSE CAPACITY	Test to measure how well gases diffuse across lung surfaces.
95004	PERCUT ALLERGY SKIN TESTS	Allergy test.
95115	IMMUNOTHERAPY ONE INJECTION	Allergy shot-1 shot.
95117	IMMUNOTHERAPY INJECTIONS	Multiple allergy shots.
95810	POLYSOM 6/> YRS 4/> PARAM	Sleep monitoring of patient (6 years or older) in sleep lab.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
95811	POLYSOM 6/>YRS CPAP 4/> PARM	Sleep monitoring of patient (6 years or older) in sleep lab using CPAP.
95860	MUSCLE TEST ONE LIMB	Test to measure electrical activity of muscles or nerves in 1 limb.
95861	MUSCLE TEST 2 LIMBS	Test to measure electrical activity of muscles or nerves in 2 limb.
95886	MUSC TEST DONE W/N TEST COMP	Test to assess for nerve damage.
96110	DEVELOPMENTAL SCREEN W/SCORE	Childhood test to screen for developmental disabilities.
96365	THER/PROPH/DIAG IV INF INIT	Intravenous infusion, for therapy, prophylaxis, or diagnosis-initial infusion.
96366	THER/PROPH/DIAG IV INF ADDON	Intravenous infusion, for therapy, prophylaxis, or diagnosis-additional infusions.
96374	THER/PROPH/DIAG INJ IV PUSH	Intravenous infusion, for therapy, prophylaxis, or diagnosis-IV push.
96375	TX/PRO/DX INJ NEW DRUG ADDON	Intravenous infusion, for treatment, prophylaxis, or diagnosis-new drug add on.
96376	TX/PRO/DX INJ SAME DRUG ADON	Intravenous infusion, for treatment, prophylaxis, or diagnosis-same drug add on.
96415	CHEMO IV INFUSION ADDL HR	Chemotherapy infusion-each additional hour.
96417	CHEMO IV INFUS EACH ADDL SEQ	Chemotherapy infusion-additional IV pushes of the same medication.
97010	HOT OR COLD PACKS THERAPY	Use of external hot or cold packs.
97012	MECHANICAL TRACTION THERAPY	Form of decompression therapy of the spine.
97014	ELECTRIC STIMULATION THERAPY	One time use unattended.
97016	VASOPNEUMATIC DEVICE THERAPY	Machines designed to pump cold water into an inflatable wrap or brace, compressing the enveloped area of the body.
97026	INFRARED THERAPY	Light-based method to treat pain and inflammation.
97032	ELECTRICAL STIMULATION	Repeated application to one or more parts of the body.
97033	ELECTRIC CURRENT THERAPY	Psychiatric treatment in which seizures are electrically induced in patients to provide relief from mental disorders.
97035	ULTRASOUND THERAPY	Use of sound waves to treat medical problems, especially musculoskeletal problems like inflammation from injuries.
97110	THERAPEUTIC EXERCISES	Therapeutic exercise to develop strength, endurance, range of motion, and flexibility, each 15 minutes.
97112	NEUROMUSCULAR REEDUCATION	A technique used by physical therapists to restore normal body movement patterns.
97113	AQUATIC THERAPY/EXERCISES	Use of water for therapy/exercises.
97116	GAIT TRAINING THERAPY	A type of physical therapy.
97124	MASSAGE THERAPY	Use of massage.
97140	MANUAL THERAPY 1/> REGIONS	Manipulation of 1 or more regions of the body.
97530	THERAPEUTIC ACTIVITIES	Incorporates the use of multiple parameters, such as balance, strength, and range of motion, for a functional activity.
97535	SELF CARE MNGMENT TRAINING	Occupational therapy.
97597	RMVL DEVITAL TIS 20 CM/<	Debridement (for example, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel, and forceps).
97811	ACUPUNCT W/O STIMUL ADDL 15M	Acupuncture without stimulation.
97813	ACUPUNCT W/STIMUL 15 MIN	Acupuncture with stimulation.
98940	CHIROPRACT MANJ 1–2 REGIONS	Chiropractic manipulation in 1–2 regions.
98941	CHIROPRACT MANJ 3–4 REGIONS	Chiropractic manipulation in 3–4 regions.
98943	CHIROPRACT MANJ XTRSPINL 1/>	Chiropractic manipulation not of the spine.
98966	Hc pro phone call 5–10 min	Telephone assessment and management service, 5–10 minutes of medical discussion.
98967	Hc pro phone call 11–20 min	Telephone assessment and management service, 11–20 minutes of medical discussion.
98968	Hc pro phone call 21–30 min	Telephone assessment and management service, 21–30 minutes of medical discussion.
98970	Qualified non physician health care professional online digital assessment and management est. patient 5–10 minutes.	Qualified non physician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.
98971	Qualified non physician health care professional online digital assessment and management est. patient 11–20 minutes.	Qualified non physician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes.
98972	Qualified non physician health care professional online digital assessment and management for est. patients 21+ minutes.	Qualified non physician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes.
99051	MED SERV EVE/WKEND/HOLIDAY	Medical service during off-hours.
99173	VISUAL ACUITY SCREEN	Eye test.
99201	OFFICE/OUTPATIENT VISIT NEW	New patient office or other outpatient visit, typically 10 minutes.
99202	OFFICE/OUTPATIENT VISIT NEW	New patient office or other outpatient visit, typically 20 minutes.
99203	OFFICE/OUTPATIENT VISIT NEW	New patient office or other outpatient visit, typically 30 min.
99204	OFFICE/OUTPATIENT VISIT NEW	New patient office of other outpatient visit, typically 45 min.
99205	OFFICE/OUTPATIENT VISIT NEW	New patient office of other outpatient visit, typically 60 min.
99211	OFFICE/OUTPATIENT VISIT EST	Outpatient visit of established patient not requiring a physician.
99212	OFFICE/OUTPATIENT VISIT EST	Outpatient visit of established patient requiring a physician.
99213	OFFICE/OUTPATIENT VISIT EST	Established patient office or other outpatient visit, typically 15 minutes.
99214	OFFICE/OUTPATIENT VISIT EST	Established patient office or other outpatient visit, typically 25 minutes.
99215	OFFICE/OUTPATIENT VISIT EST	Established patient office or other outpatient, visit typically 40 minutes.
99243	OFFICE CONSULTATION	Patient office consultation, typically 40 min.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
99244	OFFICE CONSULTATION	Patient office consultation, typically 60 min.
99283	Emergency dept visit	Emergency department visit, moderately severe problem.
99284	Emergency dept visit	Emergency department visit, problem of high severity.
99285	Emergency dept visit	Emergency department visit, problem with significant threat to life or function.
99381	INIT PM E/M NEW PAT INFANT	Initial visit for an infant.
99382	INIT PM E/M NEW PAT 1–4 YRS	Initial visit for new patients 1–4 years old.
99383	PREV VISIT NEW AGE 5–11	New preventative visit in new patients 5–11 years old.
99384	PREV VISIT NEW AGE 12–17	New preventative visit in new patients 12–17 years old.
99385	PREV VISIT NEW AGE 18–39	Initial new patient preventive medicine evaluation (18–39 years).
99386	PREV VISIT NEW AGE 40–64	Initial new patient preventive medicine evaluation (40–64 years).
99387	INIT PM E/M NEW PAT 65+ YRS	Initial visit for new patients 65 and older years old.
99391	PER PM REEVAL EST PAT INFANT	Periodic primary re-evaluation for an established infant patient.
99392	PREV VISIT EST AGE 1–4	Initial visit for new patients 1–4 years old.
99393	PREV VISIT EST AGE 5–11	New preventative visit in new patients 5–11 years old.
99394	PREV VISIT EST AGE 12–17	New preventative visit in new patients 12–17 years old.
99395	PREV VISIT EST AGE 18–39	Established patient periodic preventive medicine examination age 18–39 years.
99396	PREV VISIT EST AGE 40–64	Established patient periodic preventive medicine examination age 40–64 years.
99397	PER PM REEVAL EST PAT 65+ YR	Periodic primary re-evaluation for an established patient 65 and older.
99421	ONLINE DIGITAL EVALUATION AND MANAGEMENT SERVICE; 5–10 MINUTES.	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.
99422	Online digital evaluation and management service; 11–20 minutes.	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes.
99441	Phone e/m phys/qhp 5–10 min	Physician telephone patient service, 5–10 minutes of medical discussion.
99442	Phone e/m phys/qhp 11–20 min	Physician telephone patient service, 11–20 minutes of medical discussion.
99443	Phone e/m phys/qhp 21–30 min	Physician telephone patient service, 21–30 minutes of medical discussion.

As outlined above, below are the five codes that appear on the commenter list of recommended items and services that are not being required for the initial list of 500 items and services.

Commenter codes not used	Reason for removal
10022	Code Retired.
11100	Code Retired.
11101	Code Retired.
77059	Code Retired.
A288	Code Retired.

The Departments understand that plans and issuers may use different billing codes (for example, MS–DRGs vs. APR DRGs). Therefore, in the first year of the implementation of the self-service tool, when plans and issuers are required to provide cost estimates for the 500 items and services identified by the Departments, plans and issuers are permitted to make appropriate code substitutions as necessary to allow them to disclose cost-sharing information for the 500 items and services through the self-service tool. If necessary, the Departments will issue future guidance regarding standards for code substitutions.

a. First Content Element: Estimated Cost-Sharing Liability

The first content element that plans and issuers are required to disclose under the final rules is an estimate of the cost-sharing liability for the furnishing of a covered item or service by a particular provider or providers. The calculation of the cost-sharing liability estimate is required to be computed based on the other relevant cost-sharing information that plans and issuers are required to disclose, as described later in this section of this preamble.

The proposed rules defined ''cost-sharing liability'' as the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the plan or coverage. The disclosure must include all applicable forms of cost sharing, including deductibles, coinsurance requirements, and copayments. The term cost-sharing liability does not include premiums, any applicable balance billing amounts charged by out-of-network providers, or the cost of non-covered items or services. For QHPs offered through Exchanges, an estimate of cost-sharing liability for a requested covered item or service provided must reflect any cost-sharing reductions the individual would receive under the coverage.

Many commenters supported the disclosure of cost-sharing liability for a particular item or service. One stated that providing cost-sharing amounts to consumers in advance of receiving a service would likely make it easier for providers to collect consumers' cost-sharing amounts. However, some commenters were concerned that information provided in advance of care would not provide an accurate estimate of actual participant, beneficiary, or enrollee liability, which would lead to consumer confusion and frustration. A few commenters requested that the tool include additional information, such as all providers expected to be involved in providing an item or service, and the price of items and services historically provided along with that particular item or service by the provider. Some commenters urged the Departments to ensure appropriate educational information is provided to patients to help them better understand and navigate the information being displayed. Others recommended a federally funded and coordinated outreach and education campaign to encourage the use of price transparency tools and help patients understand the complexities of health care prices. One commenter urged the Departments to clarify that, to the extent that the actual services provided are consistent with those provided under the estimate, plans would not be permitted to hold an enrollee responsible for more than what was provided under the estimate.

The Departments underscore that the estimates required by the final rules are

not required to reflect the actual or final cost of a particular item or service. Unforeseen factors during the course of treatment (which may involve additional services or providers) can result in higher actual cost-sharing liability following receipt of care than the estimate provided in advance. Nonetheless, the Departments are finalizing the requirement that cost-sharing liability estimates be built upon accurate information, including the relevant cost-sharing information described in 26 CFR 54.9815–2715A2(b)(1)(ii)–(iv), 29 CFR 2590.715–2715A2(b)(1)(ii)–(iv), and 45 CFR 147.211(b)(1)(ii)–(iv). However, this requirement does not mean that the estimates must reflect the amount ultimately charged to a participant, beneficiary, or enrollee. Instead, the estimate should reflect the amount a participant, beneficiary, or enrollee would be expected to pay for the covered item or service for which cost-sharing information is sought. Thus, the final rules do not require the cost-sharing liability estimate to include costs for unanticipated items or services the individual could incur due to the severity of his or her illness or injury, provider treatment decisions, or other unforeseen events. Attendant notice requirements in 26 CFR 54.9815–2715A2(b)(1)(vii), 29 CFR 2590.715–2715A2(b)(1)(vii), and 45 CFR 147.211(b)(1)(vii) also require inclusion of a statement that actual charges for the participant's, beneficiary's, or enrollee's covered items and services may be different from those described in a cost-sharing liability estimate, depending on the actual items and services received at the point of care.

Additionally, while the Departments acknowledge the value of not allowing group health plans and health insurance issuers to impose higher cost sharing than estimated, to the extent that the actual services provided were consistent with those provided under the estimate, the Departments are of the view that it would not be prudent to hold plans and issuers liable to the exact estimate that is provided through the tool, as cost-sharing obligations may ultimately vary from the estimates provided in advance. Additionally, the Departments are concerned that such a requirement could incentivize plans and issuers to provide high estimates, rather than the most accurate estimates.

Commenters recommended the final rules provide plans and issuers with the flexibility to apply a reasonable methodology for estimating reliable out-of-pocket costs for a specific network provider, and recommended that this methodology could include, but should not be limited to, using current year negotiated rates, historical negotiated rates, historical claims, or a combination of these data points. One commenter urged the Departments to remove the proposed requirement that cost-sharing liability information be calculated based on negotiated rates, stating that this is not the methodology used by most existing cost-estimate tools.

The Departments understand that plans and issuers with existing cost-estimate tools may use advanced analytics in calculating cost-sharing liability estimates. However, the Departments are of the view that the most accurate estimates of cost-sharing liability should be provided using the actual rates and fees upon which liability is determined. It is the Departments' understanding that, while provider reimbursement may be based on negotiated rates, plans and issuers do not always calculate a consumer's liability using the negotiated rate as defined in paragraph (a) of the proposed rules, such as in capitation arrangements where the provider is reimbursed retrospectively. Rather, some plans and issuers may determine a participant's, beneficiary's, or enrollee's cost-sharing liability on a contractually agreed upon underlying fee schedule between the provider and the plan or issuer.

Therefore, the final rules require that cost-sharing liability for a particular item or service be calculated based on in-network rates, out-of-network allowed amounts, and individual-specific accumulators, such as deductibles and out-of-pocket limits. However, the Departments clarify that plans and issuers may incorporate additional metrics and analytics beyond this minimum standard: For example, by using complex historical analytics to predict total costs of items and services available through a bundled payment arrangement. The Departments will assess how additional useful information can be provided to consumers in this area going forward.

Under the proposed rules, plans and issuers would be required to provide participants, beneficiaries, and enrollees with cost-sharing information for either a discrete item or service or for items or services for a treatment or procedure for which the plan uses a bundled payment arrangement, according to how the plan or issuer structures payment for the item or service. Several commenters pointed out that providing cost-sharing liability estimates for bundled payment arrangements might introduce confusion as consumers may not realize that billing and payment rates are different when items and services are rendered individually versus as part of a bundled item or service. Commenters stated that ultimately, patients would very likely receive inaccurate or misleading estimates in a significant proportion of self-service estimate requests. Similarly, several commenters sought clarification regarding how plans and issuers that incorporate innovative and cost-saving methods like reference-based pricing, value-based insurance design, and direct primary care as part of their services and plan designs would comply with the requirements of the proposed rules.

The Departments recognize the variability in pricing structures and plan designs for many plans and issuers. The Departments understand that developers have demonstrated that formulas for unique pricing models are already being incorporated into existing estimator tools. The Departments further understand that while providing cost estimates in advance for a plan or issuer that incorporates reference-based reimbursement may be complex, it is still feasible to estimate such costs. For example, plans or issuers could develop a method for analyzing past claims of specific providers to look for patterns in their payment rates from which to derive an accurate predictive estimate in advance. In response to the Hospital Price Transparency final rule, one hospital claims to have developed a tool that provides cost estimates with 95 percent to 99 percent accuracy.[110] While some factors associated with the course of care are incorporated after services are rendered, others, like gender or location, are known in advance. Therefore, the Departments expect plans and issuers to provide a reasonable estimate using information the plan or issuer knows about the participant, beneficiary, or enrollee or the average participant, beneficiary, or enrollee.

The Departments again acknowledge that how a provider is reimbursed does not necessarily indicate how a participant, beneficiary, or enrollee will be billed. Specifically, as commenters explained, the bundled payment arrangement as defined in the proposed rules may not reflect the cost-sharing liability for which the consumer is liable. For instance, if a provider is reimbursed in a bundled payment arrangement for a surgical procedure that includes the surgery and pre- and post-surgery office visits, but the

[110] Meyer, H. ''Hospitals roll out online price estimators as CMS presses for transparency.'' Modern Healthcare. June 23, 2018. Available at *https://www.modernhealthcare.com/article/20180623/NEWS/180629994/hospitals-roll-out-online-price-estimators-as-cms-presses-for-transparency*.

enrollee is billed a copayment for each office visit and coinsurance for the surgical procedure, the enrollee should be able to obtain the separate copayment liabilities for each of the office visits and the surgical procedures, not one bundled charge. However, under this example, if the individual is only responsible for one copayment that includes all office visits and the surgical procedures, the plan or issuer could provide the cost-sharing liability estimate for that bundled payment arrangement.

Therefore, the final rules clarify that plans and issuers should provide one overall cost-sharing liability estimate for a bundled payment arrangement if that is the only cost sharing for which the participant, beneficiary, or enrollee would be liable. However, if a plan or issuer reimburses a provider under a bundled payment arrangement for all covered items and services provided for a specific treatment or procedure, but cost sharing is imposed separately for each unique item and service included in the bundled payment, plans and issuers should disclose the cost-sharing liability for those distinct items and services to the participant, beneficiary, or enrollee. The Departments also recognize that providing one estimate that includes all items and services that are typically provided within an episode of care may be consumer-friendly in some situations, even where the items and services are not subject to a bundled payment arrangement. Therefore, the final rules clarify that while plans and issuers are not required to provide bundled estimates where the provider is not reimbursed through a bundled payment arrangement, nothing prohibits plans or issuers from providing bundled estimates in situations where such estimates could be relevant to participants, beneficiaries, or enrollees, as long as the plan or issuer also discloses information about the relevant items or services individually, as required by the final rules.

Plans and issuers should take a similar approach for plan designs that incorporate alternative payment structures such as direct primary care or other bundled or capitated payment arrangements. The Departments understand that there are many unique plan designs and may issue additional guidance to address specific questions from plans, issuers, and enforcement entities regarding the requirements of the final rules.

The Departments appreciate comments requesting education and outreach to help ensure that participants, beneficiaries, and enrollees know that these consumer tools exist and can understand the information displayed. The Departments recognize that more than 94 percent of plans and issuers recently surveyed already have some variation of an internet self-service tool,[111] yet another study noted that only 12 percent of participants, beneficiaries, or enrollees currently use the tools available to them,[112] which might suggest that there is an opportunity for improved awareness and understanding of these tools. However, the Departments are also of the view that plans and issuers have their own incentives to provide quality customer service and know what types of outreach and messaging would be most helpful to their participants, beneficiaries, and enrollees. Therefore, the Departments have decided not to institute specific outreach and education requirements, but rather strongly encourage plans and issuers to develop educational and outreach materials to promote awareness that self-service tools exist, where to find them on the plan's or issuer's website, how to use the tool, what, if any, further innovations above the baseline standards that differentiates their tool from competitors, and what additional information may be available. In addition, the Departments are of the view that employers may want to conduct outreach and education to encourage their employees to shop for lower-priced services that may slow increases in employer-sponsored coverage premiums.

One commenter stated that the final rules should provide the flexibility for health plans to display cost-sharing information either as dollars or using some proxy variable that either conveys costs relative to other providers or the cost-effectiveness of the providers for a given items or service relative to their peers. Another commenter recommended that cost estimates include both an average price and a reasonable range of the possible prices that the treatment could cost. Other commenters recommended the Departments allow cost estimates to be provided as a range.

The Departments are of the view that cost-sharing averages and ranges would not provide personalized and specific cost-sharing information and therefore the final rules adopt, as proposed, the provision that estimated cost-sharing liability be reflected as a dollar amount. However, the Departments understand that providing an estimated range could help consumers understand how their costs may vary depending on the complexity of a procedure. In addition to providing a cost-sharing estimate that is specific to the participant, beneficiary, or enrollee, plans and issuers may also choose to provide low and high ranges of what the consumer may expect to pay to reflect other needed services, complications, and other factors.

Several commenters expressed concerns about the ability of plans and issuers to provide these cost-sharing estimates, noting that few, if any, currently provide this level of disclosure to participants, beneficiaries, or enrollees before the incurrence of a claim. Commenters stated that most major issuers have treatment cost estimators available, but these tools are rudimentary and are not necessarily available for all plan designs. Commenters also stated that few regional issuers currently make any cost-estimation data available and the vast majority of data provided via online tools currently relies on estimated costs drawn from publicly available sources rather than personal information and circumstances.

Another commenter stated that most self-insured group health plans do not have easy access to all the data necessary to provide beneficiaries with what they described as upfront adjudication of the beneficiary's claim, like an EOB. One commenter expressed concern, stating that plans could be subject to significant penalties for failure to comply and highlighted that self-insured plans typically do not establish their own networks, but rather contract with an issuer, TPA or other entity for the use of their network. Another commenter stated that issuers, preferred provider networks, and TPAs continue to maintain network pricing information as confidential and proprietary, even with respect to their own plan clients. Some commenters stated that while the preamble to the proposed rules suggests that plans could renegotiate their contracts in order to gain access to this proprietary information, this ignores the realities of the market. These commenters opined that, in the absence of clearer guidance applicable to issuers and TPAs, plans and issuers will be burdened with trying to force disclosure of this information.

The Departments are of the view that the ability to access cost-sharing liability information in advance of

[111] Sharma A., Manning, R., and Mozenter, Z. ''Estimating the Burden of the Proposed Transparency in Coverage Rule.'' Bates White Economic Consulting. January 27, 2020. Available at: *https://www.bateswhite.com/newsroom-insight-Transparency-in-Coverage-Rule.html.*

[112] *See* Mehrotra, A., Chernew, M., and Sinaiko, A. ''Promises and Reality of Price Transparency.'' April 5, 2018. 14 N. Eng. J. Med. 378. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMhpr1715229.*

seeking care should not be limited by the participant's, beneficiary's, or enrollee's plan or issuer type. The Departments are aware of several issuers that provide advance cost estimates that are based on an individual's specific information, such as out-of-pocket amount accumulators. The intent of the final rules is to make this information available to a larger number of participants, beneficiaries, and enrollees, empowering them to shop for care that best meets their needs.

Additionally, while the Departments recognize that some self-insured group health plans (or TPAs acting on their behalf) may not currently have access to the information that would be required to calculate a participant's or beneficiary's cost liability, the Departments do not foresee any barriers that would prohibit the plan or TPA from obtaining this information. As discussed in the preamble to the proposed rules, plans may have to amend existing contracts with issuers, TPAs, or providers. Consistent with the discussion of legal authority elsewhere in this preamble, even if a contract between a self-insured plan and a TPA contains a provision prohibiting the public disclosure of its terms, it is the Departments' understanding that such contracts typically include exceptions where a particular disclosure is required by Federal law, and Federal law would control over contractual terms in any case.

In response to whether other types of information are necessary to provide an estimate of cost-sharing liability prior to an individual's receipt of items or services from a provider(s), one commenter suggested—in order to enhance the usability and accuracy of these data—that CMS and payers utilize the open-source episode grouper maintained by the not-for-profit Patient-Centered Episode System (PACES) Center, to create a single industry standard for defining clinical episodes of care using current medical record and payment systems and based on consensus across multiple stakeholders including providers, payers, purchasers, and consumers.

While the Departments generally support standardization across the complex health care ecosystem, there is no current required standardization of items and services provided for certain common episodes of care. Because of the lack of this particular standard, requiring plans and issuers to use PACES or similar services to determine costs will not accurately reflect what different plans and issuers actually reimburse for different episodes of care.

The Departments acknowledge that section 2713 of the PHS Act requires non-grandfathered group health plans and issuers offering non-grandfathered coverage in the individual or group markets to provide coverage without the imposition of any cost-sharing requirements for select preventive items and services. However, if the same items or services are furnished for non-preventive purposes, the participant, beneficiary, or enrollee may be subject to the cost-sharing terms of his or her plan. The Departments are of the view that if an item or service will be furnished at no cost to the participant, beneficiary, or enrollee, the participant, beneficiary, or enrollee should know this information. One commenter expressed a desire that price transparency not serve as a disincentive for individuals seeking preventive and maintenance therapy services. The Departments are of the view that clearly indicating when items and services have a $0 cost-sharing liability may have the opposite effect—it may actually encourage consumers to seek preventive care. The Departments understand that determining whether an item or service is preventive or not for an individual may be complex, and, indeed, may be impossible prior to service. Therefore, to the extent an item or service is a recommended preventive service under section 2713 of the PHS Act, and the plan or issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the non-preventive cost-sharing liability in the internet-based self-service tool, along with a statement that the item or service may not be subject to cost sharing if it is billed as a preventive service. For example, if an individual requests cost-sharing information for an in-network colonoscopy, the plan should display the applicable cost-sharing information for a diagnostic colonoscopy and a statement that the service may not be subject to cost sharing if it is billed as a preventive service from an in-network provider. As an alternative, a plan or issuer may allow an individual to request cost-sharing information for the specific preventive or non-preventive item or service by including the appropriate terms such as ''preventive,'' ''non-preventive,'' or ''diagnostic'' as a means to request the most accurate cost-sharing information.

b. Second Content Element: Accumulated Amounts

The second content element is a participant's, beneficiary's, or enrollee's accumulated amounts. The proposed rules defined ''accumulated amounts'' as the amount of financial responsibility that a participant, beneficiary, or enrollee has incurred at the time the request for cost-sharing information is made, with respect to a deductible and/or an out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts would include the financial responsibility a participant, beneficiary, or enrollee has incurred toward meeting his or her individual deductible and/or out-of-pocket limit, as well as the amount of financial responsibility that the individuals enrolled under the plan or coverage have incurred toward meeting the other than self-only coverage deductible and/or out-of-pocket limit, as applicable. The Departments interpret section 2707(b) of the PHS Act as requiring non-grandfathered group health plans to comply with the maximum out-of-pocket limit promulgated under section 1302(c)(1) of PPACA, including the HHS clarification that the self-only maximum out-of-pocket limit applies to each individual, regardless of whether the individual is enrolled in self-only coverage or in other than self-only coverage. Accordingly, the self-only maximum out-of-pocket limit applies to an individual who is enrolled in family coverage or other coverage that is not self-only coverage under a group health plan.[113] For this purpose, the Departments proposed that accumulated amounts would include any expense that counts toward the deductible or out-of-pocket limit (such as copayments and coinsurance), but would exclude expenses that would not count toward a deductible or out-of-pocket limit (such as premium payments, out-of-pocket expenses for out-of-network services, or amounts for items or services not covered under a plan or coverage).

Furthermore, to the extent a plan or issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the accumulated amounts would also include the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant, beneficiary, or enrollee has used).

[113] 80 FR 10750, 10824–10825 (Feb. 27, 2015); *see also* FAQs About Affordable Care Act Implementation (Part XXVII), Q1. Available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA/-FAQs-Part-XXVII/-MOOP/-2706/-FINAL.pdf* and *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvii.pdf*.

As discussed in the proposed rules, the Departments understand that independent of cumulative treatment limitations, cost-sharing liability may vary by individual based on a determination of medical necessity and that it may not be reasonable for a plan or issuer to account for this variance as part of the accumulated amounts. Therefore, under the final rules, plans and issuers are required to provide cost-sharing information with respect to an accumulated amount for a cumulative treatment limitation that reflects the status of the individual's progress toward meeting the limitation, and this information does not include any individual determination of medical necessity that may affect coverage for the item or service. For example, if the terms of an individual's plan or coverage limit coverage of physical therapy to 10 visits per plan or policy year, subject to a medical necessity determination, and at the time the request for cost-sharing information is made the individual has had claims paid for three physical therapy visits, the plan or coverage would make cost-sharing information disclosures based on the fact that the individual could be covered for seven more physical therapy visits in that plan or policy year, regardless of whether or not a determination of medical necessity for future visits has been made at that time.

Several commenters supported the inclusion of the accumulated amounts as one of the content elements. One commenter agreed with the proposed requirement that the accumulated amounts include the financial responsibility incurred toward both an individual deductible and/or out-of-pocket limit and toward the other than self-only coverage deductible and/or out-of-pocket limit. One commenter recommended that plans be required to disclose to prospective enrollees whether an enrollee's accumulated amounts are reduced through a plan's accumulator adjustment program because, the commenter noted, having this information prior to enrollment in a plan is crucial because of the impact such programs have on participant, beneficiary, and enrollee access, adherence, and outcomes.

The Departments agree that an essential part of providing accurate cost-sharing estimates is disclosing individuals' progress toward their accumulated amounts. However, the intent of the self-service tool is to provide current participants, beneficiaries, and enrollees with information about their plan or issuer, and, therefore, the Departments are not finalizing any provisions related to disclosures to potential enrollees. The final rules adopt this provision as proposed.

One commenter recommended the Departments confirm amounts made available in account-based arrangements that can or must be used toward cost-sharing expenses under a separate plan need not be reflected in the accumulated amounts or cost-sharing estimate under the tool. The commenter stated that there is an array of these types of arrangements of varying types and structures and to incorporate them into the cost-sharing estimate could be administratively challenging and would impose a significant burden.

The Departments clarify that the estimates do not include amounts made available through separate account-based arrangements. In addition, the Departments encourage, but are not requiring, plans and issuers to issue a disclaimer regarding such arrangements, as necessary.

Certain commenters stated that the proposed requirement to display accumulated amounts toward a cumulative treatment limitation on a particular item or service would be difficult to implement and requested elimination or delay of this requirement. Commenters expressed that in some cases, this information may be tracked by third-party vendors and not integrated into claims systems; for example, plans and issuers often contract with third parties that provide medical benefits management for certain services (physical therapy, for example). Commenters stated that building the connectivity necessary to exchange information on accumulated amounts in real time would take significant time. Other commenters recommended this requirement be optional.

The Departments acknowledge that disclosure of accumulated amounts may present challenges for plans and issuers. However, an accurate estimate of cost-sharing liability cannot be achieved without taking into account a participant's, beneficiary's, or enrollee's accumulated amounts, including cumulative treatment limitations. Nonetheless, to give plans and issuers additional time to prepare, the disclosure requirements related to cost-sharing liability estimates in the final rules are not applicable until plan years (or in the individual market, policy years) beginning on or after January 1, 2023, providing two years for implementation, which should give plans and issuers sufficient time to ensure that they are able to comply.

One commenter urged the Departments to include a requirement for plans to provide the cost for the beneficiary to purchase a non-covered prescription drug and to indicate whether and, if so, to what extent, that cost will be applied against the deductible. The commenter stated that knowing to what extent a non-covered drug expense will count towards meeting a deductible and the annual limitation on cost sharing, if at all, especially with regard to specialty drugs, is critical because there are significant coverage gaps.

While the Departments appreciate the suggestions related to non-covered prescription drugs, this rulemaking is focused on covered items and services. The Departments are not inclined to increase the burden imposed by the final rules by adding requirements to disclose information regarding non-covered services, given that plans and issuers may not have access to the costs of drugs they do not cover and include in their formulary. The Departments will take this suggestion into consideration for future rulemaking.

c. Third Content Element: In-Network Rates

Negotiated Rates

In the proposed rules, the Departments proposed to require group health plans and health insurance issuers to disclose the negotiated rate, reflected as a dollar amount, for an in-network provider or providers for a requested covered item or service, to the extent necessary to determine the participant's, beneficiary's, or enrollee's cost-sharing liability. Many commenters did not support the disclosure of negotiated rates, stating that publishing negotiated rates would not meet the Departments' purported goal of helping consumers understand costs and would possibly make purchasing more confusing and difficult for consumers. Additionally, some commenters expressed concerns that publication of negotiated rates would force plans and issuers to violate non-disclosure contracts with providers. Conversely, many other commenters did support the disclosure of negotiated rates and offered support for their disclosure to participants, beneficiaries, and enrollees. These commenters stated that consumers should be engaged and educated about health care spending, and as discussed in more detail below, several commenters supported the disclosure of negotiated rates even when it is not relevant to a consumer's cost-sharing liability.

The Departments maintain that the disclosure of the negotiated rates is a key element of overall price transparency. Participants, beneficiaries,

and enrollees are often responsible for a percentage of the negotiated rate through coinsurance or the entire negotiated rate if they have not yet met their deductible. Consistent with discussions elsewhere in this preamble, the Departments are of the view that such contracts typically include exceptions where a particular disclosure is required by Federal law.

In the preamble to the proposed rules, the Departments acknowledged that some provider contracts express negotiated rates as a formula (for example, 150 percent of the Medicare rate), but disclosure of formulas is not likely to be helpful or understandable for many participants, beneficiaries, and enrollees viewing this information. For this reason, the final rules require plans and issuers to disclose the negotiated rates and underlying fee schedules that result from using such a formula, as a dollar amount.

A few commenters recommended disclosing negotiated rate ranges or benchmarks to help consumers compare prices among providers. One commenter stated it would be useful if plans disclosed their range of in-network rates (or their average or median rate) for each service. This commenter stated that, for certain services such as complex surgeries, for which fees may be bundled and may vary widely depending on the severity of a participant's, beneficiary's or enrollee's condition, providing the range of in-network fees may be particularly appropriate. This type of disclosure could alert participants, beneficiaries, and enrollees to consider, and prompt them to consult providers about, the full range of potential expenses for their care. Another commenter recommended that, regardless of the participant's, beneficiary's, or enrollee's out-of-pocket liability, the participant, beneficiary, or enrollee should always be provided the full in-network amount, as well as a comparison of that amount to a benchmark such as the Fair Price or median in-network price. This commenter stated that the in-network price for a service can vary by as much as 200 to 1,000 percent, depending on the provider selected. In order to achieve the goals of transparency, consumers need to know the full price of a service prior to care so they are able to effectively compare providers' prices.

In the Departments' view, disclosure of formulas or ranges are not likely to be helpful or understandable for many participants, beneficiaries, and enrollees viewing this information. The purpose of the internet-based self-service tool is to provide personalized costs based on the participant's, beneficiary's, or enrollee's specific plan or coverage, and ranges and formulas do not achieve this goal. For this reason, the final rules retain the proposed requirement to disclose the rate that results from using such a formula, which is required to be expressed as a dollar amount.

Underlying Fee Schedule Rate

Given the unique nature of certain plan designs, in the proposed rules, the Departments requested comment on whether there were certain reimbursement or payment models that should be exempt from all or certain aspects of the proposed rules. A few commenters urged the Departments to clarify how capitation arrangements and value-based reimbursement designs, including bundled payment arrangements and reference-based pricing, would be regulated under the proposed rules. Commenters stated that provider payment amounts are not knowable under these types of arrangements until after care is provided and that they cannot be attributed to a particular item or service provided to a particular participant, beneficiary, or enrollee. Other commenters stated that participants, beneficiaries, and enrollees should have access to cost-sharing liability data for items and services that might be rendered in the course of their care, but that the Departments' proposed approach downplayed the complexity of payer-provider contracts in a way that could inadvertently lead to participants, beneficiaries, and enrollees receiving misleading estimates of their cost-sharing liability. The commenter stated that only the consumer's cost sharing and the fee-for-service component of reimbursement should be required to be disclosed under these requirements. Another commenter stated that the vast majority of bundled payment arrangements use a retrospective settlement, in which the payer and provider determine a final settlement after all care in the relevant episode has been delivered, suggesting that a negotiated rate under these arrangements could not be provided in advance.

The Departments are of the view that, for transparency in coverage to be truly effective, consumers should have access to all pricing information related to their care so they can make meaningful decisions about their health care spending. Further, the Departments do not agree that the disclosure of negotiated rates will be misleading to participants, beneficiaries, or enrollees. Negotiated rates are already an element of an EOB that participants, beneficiaries, and enrollees are accustomed to receiving after receiving health care items or services. As stated elsewhere in this preamble, providing this information in advance equips a more cost-conscious participant, beneficiary, and enrollee with the necessary information to make a more informed decision about their health care. Furthermore, the Departments are of the view that it is in the best interest of plans and issuers to indicate, when disclosing these rates, what each rate is and how it is applicable to the participant's, beneficiary's, or enrollee's plan or coverage.

To more fully understand the complexity of payer-provider contracts and, in an effort to clarify how the proposed rules would apply to capitated, bundled, and other alternative reimbursement designs, the Departments considered these public comments and conducted additional research to understand different contracting models and the inputs that would be necessary for determining a participant's, beneficiary's, or enrollee's cost-sharing liability under these models.

Under some capitation arrangements, payers reimburse a provider a set amount per participant, beneficiary, or enrollee for a pre-defined amount of time, regardless of whether the participant, beneficiary, or enrollee uses the provider's services. Capitation payments are generally guided by actuarial principles and may be determined by different factors, such as a participant's, beneficiary's, or enrollee's age and gender. For instance, under some capitated models, plans and issuers pay a provider or a collective panel of providers a per-member-per-month (PMPM) capitation amount, which is the negotiated rate. It is the Departments' understanding that under certain capitated and bundled payment arrangements, providers' payments may be reconciled retrospectively to account for utilization, value adjustments, or other weighting factors that can affect the final payment to a provider. The Departments understand that capitation arrangements also may include at least one underlying fee schedule rate upon which a participant's, beneficiary's, or enrollee's cost-sharing liability is determined.

As the Departments acknowledged earlier in this preamble, negotiated rates, as defined in the final rules, do not always affect a participant's, beneficiary's, or enrollee's cost-sharing liability. To account for alternative reimbursement arrangements such as capitated and bundled payment arrangements, the Departments are renaming the third content element as ''in-network rates,'' comprised of the

following elements, as applicable to the plan's or issuer's payment model: negotiated rate and underlying fee schedule rate, reflected as dollar amounts. Plans and issuers must disclose the underlying fee schedule rate used to determine participant, beneficiary, or enrollee cost-sharing liability only where that rate is different from the negotiated rate. As discussed earlier in this preamble, the final rules require that the cost-sharing liability estimate for a requested covered item or service be calculated using the current underlying fee schedule rate if the plan or issuer uses such a fee schedule. The Departments are of the view that disclosing underlying fee schedule rates will provide the most relevant data on which cost sharing is based, if cost sharing is not based on the negotiated rate, as originally proposed.

Disclosing the Negotiated Rate and Underlying Fee Schedule Rate

In the proposed rules, the Departments acknowledged that if the negotiated rate does not impact an individual's cost-sharing liability under a plan or coverage for a covered item or service (for example, if the copayment for the item or service is a flat dollar amount or zero dollars and the individual has met a deductible, or a deductible does not apply to that particular item or service), disclosure of the negotiated rate may be unnecessary to calculate cost-sharing liability for that item or service. Therefore, the Departments proposed that disclosure of a negotiated rate would not be required if it is not relevant for calculating an individual's cost-sharing liability for a particular item or service. The Departments sought comment on whether there are any reasons disclosure of negotiated rates should nonetheless be required under these circumstances.

Many commenters agreed that negotiated rates should only be disclosed to the extent they are used for determining cost-sharing liability. Commenters further expressed that only information meaningful to consumers' cost-sharing liability should be required to be disclosed. One commenter stated that this interpretation should be extended to payments tied to value, such as ''shared savings,'' bonuses, and other performance-based reimbursements.

Conversely, as stated earlier, many commenters supported the disclosure of negotiated rates in all circumstances. One commenter stated that disclosing the amount of the negotiated rate is extremely valuable regardless of whether the disclosure of this information impacts a participant's cost-sharing liability, because it will illuminate the costs of these particular items and services—reflecting the benefit consumers receive from their enrollment in the plan or coverage, as well as helping them to be conscious of the costs incurred by the plan overall. This commenter pointed out that if the plan or issuer has different negotiated in-network rates with different providers furnishing the same item or service, participants, beneficiaries, and enrollees will have the opportunity to compare the different rates among the different providers.

Another commenter suggested a number of benefits that could come from the disclosure of negotiated rates through the cost-sharing tool, even in cases in which that information is not relevant to the specific cost-sharing inquiry. The commenter pointed out that even if the participant's, beneficiary's, or enrollee's cost is not affected, the plan's or issuer's cost could be significantly affected and that allowing participants, beneficiaries, and enrollees awareness and visibility of negotiated rates could provide consumers with a greater understanding of health care costs and enable participants, beneficiaries, and enrollees to seek out lower cost providers. The commenter further stated that although participants, beneficiaries, and enrollees will use the tool to look up estimated cost-sharing for specific items and services, often they will also expect to seek services from the same provider repeatedly (for example, for ongoing treatment and follow-up care).

The Departments agree with those commenters who favored requiring disclosure of negotiated rates even when the negotiated rate is not relevant to determining cost sharing, because it may promote awareness and understanding of health care prices and promotes transparency in coverage. Accordingly, the phrase ''to the extent relevant to the participant's or beneficiary's cost-sharing liability'' that appeared in paragraph (b)(1) of the proposed regulations has been removed from the final rules. The final rules modify the third content element to require that the negotiated rate always be disclosed with cost-sharing liability estimates, even if it is not used to determine cost sharing, and that the underlying fee schedule rate also be disclosed, to the extent that it is different from the negotiated rate, as applicable to the plan's payment model.

With regard to plans and issuers using an alternative reimbursement model, such as a capitated or bundled payment arrangement that does not have negotiated rates or an underlying fee schedule, one commenter stated that issuers do not always have access to the negotiated rates or internal payment methodologies utilized by capitated medical groups or other providers and would not be able to reliably provide cost transparency based on a negotiated rate at the service level. In contrast, another commenter stated there is no justification for excluding plans that reimburse their providers based on capitation from the internet-based self-service tool requirements as this would result in an incomplete data set, and these plans already assign values to services to administer benefits with deductibles and coinsurance, as well as for risk adjustment and internal reporting purposes. Another commenter stated that the Departments should include Accountable Care Organizations (ACOs) and other capitated arrangements within the ambit of the final rules and should require transparency and full disclosure of financial incentive arrangements that underlie capitated arrangements under a specific plan or contract, not just a consumer's anticipated liability. This commenter stated that any exemptions may actually be incentives for plans and issuers to move toward opaque pricing models.

The Departments acknowledge that it is possible that some plans and issuers using alternative reimbursement models may not have negotiated rates or underlying fee schedule rates to disclose in the internet-based self-service tool. However, the numbers of plans and issuers without negotiated rates or underlying fee schedule rates is limited and the Departments are of the view that an exemption for such arrangements is not necessary. Additionally, the Departments are of the view that providing an exemption for such arrangements will result in incomplete data sets. As stated in the final rules, the in-network rate must be disclosed, as applicable to the plan's or issuer's payment model. If the plan or issuer does not have negotiated rates or underlying fee schedule rates, the third content element does not apply.

Prescription Drugs

The final rules adopt the requirement that group health plans and health insurance issuers disclose to participants, beneficiaries, or enrollees an estimate of cost-sharing liability for each item or service, including prescription drugs. As discussed in the preamble to the proposed rules, this would allow participants, beneficiaries, and enrollees to request cost-sharing information for a specific billing code

(as described later in this preamble) associated with a prescription drug or by descriptive terms (such as the name of the prescription drug), which would permit participants, beneficiaries, and enrollees to learn the estimated cost of a prescription drug obtained directly through a provider, such as a pharmacy or mail order service. In addition to allowing participants, beneficiaries, and enrollees to obtain cost-sharing information by using a billing code or descriptive term, the proposed rules would also have permitted participants, beneficiaries, and enrollees to learn the cost of a set of items or services that include a prescription drug or drugs that is subject to a bundled payment arrangement for a treatment or procedure. In the proposed rules, the Departments acknowledged that outside of a bundled payment arrangement, plans and issuers often base cost-sharing liability for prescription drugs on the undiscounted list price, such as the AWP or WAC, which frequently differs from the price the plan or issuer has negotiated for the prescription drug.[114] In these instances, providing the participant, beneficiary, or enrollee with a rate that has been negotiated between the issuer or plan and its PBM could be misleading, as this rate would reflect rebates and other discounts, and could be lower than what the individual would pay—particularly if the participant, beneficiary, or enrollee has not met his or her deductible.

The Departments sought comment as to whether a rate other than the negotiated rate, such as the undiscounted price, should be required to be disclosed for prescription drugs, and whether and how to account for any and all rebates, discounts, and dispensing fees to ensure participants, beneficiaries, and enrollees have access to meaningful cost-sharing liability estimates for prescription drugs.

Several commenters supported disclosure of rebates, discounts, and other price concessions for drugs. One commenter referred to drug price concessions as one of the ''most confounding black boxes of health care'' and stated that data suggests these concessions are actually increasing out-of-pocket costs for participants, beneficiaries, and enrollees. This commenter urged the Departments to require plans and issuers to disclose the list price, the negotiated rate, a single dollar value reflecting the total amount of price concessions, and the price used to calculate the participant's, beneficiary's, and enrollee's coinsurance along with, if different from the negotiated rate, an explanation as to why the price is different from the negotiated rate. Another commenter opined that participants, beneficiaries, and enrollees have the right to know a drug's undiscounted price, discounted or negotiated price, and the total sum of all price concessions for that drug, including fees, rebates, and discounts. This commenter stated that providing a beneficiary with these three data points strikes the appropriate balance between improving transparency without misleading or overwhelming the participant, beneficiary, or enrollee.

Many commenters suggested that plans and issuers be required to disclose when the participant's, beneficiary's, or enrollee's cost-sharing requirement exceeds the price paid by the plan or issuer. One commenter stated that in cases where plans pass through some or all rebates and other price concessions to participants, beneficiaries, and enrollees, the prices disclosed to participants, beneficiaries, and enrollees should be the price net of those rebates and concessions. The commenter emphasized the importance of plans and issuers also disclosing to participants, beneficiaries, and enrollees when manufacturer rebates and discounts are not passed through to them at the point-of-sale or factored into cost-sharing. One commenter noted that negotiated prices for prescriptions or cash price alternatives may sometimes appear less expensive, but that such alternative rates (for example, cash price options) may increase overall costs if such rates offset the ability to reach a plan's deductible or out-of-pocket maximum thresholds. Therefore, this commenter requested that the Departments provide clarity as to whether plans and issuers would be responsible for notifying participants, beneficiaries, and enrollees of such considerations and/or making such calculations. Similarly, two commenters urged the Departments to require disclosure of the negotiated rate for drugs in all situations, even where the beneficiary owes a fixed-amount copayment, and cited reports of cases when, for inexpensive generics, the beneficiary's fixed-amount copay actually exceeded the negotiated rate.

Three commenters recommended that the Departments provide plans the flexibility to display the most meaningful price to an enrollee for drugs. One commenter stated that if the participant, beneficiary, or enrollee's cost sharing is based upon a specified benchmark, the plan should be allowed to specify the benchmark used in the tool's documentation. This commenter suggested that requiring plans to conform to a single standard is not possible, and in effect may be unhelpful to consumers, given the multitude of contracts (and different contract terms) that each plan's PBM may have with pharmacies. Another commenter stated providing this flexibility will allow for issuer innovation in developing cost-estimator functionality that provides real-time, accurate, and useful prescription drug estimates to participants, beneficiaries, or enrollees.

One commenter recommended the Departments consider using ''net price'' rather than the ''negotiated rate'' for estimating cost-sharing liability for prescription drugs. The commenter explained that direct and indirect remuneration (DIR) fees under Medicare Part D and similar PBM practices in the private market were originally designed to capture rebates and other mechanisms not included at the point-of-sale. However, the commenter stated that DIR fees and other retroactive fees utilized by PBMs are now being used beyond their original purpose to retroactively adjust pharmacies' payment months after the sale, sometimes below the price paid by the pharmacy.

Some commenters stated that the Departments should not require display of negotiated drug prices, rebates, or other discounts or fees. Two commenters expressed that, rather than increasing transparency or providing actionable or meaningful information to participants, beneficiaries, or enrollees, estimated rebate information would simply confound and frustrate participants, beneficiaries, or enrollees, given its lack of direct relevance to the amount the participant, beneficiary, or enrollee is required to pay for the drug at a pharmacy. Another commenter stated that disclosing highly confidential dispensing fees would benefit only those parties being paid dispensing fees, by giving them a window into the dispensing fees paid to their competitors, and advised that the Departments should avoid requiring any disclosure of drug prices, rebates, discounts, or fees that would undermine plans' and issuers' ability to negotiate lower drug costs.

The Departments also solicited comment as to whether there are scenarios in which including drug pricing information in cost estimates would be problematic. One commenter recommended that the final rules require disclosure of an estimate of the cost-sharing liability associated with a drug only when there is an out-of-pocket cost to the participant, beneficiary, or enrollee that is directly

[114] ''Follow the Dollar.'' PhRMA. November 30, 2017. Available at: *https://www.phrma.org/report/follow-the-dollar-report.*

attributable to the drug. Another recommended that when the price of a drug is not the basis of the enrollee's cost-sharing liability, plans should be given the option to publish the benchmark price or omit a price altogether, displaying only the enrollee's cost-sharing liability.

The Departments also sought comment on whether the relationships between plans or issuers and PBMs allow plans and issuers to disclose rate information for drugs, or if contracts between plans and issuers and PBMs would need to be amended to allow plans and issuers to provide a sufficient level of transparency. If those contracts would need to be amended, the Departments sought comment on the time that would be needed to make those changes. While some commenters stated that the rates negotiated between PBMs and pharmacies are considered confidential, other commenters stated that existing contracts would not prevent PBMs or issuers from disclosing the required information. One commenter stated that it is common that contracts be modified in response to changes in a statute or regulation, and that Federal public policy imperatives override existing contractual provisions. This commenter stated the public interest in complete disclosure to reduce costs for consumers unquestionably outweighs any confidentiality provisions in current contracts that might otherwise protect disclosure of relevant information to the Federal Government.

The Departments agree that participants, beneficiaries, and enrollees, as well as health care payers such as employers, should have access to meaningful pricing information related to drug pricing in order to meaningfully evaluate plan and issuer offerings and gain transparency into potential out-of-pocket costs.

The Departments also acknowledge that contract terms may need to be amended based on the final rules. The Departments agree that disclosure of rebates, discounts, and other price concessions would further the goals of price transparency, but also acknowledge other commenters' concerns that disclosing all these elements might cause consumer confusion. The Departments also acknowledge that there could be value in using ''net price'' rather than ''negotiated rate'' and in disclosing when a participant's, beneficiary's, or enrollee's cost-sharing liability exceeds the price paid by the plan or issuer. As described by commenters, there are numerous pricing inputs throughout the drug supply chain that affect the final price for the consumer—making complete transparency on drug pricing more complex than that of other items and services. The Departments aim to strike a balance between illuminating some of the factors that drive drug costs and not overwhelming consumers with information that is not directly relevant to their cost-sharing liability. To that end, the final rules require plans and issuers to disclose in element (i), an individual's out-of-pocket cost liability for prescription drugs, and in element (iii), the negotiated rate of the drug. As discussed elsewhere in this preamble, the Departments recognize that the negotiated rate might be different for branded and generic drugs. For instance, the negotiated rate might be the WAC for branded drugs and the Maximum Allowed Cost (MAC) for generic drugs. The Departments also acknowledge that this price might be established differently for different plans and issuers. The Departments anticipate this disclosure generally will not necessitate the disclosure of information on discounts, rebates, or price concessions for a drug.

The Departments recognize there may be circumstances in which a drug carries no cost-sharing liability for a participant, beneficiary, or enrollee. If there is no cost sharing associated with a prescription drug, under the final rules, the tool should reflect a cost-sharing value of $0 for clarity, but the negotiated rate must be displayed.

The proposed rules sought comment on the possibility of requiring access to the APIs used by pharmacies in accessing drug prices. One commenter stated that drug prices frequently differ from period to period over the course of the year, as well as across pharmacy locations even within the same national pharmacy chain. The commenter recommended that the Departments consider requiring PBMs to provide payers, group plans, and third parties with access to the same price APIs accessed by pharmacies, stating that, with access to an open API, the plan or third party could request the estimated price for the same prescription at multiple retail pharmacies and receive real-time retail pricing based upon the participant's, beneficiary's, or enrollee's plan. The Departments recognize the value in requiring cost-sharing information be made available through an API and will use the comments received to inform future rulemaking.

Commenters requested that the Departments confirm that issuers may provide a link to prescription drug cost tools offered through PBMs or vendors to satisfy the requirement to provide pricing information for prescription drugs. One commenter also urged the Departments to prohibit the internet-based, self-service tool from being used by prescribers' e-prescribing and electronic medical record systems or by plans to steer patients to pharmacies other than a patient's pharmacy of choice, such as those owned wholly or partially by health plans or PBMs.

The Departments agree that plans and issuers who provide participants', beneficiaries', or enrollees' cost-sharing liability estimates and negotiated rates through a standalone tool provided by a PBM or third-party vendor satisfy the requirements under the final rules. The Departments also clarify that if the PBM or other third-party vendor fails to provide full or timely information, then the plan or issuer, not the PBM or third-party vendor, violates these transparency disclosure requirements. Regarding a prohibition on steering patients to certain pharmacies by plans or prescribers, the Departments are not finalizing any prohibitions at this time and will monitor the implementation of these disclosure requirements.

d. Fourth Content Element: Out-of-Network Allowed Amount

The fourth content element is the out-of-network allowed amount for the requested covered item or service. In the proposed rules, the Departments proposed to define ''out-of-network allowed amount'' to mean the maximum amount a group health plan or health insurance issuer would pay for a covered item or service furnished by an out-of-network provider. Under the proposed rules, plans and issuers would be required to disclose an estimate of cost-sharing liability for a participant, beneficiary, or enrollee. Therefore, the Departments proposed that, when disclosing an estimate of cost-sharing liability for a covered item or service from an out-of-network provider, a plan or issuer would disclose the out-of-network allowed amount and any cost-sharing liability the participant, beneficiary, or enrollee would be responsible for paying. For example, if a plan has established an out-of-network allowed amount of $100 for an item or service from a particular out-of-network provider and the participant, beneficiary, or enrollee is responsible for paying 30 percent of the out-of-network allowed amount ($30), the plan would disclose both the allowed amount ($100) and the individual's cost-sharing liability ($30), indicating that the individual is responsible for 30 percent of the out-of-network allowed amount. Under the proposed rules, this element would only be relevant when a participant, beneficiary, or enrollee

requests cost-sharing information for a covered item or service furnished by an out-of-network provider.

In the proposed rules, the Departments explained that the definition of cost-sharing liability does not include amounts charged by out-of-network providers that exceed the out-of-network allowed amount, which participants, beneficiaries, or enrollees must pay (sometimes referred to as balance bills). Therefore, it may be difficult for participants, beneficiaries, or enrollees to determine their likely out-of-pocket costs for covered items and services furnished by an out-of-network provider. The Departments also explained that the statutory language of section 1311(e)(3)(A)(vii) of PPACA and section 2715A of the PHS Act indicates that Congress intended that participants, beneficiaries, enrollees, and other members of the public have access to accurate and timely information regarding cost sharing and payments with respect to any out-of-network coverage. In the Departments' view, requiring plans and issuers to disclose out-of-network allowed amounts and a participant's, beneficiary's, or enrollee's cost-sharing obligation for covered items and services is necessary and appropriate to fulfill this statutory mandate, and would give individuals information necessary to estimate their out-of-pocket costs, assuming they request additional information from an out-of-network provider about how much the provider would charge for a particular item or service.

One commenter encouraged the Departments to eliminate the proposed ''maximum amount'' standard and to instead incorporate usual, customary, and reasonable (UCR) amounts as the required plan disclosure for out-of-network cost estimates under any final rulemaking. The commenter stated that the ''maximum amount'' a plan may be willing to pay a given provider for a service is not necessarily predetermined. This commenter stated that while some out-of-network providers and plans may participate in super-regional or national ''discount'' arrangements through third parties, in many cases payments to out-of-network providers are individually negotiated. Further, while a plan might generally start with payment that is consistent with UCR calculations (with every intention of paying no more than this amount), other circumstances may result in negotiated increases to that reimbursement. As such, prospectively reporting an accurate ''maximum amount'' is impossible in some cases. Additionally, this commenter stated that because many out-of-network reimbursements, and in particular high-cost claims, are individually negotiated, initial disclosure of a plan's true maximum reimbursement, insofar as this can be calculated or even estimated in advance, would materially reduce a plan's bargaining power by notifying non-contracted providers in advance of the amount they are likely to secure from a plan if they assert all available leverage in a negotiation. To the extent participant, beneficiary, or enrollee cost-sharing liability is ultimately derived from out-of-network payment amounts, this requirement is likely to increase out-of-pocket costs for consumers when seeking care from out-of-network providers.

Conversely, one commenter stated that while larger, for-profit, national health plans can afford to utilize the UCR, smaller, regional health plans are at a market disadvantage if they are compelled to base allowed amounts on the UCR, rather than negotiating on a case-by-case basis in a constrained market. As a result, some health plans will struggle to determine and provide information about maximum out-of-network allowed amounts—a range of possible ''allowed amounts'' may be the most information some health plans have available.

The Departments agree with commenters that the UCR may be a more accurate estimate of the amount a plan or issuer will pay an out-of-network provider for covered items or services, if the plan relies on UCR to determine out-of-network rates. However, the Departments acknowledge that basing allowed amounts on the UCR may disadvantage smaller plans. The Departments also acknowledge that a plan or issuer may be able to provide a participant, enrollee, or beneficiary with a more accurate estimate of an out-of-network allowed amount by using calculations based on historical claims data, because the plan or issuer does not have a pre-determined negotiated rate with out-of-network providers. The Departments acknowledge the concern that plans may lose bargaining power by disclosing out-of-network allowed amount to consumers; however, the Departments are of the view that the out-of-network allowed amount is a critical element of price transparency and its disclosure is essential to enabling consumers to estimate their out-of-network costs in advance. To this end, the Departments are modifying this provision to require plans and issuers to disclose the out-of-network allowed amount or any other calculation that provides a more accurate estimate of the amount a plan will pay for the requested covered item or service, such as a UCR. Allowing plans and issuers to provide an amount other than the out-of-network allowed amount could better serve consumers with a more accurate estimate of what a plan or issuer may reimburse an out-of-network provider. The Departments clarify that if a plan or issuer chooses to use another metric that provides a reasonably accurate estimate of what a plan or issuer will pay for a covered item or service from an out-of-network provider, the plan or issuer must still provide a participant, beneficiary, or enrollee with information regarding any cost sharing the participant, beneficiary, or enrollee would be responsible for paying.

Some commenters recommended the Departments not require plans and issuers to provide allowed amount and cost-sharing information for covered services furnished by an out-of-network provider. One commenter stated it is not possible for issuers to include allowed amounts for out-of-network providers because, without a provider contract, issuers do not have the necessary information, including provider names, National Provider Identifier (NPI), address, specialty, or other demographic information to include these providers in a price transparency tool. One commenter stated that providing real-time disclosures of allowed amounts could be challenging to the extent that plans and issuers determine the allowed amount for certain out-of-network items and services based on a percentage of billed charges, as billed charges are unknown by the plan or issuer prior to a claim for health care services.

The Departments acknowledge the challenges plans and issuers may face disclosing this element, but the Departments are of the view that information regarding out-of-network coverage is essential to the goal of price transparency. With regard to plans and issuers lacking the necessary information for providers with whom they do not contract, the Departments are of the view that plans and issuers should know what they are willing to pay for certain items and services, irrespective of provider. The final rules provide flexibility for plans and issuers to provide an estimate of what the plan will pay by allowing plans and issuers to disclose either the out-of-network allowed amount or another amount that would provide a reasonably accurate estimate of what a plan would reimburse an out-of-network provider for a covered item or service. Given that some plans and issuers determine the allowed amount for certain out-of-network items and services based on a percentage of billed charges, the final rules provide that a percentage can be

disclosed instead of a dollar amount, if plans and issuers reimburse out-of-network providers a percentage of the billed charges for a covered item or service.

One commenter sought clarification that the tool is meant to provide cost-sharing information for out-of-network providers and not just the allowed amounts.

As discussed earlier in this preamble under the first content element, under the final rules, the plan or issuer is required to disclose both the out-of-network allowed amount, as described earlier in this preamble, and any cost-sharing liability, based on that allowed amount, that the participant, beneficiary, or enrollee would be responsible for paying.

One commenter stated that the Departments should not require Health Maintenance Organizations' (HMOs') out-of-pocket calculators to provide out-of-network data. The commenter noted that the proposed rules limited the tool to covered services, and HMOs generally do not cover benefits provided by out-of-network and, therefore, should not be required to estimate out-of-network costs.

The Departments understand that some plans and issuers may not provide any reimbursement to an out-of-network provider for an otherwise covered item or service. Nonetheless, it is the Departments' understanding that some HMOs reimburse an out-of-network provider for covered items and services in certain circumstances and, therefore, the Departments expect HMOs to provide cost-sharing information with regard to out-of-network coverage. The Departments recognize that in many cases, an HMO's maximum allowed amount for an out-of-network service will be $0. However, the Departments are of the view that it is important for a participant, enrollee, or beneficiary to understand what the plan or issuer will or will not pay for out-of-network costs. Therefore, if the plan or issuer, including an HMO, does not provide any reimbursement for an item or service provided by an out of network provider, the Departments expect the plan or issuer to disclose $0 as the allowed amount.

e. Fifth Content Element: Items and Services Content List

The fifth content element is a list of those covered items and services for which cost-sharing information is being disclosed for items or services subject to a bundled payment arrangement. The Departments proposed that this requirement would apply only when a participant, beneficiary, or enrollee requests cost-sharing information for an item or service that is subject to a bundled payment arrangement that includes multiple items or services. The Departments proposed that, in cases in which an individual requests a cost-sharing liability estimate for a covered item or service that is subject to a bundled payment arrangement, plans and issuers would be required to disclose a list of each covered item and service included in the bundled payment arrangement and the individual's cost-sharing liability for those covered items and services as a bundle, but not a cost-sharing liability estimate separately associated with each covered item or service included in the bundle.

While some commenters supported the inclusion of cost-sharing information for bundled payment arrangements, others did not support requiring the disclosure of bundled payment arrangements and the items and services included in the arrangement. These commenters stated disclosure of this information would likely be unhelpful to the participant, beneficiary, or enrollee and might cause confusion. One commenter encouraged the Departments to clarify that disclosure for diagnostic imaging procedures in particular should be presented to consumers in a method that is inclusive of the combined professional and technical rates, or the globally billed rate.

The Departments are of the view that understanding which items and services are included in a bundled payment arrangement will provide helpful information for participants, beneficiaries, and enrollees, so that they understand what items and services are accounted for in calculating their cost-sharing liability. The Departments are of the view that this list is unlikely to cause confusion. Instead, it will reduce confusion by clearly identifying what individual items and services would be covered under their estimated cost-sharing liability. If the plan or issuer reimburses a procedure, such as imaging, at a global rate that includes both professional and technical charges, then that global rate is a rate for a bundled payment arrangement for which the applicable content elements must be disclosed, just as for all other items and services. The final rules adopt the provision that plans and issuers provide a list of items or services for items and services subject to bundled payment arrangements for which a cost-sharing liability estimate is being disclosed, with non-substantive edits for improved readability.

f. Sixth Content Element: Notice of Prerequisites to Coverage

The sixth content element is a notification, whenever applicable, informing the individual that a specific covered item or service for which the individual requests cost-sharing information may be subject to a prerequisite for coverage. The proposed rules defined the term prerequisite to mean certain requirements relating to medical management techniques for covered items and services that must be satisfied before a plan or issuer will cover the item or service. Specifically, the proposed rules provided that prerequisites include such techniques as concurrent review, prior authorization, and step-therapy or fail-first protocols. In the proposed rules, the Departments intended for the definition of prerequisite to capture medical management techniques that apply to an item or service that require action by the participant, beneficiary, or enrollee before the group health plan or health insurance issuer will cover the item or service. Accordingly, the proposed definition of prerequisite did not include medical necessity determinations generally, or other forms of medical management techniques that do not require action by the participant, beneficiary, or enrollee. While the prerequisites enumerated in the proposed rules were provided as an illustrative list, the Departments solicited comment on whether there are any additional medical management techniques that should be explicitly included as prerequisites in the final rules.

Several commenters supported the inclusion of this element. One commenter stated that helping patients understand any coverage prerequisites prior to care, such as prior authorization, may help to eliminate some of the confusion and unnecessary administrative burden following care. Another stated that requiring a plan to disclose prerequisites in an easily understandable format may help patients complete required protocols and thus would improve adherence.

A few commenters recommended additional disclosures or offered suggestions to strengthen these requirements. One commenter encouraged the Departments to include clinical coverage policies for services that are more specific than general medical necessity criteria. For example, some plans and issuers utilize coverage policies that require specific diagnoses or documented symptoms before an item or service may be covered. The commenter explained that while these

policies may not technically require an action by the beneficiary, they are important in determining whether the specific item or service is covered. Another commenter recommended that plans and issuers clearly disclose every utilization control that stands between the participant, beneficiary, or enrollee and a prescription, suggesting that this type of disclosure would help patients meet utilization control standards. Another commenter urged the Departments to strengthen this requirement by requiring plans and issuers to provide a description of the actual required prerequisites. The commenter stated that the proposed regulation requires only notification of the existence of a prerequisite, but not any detail about what the prerequisite is and how it can be satisfied. Two commenters encouraged the Departments to standardize this type of notification language to ensure that all consumers receive a consistent message regarding the provision of health care services.

One commenter requested that the Departments provide that the prerequisites listed in proposed rules (that is, concurrent review, prior authorization, step-therapy, and fail-first protocols) are an exclusive list. Another commenter stated that prerequisite notification should be limited to simple notifications that prerequisites apply to a service, and communication of specific prerequisites should not be required until a Fast Healthcare Interoperability Resources (FHIR) standard for transmission of this information is established and operationalized.

As discussed in the proposed rules, the Departments intended for the definition of prerequisite to capture medical management techniques that apply to an item or service that require action by the participant, beneficiary, or enrollee before the plan or issuer will cover the item or service. The Departments consider plan or policy provisions that require a diagnosis or documented symptoms before a service or item would be covered to be medical necessity determination requirements that do not require action on behalf of the participant, beneficiary, or enrollee. Therefore, the Departments did not include such terms in the proposed prerequisite requirement. The Departments are finalizing regulation text to reflect that concurrent review, prior authorization, and step-therapy or fail-first protocols are the exhaustive list of prerequisites about which plans and issuers would need to provide notice. Furthermore, while the Departments acknowledge that providing a complete description of prerequisites might be helpful to consumers, the Departments are not of the view that requiring plans or issuers to provide such descriptions is necessary. The Departments determined that requiring a complete description of the prerequisite would create unnecessary complexity and impose significant burdens on plans and issuers regarding information that is already available in plan documents. Additionally, while the Departments recognize the importance of FHIR in the push towards greater interoperability, it is not necessary to delay finalizing these rules until the FHIR standards are finalized as the final rules do not require any APIs to be built nor exposed for public consumption. The final rules adopt this content element requirement, with the modifications discussed in this section.

g. Seventh Content Element: Disclosure Notice

The seventh and final content element proposed is a notice that communicates certain information in plain language, including several specific disclosures. First, the Departments proposed that this notice would include a statement that out-of-network providers may bill participants, beneficiaries, or enrollees for the difference between providers' billed charges and the sum of the amount collected from the group health plan or health insurance issuer and the amount collected from the participant, beneficiary, or enrollee in the form of cost-sharing (the difference often referred to as balance billing) and that these estimates do not account for those potential additional amounts. In the proposed rules, the Departments acknowledged that there are numerous state laws that address balance-billing practices such that the notice described in the proposed content element regarding balance bills may be misleading or inaccurate for beneficiaries, participants, or enrollees enrolled in a plan or coverage in certain states. The Departments requested comment on whether any modifications to this content element would be appropriate to allow plans and issuers to accurately advise participants, beneficiaries, or enrollees of their potential exposure to or protection from any balance bills.

Second, the Departments proposed that the notice be required to convey that actual charges for the participant's, beneficiary's, or enrollee's covered items and services may be different from those described in a cost-sharing liability estimate, depending on the actual items and services received at the point of care.

Third, the Departments proposed that the notice be required to include a statement that the estimated cost-sharing liability for a covered item or service is not a guarantee that coverage will be provided for those items and services.

Finally, the Departments proposed that plans and issuers be permitted to include any additional information, including other disclaimers that the plan or issuer determines appropriate, so long as the additional information does not conflict with the information they are required to provide. For example, plans and issuers would have been permitted to include additional language so long as the language could not reasonably be read to disclaim the plan's or issuer's responsibility for providing a participant, beneficiary, or enrollee with accurate cost-sharing information, or plans and issuers could choose to provide a disclaimer that informs consumers who are seeking estimates of cost-sharing liability for out-of-network allowed amounts that they may have to obtain a price estimate from the out-of-network provider in order to fully understand their out-of-pocket cost liability. Plans and issuers would also have been permitted to provide a disclaimer indicating how long the price estimate will be valid, based on the last date of the contract term for the negotiated rate or rates (if multiple providers with different contract terms are involved). The Departments are of the view that this type of disclaimer could provide participants, beneficiaries, and enrollees with a better understanding of how their cost estimate may change over time. The Departments sought comment on whether a specific disclaimer indicating the expiration of the cost estimate should be required. Furthermore, the Departments explained in the proposed rules that plans and issuers may also include disclaimer information regarding prescription drug cost estimates and whether rebates, discounts, and dispensing fees may impact the actual cost to the participant, beneficiary, or enrollee.

The Departments developed model language that plans and issuers could use, but would not be required to use, to satisfy the disclosure notice requirements described above. This model language was proposed contemporaneously with, but separate from, the proposed rules.[115] The

[115] ''Transparency in Coverage. Model Notice.'' United States Department of Labor. Available at: *https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-*

Continued

Departments sought comment on the proposed model language and any additional information that stakeholders believed should be included in the model notice or any information that should be omitted from the model notice.

The proposed rules clarified that this disclosure notice would be in addition to the information that QHP issuers are currently required to publish on their websites pursuant to 45 CFR 156.220(a)(7) regarding cost-sharing and payments with respect to out-of-network coverage. In addition, some portions of this disclosure may overlap with network adequacy disclosure standards under 45 CFR 156.230(e). That section requires QHP issuers to count the cost-sharing paid by an enrollee for an out-of-network essential health benefit (EHB) provided by an out-of-network ancillary provider in an in-network setting toward the enrollee's out-of-pocket limit or provide a notice to the enrollee that additional costs may be incurred for an EHB, including balance billing charges, if applicable.

The Departments requested comment on the proposed notice disclaimers and whether any additional disclaimers would be necessary or beneficial to participants, beneficiaries, and enrollees in learning about their potential cost-sharing liability for covered items and services. For example, the Departments inquired whether the Departments should require a notice that explains that the cost-sharing information provided may not account for claims a participant, beneficiary, or enrollee has submitted that the plan or issuer has not yet processed. The Departments also considered whether to require plans and issuers to provide a participant, beneficiary, or enrollee information regarding non-covered items or services for which the individual requests cost-sharing information. For example, there could be a requirement that a plan or issuer provide a statement, as applicable, indicating that the item or service for which the participants, beneficiaries, and enrollees has requested cost-sharing information is not a covered benefit under the terms of the plan or coverage, and expenses charged for that item or service will not be reimbursed by the plan or coverage.

Several commenters agreed with the proposed disclosure notice requirements. Specifically, many commenters supported the disclosure that estimates may not reflect the amount ultimately charged to the participant, beneficiary, or enrollee. One commenter recommended the disclosure include examples of circumstances under which a participant's, beneficiary's, or enrollee's actual cost-sharing liability may differ from the estimate provided by their plan or issuer (for example, comorbidities or unanticipated complications). The commenter stated that a more comprehensive explanation of how participant, beneficiary, or enrollee characteristics might affect charges for covered items and services would help them better understand their potential exposure to higher cost-sharing amounts. One commenter suggested that the notice include stronger wording to educate the plan participant about the strong likelihood of a surprise amount due that differs greatly from the estimate. One commenter recommended that the notice include information that DIR Fees charged to pharmacies inflate participants', beneficiaries', and enrollees' cost sharing and that plans and issuers may claw back that inflated cost sharing from the pharmacy.

One commenter recommended that plans and issuers be required to disclose additional information to help participants, beneficiaries, and enrollees understand the appropriate point of contact for questions and complaints. This commenter recommended that the final rules require issuers to provide participants, beneficiaries, and enrollees with contact information for their state departments of insurance when covered by insurance that is primarily state-regulated. For group health plans that are not fully insured, the commenter recommended that the plan provide contact information for the appropriate Federal regulator.

One commenter requested flexibility with disclaimer language regarding a notice provided in paper form to reflect that the estimate may not be reflective of services received or claims processing, or to direct the participant, beneficiary, or enrollee to call their plan or issuer or use the internet for more up-to-date information. Similarly, one commenter recommended that a timestamp be required for notices provided in paper form to account for potential price changes. Several commenters supported requiring plans and issuers to add to the notice a date on which the estimate will expire, while other commenters did not.

One commenter expressed concern regarding the statement in the preamble to the proposed rules that the required disclosure notice regarding balance-billing information ''may be misleading or inaccurate for beneficiaries, participants, or enrollees enrolled in a plan or coverage in certain states,'' given the multi-state nature of most employer-sponsored plans. Another commenter stated that state regulators should be able to direct issuers to include information in the disclosure that accurately describes the state's balance billing laws, and that any notice provided to consumers in advance of receiving services should have information as to whether the participant, beneficiary, or enrollee is likely to be protected from liability under state or Federal balance billing laws. The commenter further stated that some states already have state laws related to disclosure of costs to consumers and the final rules should be clear that this requirement does not preempt these state requirements. Two commenters urged the Departments to make clear that participants, beneficiaries, and enrollees are not protected from out-of-network provider and facility balance billing, except where balance billing would be barred by state law.

The final rules are not intended to preempt state laws regarding balance billing. In the final rules, the Departments have modified this requirement to clarify that the balance billing statement is only required if balance billing is permitted under state law. Plans and issuers have flexibility to use the model notice language or create their own notices with greater specificity regarding their state's laws.

One commenter expressed concern that allowing plans to include a statement that the estimated cost-sharing liability is not a guarantee of coverage negates the intent of the proposed rules, given that consumers who receive a notice from their health plan regarding estimated out-of-pocket costs would naturally assume coverage of those services.

The Departments acknowledge this concern; however, there are many reasons estimated cost-sharing information may not be accurate when items and services are ultimately furnished. For example, it is possible for coverage to end (for example, due to non-payment of premiums) between the time an estimate is provided and an item or service is furnished. Additionally, an estimate may show the cost for an item or service as a treatment for a certain condition, but the item or service may not be covered for the condition that is ultimately diagnosed at the point of care. Therefore, the final rules adopt the provision as proposed.

Several commenters recommended that the Departments issue guidelines as to what is considered ''plain language.'' The commenters recommended that the Departments provide examples of

employers-and-advisers/transparency-in-coverage-draft-model-disclosure.pdf.

typical disclosure language compared to its ''plain language'' equivalent. They further recommended that these examples be tested through various focus groups to ensure consumer comprehension.

The final rules define ''plain language'' to mean language written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee.[116] Determining whether this standard has been satisfied requires taking into account such factors as the level of comprehension and education of typical participants, beneficiaries, or enrollees in the plan or coverage and the complexity of the terms of the plan. Accounting for these factors would require limiting the use of technical jargon and long, complex sentences, so that the information provided will not have the effect of misleading, misinforming, or failing to inform participants, beneficiaries, or enrollees. The Departments are of the view that the final rules and this preamble provide sufficient detail regarding the meaning of plain language.

Some commenters recommended that plans and issuers should disclose whether they count copayment assistance and other third-party payments in the calculation of the beneficiary's deductible and out-of-pocket maximum. The commenter noted that as more plans implement copay accumulators that do not count these payments, issuers should be required to disclose these policies to their beneficiaries.

The Departments are of the view that knowing whether these payments apply to accumulators is germane to price transparency and should be required in the final rules. To that end, the final rules adopt a fifth notice content requirement (codified at 26 CFR 54.9815–2715A2(b)(1)(vii)(D), 29 CFR 2590.715–2715A2(b)(1)(vii)(D), and 45 CFR 147.211(b)(1)(vii)(D)) that plans and issuers must provide a statement disclosing whether copayment assistance and other third-party payments are included in the calculation of the participant's, beneficiary's, or enrollee's deductible and out-of-pocket maximum.

As discussed under the first content element, some items or services may not be subject to cost sharing if they are furnished as preventive items or services, while the same item or service could be subject to cost sharing if it is furnished for non-preventive purposes or provided by an out-of-network provider. Therefore, the final rules adopt an additional notice requirement (codified at 26 CFR 54.9815–2715A2(b)(1)(vii)(E), 29 CFR 2590.715–2715A2(b)(1)(vii)(E), and 45 CFR 147.211(b)(1)(vii)(E)) stating that, for an item or service that is a recommended preventive service under section 2713 of the PHS Act where the plan or issuer cannot determine whether the request is for a preventive or non-preventive item or service, the plan or issuer must provide a statement that the item or service may not be subject to cost-sharing if it is billed as a preventive service.

One commenter recommended information be included to help participants, beneficiaries, and enrollees understand the appropriate point of contact for questions and complaints. This commenter recommended issuers provide consumers with contact information for the appropriate regulator—either the State Department of Insurance or the appropriate Federal office.

The Departments appreciate this recommendation, but are declining to finalize this additional requirement because the Departments are of the view that plans and issuers already have avenues in place to address participants', beneficiaries', and enrollees' complaints.

Several commenters recommended that additional notice disclaimers be provided. One commenter suggested that the final rules require a statement that cost-sharing liability estimates may differ from actual costs, depending on changes after claims are processed. Another commenter recommended that the Departments develop model disclaimers stating that quoted amounts for drugs may be time-limited and subject to manufacturer pricing practices. Another commenter recommended the addition of consumer disclaimers indicating that ''services subject to the cost estimate may be provided and billed by providers associated with multiple payer contracts which will result in multiple EOBs.'' Another commenter recommended the Departments permit plans to require participants, beneficiaries, and enrollees to review and acknowledge a disclaimer prior to viewing or searching for any pricing information, which would help ensure that consumers understand that what they are receiving may not be an accurate estimate of their total out-of-pocket costs. Another commenter recommended that the presentation of the out-of-network information make clear that the issuer is unable to provide an estimate for the full cost of the service. The commenter suggested that this disclosure should be presented on the same screen as the maximum allowed amount and the participant, beneficiary, or enrollee's cost liability because it may be unclear that the maximum allowed amount is not the total cost of care. Another commenter requested that the Departments add a requirement that plans or issuers provide participants, beneficiaries, or enrollees with meaningful and simple explanations regarding emergency care, including informing them of the prudent layperson standard.[117] Another commenter that recommended plans and issuers be required to provide explanatory information about the operation of their plans, including glossaries of relevant terms and explanations of insurance plan features and health care services, including in-network and out-of-network costs, limited plan designs, deductibles, telehealth, and additional features in consumer-friendly language.

The Departments decline to adopt these commenters' suggestions for additional notice disclaimers. The Departments are of the view that adopting these additional requirements would add to the burden imposed on plans and issuers without creating corresponding benefits for participants, beneficiaries, or enrollees that would outweigh the burden, and would be unhelpfully prescriptive regarding the information plans and issuers are required to convey to these individuals. Existing plan and issuer resources for this information, such as the uniform glossary required under the Summary of Benefits and Coverage (SBC) final regulation[118] provide consumer-friendly language definitions of insurance terms. Additionally, in response to comment, the Departments are providing flexibility to plans and issuers to design their internet-based tools and disclosures so that they meet the needs of their participants, beneficiaries, and enrollees. However, the Departments encourage plans and issuers to provide additional information at their discretion, if appropriate. The final rules adopt these provisions as proposed, with one correction of a typographical error (''bill'' rather than ''billed'') in 26 CFR 54.9815–2715A2(b)(1)(vii)(A), 29 CFR 2590.715–2715A2(b)(1)(vii)(A), and 45 CFR 147.211(b)(1)(vii)(A) and a clarification that this statement element is only required if balance billing is permitted under state law, with paragraph (b)(1)(vii)(D) redesignated as paragraph (b)(1)(vii)(F), and with new paragraphs (b)(1)(vii)(D) and (E) added,

[116] 29 CFR 2520.102–2(a).

[117] 42 CFR 438.114.

[118] 80 FR 34292 (Jun. 16, 2015).

as described earlier in this section of this preamble.

2. Required Methods for Disclosing Information to Participants, Beneficiaries, or Enrollees

Section 1311(e)(3)(C) of PPACA requires that cost-sharing information be made available through an internet website and other means for individuals without access to the internet. Therefore, in the proposed rules, the Departments proposed to require that group health plans and health insurance issuers disclose to participants, beneficiaries, or enrollees the cost-sharing information described earlier in this preamble in two ways: (1) Through a self-service tool that meets certain standards and is available on an internet website, and (2) in paper form.

a. First Delivery Method: Internet-Based Self-Service Tool

Under the proposed rules, plans and issuers would be required to make available a self-service tool on an internet website for their participants, beneficiaries, or enrollees to use, without a subscription or other fee, to search for cost-sharing information for covered items and services. The tool would be required to allow users to search for cost-sharing information for a covered item or service provided by a specific in-network provider, or by all in-network providers. The tool also would be required to allow users to search for the out-of-network allowed amount for a covered item or service provided by out-of-network providers. The tool would be required to provide users real-time responses that are based on cost-sharing information that is accurate at the time of the request.

Many commenters supported the Departments' proposal to require plans and issuers to make available personalized out-of-pocket cost information for all covered health care items and services through an internet-based self-service tool and urged the Departments to finalize this section of the regulation as proposed. Some commenters recommended the Departments identify a core set of functional requirements that must be included in all price transparency tools. Commenters suggested that these functional requirements should ensure all people enrolled in commercial products have access to the same baseline functionality, while providing enough flexibility for issuers to develop, and iterate on, innovative existing internet-based self-service tools. Examples of functional requirements include providing tailored information to participants, beneficiaries, or enrollees on their benefit summary (plan coverage, copayments, deductibles); being able to browse by service category (for example, medical specialty, procedures, drugs, imaging, labs) or diagnosis; or being able to select from an A–Z list of popular searches or episodes of care. One commenter recommended the following functional requirements: (1) Provide individuals with their personal health plan details, a digital ID card, deductible and copay information, the ability to download and view claims, and information on provider network status and quality performance; (2) display cost and quality information in clear, user-friendly language to facilitate and inform health care decisions; (3) allow consumers to compare facilities and clinicians based on curated cost estimates, common quality measures, value metrics, and patient ratings; (4) offer personalized out-of-pocket cost estimates for episodes of care, services, and prescriptions, calculated using their specific health plan design before they receive care; (5) comply with all state and Federal health care data privacy and security laws, including the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules and the Health Information Trust (HITRUST) Common Security Framework.

The Departments agree that the self-service tool requirements should ensure all people enrolled in group health plans and health insurance coverage have access to the same baseline functionality, while providing enough flexibility for plans and issuers to develop and iterate on innovative internet-based self-service tools. It is the Departments' intent that the required elements be broad enough to avoid being overly prescriptive for plans and issuers. The Departments agree that certain additional content elements could be beneficial to participants, beneficiaries, and enrollees, including general benefit summary information and quality metrics. However, the primary initial goal of the self-service tool is to provide personalized out-of-pocket cost estimates for episodes of care, services, and prescriptions, and to provide transparency around the pricing elements that determine out-of-pocket costs. Therefore, the Departments are not inclined to require additional elements unrelated to this primary goal at this time. The Departments note that the intent of the final rules is to provide a minimum standard for the disclosure of pricing information to lay a foundation for transparency in coverage and the Departments may consider additional disclosure requirements to build upon the final rules in the future. To that end, the Departments are finalizing the required content elements for the self-service tool as described earlier in this preamble to the final rules. The final rules include a change regarding the search function related to out-of-network allowed amounts. Specifically, that element is modified to include the other metrics that a plan or issuer is permitted to use in place of out-of-network allowed amounts, as discussed earlier in this preamble in connection with the fourth content element that must be disclosed to participants, beneficiaries, and enrollees. Additionally, the Departments encourage plans and issuers to add additional elements to their tools according to the needs of the populations they serve.

In order for plans and issuers to provide accurate cost-sharing information, the Departments noted that the participant, beneficiary, or enrollee will have to input certain data elements into the tool. Therefore, under the proposed rules, plans and issuers would be required to make available a tool that allows users to search for cost-sharing information: (1) By billing code (for example, Current Procedural Terminology (CPT) Code 87804) or, (2) by a descriptive term (for example, ''rapid flu test''), at the option of the user. The tool also would be required to allow users to input the name of a specific in-network provider in conjunction with a billing code or descriptive term, to produce cost-sharing information, and a cost-sharing liability estimate for a covered item or service provided by that in-network provider. Regarding a request for cost-sharing information for all in-network providers, under the proposed rules, if a plan or issuer utilizes a multi-tiered network, the tool would be required to produce the relevant cost-sharing information for the covered item or service for individual providers within each tier. In the proposed rules, the Departments explained that to the extent that cost-sharing information for a covered item or service under a plan or coverage varies based on factors other than the provider, the tool would also be required to allow users to input sufficient information for the plan or issuer to disclose meaningful cost-sharing information. For example, if the cost-sharing liability estimate for a prescription drug depends on the quantity and dosage of the drug, the tool would be required to allow the user to input a quantity and dosage for the drug for which he or she is seeking cost-

sharing information. Similarly, to the extent that the cost-sharing liability estimate varies based on the facility at which an in-network provider furnishes a service (for example, at an outpatient facility versus in a hospital setting), the tool would be required to either permit a user to select a facility, or display in the results cost-sharing liability information for every in-network facility at which the in-network provider furnishes the specified item or service.

It remains the Departments' understanding that a plan or issuer may require certain information, in addition to the identification of a covered item or service, before it can provide an out-of-network allowed amount for a covered item or service, and that plans and issuers may have different ways of establishing an allowed amount for covered items or services from an out-of-network provider (such as by zip code or state). Therefore, under the final rules, plans and issuers are required to allow users to search for the out-of-network allowed amount or other metric as discussed in the fourth content element, for a covered item or service provided by out-of-network providers, by inputting a billing code or descriptive term and the information that is necessary for the plan or issuer to produce the out-of-network allowed amount (such as the zip code for the location of the out-of-network provider).

To the extent a user's search returns multiple results, the tool would be required to have functionalities that would allow users to refine and reorder results (also referred to as sort and filter functionalities) by geographic proximity of providers and the amount of estimated cost-sharing liability. The Departments solicited comment on whether the tool should be required to have additional refining and reordering functionality, including whether it would be helpful or feasible to refine and reorder by provider subspecialty (such as providers who specialize in pediatric psychiatry), or by the quality rating of the provider, if the plan or issuer has available data on provider quality.

Some commenters stated that it is unrealistic to expect consumers to know and understand CPT/Diagnosis Related Group (DRG)/International Classification of Disease-10 (ICD–10) codes and supported the inclusion of descriptive terms. One commenter stated that search capability by standard medical terms will be crucial, and that, to be successful, this type of search system will need to be broad and user-friendly, accommodating an extensive range of consumer inputs and terms. Another commenter recommended the tool also contain a layperson-friendly descriptor of the service to improve understanding. Other commenters lauded the requirement that issuers must use plain language when disclosing price information, which would ensure that patients can understand their expected costs without expert knowledge of insurance language and practices. Some commenters recommended that the Departments follow industry standards and use the CMS-approved National Correct Coding Initiative (CCI) for consumer searches, as well as for any information relating to standards for services that fall into bundled payment arrangements.

One commenter expressed concern that the conversion of thousands of CPT codes into plain English by thousands of health plans, carriers, and TPAs is inefficient, and will result in inconsistencies across the country. For example, there are multiple CPT codes for procedures in a hospital that differ in price depending upon severity, which is often unknown when a procedure is first recommended.

The Departments agree that it is essential for tools to support descriptive terms because consumers may not be familiar with specific procedure codes. The Departments acknowledge the challenge of converting CPT code descriptions to plain language but are of the view that the benefit to consumers outweighs the burden to plans and issuers. The Departments also acknowledge the potential value in requiring the use of CCI standards but are of the view that their use should be voluntary, not required, in order to avoid placing additional burdens on plans and issuers in the absence of clear benefits to consumers. As noted earlier in this preamble, the intent of the final rules is to provide foundational requirements and to allow plans and issuers maximum flexibility to build upon existing tools while providing consumers with reliable cost estimates. The Departments also highlight that the phased implementation of the final rules affords plans and issuers additional time to address administrative challenges. Accordingly, the final rules adopt this provision as proposed.

One commenter sought clarification that the tool is not required to support searches with multiple parameters at the same time (for example, by provider name and medical code at once). Another commenter suggested that the Departments allow that, as one permissible method, the tool may provide for geographic proximity based on a zip code entered by the participant, beneficiary, or enrollee to enable the consumer to choose whether to search based on the proximity to home or work or some other location.

The self-service tool must allow users to search for cost-sharing information for a covered item or service by inputting the name of a specific in-network provider in conjunction with a billing code or descriptive term, as well as other relevant factors like location of service, facility name, or dosage. For covered items and services provided by out-of-network providers, the tool should provide the out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a plan or issuer will pay by allowing consumers to input a billing code, descriptive code, or other relevant factor, such as location. In addition, the final rules adopt the requirement that the tool must allow the user to refine and reorder search results based on geographic proximity of in-network providers. The final rules require refining and reordering search results only for in-network providers, as the Departments are of the view that doing so for out-of-network providers would be too burdensome at this stage. The Departments expect that in order for beneficiaries, participants, and enrollees to search for out-of-network providers, they would have to input, at minimum, the billing code or name of an item or service and the geographical location of the provider. In addition, in order to align with revisions to the fourth content element allowing flexibility to provide another rate instead of the out-of-network allowed amount, the final rules have been revised to reflect that participants, beneficiaries, and enrollees can search for the out-of-network allowed amount, the percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a plan or issuer will pay for a covered item or service provided by out-of-network providers. This ''other rate'' is also included in paragraph (b)(2)(i)(B)(*2*) of the final regulations for consistency.

Regarding refining and reordering features, one commenter suggested that the tools include an ability to display only in-network providers and an ability to filter or sort by provider quality if a quality metric is made available. Three commenters requested that requirements not limit plans to developing provider and service filters that only account for price and geographic proximity: they suggested that the tools should also have functionality filters based on sub-specialty and a measure of value. Another commenter requested that any

additional functionality relating to refining and reordering search results be optional for plans and issuers at this time.

One commenter stated that, to enhance the accuracy of the tool and better account for fluctuations in cost-sharing amounts, the Departments should require that it be configured to allow users to self-select health characteristics (for example, chronic conditions, body mass index) in order to further personalize its outputs for consumers. The commenter recommended that payers be given flexibility to dictate the specific health characteristics to be included in their tools based on their participant, beneficiary, and enrollee populations, the types of products that they offer, and other elements that might cause cost-sharing estimates to fluctuate.

The Departments agree that plans and issuers should have flexibility to design tools that can maximize consumer utility and acknowledge that the suggested additions to search functionality could be beneficial to consumers. However, the Departments decline to require the adoption of these suggestions to preserve plans and issuers' discretion regarding the most effective way to provide search results and to avoid being overly burdensome or prescriptive.

The Departments intend that plans and issuers create user-friendly internet-based self-service tools, but the proposed rules did not include a definition for ''user-friendly'' because there are a variety of ways a tool can be designed to be user-friendly. The Departments wish to preserve plan and issuer flexibility to create tools that are best for their participants, beneficiaries, or enrollees, including by soliciting user feedback and consumer testing in the development of their tools. However, it is the Departments' view that a user-friendly tool would mean a tool that allows intended users to search for the cost-sharing information outlined in the final regulations efficiently and effectively, without unnecessary steps or effort. The Departments are of the view that plans and issuers can look to Federal plain language guidelines, ERISA requirements for a Summary Plan Description's method of presentation at 29 CFR 2520.102–2(a), and general industry standards for guidance when designing and developing their internet-based self-service tools.[119]

[119] ''Federal plain language guidelines.'' United States General Services Administration. Available at: *https://www.plainlanguage.gov/guidelines/*.

The Departments also received comments on whether the self-service tool should be made available through an internet website, through a mobile application, or both. The proposed rules provided that the self-service tool be made available on an internet website to be consistent with section 1311(e)(3)(C) of PPACA, which provides that ''at a minimum,'' cost-sharing information be made available through an ''internet website.'' However, the Departments sought feedback on whether this term should be interpreted to include other comparable methods of accessing internet-based content. The statute was enacted in 2010, when the primary mode of accessing internet-based content was through a personal computer. Since that time, ownership of mobile devices with internet access and use of internet-based mobile applications has become much more common. The Departments acknowledged that there may be technical differences between a website and other methods of viewing internet-based content, such as mobile applications. However, as stated in the proposed rules, the Departments also understand that technology evolves over time, and it is the Departments' view that Congress did not intend to limit the ability to access information via alternative methods of viewing internet-based content that may be available now or in the future.

The Departments acknowledged that mobile applications may provide benefits beyond those of traditional websites. Due to the portability of mobile devices, a self-service tool that is made available through a mobile application might provide participants, beneficiaries, enrollees, and their health care providers greater opportunities to use the tool together at the point of care to evaluate treatment options based on price. The Departments further acknowledged that mobile applications, as a general matter, may offer greater privacy and security protections than an internet website, accessed either from a mobile device or a computer.[120] Accordingly, the Departments sought comment on whether the final rules should permit the proposed disclosure requirements to be satisfied with a self-service tool that is made available through a website or comparable means of accessing the internet, such as a mobile application, or whether multiple means, such as websites and mobile applications, should be required. The Departments also sought comment on the relative resources required for building an internet website versus an internet-based mobile application.

[120] Kassner, M. ''Apps vs. mobile websites: Which option offers users more privacy?'' Tech Republic. September 30, 2016. Available at *https://www.techrepublic.com/article/apps-vs-mobile-websites-which-option-offers-users-more-privacy/*; *see also* Colburn, K. ''Is using a banking app safer for managing your account online?'' AZcentral. September 17, 2018. Available at *https://www.azcentral.com/story/money/business/tech/2018/09/17/online-banking-app-safety-security-smartphone-tech-tips/1212736002/*; *see also* Ogata, M., et al. ''Vetting the Security of Mobile Applications.'' National Institute of Standards and Technology, United States Department of Commerce. April 2019. Available at: *https://doi.org/10.6028/NIST.SP.800–163r1*.

Some commenters recommended that the Departments finalize the proposed rules with the self-service tool requirement satisfied by being made available through a website or comparable means of accessing the internet. Others believed that plans and issuers should be free to determine whether to offer a mobile app, an internet website, or both. One commenter stated the resources necessary for building and supporting a mobile application are significantly greater than building a website and did not support a proposal to require multiple applications, while other commenters supported a mobile application to enable patients to make cost-effective decisions in the doctor's office. Another commenter recommended both a mobile application and an internet-based platform with fully responsive internet-based design. Two commenters recommended that the requirements not preclude a plan, issuer, or TPA from developing other means of electronic delivery beyond internet disclosure.

The Departments have considered these comments and are of the view that requiring an internet website, as opposed to a comparable means of accessing the internet, such as a mobile application or both, ensures access to a broader set of consumers while limiting the burden on plans and issuers to produce both an internet site and a mobile application. Internet websites can be accessed on mobile devices and people without access to the internet or mobile devices can access tools through resources where internet access may be available, such as a local library. Conversely, if the tool were available only through a mobile device, people without a capable mobile device would not have access to the tool. The final rules, therefore, adopt the requirement that the self-service tool be provided via internet website; however, the Departments encourage plans and issuers to also provide a mobile application version in addition to an internet website.

b. Second Delivery Method: Paper Form

Paragraph (e)(3)(C) of section 1311 of PPACA specifies that at a minimum, cost-sharing information be made available to an individual through an internet website and such other means for individuals without access to the internet. Therefore, the proposed rules included a proposal that group health plans and health insurance issuers would have to furnish, at the request of the participant, beneficiary, or enrollee, without a fee, all of the information required to be disclosed under paragraph (b)(1) of the proposed regulations, as outlined earlier in this preamble, in paper form. Further, the proposed rules included a proposal that a plan or issuer would be required to provide the information in accordance with the requirements under paragraph (b)(2)(i) of the proposed regulations and as described earlier in this preamble. That is, the plan or issuer would be required to allow an individual to request cost-sharing information for a discrete covered item or service by billing code or descriptive term, according to the participant's, beneficiary's, or enrollee's request. Further, the plan or issuer would be required to provide cost-sharing information for a covered item or service in connection with an in-network provider or providers, or an out-of-network allowed amount for a covered item or service provided by an out-of-network provider, according to the participant's, beneficiary's, or enrollee's request, permitting the individual to specify the information necessary for the plan or issuer to provide meaningful cost-sharing liability information (such as dosage for a prescription drug or zip code for an out-of-network allowed amount). To the extent the information the individual requests returns more than one result, the individual would also be permitted to request that the plan or issuer refine and reorder the information disclosed by geographic proximity and the amount of the cost-sharing liability estimates.

The Departments proposed that this information would be required to be mailed to a participant, beneficiary, or enrollee via the U.S. Postal Service or other delivery system no later than 2 business days after a participant's, beneficiary's, or enrollee's request is received.

Two commenters supported the Departments' proposal to allow individuals the ability to access their information through electronic means or via paper form, given that many Americans lack access to high-speed internet services. Some commenters opposed the requirement to deliver the cost-sharing information to participants in paper form due to administrative burden, while others recommend limiting the requirements. Several recommended the timeframe to respond be expanded, including a range of 5 days to 10 days. One commenter requested that the compliance time for producing paper copies of personalized information be consistent with current Federal requirements for furnishing paper copies of the SBC, Summary Plan Description, or Consolidated Omnibus Budget Reconciliation Act (COBRA) notices. Other commenters expressed concern about volume, given that a participant, beneficiary, or enrollee could request cost estimates for all in-network providers of a given service, which could be tens of thousands of providers, resulting in thousands of pages of results. Some recommended a reasonable limit to the volume of information that would be provided in response to any single request for a covered item or service—for, example, no more than 20 or 25 providers per request.

Several commenters recommended that the Departments reconsider mandating paper responses ''without a fee.'' While these commenters did not support charging participants, beneficiaries, or enrollees for access to cost-sharing information in general, they asserted that it is unreasonable to expect health plans to provide what could easily be boxes worth of information in response to multiple requests per enrollee.

Nothing in the proposed rules would have prohibited a plan or issuer from providing participants, beneficiaries, or enrollees with the option to request disclosure of the information required under paragraph (b)(1) of the proposed regulations through other methods (such as, over the phone, through face-to-face encounters, by facsimile, or by email). The Departments requested comment on these proposed disclosure methods, including whether additional methods of providing information should be required, rather than permitted. The Departments were particularly interested in feedback on whether plans and issuers should be required to provide the information over the phone, or by email, at the request of a participant, beneficiary, or enrollee.

Several commenters requested alternatives to the paper disclosure, particularly a phone option. One commenter recommended the final rules require that plans or issuers set up a designated toll-free number that participants, beneficiaries, or enrollees can call to receive pricing information, in addition to offering that as an option on their main consumer information phone line. Two commenters urged the Departments to consider making the second form of disclosure one of the plan or issuer's choice (that is, paper or phone service). Conversely, one commenter stated that the volume and complexity of information that a given request could produce would preclude providing this information over the phone or in-person. Another commenter recommended the alternative format to include telephone, in-person, or fax. One commenter recommended emailing digital versions of the paper requests to a participant's, beneficiary's, or enrollee's inbox at the participant's, beneficiary's, or enrollee's request, and another requested that if results were emailed, the same information should not also need to be provided via paper form.

The Departments acknowledge commenters' concerns that the volume of paper requests could be unwieldy. To that end, the final rules adopt the requirement that cost-sharing information be provided in paper form, but a plan or issuer may limit any results for a paper request to 20 providers per request, as suggested by some commenters. The Departments are of the view that the commenters' suggestion of limiting paper request to 20 providers per request is a reasonable approach to balancing the burdens on plans and issuers with the benefits of providing consumers with enough information to be able to compare cost and provider options. The final rules provide an additional flexibility that, to the extent participants, beneficiaries, or enrollees request disclosure by another means (for example, by phone or email), plans and issuers may provide the disclosure through the means requested by the participant, beneficiary, or enrollee, provided the participant, beneficiary, or enrollee agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method. The Departments further acknowledge that requiring plans and issuers to set up a designated toll-free number for pricing information could be beneficial to participants, beneficiaries, and enrollees, but are not requiring this step given the Departments' view that its burden outweighs its benefit in light of the other available disclosure methods, including the flexibility to provide this information via the preferred disclosure method of the participant, beneficiary, or enrollee.

3. Special Rule To Prevent Unnecessary Duplication

a. Insured Group Health Plans

The proposed rules included a special rule to streamline the provision of the required disclosures and to avoid unnecessary duplication of the disclosures with respect to group health insurance coverage. The Departments are finalizing this special rule, which provides that, to the extent coverage under a plan consists of fully-insured group health insurance coverage, the plan satisfies the requirements of the final rules if the plan requires the issuer offering the coverage to provide the information pursuant to a written agreement between the plan and issuer. For example, if a plan and an issuer enter into a written agreement under which the issuer agrees to provide the information required under the final rules, and the issuer fails to provide full or timely information, then the issuer, but not the plan, has violated the transparency disclosure requirements.[121]

Many commenters requested that the Departments extend the special rule to self-insured group health plans that are administered by an administrative service organization or other TPA. These commenters stated that self-insured plan sponsors that contract in good faith with their TPAs to comply with the reporting requirements should be held harmless with respect to compliance obligations and liability under this regulation because in many instances a provider network is merely rented from a TPA, necessary information may not be held by the plan itself, and because liability could be contractually assigned to the TPA.

Section 2715A of the PHS Act provides the authority for the Departments to require this information from plans and issuers, but not TPAs. Therefore, it is ultimately the responsibility of the plan or issuer to provide the information required by the final rules. Nonetheless, the Departments note that nothing in the final rules prevents a self-insured plan from contracting with another party to provide the required disclosure, including, to the extent permitted under other Federal or state law, entering into an agreement for the other party to indemnify the plan in the event the other party fails to make the full or timely disclosure required by the final rules. However, the plan must monitor the other party to ensure that the entity is providing the required disclosure. Moreover, the Departments are of the view that the special rules providing certain safe harbors for actions taken in good faith as further described later in this preamble provide adequate protections for self-insured plans. The final rules also include the addition of the phrase ''insured group health plans'' to clarify that this special rule applies to insured group plans.

b. Other Contractual Arrangements

The Departments also received requests for clarification about the responsibility of employer plan sponsors that offer benefits under a level-funded arrangement. In general, under a level-funded arrangement, a plan sponsor self-insures expected claims and purchases stop-loss insurance for claims that exceed a specified threshold. Group health plans that are offered through a level-funded arrangement are subject to the final rules. Just like self-insured plans that are not level-funded, nothing in the final rules prevents a level-funded plan from contracting with another party to provide the required disclosures, but the level-funded plan remains liable for compliance with the final rules, and must monitor the other party to ensure that the entity is providing the required disclosure.

In several of the comments that addressed the special rule to prevent unnecessary duplication, commenters requested that the Departments permit plans and issuers to fulfill pricing disclosure requirements for prescription drugs through a third-party tool, such as a PBM tool. The Departments agree that this approach is permissible under the final rules. The Departments recognize that self-insured plans may rely on written agreements with other parties, such as PBMs, to obtain the necessary data to comply with the disclosure requirements. A plan or health insurance issuer may satisfy the requirements for prescription drug items and services under paragraph (b) by entering into a written agreement under which another party (such as a PBM or other third-party) provides the information required by paragraph (b) related to prescription drugs in compliance with this section. Nonetheless, if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with the final rules, the plan or issuer may be held responsible for violating the transparency disclosure requirements of the final rules for the same reasons explained above in connection with self-insured plans entering into agreements with TPAs.

c. Application to Account-Based Arrangements

Another commenter sought clarification about the responsibility of employer plan sponsors that offer the following types of coverage to employees: (1) Individual coverage health reimbursement arrangements (HRAs); (2) qualified small employer HRAs (QSEHRAs); and (3) flexible spending arrangements (FSAs) that are not fully integrated with group major medical coverage, stating that these types of plans were not explicitly addressed in the exemptions and the anti-duplication provisions outlined in the proposed rules.

The final rules do not apply to account-based group health plans, such as HRAs, including individual coverage HRAs, or health FSAs. QSEHRAs are not group health plans and are, thus, not subject to the requirements of section 2715A of the PHS Act.[122] Therefore, these types of arrangements are not required to comply with the final rules.

4. Privacy, Security, and Accessibility

The requirements for group health plans and health insurance issuers to provide cost-sharing liability estimates and related cost-sharing information will operate in tandem with existing state and Federal laws governing the privacy, security, and accessibility of the information that will be disclosed under these disclosure requirements. For example, the Departments are aware that the content to be disclosed by plans and issuers may be subject to the privacy, security, and breach notification rules under HIPAA or similar state laws. Nothing in the final rules is intended to alter or otherwise affect plans', issuers', and other entities' data privacy and security responsibilities under the HIPAA rules or other applicable state or Federal laws.

The Departments also expect that plans and issuers will follow applicable state and Federal laws regarding persons who may or must be allowed to access and receive the information that is required to be disclosed under the final rules. The final rules refer to such persons as ''authorized representatives'' and do not establish any new class of persons or entities who are authorized

[121] Under section 4980D(d)(1) of the Code, the excise tax for group health plans failing to satisfy the final rules is not imposed on a small employer (generally fewer than 50 employees) which provides health insurance coverage solely through a contract with an issuer on any failure which is solely because of the health insurance coverage offered by the issuer.

[122] Section 9831(d)(1) of the Code; section 733(a)(1) of ERISA; and section 2791(a)(1) of the PHS Act.

to access the information specified by the final rules.

One commenter expressed concerns about potential privacy violations related to implementation and compliance with the proposed measure. This commenter stated that all entities need to be made aware of their existing privacy and data-security responsibilities and that states and Federal regulators need to be diligent about compliance and enforcement. This commenter further stated it is important to note that employers, TPAs, and carriers may incur increased costs related to complying with the proposed rules regarding potential data breaches, increased liability, and cyber-coverage costs that could impact plan premiums.

The Departments agree that it is important that entities subject to the final rules be aware of their privacy and data-security responsibilities. Accordingly, the Departments are finalizing, as proposed, a provision that reminds plans and issuers of their duty to comply with requirements under other applicable state or Federal laws, including requirements governing the accessibility, privacy, or security of information, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

The Departments further appreciate the concern that employers, TPAs, and issuers may incur cybersecurity costs related to providing an online tool that provides some access to participant, beneficiary, and enrollee protected health information (PHI). However, given the Departments' understanding that as many as 94.4 percent of surveyed plans and issuers already maintain and operate an internet-based self-service tool,[123] the Departments anticipate any additional costs associated with cybersecurity will not be substantial.[124] The Departments have otherwise evaluated the burden of operating an internet-based self-service tool in section VI, later in this preamble.

One commenter expressed concern that certain requests for cost-sharing information could include items and services that may reveal particularly sensitive health information (for example, information related to substance abuse, mental health, or HIV). This commenter recommended the Departments provide carve-outs so that plans and issuers are not required to disclose such information through unsecured methods of communication (for example, email or phone). Alternatively, they recommended that the Departments provide more clarity or examples of when plans and issuers are not required to disclose certain information to comply with HIPAA and other Federal and state privacy laws.

The Departments remind stakeholders that current privacy and security requirements applicable under HIPAA rules and other applicable Federal requirements continue to apply under these rules. As noted earlier in this section of the preamble, the final rules are not intended to alter or otherwise affect plans', issuers', or other entities' responsibilities under HIPAA or other applicable Federal privacy laws. Furthermore, to the extent that state laws are more stringent regarding the disclosure of information subject to the final rules, plans and issuers are required to comply with the relevant state laws. The Departments acknowledge that there have been several recent security breaches affecting plans, issuers, and third-party vendors that may have compromised the PII and PHI of participants, beneficiaries, and enrollees. As acknowledged elsewhere in this preamble, privacy and security are important to the Departments and, while outside the scope of this rule, these are issues the Departments will continue to monitor. In light of existing risks and new risks that may arise as a result of increased innovation in the health care space, the Departments encourage plans and issuers to continue to educate their participants, beneficiaries, and enrollees about these risks and about ways to minimize or prevent unintended usage or sharing of their health data and encourage consumers to pay close attention to any new internet-based tools or applications they may choose to use.

C. Requirements for Public Disclosure of In-Network Rates, Historical Allowed Amount Data, and Prescription Drug Pricing Information for Covered Items and Services From In- and Out-of-Network Providers

As explained earlier in this preamble and in the proposed rules, the Departments proposed to exercise specific authority under section 1311(e)(3)(A)(vii) and (ix) of PPACA (as applied to group health plans and health insurance issuers in the individual and group markets through section 2715A of the PHS Act), which requires plans and issuers to publicly disclose information on cost-sharing and payments with respect to any out-of-network coverage and any other information the Secretary of HHS determines to be appropriate to enhance transparency in health coverage. Consistent with this authority, the Departments proposed for plans and issuers to make public negotiated rates with in-network providers and data outlining the different amounts a plan or issuer has paid for covered items or services, including prescription drugs, furnished by out-of-network providers. The Departments proposed to require plans and issuers to make this information available in machine-readable files that would include information regarding negotiated rates with in-network providers, allowed amounts for all covered items or services furnished by particular out-of-network providers, and other relevant information in accordance with specific method and format requirements. The Departments proposed to require plans and issuers to update this information on a monthly basis to ensure it remains accurate. The Departments are finalizing these policies and requirements with modifications to clarify the proposed requirements and underlying policies, and to respond to commenter suggestions and concerns.

The preamble to the proposed rules outlined several reasons why the public disclosure of negotiated rates and historical out-of-network allowed amounts is both appropriate and necessary for transparency in coverage. First, the Departments asserted that the public availability of negotiated rates and historical out-of-network allowed amounts would empower the nation's 26.1 million uninsured consumers to make more informed health care decisions.[125] Uninsured consumers generally must pay a provider's full charges for health care items and services. Though negotiated rates will not apply to the uninsured, it will offer a baseline when negotiating with providers. Pricing information is critical to their ability to evaluate their service options and control their health care spending. Uninsured consumers could also use publicly available pricing information to find which providers offer the lowest price, depending on the consumer's personal needs and priorities. The Departments noted in the preamble to the proposed rules that provider lists of standard charges often do not reflect the true cost of particular

[124] Sharma A., Manning, R., and Mozenter, Z. ''Estimating the Burden of the Proposed Transparency in Coverage Rule.'' Bates White Economic Consulting. January 27, 2020. Available at: *https://www.bateswhite.com/newsroom-insight-Transparency-in-Coverage-Rule.html.*

[125] Income, Poverty and Health Insurance Coverage in the United States: 2019.'' United States Census Bureau. September 15, 2020. Available at: *https://www.census.gov/newsroom/press-releases/2020/income-poverty.html.*

items and services.[126] Again, although a provider's negotiated rates with plans and issuers do not necessarily reflect the prices providers charge to uninsured patients, uninsured consumers could use this information to gain an understanding of the payment amounts a particular provider accepts for a service. Uninsured patients or participants, beneficiaries, or enrollees seeking care from an out-of-network provider also may use this data to negotiate a price prior to receiving an item or service or negotiate down a bill after receiving a service.[127]

Second, the Departments stated in the proposed rules that information regarding negotiated rates and historical out-of-network allowed amounts is critical for any consumer, insured, or uninsured, who wishes to evaluate available options for group or individual market coverage. Specifically, negotiated rate information for different plans or coverage and their in-network providers is key to consumers' ability to effectively shop for coverage that best meets their needs at prices they can afford, whether the consumer wishes to purchase new coverage or change existing coverage. Publicly-available negotiated rate data will assist all consumers in choosing the coverage that best meets their needs in terms of deductible requirements, coinsurance requirements, and out-of-pocket limits—all factors frequently determined by plan's or issuer's in-network rates, including negotiated rates, or out-of-network allowed amounts. This information, added to plan premium information and benefit design (for example coinsurance percentages), will give consumers an understanding of how affordable a particular coverage option will be.

In the preamble to the proposed rules, the Departments noted that publicly available historical allowed amount data for covered items and services provided by out-of-network providers would enable consumers who require specialized services to find the best coverage for their circumstances. For instance, plans and issuers often place limitations on benefits for specialized services, which causes many specialists to reject insurance; this can make it difficult, if not impossible, for consumers in need of certain services to find in-network providers in their area who are accepting new patients or who have sufficient availability or expertise to meet their needs. The Departments understand, for example, that many speech therapists and pathologists do not accept insurance because of the limitations plans and issuers place on coverage for their services, such as annual visit limits on speech therapy services. Accordingly, consumers who have a need for such specialized services may base their coverage choices primarily, if not solely, on a plan's or issuer's out-of-network benefits. Historical data outlining different amounts paid to out-of-network providers will enable consumers who rely on out-of-network providers to ascertain potential out-of-network benefits among different plans and issuers.

Third, the Departments stated in the preamble to the proposed rules that public disclosure of pricing information is necessary to enable consumers to use and understand price transparency data in a manner that will increase competition, potentially reduce disparities in health care prices, and potentially lower health care costs. One of the recognized impediments to increased competition for health care items and services is the widespread lack of knowledge many consumers have regarding health care pricing. In the preamble to the proposed rules, the Departments noted that many consumers do not fully comprehend the basics of health coverage, much less the more complex facets of the health care system that can affect an individual's out-of-pocket cost for items and services, including: Its specialized billing codes and payment processes; the various specialized terms used in plan and coverage contracts and related documents (such as copayment and coinsurance); and the various billing and payment structures plans and issuers use to compensate providers and assign cost-sharing liability to individuals (for example, bundled payment arrangements).[128] Pricing information is necessary to spur innovation that will help educate consumers on how to get the most value out of their plan or coverage. Making the required pricing information public could facilitate and incentivize the design, development, and offering of internet-based self-service tools and support services that are necessary to address the general inability of consumers to use or otherwise understand the available health care pricing information.

In developing the proposed rules, the Departments considered that, due to the complexity of the health care system and the data that drives plan and issuer payments for health care items and services, such raw data is likely to be difficult for the average consumer to understand and effectively use. As a result, the Departments determined that proposing to make public negotiated rates with in-network providers and historical payment data outlining out-of-network allowed amounts would be appropriate because it would encourage innovation that could ultimately help consumers understand and effectively use price transparency information.

The Departments stated that the proposed requirement to make pricing information publicly available could allow health care software application developers and other innovators to compile, consolidate, and present this information to consumers in a manner that allows consumers to consider price as a factor when making meaningful comparisons between different coverage options and providers.[129] For instance, third-party developers could develop mobile applications that operate as look-up tools and permit comparison of prices for specific services across plans. The tools could also allow consumers to access their medical records or other information about their health care utilization and create estimates based upon patient-specific information. Ultimately, the Departments are of the view that improved access and usability of this information has the potential to increase health insurance literacy, consumerism, and competition, resulting in more reasonable costs for health care items and services.

Fourth, in the proposed rules the Departments noted that, along with

[126] Arora, V., Moriates, C., and Shah, N. ''The Challenge of Understanding Health Care Costs and Charges.'' 17 AMA J. Ethics 1046 (2015). Available at: *https://journalofethics.ama-assn.org/article/challenge-understanding-health-care-costs-and-charges/2015-11*.

[127] ''How to Research Health Care Prices.'' Wall Street Journal. Dec. 4, 2009. Available at: *https://guides.wsj.com/health/health-costs/how-to-research-health-care-prices/* (''Researching health-care pricing online can also help after you've already had a medical procedure, if you want to dispute a bill, negotiate it down, or figure out if you've been overcharged.'').

[128] Satter, M. ''Survey: Most workers don't understand health insurance.'' BenefitsPRO. September 30, 2016. Available at: *https://www.benefitspro.com/2016/09/30/survey-most-workers-dont-understand-health-insuran/?slreturn=20190803010341* (a UnitedHealthcare Consumer Sentiment Survey found that even though 32 percent of respondents were using websites and mobile apps to comparison shop for health care, only 7 percent had a full understanding of all four basic insurance concepts: Plan premium, deductible, coinsurance, and out-of-pocket maximum; although 60 percent of respondents were able to successfully define plan premium and deductible, respondents were not as successful in defining out-of-pocket maximum (36 percent) and coinsurance (32 percent)).

[129] The Departments recognize that implementation of the API discussed in section III, Request for Information, could go even further toward the goal of empowering application developers and other innovators to support price transparency in the health care market.

consumers, sponsors of self-insured and fully-insured group health plans are also disadvantaged by the lack of price transparency.[130] Absent action taken such as through the final rules, health care cost trends are expected to continue to outpace inflation, with employer-sponsored large group plans' annual per employee costs expected to increase between 5.5 to 9.0 percent over the next decade.[131] Without information related to what other plans or issuers are actually paying for particular items and services, employer plans currently lack the pricing information necessary to shop or effectively negotiate for the best coverage for their participants and beneficiaries. In the proposed rules, the Departments stated that public availability of pricing information is appropriate to empower plans to make meaningful comparisons between offers from issuers and evaluate the prices offered by providers who wish to be included in their pool of in-network providers. The Departments noted that the pricing information would also assist employer plans that contract with TPAs or issuers to provide a network of physicians. That information would provide valuable data an employer plan could use to assess the reasonableness of network access prices offered by TPAs and issuers by evaluating the specific price providers in a TPA's or issuer's network are accepting for their services.

Armed with transparency data, employers could also use their leverage to negotiate for lower prices for their participants and beneficiaries and, potentially, if enough employers take action, it could help lower health care prices.[132] For instance, employers could employ network and benefit design tools to move participants and beneficiaries toward lower-priced providers and shift from less favorable provider contracting models (such as a discounted-charge contact, which can be vulnerable to list-price inflation) to more favorable, alternative value-based contracting models (such as reference-based pricing and bundled payment arrangements).[133] As stated elsewhere in this preamble, based on 2019 Census data, there are 183 million Americans enrolled in employer-sponsored health coverage through a household member's employer at some point during the year.[134] Based on estimates of the United States population in 2019, this would mean that more than 56 percent of the nation's insured population has employer-sponsored coverage. Therefore, the ability of employer plans to effectively negotiate pricing for coverage and services could be a boon to competition in the health care market.

Fifth, the Departments stated in the proposed rules that public disclosure of price transparency information is also appropriate because it could assist health care regulators in carrying out their duties to oversee issuers in their states, as well as in designing and maintaining sustainable health care programs. Regulators may be able to independently access, aggregate, and analyze the data to support oversight of plans and issuers. For example, because the machine-readable files must be updated regularly, regulators could use the pricing information to identify trends in rates of items and services over time or identify potentially collusive practices or substantial price variations within a geographic area that may be in need of additional monitoring or future regulatory action. It may also become possible for regulators to use the pricing information related to items and services to assist in better understanding and monitoring premium rate fluctuations and increases in their respective markets; further allowing them to assess whether the trend rates issuers use in their rate filings are reasonable in order to assess whether proposed rates should be approved. Because the in-network applicable rate data will be reasonably current, regulators may be able to address potential concerns more quickly than at present.

Local, state, and Federal agencies responsible for implementing health care programs that rely on issuers to provide access to care would be privy to actual pricing information that could inform their price negotiations with issuers. Insights gained from research using the pricing information could support regulators in their oversight of plans and issuers and could also help identify new ideas for market reforms to enhance the performance and efficiency of health insurance markets.

The public availability of health care pricing information offers researchers the ability to better understand the impact of specific plan, issuer, and provider characteristics on negotiated rates and out-of-network payments, evaluate and supplement existing models and predictions, and formulate new policies and regulatory improvements to improve competition and lower health care spending. Researchers have already utilized localized and state-wide data to review trends in issuer market share, issuer location, and covered services and their corollary effects on consumer pricing and experience in the market.[135] They have also examined these similar effects on consumers by provider market shares, structures, and offered similar data. Expanding the availability of this data could allow for the expansion and validation of these and other models and hypotheses. With larger and more complete datasets, researchers could refine their policy and regulatory suggestions regarding payment and delivery models, including those that are most likely to mitigate upwards pricing pressure from issuer, provider, consumer, and geographic factors. The release of this data could also supplement ongoing efforts to help control health care costs.

The Departments acknowledge that these stakeholders, notably researchers, may have access to some pricing data through existing sources, such as the Health Care Cost Institute (HCCI) and databases established through state health care price transparency efforts. However, it is the Departments' understanding that these health care pricing datasets are often costly to purchase, only contain older, historical data, and generally only include de-identified plan data for a limited number of plans and issuers who voluntarily participate in the data collection.[136]

[130] Whaley, C., et al. ''Nationwide Evaluation of Health Care Prices Paid by Private Health Plans: Findings from Round 3 of an Employer-Led Transparency Initiative.'' RAND Corporation. 2020. Available at: *https://www.rand.org/pubs/research_reports/RR4394.html*.

[131] Congressional Budget Office, ''The Budget and Economic Outlook: 2019 to 2029.'' Congress of the United States Congressional Budget Office. January 2019. Available at: *https://www.cbo.gov/system/files/2019-03/54918-Outlook-3.pdf*; *see also* ''Medical cost trend: Behind the numbers 2020.'' PwC Health Research Institute. June 2019. Available at: *https://heatinformatics.com/sites/default/files/images-videosFileContent/pwc-hri-behind-the-numbers-2020.pdf*.

[132] Whaley, C., et al. ''Nationwide Evaluation of Health Care Prices Paid by Private Health Plans: Findings from Round 3 of an Employer-Led Transparency Initiative.'' RAND Corporation. 2020. Available at: *https://www.rand.org/pubs/research_reports/RR4394.html*.

[133] *Id.*

[134] ''Income, Poverty and Health Insurance Coverage in the United States: 2019.'' United States Census Bureau. September 15, 2020. Available at: *https://www.census.gov/newsroom/press-releases/2020/income-poverty.html*.

[135] *See* Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' The Review of Economics and Statistics. Volume. 101. No. 4. September 30, 2019. Available at: *https://www.mitpressjournals.org/doi/full/10.1162/rest_a_00765*; *see also* Wu, S. et al ''Price Transparency For MRIs Increased Use Of Less Costly Providers And Triggered Provider Competition.'' Health Affairs. August 2014. Available at: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0168*.

[136] For example, HCCI is expected to release their ''2.0'' dataset in December 2020. The ''2.0'' dataset

Continued

By contrast, the pricing information required through the final rules would generally be current data for all plans and issuers and will be available to the public free of charge. This data, where it is related to in-network coverage, can also be tied back to specific plans and issuers and the geographic regions in which they provide plans or coverage. With access to the pricing data required through the final rules, researchers may be able to design new studies that develop novel insights into the health insurance markets. Stakeholders, including employers, may be able to gain insights, inform oversight efforts, negotiate improved terms for items and services, or make improvements to insurance products, such as plans and issuers moving toward value-based plan designs or broadening or narrowing networks based on customer shopping habits. The pricing information could also support market innovation and improvements by plans and issuers. For example, researchers and industry experts could use pricing information to establish baseline data to assist in identifying, designing, and testing new or existing health care delivery and coverage models.

While all of these stakeholders stand to benefit from access to the pricing information required through the final rules, the Departments continue to be of the view that the ultimate beneficiaries of access to pricing information are consumers. Indeed, public access to health care pricing information could lead to more targeted oversight, better regulations, market reforms to ensure healthy competition, improved benefit designs, and more consumer-friendly price negotiations.

The Departments expressed the view that effective downward pressure on health care pricing cannot be fully achieved without public disclosure of pricing information. Standard economic theory holds that markets work best when there is price competition.[137] When consumers shop for services and items based on price, providers and suppliers typically compete to lower prices and improve quality.[138] Based on this understanding of standard economic principles and past experience, the Departments are persuaded that innovators and other entities in the health care market will be incentivized to innovate in the price transparency and health care consumerism space once access to pricing information that allows for meaningful evaluation of different options for delivering health care items or services, coverage options, and provider options becomes available.

1. Information Required To Be Disclosed to the Public

The Departments are finalizing requirements, under 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), and 45 CFR 147.212(b), for plans and issuers to make public applicable rates, including negotiated rates, with in-network providers; data outlining the different billed charges and allowed amounts a plan or issuer has paid for covered items or services, including prescription drugs, furnished by out-of-network providers; and negotiated rates and historical net prices for prescription drugs furnished by in-network providers.[139] The Departments are of the view that public availability of in-network applicable rates, including negotiated rates, billed charges and historical out-of-network allowed amounts, and in-network negotiated rates and historical net prices for prescription drugs is appropriate and necessary to provide comprehensive effective transparency in coverage, which may, in turn, empower consumers to make informed decisions about their health care, spur competition in health care markets, and slow or potentially reverse the rising cost of health care items and services.

The vast majority of the commenters agreed with the Departments' objectives of price transparency under the proposed rule. Many commenters offered general support (in whole or in part) of the proposed requirements for public disclosure of in-network negotiated rates and out-of-network allowed amounts. One commenter supported the public disclosure of out-of-network allowed amounts but expressed concerns about disclosure of in-network negotiated rates.

Disclosure of Pricing Information Generally

Some commenters who offered support stated that the requirements will help create more efficient and value-based health care systems by, for example, encouraging plans and issuers to adopt innovative benefit designs that push patients toward lower-cost care. Another commenter who offered support stated that requiring plans and issuers to share publicly the negotiated rates for in-network providers and allowed amounts for out-of-network providers has the potential to increase competition among issuers. One commenter stated that public disclosure of negotiated rates is needed to address the provider consolidation that is driving up health care costs and leading to more favorable reimbursements to large hospitals with bargaining power. Another commenter recommended the Departments reject arguments against transparency that payment data should be protected as proprietary, and adopt a presumption in favor of transparency.

The Departments received comments from state and local government regulators who were supportive of the rules generally and provided suggestions for improving the proposals. Regulators recognized that greater transparency holds promise in improving pricing of health care items and services in ways that improve consumer comprehension and policymakers' ability to manage the health care system. One local government commenter supported the goal of price transparency, but voiced concern that the proposed rules might unintentionally drive up the cost of health care. Individual consumers who submitted comments offered general support and emphasized the importance of obtaining pricing information in advance of receiving health care for their personal health care decision-making. Some individual commenters noted that consumers seek the price of a product or service in every other sector prior to making a spending decision and should be able to do so when purchasing health care. Other individual commenters stated their support for policies that will help consumers choose whether to seek care

includes over one billion commercial claims and 60 million covered lives per year from Aetna, Humana, Kaiser Permanente, and the Blue Cross Blue Shield (BCBS) companies from 2012 through 2018. The data is nearly three years old and will cost $45,000 annually on a per-project basis and does not include other ''standard add-ons,'' such as data mergers. Institutional membership prices will be customized for each organization. Taken from ''Power Up Your Analytics on the Privately Insured.'' Health Care Cost Institute. Available at: *https://healthcostinstitute.org/images/pdfs/Health_Care_Cost_Institute_-_Power_Up_Your_Analytics.pdf*. In addition to the HCCI dataset, BCBS companies also sell their data through their analytics and consulting platform, Blue Health Intelligence, with 20.3 billion claims from 203 unique member organizations. The access price is not listed on their website. More information is available at: *https://www.bluehealthintelligence.com/*.

[137] ''FTC Fact Sheet: How Competition Works.'' United States, Federal Trade Commission. Available at: *https://www.consumer.ftc.gov/sites/default/files/games/off-site/youarehere/pages/pdf/FTC-Competition_How-Comp-Works.pdf*.

[138] Kessler, D., and McClellan, M. ''Is Hospital Competition Socially Wasteful?'' 115 Q. J. of Econ. 577. May 2, 2000. Available at: *https://www.nber.org/papers/w7266*.

[139] As discussed in section II.B of this preamble, the Departments are also finalizing requirements under 26 CFR 54.9815–2715A2(b)(1)(iii)–(iv), 29 CFR 2590.715–2715A2(b)(1)(iii)–(iv), and 45 CFR 147.211(b)(1)(iii)–(iv) that plans and issuers include negotiated rates and out-of-network allowed amounts within the internet-based self-service tool.

from an in-network or out-of-network provider.

Many other commenters, comprised largely of health insurance issuers and health care providers, offered support for the objective of price transparency, but did not support the requirements for public disclosure of in-network provider rates and out-of-network allowed amounts, expressing particular concerns about the in-network provider rate disclosure requirements

Commenters stated that, as proposed, the disclosure of payer-specific negotiated rates could distort the markets, creating an unbalanced focus on costs at the expense of other factors influencing market dynamics, such as quality, efficiency, and effectiveness. Some commenters stated that negotiated rates reflect factors other than price such as experience, previous volumes/market power, anticipated growth, strategic initiatives, and select concessions.

The Departments do not agree that publication of negotiated rates for items and services will have negative distortive effects on health care markets. Rather, the Departments are of the view that the final rules will help to counteract the recognized price distortions that result from the unavailability of pricing information to health care consumers.[140] As discussed elsewhere in this preamble, the current unavailability of pricing information for health care items and services prohibits the health care markets from achieving a meaningful level of competition based on price because it ensures that health care consumers typically are not able to include price in their health care purchasing decisions. The Departments are of the view that making pricing information available could begin to ameliorate price distortions in health care by encouraging consumer decision-making that takes cost into account.

Another commenter stated that the release of negotiated rates would inappropriately result in the steering of consumers to particular providers based on contractual prices. The commenter stated that informed decision-making is not solely based on price, but is multi-factorial, involving looking at a provider's clinical expertise, ability to coordinate care, quality, effectiveness of utilization management, and guidance from a referring physician. The Departments agree that informed decision-making is not solely based upon price. The final rules are only one part of the solution to address issues contributing to the lack of competition in the health care market and resulting increases in health care costs. While the Departments address the problem of price transparency through this rulemaking, other government and industry stakeholders are working to address other issues highlighted by commenters, such as the availability of reliable quality data.

The Departments, in shaping the proposed and final rules, considered that there is quality data available to individual consumers and other consumers of health care like employers and government programs. Various government and industry stakeholders sponsor programs that aim to provide reliable health care quality information to health care purchasers. For instance, HHS engages in continual efforts to develop quality measures that are meaningful and accurately reflect hospital quality. CMS's Hospital Inpatient Quality Reporting Program collects quality data from certain hospitals with the goal of driving quality improvement through measurement and transparency.[141] CMS publicly displays this quality data to help consumers make more informed decisions about their health care.[142] HHS's Agency for Healthcare Research and Quality (AHRQ) publishes comparative information on health plans that include reports sponsored by Federal and state agencies, private organizations, and purchasing coalitions.[143] The Departments appreciate comments received through the RFI in the proposed rule and are also evaluating future actions to help ensure quality information is more readily available.

The Departments are also of the view that it is worth noting that private sector entities have been working to provide useful quality information to consumers.[144] For example, the National Quality Forum (NQF) is a private standard-setting organization focused on the evaluation and endorsement of standardized performance measurements that makes available on its website all NQF work products, reports, and quality measures.[145] As another example, the Joint Commission is a not-for-profit organization that develops and applies standards that focus on patient safety and quality of care.[146] Finally, the National Committee for Quality Assurance (NCQA) measures and accredits health plans as well as the quality of medical providers and practices. For example, more than 191 million people are enrolled in health plans that report quality results using NCQA's Healthcare Effectiveness Data and Information Set (HEDIS),[147] which includes more than 90 measures across six ''domains of care,'' including effectiveness of care, access/availability of care, and experience of care.[148]

Once pricing data is available through the final rules, existing quality data can be considered with pricing data to produce a more complete and accurate picture of total value. The same third-party developers who will have access to the information published pursuant to these final rules could develop platforms capable of presenting available quality data alongside pricing information. The Departments, therefore, anticipate that making health care prices transparent may spur consumers to seek and consider available quality and price information to determine whether a particular item or service is worth a higher or lower price. There is evidence from retail sector studies showing that consumers want high-quality, low-priced goods and will seek the lower price among

[140] Under ideal market conditions, consumers have sufficient information to make good choices. When consumers do not have information on price, standard market forces cannot operate, and prices for health care are distorted resulting in price discrimination (charging consumers different prices for the same product) and other problems that currently plague the health care markets. *See generally* Mwachofi, Ari, and Assaf F. Al-Assaf. ''Health care market deviations from the ideal market.'' Sultan Qaboos University Medical Journal vol. 11, 3 (2011): 328–37. Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3210041/*.

[141] *See* CMS Hospital inpatient Quality Reporting Program web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU*, last accessed Sep. 21, 2020.

[142] CMS Hospital Compare website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU*, last accessed Sept. 21, 2020.

[143] AHRQ Comparative Reports on Health Plans, *https://www.ahrq.gov/talkingquality/resources/comparative-reports/health-plans.html*, last accessed Sept. 21, 2020.

[144] *See, for example,* Ranard, B.L., Werner, R.M., Antanavicius, T., Schwartz, H.A., Smith, R.J., Meisel, Z.F., Asch, D.A., Ungar, L.H., & Merchant, R.M. (2016). ''Yelp Reviews Of Hospital Care Can Supplement And Inform Traditional Surveys Of The Patient Experience Of Care. Health Affairs'' (Project Hope), 35(4), 697–705. Available at: *https://doi.org/10.1377/hlthaff.2015.1030* (''Online consumer-review platforms such as Yelp can supplement information provided by more traditional patient experience surveys and contribute to our understanding and assessment of hospital quality.'').

[145] *See* the National Quality Forum website, *http://www.qualityforum.org/how_we_do_it.aspx*, last accessed Oct. 8, 2020.

[146] *See* The Joint Commission website, *https://www.jointcommission.org/about-us/facts-about-the-joint-commission/joint-commission-faqs/*, *last accessed Oct. 8, 2020.*

[147] *See* NCQA website, *https://www.ncqa.org/hedis/*, last accessed Oct. 8, 2020.

[148] *Id.*

products of the same quality.[149] Given the high cost of health care, the Departments are of the view that the same trend toward seeking lower prices will more likely than not hold true in the health care market when prices become transparent.[150]

The Departments received many comments stating that publishing negotiated rates is unlikely to meet the Departments' goal of helping consumers understand their health coverage and reasonably predict their out-of-pocket costs. Many of these commenters stated that negotiated rates information would not provide consumers with meaningful, actionable pricing information, and could possibly make purchasing decisions more confusing and difficult for consumers. One commenter noted that the public disclosure of negotiated rate information could distract from relevant participant, beneficiary, or enrollee-specific cost-sharing information such as accumulated amounts. One commenter stated that confusing and unhelpful pricing information would erode consumer trust and present long-term challenges for the health care system.

The Departments disagree that public knowledge of the price of health care items and services will increase individual consumers' confusion regarding health coverage or distract them from other information relevant to their out-of-pocket costs, such as the status of their accumulated amounts and note that commenters who raised this point cited no empirical or anecdotal evidence supporting these concerns. On the contrary, as explained throughout this preamble, the Departments are of the view that standard economic theory, experience from several states, and evidence from other markets demonstrate that increased transparency leads to better-informed purchasing decisions, generally lower prices, and quality improvements. Moreover, the Departments expect that third-party developers will compete to make pricing information available to the public in formats that are user-friendly, so disclosure of detailed pricing information is unlikely to lead to significant consumer confusion.

As noted earlier in this preamble, the Departments expect the public disclosure of pricing information related to health care items and services to help both uninsured and insured individuals in their health care and health coverage purchasing decisions. Furthermore, research suggests that having access to pricing information can increase consumers overall satisfaction and provide opportunities for education and engagement on health care pricing.[151] For instance, when the Children's Hospital of Philadelphia incorporated a Patient Cost Estimate Department, they found that cost estimates resulted in ''fewer billing-related complaints, decreased revenue losses, and increased overall patient satisfaction.'' [152] A targeted study in the American Surgeon journal found five out of six medical centers that adopted price transparency reported increases in patient satisfaction and patient engagement after price transparency.[153]

One commenter stated that public disclosure of pricing information through the machine-readable files is unlikely to benefit uninsured consumers, in particular, as it will be difficult for them to make the necessary comparisons or negotiate with providers as providers are not incentivized to negotiate with uninsured consumers. Another commenter stated that the machine-readable files would not be very helpful for current beneficiaries, participants, or enrollees, but acknowledged they could benefit uninsured individuals and enrollees considering alternative coverage.

By contrast, other commenters, including many individual commenters, stated that access to negotiated rate information would empower both insured and uninsured consumers by helping to correct the lack of consumer choice and information and help support efforts by other market actors. In particular, one commenter stated that consumers would likely use the pricing information, especially if their cost-sharing liability is in the form of coinsurance that is tied to the negotiated rates. One commenter stated that release of information on negotiated rates would help consumers by spurring innovation by third-party application developers to create tools to help consumers and payers, especially self-insured group health plans. Finally, one commenter did not support the requirements for public disclosure of in-network provider rates but did acknowledge that public disclosure of de-identified aggregated data for both in-network and out-of-network providers could empower consumer decision-making.

The Departments agree that transparency would help provide more consumer information and support consumer choice for both insured and uninsured consumers. The Departments continue to be of the view that market actors, including IT developers, researchers, industry experts, and plans and issuers would be incentivized to innovate in the price transparency and health care consumerism space once access to the pricing information required to be disclosed through the final rules becomes available. In the proposed rule, the Departments emphasized that individual consumers need easy to use tools and resources to help them better understand their current health care coverage, health coverage they consider purchasing, and their out-of-pocket exposure under those plans. Health care stakeholders and other industry participants, including web and mobile application developers, are already attempting to meet this need, despite the incomplete pricing information available to them. Given actionable data that can improve such tools and resources, industry actors will likely be incentivized to design innovations to deliver the help and information consumers need to make informed health care decisions based, at least in part, on the important factor of price. The final rules will support current and future efforts to help guide consumers to the lowest cost items and services that meet their specific needs and qualifications. To spur this innovation, the pricing information must allow for meaningful evaluation of different options for delivering health care items or services, coverage options, and provider options. One of the main avenues through which

[149] Shirai, M. ''Impact of 'High Quality, Low Price' Appeal on Consumer Evaluations.'' Journal of Promotion Management. December 2015. Available at *https://www.tandfonline.com/doi/full/10.1080/10496491.2015.1088922*.

[150] Recent research evaluating the impact of New Hampshire's price transparency efforts shows that providing insured patients with information about prices can have an impact on the out-of-pocket costs consumers pay for medical imaging procedures, not only by helping users of New Hampshire's website choose lower cost options, but also by leading to lower prices that benefited all patients, including consumers in New Hampshire that did not use the website. *See* Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' The Review of Economics and Statistics. Volume. 101. No. 4. Available at: *https://www.mitpressjournals.org/doi/full/10.1162/rest_a_00765*; *see also* Brown, Z.Y. ''An Empirical Model of Price Transparency and Markups in Health Care.'' August 2019. Available at: *http://www-personal.umich.edu/~zachb/zbrown_empirical_model_price_transparency.pdf*.

[151] Revere, F.L., et al. ''A consumer-based evaluation of Healthcare Price and Quality Transparency.'' Journal of Health Care Finance. Summer 2016. Available at: *http://www.healthfinancejournal.com/index.php/johcf/article/download/72/74*.

[152] Otero, H., et al. ''The Cost-Estimation Department: A Step Toward Cost Transparency in Radiation.'' Journal of the American College of Radiology. Vol 16. Issue 2. February 2019. Available at: *https://doi.org/10.1016/j.jacr.2018.07.033*.

[153] Mehta, A., et al. ''The Impact of Price Transparency for Surgical Services.'' The American Surgeon. April 2018. Available at: *https://pubmed.ncbi.nlm.nih.gov/29712614/*.

the Departments assumed this innovation would materialize is through IT developers who could be incentivized to design and make available internet-based tools and mobile applications that could guide consumers in accessing available price information; as well as researchers who would have the ability to analyze health care pricing at local and national levels and provide the public with their findings. Industry experts and plans and issuers would also have the ability to use pricing information to develop innovative plan benefit designs that could result increased competition and cost savings. Based on comments received from interested IT developers and other innovators, the Departments continue to believe many innovators are interested in utilizing this pricing information, once available, to spur innovation in the health care space, as intended. The Departments expect internet-based tools and mobile applications will increase the likelihood that both insured and uninsured consumers will be able to use the information to make informed health care purchasing decisions. And, as stated by a commenter, the information required to be made public through the proposed rules would help reduce wasteful spending because it would support efforts by employers, state regulators, and other purchases of health care to evaluate prices and identify unwarranted spending variation. Therefore, the Departments did not intend or expect that behavioral changes emanating from public disclosure of this information will be limited to consumers but will benefit a variety of stakeholders.

The goals the Departments seek to achieve through these requirements for public disclosure are not mutually exclusive. The Departments expressed a desire to bring about an outcome where innovators, including researchers, would enter or expand in the health care purchasing space to develop tools, applications, and public information that would support consumer decision-making. Thus, the Departments disagree with commenters who argued that public disclosure of negotiated rates would not support consumer decision-making.

The Departments disagree with commenters who suggested that pricing information presented through the public disclosures would be confusing and misleading to consumers and could erode consumer trust and present long-term challenges for the health care system. Based on the review of the over 25,000 comments received on the proposed rules, the vast majority of which were submitted by individuals, consumer trust in the health care system is already quite low, due in substantial part to the opacity of health care pricing.[154] In one study of a nationally representative sample, researchers found that participants often believed that providers and issuers set prices that do not reflect either the quality or the cost of goods and services, contributing to the study's conclusion that most Americans do not perceive the price and quality of health care to be associated. Study participants described prices as both too high and irrational, noting that prices varied within their regions for unknown reasons.[155] The Departments' transparency efforts are meant to increase transparency of health care pricing information. The Departments do not agree that this information would further frustrate consumers compared to the status quo, even if it is difficult to navigate for the average consumer without the use of internet-based tools or applications.

One commenter stated that disclosure of negotiated rates could harm the ability of health issuers to reward high performing providers with higher reimbursements. Additionally, some commenters noted that focus on price could particularly harm small health plans and TPAs who may have been able to negotiate discounted rates by offering health plans in a limited service area.

The Departments understand that requiring release of this pricing information may impact commercial arrangements and result in certain one-time and ongoing administrative costs, which could disproportionately affect small group plans, TPAs, and issuers offering coverage in the small group market. However, the Departments view making this information available to consumers and the public as beneficial to the public's long-term interests in facilitating a consumer-oriented, information-driven, and more competitive market. In addition, as discussed below, the Departments are establishing several special rules for streamlining the provision of public disclosures required through the final rules. These special rules will help mitigate the concerns of small group plans and issuers by allowing them to leverage a contractual relationship through an issuer or clearinghouse to satisfy the public disclosure requirements of the final rules.

Several commenters submitted feedback on how disclosures in the proposed rules could affect contractual arrangements. One commenter expressed the view that the requirement to release negotiated rates threatens contracts negotiated between two private entities. Several commenters submitted comments related to gag clauses or non-disclosure agreements contained in provider contracts as well as other contract terms that are often included in contracts between providers and payers (such as anti-steering and anti-tiering provisions) that may limit the ability of third parties to use the data. Gag clauses, which also may be referred to as non-disclosure agreements, are terms that are often included in provider-payer contracts, which prohibit one or both parties from making public the negotiated rates therein.[156] Anti-steering and anti-tiering provisions are terms that may be included in provider-payer contracts (usually between issuers and hospital systems), which prohibit the plan or issuer from directing participants, beneficiaries, or enrollees toward higher-quality or lower-cost providers, and require that all providers associated with the contracting provider (for example, for a hospital system this could include hospitals, other affiliated facilities, and physicians) to be placed in the most favorable tier of providers.[157]

One commenter stated that if the Departments do not fully address the implications of non-disclosure agreements in provider and payer contracts, legal complications could arise from payers attempting to meet the requirements to disclose negotiated rates and violating these agreements in the process. Another commenter strongly supported revisions to the proposed rules to address the barriers associated with gag clauses. To address this issue, another commenter recommended the Departments provide that the final rules supersede any provider contract gag clause to the extent the final rules conflict with current or future contractual language.

The Departments understand that this requirement may require alterations to some existing contracts. For example, payers and providers may need to remove contract terms that conflict with the requirement to disclose negotiated

[154] *See, for example,* Phillips, K.A., Schleifer, D., and Hagelskamp, C. ''Most Americans Do Not Believe That There Is An Association Between Health Care Prices And Quality Of Care.'' Health Affairs. 2016. Available at *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2015.1334.*

[155] *Id.*

[156] ''Provider Contracts.'' The Source on Healthcare & Price Competition, UC Hastings College of Law. Available at: *https://sourceonhealthcare.org/provider-contracts/.*

[157] *Id.*

rates such as gag clauses or non-disclosure agreements.[158] It is not uncommon for new or modified regulatory requirements or new statutory provisions to alter private contractual arrangements such as those between a health insurance payer and health care provider. Because changes in law or statute that may need to be reflected in payer-provider contracts is not uncommon, the Departments expect that providers and payers have processes in place address to these requirements of the final rules. Often, the possibility that that new or modified regulatory requirements or new statutory provisions could alter such contracts is contemplated by the contracts themselves; for example, drafters may include contract language that indicates terms may be altered by changes in law or regulation. Such language would obviate the need for updates outsides of the regular contracting schedule.

As a general matter, the onus for ensuring a contract provision does not violate applicable law rests with the parties to the contract. Nothing in the final rules prevents providers and payers from implementing contract revisions to ensure terms are not in conflict with the requirements of the final rules. Because the Departments are of the view that prescription or prohibition of specific contract terms or language in payer-provider contracting is not necessary, the Departments leave it to plans, issuers, and providers to avoid contract terms that would prohibit or frustrate either party's compliance with the final rules.

Many commenters who did not support the requirements for public disclosure of in-network provider rates and out-of-network allowed amounts requested that the Departments withdraw the proposed rules or otherwise work with stakeholders to develop policy solutions that meet consumer needs with less burden and guard against potential unintended consequences. Some commenters suggested the Departments collect more data about the potential impacts of public disclosure of negotiated rates to ensure the policy is modified, if needed, to protect against the risk of unintended consequences, noted earlier. One commenter suggested the Departments pilot the requirement for public disclosure of negotiated rates. Another commenter recommended the Departments pilot the release of negotiated rates in a state where there are a few small carriers to gain a clearer understanding of potential consequences of the public disclosure requirements. Another commenter recommended the Departments pilot full price transparency in several markets and conduct longitudinal studies on the impacts.

Some commenters suggested the Departments refocus transparency efforts to already existing solutions or different initiatives. Some commenters recommended that the final rules require plans and issuers to send claims data to the HCCI to ensure that health care cost data reaches the public domain through researchers without disclosing confidential information or distorting the market. A few commenters suggested the Departments leverage existing data sources such as all-payer claims databases to promote transparency goals. One commenter stated the Administration should support congressional and states' efforts to pursue and expand upon transparency efforts, including through all-payer claims databases.

The Departments appreciate both private and public transparency efforts already underway. In the development of the proposed and final rules, the Departments sought feedback from industry and other stakeholders. While the Departments agree that expanding data sent to HCCI will help researchers gain a better understanding of market dynamics, the Departments are of the view that health care pricing data should be coupled with plan and issuer information. If the information were to be decoupled, as through HCCI or in an all-payer claims database, it would not provide the degree of transparency in prices needed to effectuate the objectives the Departments seek to achieve through the final rules. For example, pricing data, decoupled from plan and issuer data, would not provide actionable information to consumers that seek to evaluate health coverage options, as they would not be able to connect pricing to specific plans.

The Departments view the disclosure requirements set forth in the final rules as complementary to and supportive of state-level efforts. States act as incubators for transparency efforts. Nothing in the final rules precludes states from continuing to establish and run state-level transparency efforts. Indeed, the Departments intend for state regulators to be able to use the disclosures required to be made public through the machine-readable files to support their oversight of health insurance markets, including supporting their own state-level transparency efforts such as all-payer claims databases. However, the Departments are also aware that there are limits to the pricing information that states can obtain through state-level transparency efforts. For instance, states are not able to obtain pricing information from self-insured group health plans; the final rules will help states obtain this information.

The Departments further maintain that the final rules are significantly more likely to achieve positive results for consumers and health care markets than they are likely to result in the potential negative consequences outlined by certain commenters. The Departments are of the view that traditional market forces that affect prices in any market, including competition between providers; the threat of new market entrants that offer quality, lower cost services; and the increased bargaining power of consumers will be supported by the final rules. The Departments also are of the view that providers who choose to arbitrarily or unreasonably increase their prices based on publicly-available negotiated rate data are more likely to damage their own competitive positions and reputation than they are to cause widespread health care cost increases in their particular markets. For these reasons, the Departments remain confident that the final rules' requirements for disclosure of negotiated rate information will benefit health care consumers by giving them information necessary to effectively shop for and choose the health care coverage and providers that fit their needs and budgets. As consumers make more informed choices, based on available price data, market forces will have a chance to operate and potentially correct the current course of unsustainable increases in health care costs.

In light of the Departments' commitment to health care price transparency and the importance of addressing the distortive effects of the absence of pricing information, the Departments are not convinced there is a need to change the policies in the final rules to mitigate the risk of unintended consequences or violations of law such as price fixing and collusion among providers. As discussed elsewhere in this preamble, research, academic literature, and the experience of various state efforts have provided support for the Departments' conclusion that the public availability of in-network rate

[158] The Departments note that gag clauses that would prohibit a pharmacy from informing a participant, beneficiary, or enrollee of any differential between that individual's out-of-pocket cost under the coverage option offered by his or her plan or issuer regarding acquisition of the drug and the amount that individual would pay without using any health plan or health coverage are already prohibited. *See* Sec. 2729 of the PHS Act.

information is substantially more likely than not to lead to more informed health care choices, increased competition, and lower prices.

The Departments note that price transparency is not a novel concept, even in health care pricing. Several states, including New Hampshire and Maine, have implemented state-level price transparency efforts. While the Departments acknowledge that these state efforts differ in material ways from the disclosure requirements of the final rules, the same underlying principle of price transparency that undergirds state efforts also undergirds the final rules. These state efforts provide evidence that transparency at a more localized geographic level does not result in the extreme unintended consequences postulated by some commenters. The Departments acknowledge that other national health policy initiatives are sometimes tested through pilots; however, the Departments are of the view that such an approach is not necessary for price transparency, in part, because there is already evidence through state initiatives that price transparency is achievable.

The proposed and final rules reflect the Departments' conclusion that an expansive implementation of these requirements will be the most effective manner in which to reasonably ensure that the impact will be spread across all markets, rather than isolated to particular geographic areas, markets, or groups of consumers. The goal of the final rules is to expand access to price transparency information among the public, which will not be realized without an expansive implementation. The Departments are concerned that if pricing information for group health plans and insurance in the individual and group markets is not made available to the public or is made public in a piecemeal fashion, there will be little incentive for health care researchers, third-party application developers, or other industry actors to invest scarce resources into a tool that will only offer regional or otherwise limited pricing data. Other stakeholders, such as researchers and regulators, would also find incomplete pricing information less useful to their efforts to better understand, better oversee, and develop innovations in the health care markets. Finally, the Departments are concerned that limiting the implementation of this rule, by scope or by geographic market area, will limit the impact for the millions of consumers (both individuals and employers) who are expected to benefit from the public disclosures required through the final rules. Consumers located in a geographic market where data would not be made available under a more limited requirement would not experience any benefit from the availability of actionable pricing information in other markets. Even those consumers located in geographic markets where pricing information would be made available under a more limited requirement would likely experience more limited benefits than with a market-wide requirement to release pricing information because these consumers would likely not have access to tools developed by third-party application developers. These consumers would also be less likely to experience downstream benefits from contributions expected from other stakeholders, such as researchers and regulators.

In addition to establishing a preference for establishing market-wide rules, in the preamble to the proposed rules, the Departments explained the importance of timely action to increase transparency.[159] The Departments observed that continuously rising health care costs and increases in out-of-pocket liability, without transparent, meaningful information about health care pricing, have left consumers poorly equipped to make cost-conscious decisions when purchasing health care items and services. In addition, consumers across all markets should come to expect and receive the same access to standardized pricing information and estimates. This broader applicability also has the greatest potential to reform health care markets. The Departments recognized the need for a faster and nimbler approach to addressing the pressing issue of rising health care prices. For these reasons, the Departments are of the view that a pilot approach in a specific geographic area or an otherwise phased-in approach for the requirement to publicly disclose negotiated rates through the machine-readable files would not be sufficient to meet the requirement for transparency in coverage.

Because the Departments have determined a need for an expansive implementation of transparency in coverage requirements, and for the reasons discussed at length in response to public comments, the final rules adopt the requirement to publicly disclose negotiated rates for all group health plans and individual and group market issuers, regardless of geographic market.

[159] 84 FR 65464, 65465 (Nov. 27, 2019).

Scope of Pricing Information To Be Made Publicly Available

Several commenters explicitly supported public disclosure of negotiated rates and out-of-network allowed amounts for all items and services. However, other commenters recommended the Departments limit the items and services to only the most common items and services or a narrow set of shoppable services in order to make the machine-readable files more meaningful to consumers. Another commenter did not support the negotiated rate disclosure proposals, but acknowledged that disclosure of rates for a subset of shoppable services would be manageable, could allow issuers to account for innovative payment arrangements, and could be used to gather empirical evidence on the impact of transparency on the health care markets.

The Departments understand that requiring plans and issuers to include all items and services in the machine-readable files could produce large data sets that could be cumbersome and may be costlier to maintain than a more limited file of shoppable services. However, the Departments are of the view that release of this information for all items and services, as proposed, is crucial for advancing the key objectives of the final rules to spur innovation, increase competition, and empower consumer activities in the health insurance markets. The Departments are of the view that limiting the data in the machine-readable files would undermine efforts to achieve these objectives. In particular, the Departments are concerned that if the requirement were to be modified to apply to only a shoppable subset of items and services, then third-party application developers may not be as interested in innovating in this area.

Furthermore, the Departments are of the view that efficiencies will be gained after initial development of these files. Although the initial implementation burden for some plans and issuers may be sizeable, future releases of data could be automated, greatly reducing the burden in subsequent years.

One commenter stated the type of data being required to be disclosed is prohibited from disclosure by CMS for laboratory services under section 1834A of the SSA, which requires CMS to keep confidential payer rates reported by applicable laboratories. The commenter stated section 1834A of the SSA should also apply to disclosure of similar information by health plans.

Section 1834A of the SSA is applicable to reporting of private sector

payment rates for the limited purpose of establishing Medicare reimbursement rates for laboratory services. Section 1834A protects the confidentiality of information disclosed to HHS by a laboratory and prohibits the Secretary of HHS or a Medicare contractor from disclosing the information in a manner that identifies the particular payer or laboratory, identifies the prices charged, or identifies the payments made to any such laboratory notwithstanding any other provision of law. The confidentiality protections of the data required to be disclosed to HHS under section 1834A protects laboratories and payers from re-disclosure by HHS and Medicare contracts. These protections are not applicable to the public disclosures required under the final rules. First, the final rules require plans and issuers to publicly disclose in-network providers' negotiated rates and out-of-network providers' allowed amounts for all covered items and services. These disclosures must be made through machine-readable files posted in a public location on a plan or issuer's website. HHS or contractors of HHS will have no active role in publicizing the information required to be public through the final rules. Second, the confidentiality requirements in section 1834A are applicable ''notwithstanding any other provision of law.'' The public disclosure requirements in the final rules are being finalized through an exercise of specific authority under section 1311(e)(3)(A)(vii) and (ix) of PPACA (as applied to plans and issuers in the individual and group markets through section 2715A of the PHS Act). Even if the public disclosures were to be subject to section 1834A of the SSA, the confidentiality provision of section 1834A would not be applicable because the public disclosure requirements established under the final rules are required by an exercise of authority under a separate provision of law. For these reasons, and because laboratory services fall within the scope of all covered items and services, the final rules clarify that disclosure by plans and issuers of pricing information for laboratory services is required under the final rules.

As discussed earlier in this preamble, the Departments are modifying the proposed requirements relating to inclusion of all items and services in the internet-based self-service tool. For the internet-based self-service tool, 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 adopt a phased-in approach under which plans and issuers are required to include only include a subset of items and services during the initial year of implementation. However, plans and issuers will still eventually be required to include all covered items and services in their internet-based self-service tools in order to meet the requirements of the final rules. The Departments are of the view that a similar phased-in approach for the machine-readable files is not necessary and would not support the achievement of the goals of the final rules.

For these reasons, the final rules adopt, as proposed, the requirement to include all covered items and services, including prescription drugs, in the public disclosures required to be made through the machine-readable files.

One commenter made the point that in order to provide meaningful transparency to consumers, as well as to address the issues of inconsistent pricing among hospitals in particular, the Departments should require public disclosure of data related to pricing in addition to the negotiated rate. The commenter stated the data elements should include the following: Number of procedures performed by the provider in the reported period, number of bed days, total billed charges in the reporting period, total amount received/paid for services in the reporting period, mean billed charged amount, mean accepted amount, median billed charged amount, mean accepted amount, median billed charged amount, median accepted payment, minimum billed charged amount, maximum billed charged amount, minimum accepted payment, and maximum accepted payment.

A goal of the final rules is to provide transparency for all covered health care items and services. To this end, the final rules' public disclosures are tailored to require only certain critical pricing information that the Departments view as most likely to achieve this goal, while minimizing the burdens for plans and issuers of producing and maintaining the information. Requiring additional data elements, such as those listed by the commenter, would introduce an increased level of complexity to the machine-readable files and increase the burden of making the public disclosures.

Additionally, the Departments are of the view that it would be unnecessarily burdensome to isolate hospital pricing information for additional disclosure when hospitals already have separate price transparency disclosure obligations. As discussed elsewhere in this preamble, the Hospital Price Transparency final rule requires hospitals to make public their standard charges for items or services they provide.[160] The Hospital Price Transparency final rule requires disclosure of five types of standard charges:

- The gross charge (the charge for an individual item or service that is reflected on a hospital's chargemaster absent any discounts);
- the discounted cash price (the charge that applies to an individual who pays cash, or cash equivalent, for a hospital item or service);
- the payer-specific negotiated charge (the charge that a hospital has negotiated with a third-party payer for an item or service);
- the de-identified minimum negotiated charge (the lowest charge that a hospital has negotiated with all third-party payers for an item or service); and
- the de-identified maximum negotiated charge (the highest charge that a hospital has negotiated with all third-party payers for an item or service).

The Departments are of the view that the public disclosure requirements for hospitals under the Hospital Price Transparency final rule, in combination with the public disclosure requirements of the final rules, will address the concern raised by one commenter regarding inconsistent pricing among hospitals. The disclosure required for hospitals under the Hospital Price Transparency final rule will help provide local and more specific pricing information through the availability of information on five types of standard charges, but the information will only be made publicly available for the items and services that hospitals provide. The final rules supplement this information by providing information related to negotiated rates or derived amounts and allowed amounts for all covered items and services. Thus, the final rules will provide a window into pricing for all items and services, while the Hospital Price Transparency final rule requires disclosure of more specific pricing information for the items and services provided by hospitals. Finally, the final rules also supplement the Hospital Price Transparency final rule because the final rules make the information for all contracted network hospitals available from one plan or issuer in a single, centralized file. Therefore, the final rules permit consumers—especially when using third-party web-based tools—to more readily compare hospital rates within and across plans and issuers.

Several commenters expressed concerns about participant, beneficiary,

[160] 84 FR 65524 (Nov. 27, 2019).

and enrollee privacy related to the proposed disclosures of negotiated rates and allowed amounts. Some commenters expressed concerns about how third-party developers or other downstream entities would use and protect participant, beneficiary, and enrollee data. They noted that even though the Departments' disclosure requirements do not include PHI, patients could be enticed to share personal data with third-party developers and other secondary entities who could potentially use the information to re-identify consumers. Some commenters stated that parties not subject to HIPAA could seek to commercialize consumers' information. One commenter suggested the Departments look to HCCI as an example of how de-identified data can advance the goals of transparency, which could mitigate concerns about proprietary information while maintaining meaningful, granular information that illuminates price variation in the health care system.

One commenter stated that the Departments should consider the proposed rules in the context of other HHS rules related to the interoperability of data and delay the implementation of all such rules until HHS develops consumer privacy and protection requirements for third-party applications developed by non-HIPAA-covered entities. Another commenter recommended that, if the rules are finalized without additional privacy protections, the Departments should conduct an educational campaign to inform consumers of the consequences of providing information to third-party application developers. A commenter also expressed national security concerns regarding the machine-readable files, noting that the health status of Americans is a valuable commodity for foreign intelligence services.

The Departments acknowledge commenters' concerns about third-party application developers and other entities gaining access to personally identifiable information (PII) and PHI through consumer use of online applications. The Departments further acknowledge comments that consumers may not always fully understand how their information, including sensitive medical information, will be used or stored by such third parties. However, the Departments also acknowledge that consumers have a right to access, use, and share their own health information, both generally and under HIPAA. The Departments are also of the view that there is ample evidence that consumers require help to understand their health coverage, their out-of-pocket costs for health care items and services, and how their health care choices affect the overall costs of their health coverage and health care items and services.[161] The final rules will allow access to data, supplementary resources, and other assistance consumers need to make informed choices by fostering innovation and offering access to tools that consumers may use to make informed health care choices.

The Departments likewise considered evidence of significant consumer reliance on the internet for all kinds of information, but especially for health information. In a study conducted by the Pew internet & American Life Project and published in July 2003, researchers found that 80 percent of internet users, or about 93 million Americans, have searched for a health-related topic online, a 62 percent increase since 2001.[162] Popular search topics included health insurance (25 percent); a particular doctor or hospital (21 percent); and alternative treatments (28 percent).[163] By 2013, the number of Americans searching for health information online had nearly doubled from 2003, to about 182 million people.[164] A 2018 study found a significant correlation between the use of online resources to obtain health information and the decisions consumers take concerning health care services.[165]

The Departments are of the view that many American consumers have some experience with dealing with the disclosure of sensitive health information on the internet [166] and that consumer reliance on the internet for health care information will only increase despite inherent privacy risks. The Departments considered that websites and internet applications that collect consumer information provide information through privacy policies and terms of service that are available to users of how their information may be used and shared. Federal laws and enforcement mechanisms are in place to help protect consumers from unfair and deceptive practices, including deceptive data collection and the sale of data collected without adequate consumer notice.[167] Given existing measures to protect consumer privacy on the internet, the Departments are of the view that common internet privacy risks should not operate to deprive consumers of the information, tools, and support they need to make informed choices related to health care coverage, providers, items, and services.

Even though the Departments are not persuaded that privacy risks common to the use of internet applications outweigh the benefits of the disclosures under these the final rules or the general need for price transparency, ensuring the privacy and security of consumer PII and PHI is a top priority for the Departments. The Departments will work with plans and issuers to provide information they can use to educate participants, beneficiaries, and enrollees about sharing their health information with third party applications. This will include information on about the roles of Federal agencies such as the Office for Civil Rights (OCR), the FTC, and ONC, which already focus on ensuring that consumer privacy rights and interests are appropriately protected. The Departments will encourage plans

[161] Arora, V., Moriates, C., and Shah, N. ''The Challenge of Understanding Health Care Costs and Charges.'' The American Medical Association Journal of Ethics. November 2015. Available at: *https://journalofethics.ama-assn.org/article/challenge-understanding-health-care-costs-and-charges/2015-11*.

[162] ''Health Searches and email Have Become More Commonplace, But There is Room for Improvement in Searches and overall internet access.'' internet Health Resources. Pew Research Center. July 16, 2003. Available at: *https://www.pewresearch.org/internet/2003/07/16/internet-health-resources/*.

[163] *Id.*

[164] Fox, S., and Duggan, M. ''Health Online 2013.'' Pew Research Center. January 15, 2013. Available at: *https://www.pewresearch.org/internet/2013/01/15/health-online-2013/*.

[165] Chen, Y. et al. ''Health Information Obtained From the internet and Changes in Medical Decision Making: Questionnaire Development and Cross-Sectional Survey.'' Journal of Medical internet Research. Volume 20. No. 2. February 2017. Available at: *https://www.jmir.org/2018/2/e47/pdf*.

[166] Zhu, P., Shen, J., and Xu, M. ''Patients' Willingness to Share Information in Online Patient Communities'' Questionnaire Study.'' Journal of Medical internet Research. Volume 22. No. 4. April 2020. Available at: *https://pubmed.ncbi.nlm.nih.gov/32234698/*.

[167] ''Privacy & Data Security Update: 2019.'' United States Federal Trade Commission. Available online at: *https://www.ftc.gov/system/files/documents/reports/privacy-data-security-update-2019/2019-privacy-data-security-report-508.pdf*; *see also* ''Privacy and Security Enforcement.'' United States Federal Trade Commission. Available at: *https://www.ftc.gov/news-events/media-resources/protecting-consumer-privacy/privacy-security-enforcement* (''the FTC can and does take law enforcement action to make sure that companies live up to [the] promises'' regarding how consumer information will be safeguarded); *see also* Complaint in *United States* v. *Facebook,* Case No. 19–cv–2184, U.S. District Court for the District of Columbia. Available at: *https://www.ftc.gov/system/files/documents/cases/182_3109_facebook_complaint_filed_7-24-19.pdf* (FTC complaint leading to a historic $5 billion fine for, among other things, deceptive practices in violation of section 5(a) of the FTC Act where the social media company failed to effectively disclose that consumer information would also be used for advertising). The referenced fine can be found at: *https://www.ftc.gov/news-events/press-releases/2019/07/ftc-imposes-5-billion-penalty-sweeping-new-privacy-restrictions*, last accessed Sep. 11, 2020 (press release announcing fine).

and issuers to share this information with their participants, beneficiaries, and enrollees who might elect to share health information with third-party applications.

In finalizing the rules, the Departments considered the large number of consumers who have decided to share personal information because they have determined that the benefits offered by an internet website or mobile application outweigh potential risks to their privacy. The Departments are of the view that consumers will be able to make similar determinations with regard to applications that make use of data to be disclosed through the machine-readable files required by the final rules.

As discussed earlier in the preamble to the final rules, the Departments also are not persuaded by the argument that the disclosures required under the final rules, or disclosures consumers may make to applications that leverage the data required, could introduce national security concerns. First, the information the Departments are requiring to be disclosed through the machine-readable files does not include PHI or PII. Additionally, as discussed in more detail later in this preamble, in an effort to ensure that the disclosures balance price transparency with the need to protect privacy, the Departments have modified the proposed rules to increase the minimum disclosure threshold from 10 to 20 unique payment amounts, where any historical payment amounts connected to less than 20 claims for payment would be omitted from the machine-readable file containing out-of-network allowed amounts and historical billed charges (the Allowed Amount File). The increase will further limit the possibility that individual participants, beneficiaries, and enrollees may be identified through historical allowed amount data. Second, the information a consumer could share with applications incorporating data required to be disclosed through the final rules is not significantly different from data consumers already actively share through similar applications. Therefore, the Departments are not convinced there are unique national security concerns flowing from the disclosures required by the final rules.

One commenter was concerned about allowing third parties to use plan and issuer information to provide cost and pricing information to consumers without those third parties being obligated to provide accurate and relevant information to consumers. The accuracy of third-party internet-based tools and applications will be important to achieving the goals of transparency in coverage. However, the cost and pricing information included in third-party internet-based tools, and tools developed by other secondary entities, would only be as accurate as the public disclosures made by plans and issuers. Therefore, the Departments are of the view that it is in the best interest of plans and issuers to ensure data accuracy through a robust quality assurance process if they have concerns about the accuracy of cost and pricing information being provided to consumers through third-party internet-based tools. Furthermore, nothing in the final rules prohibits plans and issuers from including comprehensive data dictionaries and other supplementary documentation along with the machine-readable files. Plans and issuers are also free to provide plan-specific disclaimers or clarifications regarding the information they are required to produce. Finally, the Departments expect that consumers, plans, issuers, and other health care stakeholders will monitor third-party internet-based tools for accuracy and will and report concerns to the developer, the public, and appropriate state and Federal agencies, including the Departments, for evaluation and potential action.

The Departments further expect that market forces will act to weed out applications that do not provide reliable information. Consumers who use a third-party application or other online tools for health care decision support and later conclude that the tool misled or misinformed them will, at minimum, cease use of the tool. Such consumers are also likely to rate the application poorly or leave unfavorable reviews, reducing the likelihood that other consumers who see the rating or review will rely on the tool. Over time, consumers and other stakeholders may collectively identify the most accurate and highest quality tools, while reducing use of less accurate, unreliable tools. The Departments also expect that third-party tools will inform users of limitations on the accuracy of their information and will present relevant disclaimers informing consumers that any estimates of out-of-pocket liability are not guarantees regarding consumer liability for services. Tool users also will have the opportunity to evaluate and could attempt to confirm any cost estimates provided by online tools by contacting the plan, issuer, or health care provider they ultimately choose based on information provided by the tool. Such measures will address the risk that consumers will be led to unreasonably rely on any cost estimate provided by a third-party tool to their financial detriment.

The Departments are of the view that it is in plans', issuers', and developers' best interests to provide accurate information. However, the Departments will monitor the accuracy of the information provided through third-party developers and secondary entities and will take information obtained through this monitoring into account for future regulatory action or guidance, as appropriate.

One commenter recommended that any information made available to the public should provide an explanation of why the cost of care is variable among hospitals. The commenter further suggested the explanation reference unique challenges faced by essential hospitals that care for a larger proportion of vulnerable patients.

Being mindful of the goal to provide sufficient technical flexibility in the formatting of the machine-readable files, the Departments decline to require plans and issuers to include specific supplementary information beyond reporting the data specified for the machine-readable file formats. As noted above, nothing in the final rules prevents a plan or issuer from providing supplementary materials, including footnotes, disclaimers, data dictionaries, and other explanatory language, as accompaniments with the machine-readable files. The Departments are of the view that any additional context around the machine-readable files that can be provided through supplementary materials are likely to be a benefit to consumers and others who seek to understand and use the data contained in the machine-readable files. The Departments recommend plans and issuers work closely with providers, consumers, developers, community leaders, and other stakeholders to ensure that all perspectives are taken into account when developing materials supplemental to the machine-readable files. While declining to require plans and issuers to include a specific explanation for why the cost of care could vary among hospitals, the Departments acknowledge that this information is an example of appropriate explanatory language that could accompany the machine-readable files.

The final rules adopt, with modifications, the requirements that plans and issuers publicly disclose applicable in-network rates (including negotiated rates, derived amounts, and underlying fee schedule rates), out-of-network allowed amounts for covered items and services, including prescription drugs, through machine-

readable files. The final rules also adopt the requirement that plans and issuers publicly disclose in-network historical net prices for covered prescription drugs through a machine-readable file. In recognition of the unique pricing attributes of prescription drugs, the final rules require the reporting of information on prescription drugs that would have been included in the In-network Rate File (referred to as the Negotiated Rate File in the proposed rules) in a separate machine-readable file, as described later in this preamble. The Departments continue to be of the view that the release of this information is appropriate and necessary to empower consumers to make informed decisions about their health care, spur competition in health care markets, and to slow or potentially reverse the rising cost of health care items and services.

The Departments stated the intention in the proposed rules to make available non-substantive technical implementation guidance through the collaborative GitHub platform (an online hosting platform for development and source code management that permits version control), which will facilitate further technical assistance in addressing how unique plan designs can comply with the requirements of the final rules, as needed. The Departments received comments that supported the Departments' development of specific technical standards for the files to which plans and issuers must adhere. One commenter recommended the Departments provide guidance to plan sponsors who are able to provide some, but not all, of the file data elements. Another commenter stated that the proposed rules do not make clear how to report items and services provided through capitated and bundled payment arrangements in the files; noting that this information is necessary for consumers to measure provider value. One commenter supported the Departments' statement that it would provide technical implementation guidance for the files but requested a robust public comment solicitation far in advance of the applicability date for the rules.

The Departments are of the view that providing specific technical direction in separate technical implementation guidance, rather than in the final rules, will better enable the Departments to update the file technical requirements to keep pace with and respond to technological developments. The Departments note that the technical implementation guidance is intended to facilitate a collaborative effort between the Departments and plans and issuers in order for plans and issuers to meet the public disclosure requirements of the final rules, while providing flexibility to account for unique IT systems, and issuer and plan attributes. To the extent a plan's or issuer's unique attributes (such as use of an alternative contracting model) are not addressed sufficiently through the technical implementation guidance, the Departments intend to provide targeted technical assistance to help ensure all plans and issuers are able to meet the public disclosure requirements under the final rules. Therefore, the Departments are developing technical implementation guidance for plans and issuers, which will be available on GitHub, to assist them in developing the machine-readable files.

In the proposed rules, the Departments indicated that minimum requirements for standardized data elements would be necessary to ensure users would have access to accurate and useful pricing information. Without such baseline requirements, the negotiated rate and allowed amount data for out-of-network services made available by each group health plan and health insurance issuer could vary dramatically. This would further create a disincentive to health care innovators developing tools and resources to enable consumers to accurately and meaningfully use, understand, and compare pricing information for covered items and services across providers, plans, and issuers. Accordingly, under the proposed rules, a plan or issuer would be required to publish two machine-readable files. The first file would include information regarding rates negotiated with in-network providers. The second file would include historical data showing allowed amounts for covered items and services furnished by out-of-network providers. The preamble to the proposed rules referred to these files as the Negotiated Rate File and the Allowed Amount File, respectively. For the final rules, the file referred to as the Negotiated Rate File in the proposed rules has been renamed the In-network Rate File to reflect modifications made in the final rules to ensure the file accommodates plans and issuers operating under payment models other than the fee-for-service (FFS) model. The final rules adopt the requirement to produce both the In-network Rate File and Allowed Amount File with the modifications discussed elsewhere in this preamble. As previously discussed, the final rules also adopt the requirement to produce an additional file, referred to in this preamble as the Prescription Drug File through which plans and issuers are required to publicly disclose negotiated rates and historical net prices connected to prescription drugs.

As noted, the final rules modify the In-network Rate File requirements to clarify the expectations for reporting negotiated rates (or comparable derived amounts, which are explained in detail later in this section) for plans and issuers using alternative reimbursement models. The final rules also clarify that plans and issuers must include an underlying fee schedule rate when one is used to determine cost-sharing liability, where that amount differs from the negotiated rate (or comparable derived amount) used to determine provider reimbursement.

The final rules modify the Allowed Amount File to clarify that it must also include information related to billed charges in addition to allowed amounts. The final rules also finalize additional requirements for the In-network Rate File, Allowed Amount File, and Prescription Drug File to require plans and issuers to include a Place of Service Code and a provider tax identification number (TIN) in addition to the provider NPI. These modifications are discussed in more detail later in this section of this preamble.

Specific Content Elements

In the proposed rule, the Departments indicated that the Negotiated Rate File and the Allowed Amount File would be required to include content elements discussed in this section of this preamble. In the final rules, these content elements continue to apply to the In-network Rate File and the Allowed Amount File, as well as to the Prescription Drug File, except where otherwise indicated.

a. First Content Element: Name and Identifier for Each Coverage Option

The first content element that plans and issuers will be required to include in the machine-readable files is the name and identifier for each coverage option offered by a group health plan or health insurance issuer. For the identifier, the Departments proposed that plans and issuers use their Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) IDs, as applicable. The Departments sought comment on whether EINs and HIOS IDs are the appropriate identifiers for this purpose. The Departments also sought comment on whether there are other plan or issuer identifiers that should be considered and adopted.

The Departments did not receive any comments on this content element, and the final rules adopt this provision with

modifications to ensure clarity of the expectations for reporting. As reflected in the updated regulatory text, the Departments are clarifying whether an EIN or HIOS ID is applicable for this element. Plans and issuers must include their HIOS ID at the 14-digit product level unless the plan or issuer does not have a HIOS ID at the plan or product level, in which case the plan or issuer must use the HIOS ID at the 5-digit issuer level. If a plan or issuer does not have a HIOS ID, it must use its EIN.

b. Second Content Element: Billing Codes

The second content element that plans and issuers will be required to include in the machine-readable files is any billing code consistent with the definition of billing code provided in the final rules, including:

- A CPT code,
- a Healthcare Common Procedure Coding System (HCPCS) code,
- a DRG,
- a National Drug Code (NDC) (The final rules define the NDC code as a unique 10-digit or 11-digit 3-segment number assigned by the Food and Drug Administration (FDA), which provides a universal product identifier for drugs in the United States),[168] or
- another common payer identifier used by a plan or issuer, such as a hospital revenue code, as applicable, and a plain language description for each billing code.

The Departments proposed to require that plans and issuers associate each negotiated rate or out-of-network allowed amount with a CPT, HCPCS code, DRG, NDC, or other common payer identifier, as applicable, because plans, issuers, and providers uniformly understand these codes and commonly use them for billing and paying claims (including for both individual items and services and items and services provided under a bundled payment arrangement). The Departments also proposed that plans and issuers must include plain language descriptions for each billing code. In the case of items and services that are associated with common billing codes (such as the HCPCS codes), the Departments specified that the plan or issuer could use the codes' associated short text description.

In order to ensure that the machine-readable files provide meaningful information to consumers, as well as other stakeholders, the final rules adopt this content element as proposed, with the following modifications. For clarity, the regulation text is amended to remove language that merely restated the definition for the term ''billing code'' for each machine-readable file.[169] This modification has been made purely to streamline the regulatory language, and it does not substantively alter the requirement to include a billing code, except as otherwise noted in this preamble. Additionally, along with separating prescription drugs into a separate machine-readable file, the final rules include a modification that clarifies that, in the case of prescription drugs, plans and issuers may only use the NDC as the billing code type because, as discussed later in this preamble, the accuracy of pricing information for prescription drugs requires precise and specific product information, including package size and manufacturer, which can only be achieved through the use of the NDC billing code. However, the Departments recognize that prescription drug products may be included in the In-network Rate File to the extent a plan or issuer uses an alternative payment arrangement, such as a bundled payment arrangement that includes prescription drugs. Therefore the final rules clarify that the In-network Rate file must include the required information under paragraph (b)(1)(i) of the final rules for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which would be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of the final rules.

The final rules require plans and issuers to include in the machine-readable files a billing code or other code used to identify covered items or services for purposes of claims adjudication, payment, and cost-sharing liability when making public the disclosure required under 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212. The final rules adopt the requirement that plans and issuers associate each amount required to be reported with a CPT, HCPCS, DRG, NDC, or other common payer code identifier, as applicable, because plans, issuers, and providers uniformly understand these codes and commonly use them for billing and paying claims (including for both individual items and services and for bundled payment arrangement). As provided by the definition of billing code in the final rules, the Departments intend to provide flexibility to plans and issuers to make the data available through the codes that they use for billing services. While the final rules do not require plans and issuers to use a specific billing code (for example, CPT codes) for making public the disclosures required through the final rules, definition of billing code states that it is the code used by the plan or issuer ''for purposes of billing, adjudicating, and paying claims for a covered item or service.'' Therefore, where a plan or issuer uses a CPT code to identify a covered item or service for purposes of billing, adjudicating, and paying claims for that covered item or service, then they would need to use the CPT code in order to make public the disclosure required through the final rules for that item or service.

One commenter recommended that the negotiated rates should be clearly stated in plain language that should be easy to understand rather than provided by billing codes through the machine-readable files. As an alternative, the Departments received some comments stating that the Departments should require hospitals and health insurance issuers to disclose all negotiated reimbursements by International Classification of Disease (ICD) code.

The preamble to the proposed rules identified several common billing codes, noting that the list provided was not exhaustive. Further, the Departments did not explicitly prohibit including ICD–10 codes on the file. The Departments note that nothing in the final rules would constrain plans or issuers from including ICD codes in the machine-readable files when these codes are used by the plan or issuer in a manner that meets the definition of a billing code in the final rules. In other words, where the plan or issuer uses an ICD code to identify health care items or services for the purpose of billing, adjudicating, and paying claims for a covered item or service, the plan or issuer may use the ICD code in the machine-readable files. As discussed earlier in this preamble, the Departments intend to issue technical implementation guidance; this guidance will include sample file schemas for the machine-readable files. To facilitate identification of the billing code type,

[168] In the preamble to the HIPAA regulations, HHS stated that it was adopting a uniform 11-digit format to conform with customary practice used in computer systems (65 FR 50314, 50329). (Aug. 17, 2000). The HIPAA 11-digit NDC format is standardized such that the labeler code is always 5 digits, the product code is always 4 digits, and the package code always 2 digits. To convert a 10-digit NDC to an 11-digit HIPAA standard NDC, a leading zero is added to the appropriate segment to create the 11-digit configuration as defined above. *See* 83 FR 38666 (Aug. 7, 2018).

[169] Specifically, the Departments have removed the following language from billing code requirements for the machine-readable files: ''. . . or other code used by the group health plan or health insurance issuer to identify covered items or services for purposes of claims adjudication and payment.''

there will be an indicator in the file schemas that will allow plans and issuers to specify the particular type of billing code entered for each data entry in the machine-readable files.

The Departments are aware that some covered items and services may not have a corresponding HCPCS, ICD, DRG, NDC or CPT code. The Departments clarify that plans and issuers are still required to include these covered items and services in their machine-readable files regardless of whether all corresponding data elements are available. When a covered item or service does not have a corresponding HCPCS, ICD, DRG, or CPT code associated with an item or service, a plan or issuer is permitted to choose its own indicator or other method to communicate to the public that there is no corresponding code. In the alternative, a plan or issuer is permitted to use the code to be defined by the Departments in technical implementation guidance issued along with the final rules that indicates that an item or service is not defined.

At this time, the Departments have concluded that the common data requirements adopted by the final rules, which include a requirement to include a plain language description for each billing code, provides consumers with sufficient information to meaningfully inform health care purchasing decisions.

Regarding information about prescription drug pricing, a commenter also suggested that, in lieu of NDC or HCPCS codes, a useful unit for reporting for drugs would be the RxNorm concept unique identifier (RxCUI).[170] The commenter suggested use of RxCUIs because it would minimize burden by reducing the list of entries (3,000 to 4,000 RxCUIs down from 100,000 active NDCs) and because existing prescription drug machine-readable file requirement for Medicare Part D (Part D) and QHPs use RxCUIs.

The Departments appreciate the commenter's alternative suggestion for including prescription drug information in the machine-readable files. The Departments considered requiring prescription drug pricing information through an alternative identifier. The Departments understand that an RxCUI could minimize the burden on plans and issuers by reducing the number of codes required to be included in the Prescription Drug File. RxCUI is a drug naming system that is produced by the National Library of Medicine (NLM), and RxCUIs are unique identifiers, which can represent multiple NDCs for similar drug products with the same brand name, active ingredient, strength and dose form (for example, multiple package sizes and/or manufacturers can be represented by a single RxCUI). The NDC, in contrast, is a unique 10-digit or 11-digit 3-segment number, which provides a universal product identifier for drugs in the United States. The three segments of the NDC identify: The labeler (any firm that manufactures the drug); the product (specific strength, dosage form, and formulation of a drug); and the commercial package size and types. As noted above, multiple NDCs can be encompassed by one RxCUI, which is why there are many fewer RxCUI codes than NDCs. However, the accuracy of pricing information requires precise and specific product information, including package size and manufacturer. The Departments are concerned that permitting drug pricing information disclosures to be made through RxCUIs would potentially lead to inaccurate or misleading information being provided to the consumer. If drug pricing information is provided in the machine-readable files in the form of RxCUIs, then plans and issuers may not be able to provide the manufacturer negotiated rate, especially for those RxCUIs that include NDCs from several manufacturers.

Some commenters noted that, because RxCUI is used by the Part D program and in the QHP program, the Departments should also require RxCUI in the machine-readable file for consistency across programs. While the Departments acknowledge that RxCUI is used in some contexts in both the Part D and QHP programs, namely formulary development, these programs do not exclusively use RxCUI. Indeed, both the Part D and QHP programs use NDC in addition to RxCUI, and NDCs are more generally used when information is required to be submitted to CMS for payment programs. For example, the Part D program receives the NDC on claims submitted by Part D plan sponsors through Prescription Drug Events (PDEs) and issuers in the individual and small group market include NDCs on claims data submitted to issuers' EDGE servers for HHS risk adjustment purposes. In short, other programs cited by commenters actually use NDCs for prescription drugs data submissions, particularly for payment that is similar to the pricing data required by the final rules. The Departments therefore conclude that requiring use of NDCs for the prescriptions drug pricing information included in the machine-readable files is consistent with the practices CMS follows in other programs. Therefore, as stated earlier, the Departments are requiring that the only allowable billing code for prescription drugs in the machine-readable files is the NDC. The Departments determined that the NDC should be the required billing code for the reasons stated above and because the NDC is a standard billing code required for prescription drug transactions.

c. Third Content Element: In-Network Applicable Amounts (Negotiated Rates, Amounts in Underlying Fee Schedules, and Derived Amounts); Out-of-Network Allowed Amounts; or Negotiated Rates and Historical Net Prices for Prescription Drugs

The third-content element in the machine-readable files depends on the type of file: in-network amounts for the In-network Rate File, allowed amounts and historical billed charges for the Allowed Amount File, or negotiated rates and historical net prices for the Prescription Drug File.

All Machine-Readable Files

The proposed rules specified that the specific pricing information within each file would have to be associated with a provider identifier, specifically the provider's NPI. Some commenters suggested additional data elements to support accurately identifying the provider through the machine-readable files. One commenter recommended that the Departments include the Place of Service Code in the machine-readable files. The commenter explained that this data element would clarify prices when provider entities associated with the same NPI have multiple sites of service. Place of Service Codes are CMS-maintained two-digit codes that are placed on professional claims, including Medicare, Medicaid, and private insurance, to indicate the setting in which a service was provided.[171] The Place of Service code set is required for use in the implementation guide adopted as the national standard for electronic transmission of professional health care claims under HIPAA.[172]

[170] The Departments note that the comments used the term ''Rx Common Unit Identifier'' to identify the full phrase for the RxCUI. The Departments assume that this is a misnomer and that the commenter was referring to RxNorm concept unique identifier, which is the generally accepted term for the acronym RxCUI.

[171] ''Place of Service Code Set.'' Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.*

[172] ''Place of Service Codes.'' Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/Medicare/Coding/place-of-service-codes.*

The Departments have considered this comment and agree that, in addition to NPI, including a Place of Service Code is important where a provider could be using the same NPI for multiple places of service. For instance, the same procedure from the same provider NPI received at an ambulatory surgery center (Place of Service Code 24) could have a significantly different price if received at an on-campus outpatient hospital (Place of Service Code 22). The Departments are of the view that being able to identify the place of service would be beneficial to consumers seeking to rely on the machine-readable files or third-party applications developed using the information publicly disclosed through the machine-readable files, in order to make health care purchasing decisions. The Departments are also of the view that this data element will help provide valuable insights regarding market dynamics for researchers, employers, regulators, and other files users. Because the Place of Service Code is information that must be included on a professional medical claim, the Departments do not foresee any issue with plans and issuers including this data element in the machine-readable files in addition to the NPI. For these reasons, the Departments are finalizing a requirement to include the Place of Service Code in all three machine-readable files.

In addition to the NPI and the Place of Service Code, the Departments have also become aware, through independent research, that a provider's TIN can be relevant to communication of accurate negotiated rates and allowed amounts information. It is the Departments' understanding that negotiated rates for items and services are based on the unique combination of a provider (NPI), service or item location (Place of Service code), and the TIN under which the provider is furnishing the item or service. If the TIN is not required in the file, the Departments are concerned that plans and issuers could report multiple negotiated rates for the same NPI for the same item or service without context to identify the underlying source of the difference. For example, if a provider NPI has a relationship with two different entities that have negotiated rates and bills under both of these entities, the same item or service for that provider NPI could appear in the report with two different negotiated rates. Without the TIN, consumers of the file would not be able to discern the reason for the difference in the two distinct negotiated rates. With the TIN, consumers of the file could see that the provider is billing for the same services under two separate entities. Therefore, if this unique combination of NPI, Place of Service Code, and TIN is not required, the pricing information represented in the machine-readable files might not present a complete and accurate picture of the market or provide consumers with reliable data upon which to base health care purchasing decisions. The Departments are of the view that this information is crucial to ensure that consumers are ultimately receiving location-specific pricing information upon which they can rely to help make informed health care purchasing decisions. In order for the machine-readable files to provide meaningful and actionable information, the final rules adopt a modification to all three machine-readable files, to require plans and issuers to provide the provider TIN in the file in addition to provider NPI and the Place of Service Code.

The Departments have updated the technical implementation guidance and schemas for all three machine-readable files, so that location-specific pricing information can be provided in the machine-readable files. This guidance will also provide more details on how the Place of Service Code, TIN, and NPI should be reported in order to represent the information for which public disclosure is required through the machine-readable files. The Departments are aware that this modification to the machine-readable files will increase the complexity and size of the machine-readable files and have considered this additional burden in the Information Collection Requests (ICR) section of the of the final rules. The benefits of including the Place of Service Code and TIN outweigh the costs, as the Departments are of the view that location-specific pricing information is critical to the meaningfulness of these files for the public.

Another commenter noted that using NPIs to identify providers would make it difficult for consumers to use the machine-readable files because consumers do not usually have NPI information. The commenter stated that it would also be useful for consumers using the In-network Rate Files (including the uninsured and those shopping for alternative coverage) to have access to public information that lists the providers who participate in local plan and issuer networks.

The Departments agree that including provider names in the machine-readable files in addition to NPIs would help consumers and other stakeholders review and use the machine-readable files. However, the Departments have some concerns about requiring inclusion of provider names in the files. From a technical perspective, the Departments are concerned that inclusion of provider names, which do not have a consistent character length and can be quite long, will increase the size of the machine-readable files and, therefore, increase the burden of the files for plans and issuers. Additionally, provider names may include non-alphanumeric or other non-standard character encoding types that could interfere with the coding of the machine-readable files and cause defects. The Departments are concerned that the additional quality assurance procedures that plans and issuers would need to implement in order to address these issues could add even more burden with limited benefit.

In addition, because the Departments expect the greatest benefits of these machine-readable files will be through the innovative tools developed by third parties, the Departments are of the view that the lack of availability of provider names in the machine-readable files is not a significant concern. The Departments anticipate that third-party internet-based developers and other secondary entities will be able to link the NPIs in the machine-readable files to publicly available provider information. The Departments note that there are several internet-based NPI lookup tools available online, including CMS's National Plan & Provider Enumeration System (NPPES) NPI registry.[173] Nothing in the final rules prevents a plan or issuer from linking to an NPI lookup tool or providing more information for consumers and other stakeholders on its website through supplementary materials supporting the machine-readable files.

For these reasons, the final rules do not require plans and issuers to include provider names in addition to NPI, TINs, and Place of Service Codes in the three machine-readable files.

In-Network Rate File

The Departments finalize with modifications the proposed requirement that group health plans and health insurance issuers publish as the third content element negotiated rates in a machine-readable file for all covered items and services—except that the Negotiated Rate File in the proposed rules has been re-named the In-network Rate File. With the exception of information relevant to prescription drug products that are included as part

[173] CMS's NPPES registry is available online at the following website address: *https://npiregistry.cms.hhs.gov/*.

of an alternative payment arrangement (such as a bundled payment arrangement), the In-network Rate File will exclude information relevant to prescription drugs, as that information will be provided in the third machine-readable file. Based on comments and technical expertise within the agencies, the Departments have made modifications to clarify the expectations for reporting negotiated rates (or comparable derived amounts as explained elsewhere in this section) for plans and issuers using alternative reimbursement models for health care items and services. These modifications also clarify that plans and issuers must include an underlying fee schedule rate when one is used to determine cost-sharing liability, where that amount differs from the negotiated rate (or comparable derived amount) used to determine provider reimbursement. The Departments also finalize this change to reflect other modifications to the proposed rules meant to ensure the required In-network Rate File accommodates plans and issuers operating under payment models other than a standard fee-for-service (FFS) model.

In the proposed rules, the third content element was negotiated rates under a plan or coverage regarding each covered item or service, including prescription drugs furnished by in-network providers. To the extent a plan or issuer reimburses providers for an item or service based on a formula or reference based-pricing (such as a percentage of a Medicare reimbursement rate), the proposed rules would have required the plan or issuer to provide the calculated dollar amount of the negotiated rate for each provider.

In the proposed rules, the Departments expressed the understanding that some plans and issuers do not vary negotiated rates across in-network providers. For instance, some plans and issuers have a negotiated rate that applies to every provider in a certain network tier. In such a case, the Departments proposed to require the plan or issuer to provide the negotiated rate for a covered item or service separately for every provider that participates in that tier of the network. If the plan or issuer reimburses for certain items and services (for example, maternity care and childbirth) through a bundled payment arrangement, the Departments proposed to require the plan or issuer to identify the bundle of items and services by the relevant billing code.

The Departments also proposed to require plans and issuers to include the last date of the contract term for each provider-specific negotiated rate that applies to each item or service (including rates for both individual and bundled items and services).

Several commenters suggested modifications to the requirement for public disclosure of negotiated rates, which they claimed would help mitigate the risk of unintended consequences, such as anticompetitive practices and increased health care prices. Commenters suggested that the final rules require plans and issuers to disclose the median rate or lowest negotiated rate instead of negotiated rates. Other commenters also expressed the opinion that information presented as summary or aggregated data would be more helpful for consumers. One of these comments noted that this could be achieved through plans identifying a range of in-network rates for common services.

The Departments considered modifying the requirement to require plans and issuers to report the median negotiated rate, the lowest negotiated rate, or some other aggregated negotiated rate. The Departments noted in the proposed rules that consumers, researchers, and regulators gaining access to pricing information, including information on the variation in prices, could place downward pressure on health care prices and reduce overall health care spending, which is one of the goals of the final rules. The Departments are concerned that using an aggregated or otherwise summarized rate would not sufficiently address issues of pricing variation and could undermine other goals of price transparency efforts. A median or summarized rate would not be as reliable for insured or uninsured consumers to use when making health care purchasing decisions as it is individual prices upon which these consumers must rely to make health care purchasing decisions. Under standard economic theory, it is individual prices, and consumers' responses to those prices, that drive market forces. If the public disclosures do not include specific individual prices for in-network items and services, consumers may not have actionable information upon which to rely to make specific decisions.[174] A median or summarized rate would not address the issue of price variation or dispersion, as it would mask the variation in a given geographic area.[175] Additionally, a median or summarized rate could mask the differences between plans and coverages in a manner incompatible with drawing comparisons between coverage options. Therefore, the Departments are of the view that release of alternative data points, such as aggregated negotiated rates, or other summarized forms of negotiated rates, would not sufficiently advance the price transparency efforts and could undermine the intended impacts of the In-network Rate File.

Commenters suggested the Departments limit the requirement for public disclosure of negotiated rate information in a way that protects plans and issuers from reverse engineering specific rates. For example, a commenter suggested the Departments limit the disclosure to plans and employer plan sponsors, while another commenter suggested that the final rules require plans and issuers to provide limited information to the public, such as statistical ranges, or rates distributions and require the provision of more detailed information to other stakeholders.

The Departments considered limiting these disclosures by stakeholder type such that the disclosure of the most detailed information to the widespread public would be more limited. The Departments' determined that these limitations would conflict with the statute, which requires public disclosure, and the goals of the final rules. The Departments' goal is to empower consumers through the disclosure of actionable pricing information through the In-network Rate Files, as translated into consumer-friendly tools by third-party application developers.

Some commenters expressed the view that public disclosure of rates by plans and issuers with alternative reimbursement models should be required and suggested the Departments work with stakeholders to establish requirements that are consistent with innovative payment models. One commenter stated that the Departments should not exclude from the negotiated file requirements plans with reimbursement arrangements different from FFS arrangements, such as plans with reimbursements based on a capitated amount or a value-based agreement. Some commenters noted that the release of negotiated rates places emphasis on FFS provider contracting and may hinder innovation in alternative payment contracting models, such as value-based contracting.

The Departments received some comments on how the Departments could require plans and issuers to report

[174] Stigler, G. ''The Economics of Information.'' The Journal of Political Economy. Volume 69. Issue 3. June 1961. Available at *https://home.uchicago.edu/~vlima/courses/econ200/spring01/stigler.pdf.*

[175] *Id.*

capitated and bundled payment arrangements through the In-network Rate File. One commenter noted that plans with a capitated arrangement should be able to assign a price to items and services based on an internal methodology. The commenter observed that plans with capitated payment arrangements must assign prices for purposes of submission of claims in support of the HHS risk adjustment program under 45 CFR 153.710(c). Some commenters, however, argued that implementing some aspects of the proposed rules would not be feasible, such as listing prices for quality-adjusted and risk-adjusted contracts, which can only be calculated after the fact.

By contrast, other commenters did not support a requirement for plans and issuers with alternative reimbursement arrangements to make public the disclosures required through the In-network Rate File. Commenters stated that releasing negotiated rate information for bundled or capitation arrangements would be a significant operational burden and could lead to inaccuracies and misinformed consumers. For example, several commenters noted that the entire suite of services that a consumer might need to look up for an episode of care is not known to patients or providers prior to the receipt of care. Another commenter noted that the information could be misleading to consumers because prices may not include the services provided by all providers that are involved in a patient's hospital care such as surgeons and anesthesiologists.

The Departments agree that plans and issuers that use alternative reimbursement arrangements should still be subject to requirements to disclose rates through the In-network Rate File. Nowhere in the proposed rules did the Departments indicate that only plans and issuers that reimburse on a standard FFS model would be required to make public the disclosure of negotiated rates. As evidenced by the discussion of reporting of bundled payment arrangements and plans and issuers using alternative reimbursement models such as formula-based or reference-based pricing in the proposed rules, the Departments intended the disclosures required through the final rules to apply to all plans and issuers, regardless of reimbursement model. The Departments clarify that plans and issuers that reimburse providers on a basis that is different from a standard FFS model would still be required to make public the disclosures of in-network negotiated rates, out-of-network allowed amounts and prices for prescription drugs as required by the final rules.

Later in this preamble, the Departments have summarized the general reporting expectations for several alternative reimbursement models, including bundled payment arrangements and capitation arrangements (including sole capitation arrangements and partial capitation arrangements), reference-based pricing without a defined network, reference-based pricing with a defined network, and value-based purchasing. This summary is not meant to be exhaustive, as the Departments are aware that other alternative reimbursement or contracting models exist. However, before clarifying how these payment arrangements would work under the final rules, the Departments note modifications to the requirements for the pricing information that must be publicly disclosed through the In-network Rate File.

Some commenters stated that the proposed rules did not acknowledge that negotiated rates alone provide an inaccurate or incomplete picture of health care item and service pricing. In response, the Departments conducted additional research to understand how the final rules could require the appropriate level of detail in the In-network Rate File and provide a more complete and transparent picture of prices of health care items and services. In response to comments, and as a result of this additional research, the Departments are modifying the language describing the requirement for the pricing information that must be publicly disclosed through the file. Specifically, the Departments are clarifying that the In-network Rate File should include all applicable rates, even where not referred to as negotiated rates. As described in the final rules, this could include negotiated rates, an underlying fee schedule rate or, derived amounts, as applicable. These modifications are intended to clarify disclosure requirements for plans and issuers that use alternative reimbursement arrangements and to ensure that the rates upon which consumer cost-sharing liability is determined as well as negotiated rates are publicly disclosed through the In-network Rate File. The Departments are of the view that this approach is consistent with the goals of transparency as outlined in the proposed rules because it ensures that the In-network Rate File will be both meaningful for consumers and requires transparency in price disclosures that will promote increased competition in health care markets. Without this clarification, the In-network Rate File could have potentially excluded rates that are used to determine cost-sharing liability, which is essential information upon which consumers would need to rely to make health care purchasing decisions. Further, retaining as proposed the requirement to include the negotiated rates that plans and issuers use to determine provider reimbursement is crucial to price transparency efforts, which will help foster competition and lower prices. Public disclosure of negotiated rates and derived amounts will also support research and regulatory oversight. For example, this information will help researchers evaluate alternative payment models in relation to the traditional FFS payment model, which could help spur more innovation in health care markets. State regulators will also be able to gain further insight into the various payment models, which would support general oversight of plans and issuers using different payment models, and could support market reform efforts.

One commenter noted that plans and issuers that use capitated reimbursement arrangements may assign prices to items and services as a normal course of business. Thus, they should be able to disclose those prices as part of the In-network Rate File. The Departments agree. The final rules require a plan or issuer that does not have a negotiated rate to disclose a ''derived amount,'' which is defined as the price that a plan or issuer assigns an item or service for the purpose of internal accounting, reconciliation with providers, or for the purpose of submitting data in accordance with the requirements of 45 CFR 153.710(c).

Title 45 CFR 153.710(c) sets forth a process through which capitated plans that do not generate individual enrollee claims in the normal course of business must submit data for the purpose of the HHS-operated risk adjustment program.[176] As stated in the preamble to the HHS Notice of Benefit and Payment Parameters for 2014 final rule, many capitated plans currently use some form of encounter data pricing methodology to derive claims' prices, often by imputing an amount based upon the Medicare fee-for-service equivalent price or the usual, customary, and reasonable equivalent that would have been paid for the service in the applicable state market risk pool.[177] For

[176] HHS has operated the risk adjustment program for the individual and small group markets under section 1343 of PPACA on behalf of all states and the District of Columbia since the 2017 benefit year.

[177] 78 FR 15410, 15499–15500 (Mar. 11, 2013).

the purposes of 45 CFR 153.710(c), an issuer offering a capitated plan is required to use its principal internal methodology for pricing those encounters for purposes of submitting risk adjustment data, such as the methodology in use for other State or Federal programs (for example, a methodology used for the Medicare Advantage market).[178] If an issuer, including an issuer of a capitated risk adjustment covered plan, has no such methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific market that the plan is serving. Given these requirements under 45 CFR 153.710(c), the Departments are of the view that most issuers offering capitated plans that do not process claims on an individual basis, and therefore do not have negotiated rates, will have a derived amount.

The Departments acknowledge that 45 CFR 153.710(c)does not apply to group health plans or all health insurance issuers subject to these rules and so they may not calculate derived amounts for this purpose. The final rules do not require plans or issuers to develop a new methodology for providing derived amounts if the plan or issuer does not have an existing methodology used in the normal course of business. Therefore, the final rules require plans and issuers that do not have a negotiated rate to provide a derived amount, to the extent these amounts are already calculated in the normal course of business. Where a plan or issuer does not have a derived amount calculated in the normal course of business, they are not required to provide a derived amount.

The Departments also note that under the final rules, where a plan or issuer includes in the In-network Rate File a comparable derived amount in lieu of the negotiated rate (for example, under a capitation arrangement where a specific negotiated rate is not available for a particular item or service), they will be required to add a notation to the machine-readable files indicating that the rate is subject to an alternative payment arrangement. The Departments are also aware that some plan and issuer contracting models use a mixture of approaches and note that plans and issuers should follow the general guidelines (to be provided by the Departments in the technical implementation guidance) based on how a particular covered item or service is reimbursed where a mixture of approaches is used in the same plan or coverage.

The final rules clarify that, where plans and issuers use negotiated rates or a comparable derived amount and an underlying fee schedule rate as defined in the final rules, they are required to report both the negotiated rate or comparable derived amount and the underlying fee schedule rate used for that item or service. Therefore, the Departments are also modifying the In-network Rate File to require public disclosure of an underlying fee schedule rate, when applicable. The Departments are aware that under some reimbursement models, one set of negotiated rates is used for provider reimbursement (or comparable derived amounts are used for internal accounting purposes) and another set of rates, referred to in the final rules as an underlying fee schedule rate, is used for determining consumer cost-sharing liability. The Departments view the modification to the In-network Rate File to require public disclosure of an underlying fee schedule rate important to ensuring the public disclosures required through the rules include transparency in the prices used by all plans and issuers in making determinations of consumer cost-sharing liability. The final rules define the underlying fee schedule rates as the rate for an item or service that a plan or issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability from a particular provider or providers, when that rate is different from the negotiated rate. For instance, under certain capitation payments which reimburse a provider a PMPM rate, the PMPM rate would be the negotiated rate. However, the plan or issuer would also have assigned a price for an item or service from that provider for the purpose determining cost-sharing liability; that amount is the underlying fee schedule rate. Therefore, in this example, in the In-network Rate File, the plan or issuer would be required to report the negotiated rate, which in this case is the PMPM rate, and the underlying fee schedule rate used to determine cost-sharing liability.

In the final rules, plans and issuers are required to disclose only those rates that are applicable to their particular reimbursement arrangement model. If a plan or issuer only uses one rate for determining both provider reimbursement and consumer cost-sharing liability, then only that rate would be applicable to the plan or issuer, and therefore required to be disclosed through the In-network Rate File. Where a plan or issuer uses an alternative reimbursement arrangement and does not have a negotiated rate, as defined in the final rules, the plan or issuer would be required to publicly disclose through the In-network Rate File the derived amount, to the extent the plan or issuer generates such an amount in the normal course of business. If a plan or issuer has a negotiated rate or a derived amount but does not also use that applicable rate to make determinations of consumer cost-sharing liability, then the plan or issuer would be required to publicly disclose both the negotiated rate or derived amount and the underlying fee schedule rate used to determine consumer cost-sharing liability.

The Departments note that, while a scenario where a plan or issuer uses both negotiated rates or a comparable derived amount and an underlying fee schedule rate in their operations is more likely to occur under an alternative reimbursement model, it is possible to have both a negotiated rate and an underlying fee schedule rate in an FFS reimbursement arrangement. Such a scenario is possible where a plan that uses a traditional negotiated rate to reimburse a provider for a particular covered item or service and bases participant, beneficiary, or enrollee cost-sharing liability upon a different rate for the same item or service.

Under bundled payment arrangements, plans and issuers may reimburse a provider for multiple services and items under a single billing code. Under these arrangements, plans and issuers should provide a negotiated rate (or comparable derived amount) for that single billing code and list the items and services, including prescription drugs, that are included in that bundle. If a negotiated rate (or comparable derived amount) exists for each item and service, including prescription drugs, within the bundle, the plan or issuer should include the negotiated rate for the total bundle and also include in the In-network Rate File the respective negotiated rates (or comparable derived amount) for all covered items or services included in the bundle.

It is the Departments' understanding that, if the bundled payment arrangement exists to the exclusion of any reimbursement arrangement for the underlying services and items, payers and providers often continue to track, for purposes of informing renegotiation of the bundle, reimbursement at the level of the individual item or service using a derived amount. For the In-network Rate File, plans and issuers with this type of model are required to disclose the negotiated rate for the total

[178] *Id., see also* 78 FR 15410, 15470–71 (Mar. 11, 2013).

bundle and the derived amounts for individual items or services in the bundled payment arrangement. If a derived amount for these purposes does not exist, then plans and issuers would not be required to report a derived amount. Where a plan or issuer uses a derived amount or reasonable estimate in lieu of the negotiated rate, they will be required to add a notation to the machine-readable files indicating that the rate is subject to an alternative payment arrangement.

The Departments acknowledge that there are many different types of capitation models. As stated in the example earlier, for capitation arrangements that reimburse a provider a capitated amount, such as a PMPM, or a similar direct primary care arrangement, the plan or issuer would report the negotiated rate, which in this case is the PMPM amount, and the underlying fee schedule, as applicable. Under certain other capitation models, the provider's capitation amount may be weighted dependent upon certain characteristics of the participant, beneficiary, or enrollee, such as age, gender, or co-morbidities. Plans and issuers with this type of capitation arrangement should provide the base negotiated rate, which is the negotiated rate before adjustments have been made for certain participant, beneficiary, or enrollee characteristics. Plans and issuers using capitation arrangements should notate any entry that represents a capitated amount and list all items and services, including prescription drugs that are covered under a particular capitation amount in the In-network Rate File.

In some cases, a sole capitation arrangement exists, such as staff model HMOs under which services are provided by in-network salaried providers and there are neither negotiated rates nor an underlying fee schedule rate. In this case, plans and issuers are required to include a derived amount in the In-network Rate File. If an applicable rate (a negotiated rate, derived amount, or underlying fee schedule rate) does not exist for an item or service, then plans and issuers are not be required to report pricing information for that particular item or service.

The Departments are aware that some plans and issuers use a partial capitation model where the plan or issuer reimburses providers under a variable FFS amount in addition to a flat capitation amount. The Departments expect plans and issuers using a partial capitation model to make public the FFS negotiated rate as well as the capitation amount. Plan and issuers must also add a notation to the file indicating that a capitation arrangement (or a partially capitated arrangement) exists. For specific items and services where plans and issuers using this model do not have an FFS negotiated rate in addition to a capitation amount (that is, for items and services where they do follow a full capitation model), plans and issuers are required to follow the reporting requirements described for sole capitation arrangements.

Reference-based pricing without a defined network is an arrangement where payers reimburse providers based on a percentage (usually 120 percent to 200 percent) of the Medicare rate, but do not have contractual agreements with providers. The Departments expect there will be no In-network Rate File for this type of arrangement because the plan or issuer does not have in-network providers as defined in the final rules.

By contrast, under a reference-based pricing model with a defined network, payers have contractual agreements to reimburse providers based on a percentage of a different rate that is known or determinable by the parties (usually 120 percent to 200 percent of the Medicare rate), which is subject to change based upon adjustments that can be specific to the participant, beneficiary, or enrollee, such as age, gender, and severity of illness. To represent this type of arrangement, and other provider reimbursement models that are based upon participant, beneficiary, or enrollee-specific adjustments, the final rules clarify that plans and issuers are required to include for each item or service in the In-network Rate File, the base negotiated rate that applies before adjusting for participant, beneficiary, or enrollee -specific characteristics. The negotiated rate in the referenced-based pricing model must be represented as a dollar value that is the result of the calculation of the referenced amount and the applicable reference-based percentage. For example, a plan calculates provider reimbursement using a reference-based pricing model that sets reimbursement to Provider X at 120 percent of the Medicare rate for covered Item A. The reference-based percentage used to determine the base negotiated rate would be 120 percent. In the general course of business, the plan determines the Medicare rate for Item A using participant, beneficiary, or enrollee-specific characteristics, but, because there is no specific participant, beneficiary, or enrollee for purposes of populating the In-network Rate File, the plan or issuer must report the base negotiated rate that would apply prior to application of any participant, beneficiary, or enrollee-specific characteristics. In this example, the Medicare rate for Item A is $150, before applying adjusters for participant, beneficiary, or enrollee-specific characteristics. Therefore, the plan would report a negotiated rate for Item A when received from Provider X of $180 ($150 multiplied by 120 percent) and must include this rate in the In-network Rate File.

Finally, under a reimbursement arrangement that adjusts payments or reconciles provider payments after providing care, such as in many value-based purchasing models, the plan or issuer must also provide the base negotiated rate for the specific provider in the In-network File. For instance, in a value-based purchasing model, payers may adjust negotiated rates for a particular provider if the provider meets certain contractual goals, which may be related to quality, volume, and efficiency of care. The Departments clarify that quality or value dependent weighting factors or adjusters are not required to be included in the negotiated rate made public under the final rules.

As noted earlier in this preamble, nothing in the final rules prevents a plan or issuer from providing supplementary materials, including footnotes, disclaimers, data dictionaries, and other explanatory language, as accompaniments with the machine-readable files. For example, a plan or issuer may choose to provide clarifying information related to how the negotiated rate, if reported as a base negotiated rate, may change depending on quality or value-dependent weighting factors, or participant, beneficiary, or enrollee-specific factors such as the severity of illness, age, or gender. Because base rates unadjusted for participant, beneficiary, or enrollee-specific factors are required to be reported for reference-based pricing arrangements, the Departments note that it is a best practice to include a disclaimer noting that the rate could change subject to participant, beneficiary, or enrollee-specific characteristics.

Some commenters noted that simply listing the negotiated rates without context regarding overall cost would not help consumers make informed decisions. The commenter further noted that consumer decision-making could be harmed if relying on negotiated rate information without context regarding provider billing practices. Other commenters stated that non-negotiated billed charges would be useful as an additional category of pricing information for the public, especially for

the uninsured and those seeking out-of-network care. Another commenter agreed that information on provider-billed charges is important for transparency, but this commenter suggested that providers, not issuers, would be the appropriate source of this information.

As discussed later in this preamble, the Departments are of the view that inclusion of billed charges in the In-network Rate File is unnecessary to achieve the goals of the final rules because in-network providers are not permitted to balance bill participants, beneficiaries, or enrollees as in-network providers have agreed to accept the negotiated rate as payment in full (less any participant, beneficiary, or enrollee cost-sharing liability) for the item or service. However, inclusion of billed charges in the Allowed Amount File will provide meaningful information when coupled with allowed amount information because it will allow consumers to estimate their potential balance billing liability when receiving items and services furnished by out-of-network providers if balance billing is allowed in their state. Therefore, inclusion of billed charges in the In-network Rate File would not provide additional value for consumers.

Moreover, the Departments are of the view that inclusion of the billed charge could be more misleading in the In-network Rate File because the billed charge is very rarely what the consumer or the payer ends up paying for a particular claim and may not have a clear relationship with the negotiated rate or underlying fee schedule. While the Departments agree that inclusion of billed charges in the In-network Rate File would provide another data point for developers in developing the tools, adding billed charges would also increase both the size and complexity of the In-network Rate File. Because it appears that inclusion of this data element could obscure other pricing information and would not increase transparency of actual prices paid by participants, beneficiaries, enrollees, or payers, the Departments decline to add a billed charge data element requirement to the In-network Rate File at this time.

As discussed earlier in this preamble, the final rules finalize a requirement for plans and issuers to associate the pricing information disclosed on each of the three machine-readable files with three data elements that identify the provider and the location where the service was provided: NPI, TIN, and Place of Service Code. For the In-network Rate File, the Departments proposed that the negotiated rate should be the rate that applies to each item or service that is associated with the last date of contract term for each provider NPI. The final rules modify this requirement to clarify that the applicable rates publicly disclosed in the In-network Rate File should be the rates that apply to each item or service that is associated with the last date of the contract term or the contract expiration date for each provider as identified by NPI, TIN, and Place of Service Code.

Allowed Amount File

For the Allowed Amount File, the third content element is historical out-of-network allowed amounts for covered items and services. The proposed rules would require plans and issuers to include in the Allowed Amount File each unique out-of-network allowed amount in connection with covered items or services furnished by a particular out-of-network provider during the 90-day time period that begins 180 days prior to the publication date of the Allowed Amount File. As with the In-network Rate File, where a plan or issuer reimburses providers for an item or service based on a formula or reference based-pricing (such as a percentage of a Medicare reimbursement rate), the plan or issuer would be required to provide the calculated dollar amount of the allowed amount for each provider. Allowed amounts would have to be associated with the provider's NPI, TIN, and Place of Service code.

The Departments designed this reporting requirement to elicit payment data that reflects recent out-of-network allowed amounts in connection with claims for out-of-network covered services. The Departments assumed these amounts would provide payment data that is useful to consumers because it is reflective of the most recent reimbursements. Specifically, the Departments proposed to require reporting based on dates of service within 180 days of the Allowed Amount File publication date to ensure that data is composed of recent claims (rather than older claims from multiple time periods) and to avoid the reporting of payments from inconsistent periods of time. The Departments took the view that payment data from defined periods of time would enable users to make meaningful comparisons across plans and coverage options.

When disclosing an out-of-network allowed amount under this requirement, the Departments proposed to require a plan or issuer to disclose the actual amount the plan or issuer paid to the out-of-network provider, plus the participant's, beneficiary's, or enrollee's share of the cost. For instance, if the out-of-network allowed amount for a covered service was $100, and the plan or issuer paid 80 percent of the out-of-network allowed amount ($80) per the terms of the plan or coverage, so that the participant, beneficiary, or enrollee was responsible for paying twenty percent of the out-of-network allowed amount ($20), the plan or issuer would report an out-of-network allowed amount of $100. This unique payment amount would be associated with the particular covered item or service (identified by billing code) and the particular out-of-network provider who furnished the item or service (identified by NPI, TIN, and Place of Service Code).

The Departments clarify that, in contrast to the In-network Rate File, no special considerations for reporting alternative payment arrangements are necessary for the Allowed Amount File because plans and issuers are required to disclose actual amounts paid in the Allowed Amount File and can therefore account for retrospective reconciliations and weighting factors that require special considerations. For the Allowed Amounts File, the Departments expect plans and issuers that reimburse in-network providers using alternative payment methodologies to adhere to the standard requirement of providing allowed amounts on historical claims paid to out-of-network providers for each covered item or service during the applicable reference period. Plans and issuers generally do not reimburse out-of-network providers, with whom they do not maintain a contractual relationship, under an alternative payment arrangement. However, to the extent a plan or issuer uses an alternative payment arrangement to reimburse out-of-network providers, the plan or issuer would still be required to report the allowed amount paid to the out-of-network provider. The Departments will address, through the technical implementation guidance, how a plan or issuer will be able to represent data in the Allowed Amount File, as necessary. The Departments anticipate that plans and issuers that reimburse providers using reference-based pricing without a network will have larger than average Allowed Amount Files, as all of the payments would be made to out-of-network providers and would therefore be subject to this requirement.

Some commenters supported disclosure of the ''historical'' payments made by plans and issuers to out-of-network providers. One commenter acknowledged that bulk de-identified data that informs a consumer of historical out-of-network allowed

amounts may be relevant to consumer decision-making regarding a particular provider or procedure. One commenter pointed out that if the Departments failed to adopt this requirement in tandem with the In-network Rate File requirement, providers could withdraw from networks to avoid transparency requirements.

By contrast, other comments were less supportive of the Allowed Amount File proposal. Several commenters stated that publishing historical out-of-network allowed amounts would not meet the Departments' purported goal of helping consumers understand costs and would possibly lead to consumer confusion. Commenters expressed concern that the Allowed Amount File could result in consumers receiving misleading information, which would lead to negative financial consequences for consumers because the file would not provide all information about potential out-of-network costs, such as those that could be incurred through balance billing, if allowed in their state. One commenter stated that inclusion of billed charges would allow the development of open source charge schedules. One commenter pointed out that the information in the machine-readable files would not address scenarios where a participant, beneficiary, or enrollee receives out-of-network care in an in-network facility. Still other commenters expressed concerns about the reliability of the data as historical allowed amounts with out-of-network providers may not provide an accurate portrait of future cost information because issuers do not have contracts with out-of-network providers. Similarly, another commenter stated that health plans should not be responsible for publishing rates for providers with whom they do not maintain a relationship.

One commenter recommended the Departments withdraw the proposal, making the argument that small health plans are unlikely to have a sufficient number of claims billed for any one procedure from a particular provider to make the file meaningful. In lieu of requiring the Allowed Amount File, another commenter suggested the Departments instead place the onus on out-of-network providers or suppliers to provide consumers with information about the costs of their services.

The Departments continue to be of the view that release of this information is appropriate and necessary to empower consumers to make informed decisions about their health care, spur competition in health care markets, and to slow or potentially reverse the rising cost of health care items and services. As noted earlier in this preamble and in the preamble to the proposed rules, limiting access to data to a subset of consumers would not promote the transparency goals of PPACA and the final rules, and would reduce the potential for the final rules to drive down health care costs by increasing competition. If the Departments were to eliminate the Allowed Amount File requirement or reduce its scope, it would significantly reduce the benefits of the final rules for uninsured consumers and insured consumers evaluating out-of-network treatment options.

The information in the Allowed Amount File, especially as filtered through innovative platforms and tools, will help consumers make more informed decisions regarding changes to their health coverage (for example, the purchase of new coverage or switching to a new plan). Furthermore, this information may help insured consumers make more informed health care decisions when seeking out-of-network treatment; and may help uninsured consumers make health care decisions and potentially allow them to negotiate more effectively with providers. Finally, the creation of Allowed Amount Files may help researchers and regulators monitor plan benefit design and help spur innovation.

While there is some potential for some consumers to be confused by the information in the Allowed Amount Files, the Departments do not agree that the files will provide misleading information to consumers. The Departments expect most consumers to access this information through tools created by third-party application developers and other stakeholders, which will be able to provide additional context for the average consumer.

The Departments proposed to require plans and issuers to report out-of-network allowed amounts for services furnished at least 90 days in the past to help ensure the availability of reasonable volumes of out-of-network allowed amount data in the Allowed Amount File. The Departments expressed the view that a 90-day lag between the end of a reporting period and the publication of required out-of-network allowed amount data will allow plans and issuers sufficient time to adjudicate and pay claims from out-of-network providers for the relevant reporting period. Claims processing times may vary between plans and issuers, and external factors may increase processing timelines. For example, the Departments noted in the proposed rules that many out-of-network providers do not send claims directly to plans and issuers but instead require participant, beneficiary, or enrollee to file out-of-network claims. This could mean that an out-of-network claim may not reach a plan or issuer for 6 to 12 months after a service is rendered. Such delays could negatively affect the volume of out-of-network allowed amount data and the ultimate usefulness of this data. For this reason, the Departments sought comment regarding whether requiring plans and issuers to report out-of-network allowed amounts for items and services furnished at least 90 days in the past is sufficient to ensure the proposed disclosures will yield sufficient volumes of historical data to be useful to consumers who wish to shop for services based on price. The Departments requested comment on whether there should be more time between the end of the reporting period and publication of the data, such as 120 days, 180 days, or longer, which would increase the likelihood that out-of-network claims from the relevant reporting period have been adjudicated and paid by the time of publication.

The Departments did not receive comments directly in response to this comment solicitation and are finalizing the Allowed Amount File historical lookback period as proposed. The final rules, therefore, adopt a requirement for the Allowed Amount Files to include data for the 90-day period beginning 180 days before the file publication date. For example, a file published on June 30, 2021, should include data for a 90-day period beginning on January 1, 2021. The Departments will monitor the implementation of this requirement for the Allowed Amount Files and may revisit the lookback period if the 90-day reporting period beginning 180 days before file publication fails to yield sufficient out-of-network data on allowed amounts.

The Departments specifically sought comment on whether the required disclosures of historical out-of-network allowed amounts would provide useful information that can assist consumers in locating services at an affordable cost, or whether there could be additional information that would be both useful to anticipated users and practical for plans and issuers to disclose for this purpose. For instance, the Departments stated in the preamble to the proposed rules that the Departments considered requiring plans and issuers to disclose amounts out-of-network providers have charged participants, beneficiaries, and enrollees for covered services in the Allowed Amount File. The Departments noted they understood that such charged amounts would be included in any

claim for out-of-network benefits and could be helpful to consumers shopping for services based on price. The Departments sought comment on this data element.

As summarized earlier in this preamble regarding the In-network Rate File, some commenters who supported the inclusion of non-negotiated billed charges in the In-network Rate File also supported inclusion of billed charges in the Allowed Amount File. These commenters noted that billed charge information would be especially useful for the uninsured or those seeking out-of-network care. Another commenter agreed that information on provider-billed charges is important for transparency, but this commenter stated that providers, not issuers, would be the appropriate source for this information.

Regarding these comments, the Departments agree that that a billed charges data element is important to ensure that the public disclosures required through the out-of-network Allowed Amount File are as useful to consumers as possible, including in the scenario where an insured consumer receives items or services from an out-of-network provider. Although the Departments are aware that the amount an out-of-network provider will ultimately balance bill (if allowed in their state) a consumer for an item or service does not always equal the difference between the billed charge and the allowed amount, the Departments are of the view that this information would aid consumers in understanding their potential out-of-pocket liability. In the jurisdictions that do not prohibit or limit balance billing, information on billed charges could aide consumers in their health care decision-making as it is possible that consumers may choose to receive or forgo a particular item or service from a particular provider based on the additional out-of-pocket liability they could be expected to pay through a balance billing charge from a provider.

Consumers may be able to shop for a particular out-of-network provider based on total cost of an item or service. For example, in a state that allows providers to balance bill, a consumer has a coinsurance of 40 percent for Service X when Service X is furnished by an out-of-network provider. Out of network Provider A's billed charge for Service X is $200, and the consumer's plan allows an amount of $100 to be paid to the provider. Therefore, the consumer is responsible for a coinsurance amount of $40 ($100 allowed amount multiplied by the consumer's 40 percent coinsurance) and the consumer may be balance billed an additional $100 ($200 billed charge minus the $100 allowed amount). In comparison, out-of-network Provider B's billed charge for Service X is $120 and the consumer's plan allows the same amount of $100 to be paid to the provider. If the consumer receives Service X from Provider B, they will be responsible for the same coinsurance amount of $40 ($100 allowed amount multiplied by the consumer's 40 percent coinsurance). However, if the consumer receives Service X from Provider B, the consumer may only be balance billed $20 ($120 billed charge minus $100 allowed amount), which would be an $80 savings to the consumer compared with receiving the Service X from Provider A. Note that this example assumes that both Provider A and Provider B will balance bill consumers, which is not always true even in states that allow balance billing. Consumers should also contact providers to inquire whether they will balance bill before making health care purchasing decisions using this information. Therefore, with information on both allowed amounts and billed charges, the consumer may choose to receive Service X from Provider B because their total out-of-pocket costs will likely be lower.

The Departments note that it is possible that plans and issuers will populate the Allowed Amount File with multiple billed charges for the same item or service furnished by the same out-of-network provider. If this is the case, the billed charge in the Allowed Amount File will present an expected range and give consumers access to a reasonably accurate estimate of how much they can expect to be balance billed by an out-of-network provider, but the billed charge cannot provide to the consumer the exact amount they can expect to be balance billed when receiving items and services furnished by the out-of-network provider.

For these reasons, the Departments are of the view that inclusion of the billed charges in the Allowed Amounts File will help provide a more complete picture of the full amount a provider could receive for a particular item or service, either from plans and issuers or directly from a participant, beneficiary, or enrollee. Furthermore, the Departments are of the view that requiring this information is consistent with the goal of providing consumers an understanding of their potential out-of-pocket liability in advance, similar to an EOB provided in advance, as billed charges are included on a participant's, beneficiary's, or enrollee's EOB and are often the first data available for understanding a participants, beneficiary's, or enrollee's out-of-pocket liability.

The Departments are aware that plans and issuers have information regarding providers' billed charges, even if they do not necessarily have information regarding specific balance billing amounts. The Departments are therefore of the view that the inclusion of billed charges in the Allowed Amount File will not substantially increase the burdens of the final rules. Nonetheless, the Departments are aware that adding billed charges will also increase both the size and complexity of the Allowed Amounts File. The Departments do not intend to increase the burden of developing and maintaining these files unless the inclusion of the additional data element is essential for providing meaningful pricing information to consumers. Because it is the Departments' view that this data element will increase transparency of actual prices paid by participants, beneficiaries, enrollees, and payers, the Departments are finalizing the Allowed Amounts File with the modification to add billed charges as an additional data point required to be disclosed through the file.

The final rules define billed charges as total charges for an item or service billed to a plan or issuer by a provider. Plans and issuers are required to publicly disclose billed charges associated with each unique allowed amount that would be required under the final rules. The final rules further clarify that plans and issuers must report each unique combination of allowed amounts and billed charges for each out-of-network provider, and their associated Place of Service Code, provider NPI, and provider TIN. For example, an out-of-network provider (under a single NPI, TIN, and Place of Service Code) submits 25 claims (or any other number of claims to meet the 20 unique claim threshold requirement discussed in more detail later in this preamble) to a plan or issuer for the service Y. The 25 claims have three [179] different billed charges ($100, $150 and $200) and two different allowed amounts ($50 and $150) for item Y. The plan or issuer should have one entry that represents each unique combination of billed charges and allowed amounts submitted by the out-of-network provider. Therefore, in this example, the Departments would expect

[179] The Departments note that it is possible for a provider to have different allowed amounts for the same item or service covered by the same out-of-network provider because the plan or issuer does not have a contractual relationship with that out-of-network provider, by definition. For similar reasons, it is also possible for the billed charged submitted by the same out-of-network provider to for the same item or service to be variable.

the plan or issuer to represent in the Allowed Amounts File no fewer than three unique entries, and no more than six unique entries for item Y from this out-of-network provider. For example:

- Entry A has a billed charge of $100 and an associated allowed amount of $50;
- Entry B has a billed charge of $150 and an associated allowed amount of $50;
- Entry C has a billed charge of $200 and an associated allowed amount of $50;
- Entry D has a billed charge of $100 and an associated allowed amount of $150;
- Entry E has a billed charge of $150 and an associate allowed amount of $150;
- Entry F has a billed charge of $200 and an associated allowed amount of $150.

The Departments do not expect to see 25 different entries, unless they represented 25 distinct combinations of billed charges and associated allowed amounts from the out-out network provider for Item Y.

In the Allowed Amount File, the file structure is envisioned as a parent/child data relationship, where certain data elements are included under or belong to other data elements, as a child to a parent. In the Allowed Amount File, the billed charge data element would serve as a child to the parent allowed amount element. Therefore, under each unique allowed amount for a particular item or service from a particular provider, the amount of each provider-billed charge is listed as a unique dollar amount.

One commenter requested the Departments clarify what is meant by ''allowed amounts for covered items or services furnished by particular out-of-network providers,'' questioning whether through inclusion of the word ''particular'' the Departments intended to reference specialized out-of-network providers upon which plans and issuers might place coverage limitations. The Departments clarify that inclusion of the word ''particular'' as a modifier of ''out-of-network providers'' was not intended to be a reference to specialized out-of-network providers upon which plans and issuers might place coverage limitations. Rather, use of the word ''particular'' indicates that Allowed Amount Files must include the historical allowed amounts for covered items and services furnished to each out-of-network provider to whom such payments were made during the reference period. The Departments clarify that under the final rules, and as contemplated in the proposed rules, plans and issuers are expected to include historical allowed amounts for every covered item or service furnished by each out-of-network provider so long as the unique claims threshold for the out-of-network provider is met.

The Departments further clarify that plans and issuers are only required to include in the Allowed Amount File those covered items and services furnished by an out-of-network provider for which the plan or issuer has adjudicated claims and determined it will pay an allowed amount. If the plan or issuer has not adjudicated claims and determined it will pay an allowed amount for items or services furnished by an out-of-network provider, the plan or issuer is not required to include those allowed amounts or billed charges in the Allowed Amount File.

In response to the comment that the information in the files would not address the scenario where a participant, beneficiary, or enrollee receives out-of-network care in an in-network facility, the Departments clarify that the expectation is that this information would be captured in the Allowed Amounts File. If a participant, beneficiary, or enrollee receives out-of-network care, even if the facility is in the participant's, beneficiary's, or enrollee's network, the provider will generate a claim and send a billed charge to the payer that will establish an allowed amount for the claim; the Departments expect this allowed amount to appear in the Allowed Amounts File in this scenario. As noted elsewhere in this preamble, the Departments will provide technical implementation guidance (as well as individualized technical assistance, as needed) to ensure that plans and issuers are able to make public the disclosures required through the final rules.

The Departments do not agree with the commenter who asserted that, because some small health plans will not have a sufficient number of any one procedure from a particular provider to make the file meaningful, the Allowed Amount File requirement should be withdrawn. The relevant commenter did not provide a number of claims that it believed would make the file meaningful. In contrast, the Departments are of the view that the files will be meaningful to the public regarding all covered items and services from a particular provider regardless of the specific numbers of claims at issue, even if a particular provider bills relatively few claims to a particular plan or issuer. As discussed elsewhere in this preamble, for privacy and security reasons, the Departments are requiring disclosure for all covered items and services from a particular provider that meets the unique claims threshold established by the final rules. If a small health plan does not have sufficient claims for a covered item or service to meet the unique claims threshold for a particular provider, then that health plan is not permitted to publicly disclose information for that particular item or service paid to the particular provider. The Departments are of the view that most health plans and issuers will meet the unique claims threshold for a large proportion of items, services, and providers to make the files sufficiently meaningful to justify this requirement.

In the preamble to the proposed rules, the Departments noted that providing this information could raise health privacy concerns. The Departments are committed to protecting PHI and other sensitive information. To address these privacy concerns, as discussed in this preamble, the Departments proposed that plans and issuers would not be required to provide out-of-network allowed amount data in relation to a particular provider and a particular item or service when compliance would require a plan or issuer to report out-of-network allowed amounts to a particular provider in connection with fewer than 10 different claims for payment. The Departments also noted that disclosure of such information would not be required if compliance would violate applicable health information privacy laws. In addition to proposing this exemption, the Departments proposed to require plans and issuers to include only unique out-of-network allowed amounts to mask the total episodes of care for a particular provider and item or service. In the proposed rules, the Departments expressed the view that these mitigation strategies, in addition to flexibilities proposed to allow the aggregation of reported data (as described later in this preamble), were sufficient to protect patients from identification based on information in the Allowed Amount File. The Departments solicited comment on whether additional privacy protections would be required.

The Departments specifically requested comment on whether a higher minimum claims threshold, such as a threshold of 20 claims, would better mitigate privacy concerns and minimize complexity in complying with Federal or state privacy laws without compromising the integrity of the compiled information. The Departments also sought comment on additional approaches that could decrease the potential for aggregated health information that would be disclosed under the proposed rules to be

identified, especially with respect to smaller group health plans.

In response, some commenters expressed concerns about maintaining HIPAA protections on the Allowed Amount File due to the small number of claims associated with specific services for out-of-network providers. Several commenters stated the threshold of 10 unique claims to require public disclosure of unique historical allowed amounts would be too low to protect consumers' PHI. One commenter requested that the Departments clarify how they arrived at the 10 claims threshold. Some commenters recommended different minimum thresholds. Some commenters recommended a minimum threshold of 50 claims. On the other hand, other commenters did not support increasing the threshold, noting that the files do not contain identifiable data and so would not pose a risk. One commenter stated that the files should be released including the lowest number of claims necessary to achieve the goal of protecting participant, beneficiary, and enrollee privacy and recommended keeping the proposed threshold of 10 claims. Another commenter requested that the Departments not make the threshold any higher, and even consider lowering the cutoff to five claims, to maintain access to price transparency data for rural Americans.

Based upon comments received the final rules adopt a 20 unique claim threshold. The Departments are of the view that the 20 unique claim threshold balances the concerns expressed by commenters who suggested the Departments increase the threshold to 50 claims with the concerns of commenters who expressed the opinion that the proposed 10 claim threshold (or an even lower threshold) would be sufficient to ensure the files include a meaningful amount of data. The Departments are of the view that 20 unique claims are sufficient to balance the privacy concerns against the needs for transparency through the Allowed Amounts File. This 20 unique claim threshold is more stringent than CMS' cell size suppression policy, which requires cells containing values of 1 through 10 to be suppressed in CMS data sets.[180] Increasing the unique claim threshold from 10 to 20 claims will not significantly reduce the amount of data that are required to be made public through the Allowed Amount File. However, if the Departments were to increase the unique claim threshold to 50 claims, as suggested by some commenters, the Departments are concerned that this could significantly reduce the amount of data that are required to be made public through the Allowed Amount File, which could undermine the goal of price transparency.

The Departments are of the view that increasing the unique claim threshold from 10 to 20 claims will better balance the policy goal of maximum transparency with the need to protect participants, beneficiaries, and enrollees from the possibility of being re-identified through the data included in the Allowed Amount File. In addition to this strategy, the Departments expect that the flexibility discussed later in this preamble under the special rule to permit aggregation of reported data will help protect participants, beneficiaries, and enrollees from identification based on information in the Allowed Amount File. Finally, the Departments reiterate that the disclosure of the information is not required if disclosure would violate applicable health information privacy laws. The Departments note that this exception does not mean that these disclosures are not required where a law that would otherwise prohibit the disclosure permits disclosure if required by law.

Prescription Drug File

The Departments finalize negotiated rates for prescription drugs as the third content element in the Prescription Drug File. The Departments received several comments related to whether negotiated rates for prescription drugs should be disclosed through the machine-readable files, and if so, which price or prices related to prescription drugs should be required to be included. Many commenters provided general support for the public release of negotiated rates for prescription drugs. One commenter asserted that releasing negotiated rates for prescription drugs would result in lower costs for health plans and consumers, which could lead to a reduction in manufacturer discounts of upwards of three percent.

Several commenters did not support disclosure of negotiated rates for prescription drug prices through the machine-readable files. Commenters recommended that the In-network Rate File should not include prescription drugs for several reasons. These reasons include: The complexity of prescription drug pricing (prices are determined by a formula that is determined at the point-of-sale and can change on a daily basis; the information would not be relevant to consumer decision-making; and the existence of established drug pricing tools that provide support for consumer decision-making. Some commenters stated that the unique nature of prescription drug pricing would make the release of negotiated rates difficult and further noted that the rates negotiated between PBMs and pharmacies are considered confidential. Another commenter stated that the Departments should only require disclosure of prescription drug prices when the information disclosed is directly related to the cost a plan participant, beneficiary, or enrollee would need to pay out of pocket so as not to undermine group health plans' and health insurance issuers' ability to negotiate lower drug costs. Some commenters claimed that plans and issuers have no control over prescription drug costs and may not be able to provide this information. Instead, commenters asserted that information related to prescription drug costs should come from PBMs or prescription drug manufacturers.

In 2018, retail prescription drug spending represented approximately nine percent ($335 billion) of overall health spending.[181] In 2017 large group health plans and issuers accounted for the largest share of prescription drug spending amongst other payers, despite generally having a younger and healthier population than public payers.[182] The Departments maintain that plans and issuers have an essential role,[183] and vested interest in controlling prescription drug spending. Moreover, as prescription spending continues to rise,[184] so does the trend of prescription rebates.[185] According to

[180] The CMS Cell Size Suppression Policy is outlined on the CMS website at the following location: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.*

[181] ''National Health Expenditures 2018 Highlights.'' Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/files/document/highlights.pdf.*

[182] Cubanski, J., and Rae, M. ''How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?'' Kaiser Family Foundation. May 20, 2019. Available at: *https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/.*

[183] ''How are prescription drug prices determined?'' American Medical Association. April 9, 2019. Available at: *https://www.ama-assn.org/delivering-care/public-health/how-are-prescription-drug-prices-determined.*

[184] ''National Health Expenditure Projections 2019–28.'' Office of the Actuary. Centers for Medicare & Medicaid Services. March 24, 2020. Available at: *https://www.cms.gov/files/document/national-health-expenditure-projections-2019-28.pdf.*

[185] According to the Academy of Managed Care Pharmacy, a prescription drug rebate is a monetary amount returned to a payer from a prescription drug manufacturer based on pharmaceutical use by a covered person or purchases by a provider. ''AMCP Guide to Pharmaceutical Payment Methods, 2013

Continued

surveyed health plan and PBM personnel, PBMs passed through 78 percent of manufacturer rebates to health plans in 2012 and 91 percent in 2016.[186] And while some plans and issuers may use these rebates to dampen premium increases,[187] there remains an unclear prescription drug supply chain that masks the true costs of prescription drugs. The Departments are of the view that it would not advance the goals of the final rules to exclude a category of items and services that comprises such a significant proportion of health care spending.

The Departments agree that prescription drug pricing is complex but are of the view that complexity is not a valid reason for inaction. There are many different players in the prescription drug supply chain that may have some control over costs, including plans and issuers, manufacturers, wholesalers, pharmacies, and PBMs.[188] As commenters stated, it is often the case that PBMs negotiate the price of a prescription drug for a plan or issuer based on a contract the plan or issuer maintains with the PBM; however, it is ultimately the plan or issuer who is responsible for deciding how the costs of prescription drugs are passed along to a participant, beneficiary, or enrollee. The Departments, therefore, are of the view that plans and issuers are aware of the negotiated rate for a prescription drug for which their participants, beneficiaries, or enrollees may have cost-sharing liability, or can be informed of this negotiated rate by their contracted PBM.

The Departments do not agree that prescription drug pricing information, such as negotiated rates, will confuse consumers. As discussed elsewhere in this preamble, the Departments recognize that the information included in the machine-readable files may not be easy for an average consumer to navigate and expect that third-party developers will use this information to make tools available that make this information more useful for the average consumer.

The Departments agree with commenters who acknowledged the existence of many tools that provide prescription drug prices. However, the Departments are of the view that existing prescription drug pricing tools are insufficient as they lack competitive pricing information across all PBMs, and health plans and issuers.[189] Once prescription drug pricing is made more fully available, health care providers will have greater opportunity to factor pricing information into their prescribing decisions. Many health care providers benefit financially when they can reduce costs and improve their patients' medication adherence.[190] This benefit to providers can also have a significant impact on overall health care spending.

For these reasons, and those discussed more fully below, the Departments are finalizing, with modifications from the proposed rules, requirements to disclose pricing information for prescription drugs through a machine-readable file. However, reflecting the unique attributes of prescription drug pricing, the final rules respond to comments by adopting requirements that are more detailed than what was included in the proposed rules, including the inclusion of a third machine-readable file for prescription drug pricing information.

The final rules require plans and issuers to produce a third machine-readable file for reporting prescription drug pricing information, the Prescription Drug File, whereas the proposed rules would have required plans and issuers to include negotiated rates for covered prescription drugs in the In-network Rate File. The Departments have made this change to ensure that prescription drug pricing information is produced in a manner that is most useful to the public. As noted earlier in this preamble, there are upwards of 100,000 NDCs for prescription drugs. Divorcing negotiated rates for prescription drugs from negotiated rates for other items and services allows the pricing information for medical items and services to be discernible from pricing information for prescription drugs. Further, a PBM may administer pharmacy benefits for a plan or issuer in addition to any other services it may provide to a plan or issuer. Therefore, keeping prescription drugs pricing data separate from pricing data for other items and services is generally better aligned with plan and issuer operations and will reduce the burden associated with combining data from different sources. As discussed in the Information Collection Requests (ICR) section of this preamble, the Departments estimate that the Prescription Drugs File requirement will not add significantly to the development and maintenance costs of the machine-readable files because the cost and burdens related to prescription drugs will largely be transferred from the In-network Rate File to the Prescription Drug File. Additionally, the Departments anticipate that removal of prescription drugs from the In-network Rate Files will significantly reduce the size of those files, which could reduce the costs associated with maintenance and storage of each individual file. The Departments are of the view that removing prescription drugs from the In-network Rate File and requiring this information to be included in a separate Prescription Drug File is consistent with the Departments' goal of separating fundamentally different types of data into distinct files. Because, as many commenters observed, prescription drug prices are unique, the Departments are of the view that this information would be more appropriately represented through a third machine-readable file. Furthermore, the updated machine-readable file structure will support consumers, researchers, and third-party developers in reviewing, ingesting, aggregating, and analyzing the data.

The Disclosure of Prescription Drugs Pricing Information

Under the proposed rules, group health plans and health insurance issuers would be required to publicly disclose negotiated rates in the In-network Rate file. The Departments defined negotiated rates in the proposed rule as the amount a group health plan or health insurance issuer, or a third party on behalf of a group health plan or health insurance issuer, has contractually agreed to pay an in-network provider for covered items and services, pursuant to the terms of an agreement between the provider and the group health plan or health insurance issuer, or a third party on behalf of a group health plan or health insurance issuer. As discussed in the Definitions section of this preamble, the final rules adopt this definition as proposed, with modifications to provide additional clarity.

In the preamble to the proposed rules, the Departments acknowledged that cost-sharing liability for prescription drugs is often based on an amount other than the negotiated rate, such as manufacturer list prices or undiscounted list prices such as AWP or

Update.'' Available at: *https://www.amcp.org/sites/default/files/2019-03/Full-Pharmaceutical-Guide-%283.0%29.pdf*; *see also* ''The Prescription Drug Landscape, Explore.'' PEW Charitable Trusts. March 8, 2019. Available at: *https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.*

[186] *Id.*

[187] *Id.*

[188] ''How are prescription drug costs really determined?'' Biotechnology Innovation Organization. Available at: *https://www.drugcostfacts.org/prescription-drug-costs.*

[189] Galewitz, P. ''Doctors Slow To Adopt Tech Tools That Might Save Patients Money On Drugs.'' NPR. July 5, 2019. Available at: *https://www.npr.org/sections/health-shots/2019/07/05/738283044/doctors-slow-to-adopt-tech-tools-that-might-save-patients-money-on-drugs.*

[190] *Id.*

WAC. The Departments further acknowledged that, because of the application of rebates and other discounts, the inclusion of just the negotiated rate for prescription drugs could mislead consumers because the rate paid by the plan could ultimately be lower than the price paid by the consumer at the point-of-sale, as it is the Departments' understanding that these rebates and other discounts typically are not passed on to the consumers at the point of sale. The Departments expressed the concern that including only the negotiated rate for prescription drugs used to determine cost-sharing liability could perpetuate the lack of transparency surrounding prescription drug pricing. To this end, the Departments solicited comment on which pricing information related to prescription drugs should be disclosed.[191]

Despite the Departments' concerns regarding negotiated rates for prescription drugs outlined in the preamble to the proposed rules, commenters responded that negotiated rates, in addition to other information, are an important data point necessary to achieving useful transparency into coverage and out-of-pocket costs for prescription drugs. Several commenters recommended that the machine-readable file include both the negotiated price and the undiscounted ''list'' price, upon which coinsurance and deductibles are often based, in order to promote competition. Other commenters suggested that plans and issuers should disclose to enrollees when they do not pass through manufacturer rebates and discounts at the point-of-sale or factor these amounts into enrollee cost sharing. Another commenter recommended the Departments consider requiring a ''net price'' for prescription drugs rather than the negotiated rates. This commenter stated that, it is vital that this ''negotiated rate'' also include the ''net price'' (which accounts for all price concessions, including direct and indirect remuneration fees (DIR) and/or similar policies/terminology, such as ''true up'' practices under employer-sponsored and private plans to accurately estimate participant, beneficiary, and enrollee cost-sharing liability for prescription drugs). One commenter noted that if the public disclosure did not include information related to rebates, the file could be misleading and could lead to a continuing overemphasis on prescription drug list prices without recognition of the role played by rebates.

Another commenter recommended that the Departments allow plans and issuers to report the most appropriate available price type based on the plan's benefit design. This commenter suggested that plans should also be required to identify the price reported, such as AWP or WAC or the contracted pharmacy reimbursement amount (for example, the Part D negotiated price).

The Departments have closely reviewed the comments to determine the prescription drug pricing information plans and issuers should provide in the Prescription Drug File in order to achieve the goals of transparency. Based on this review, the final rules are adopting as content element three for the Prescription Drug File a requirement for plans and issuers to publicly disclose two amounts for prescription drugs in the Prescription Drug File: The negotiated rate and the historical net price.

Prescription Drug Negotiated Rate Disclosure

As evidenced by the comments and the Departments' independent research, there is wide variability in how negotiated rates are assigned for prescription drugs. For instance, some commenters noted that negotiated rates for prescription drugs include rebates, price concessions, and other ''true-ups, while others likened the negotiated rates to the undiscounted list price used for determining cost-sharing liability. Therefore, plans and issuers may use varying types of prices when reimbursing providers for prescription drugs. For example, it is the Departments' understanding that for generic prescription drugs, the Maximum Allowable Cost (MAC)—an amount the plan or issuer uses as the maximum amount they will pay for a particular prescription drug product—may be the amount that plans and issuers use to pay providers for a prescription drug. Plans and issuers may reimburse providers for other prescription drugs using a UCR amount or an amount based on the undiscounted list price, such as AWP or WAC. It is the Departments' understanding that contracts negotiated between plans and issuers (or their contracted PBM) and providers generally do not include specific negotiated rates for prescription drugs, but instead include formulas that determine the type of price that will be used to reimburse providers for a particular prescription drug product. The negotiated rate may differ by drug or class of drug in the contract as the lesser of several types of prices based on one of the benchmarks described above—that is, WAC, AWP, MAC, or UCR. Because prices for prescription drugs can fluctuate on a daily basis, the price that is used to reimburse the provider can also fluctuate based on application of the contract terms.

In addition to better appreciating the wide variability in how negotiated rates are assigned, the Departments also now understand based on comments and independent research, that, contrary to the Departments' understanding as explained in the preamble to the proposed rule, no matter what benchmark or formula is used to determine the negotiated rate, the negotiated rate is frequently also the rate upon which cost-sharing liability is based for prescription drugs.

Based on the circumstances described above, the Departments therefore agree with commenters that a certain amount of flexibility is required for plans and issuers as it relates to the benchmarks and inputs required for the disclosure of negotiated rates for prescription drugs. To allow for flexibility, as proposed, the final rules do not assign a benchmark or necessary inputs to the definition of negotiated rates. The final rules include a broad definition for negotiated rates to mean the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a TPA or PBM.

As noted above, the negotiated rate can be one of several different rates and can fluctuate on a daily basis depending on the terms of the contract between plans or issuers (or the PBM for the plan or issuer) and the provider, which

[191] The Departments note that this discussion in the preamble to the proposed rules occurred in the context of the third content element (negotiated rates) for the internet-based self-service tool. However, as negotiated rates were a proposed content element for the machine-readable files, the Departments are of the view that the comments received regarding negotiated rates in the context of the internet-based self-service tool are equally applicable to the prescription drug disclosures plans and issuers are being required to make through the machine-readable files. The definition of ''negotiated rate'' for prescription drugs applies to both the internet-based self-service tool and machine-readable file provisions. Regarding the machine-readable files, the Departments proposed that plans and issuers be required to include in-network negotiated rates and out-of-network allowed amounts for all covered items and services. In the Departments' view, the use of the same term regarding both requirements underscores the relevance of these comments to all disclosure requirements applicable to items and services, including those applicable to prescription drugs. Furthermore, several commenters did not clearly separate their comments regarding the internet-based self-service tool and the machine-readable files and provided broad comments that applied to all relevant sections of the proposed rules.

includes pharmacies and other prescription drug dispensers. Therefore, the Departments clarify that, where a plan or issuer uses a formula as described above to determine the rate that will be used to reimburse providers for a prescription drug, the negotiated rate that should be included in the Prescription Drug File should be the rate that would be used by the plan or issuer to reimburse providers on the date that the file is extracted.

Notably, the final rules do not finalize a requirement to include the manufacturer list price, as contemplated in the proposed rules. The manufacturer list price is a manufacturer-specified metric for drug prices that is commonly used by both Federal and commercial health care programs as a benchmark for negotiated rates. The manufacturer list price in this context is often the WAC, which is defined in statute as, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of pricing data with respect to a drug or biological.[192]

Like negotiated rates, the list price does not include discounts, dispensing fees, rebates, or other retrospective pricing adjustments. The manufacturer list price is not plan- or issuer-specific. If the Departments were to require plans and issuers to include the manufacturer list price in the Prescription Drug File, the information included in the files would be the same or similar across all plans and issuers. Further, manufacturer list price information is already aggregated, available through several companies, and could be incorporated into third party applications to be made accessible to consumers. WAC prices for drugs and biologics are collected and published by several companies, including First Databank and Medi-Span. Additionally, CMS publishes a monthly National Average Drug Acquisition Cost (NADAC), which provides a national benchmark for the prescription drug prices paid by retail pharmacies.[193] Because information on manufacturer list prices would be largely redundant across plans and issuers, and because this information is publicly available through other existing resources, the Departments concluded this information would be of limited value for the public.

The Departments do not intend to increase the burden of developing and maintaining the machine-readable files unless the inclusion of the additional data element is essential to provide meaningful, transparent pricing information to the public. Inclusion of the manufacturer list price would not significantly advance transparency as this information is already available publicly, and it would increase the burden of developing the Prescription Drug File. The Departments expect that third-party developers will access and incorporate publicly available databases, such as those including manufacturer list pricing information, where that information is relevant to providing meaningful information to consumers.

The Departments are of the view that it is important for transparency for negotiated rates to be included in the Prescription Drug File. Consumers, both insured and uninsured, can use this information to better understand the cost of prescription drugs and to advocate for less expensive alternatives. The Departments are also of the view that making the negotiated rate public in a manner that is highly visible to consumers, researchers, innovators and regulators could potentially place pressure on manufacturers to lower their list prices, which could, in turn, lower negotiated rates upon which consumer cost-sharing liability is based.

Nonetheless, as stated in this preamble and in the preamble to the proposed rules, requiring disclosure of only the negotiated rate for prescription drugs could perpetuate the lack of transparency surrounding prescription drug pricing. As commenters noted, the negotiated rate is not generally tied to the amount a plan or issuer will ultimately pay for the prescription drug or prescription drug service due to the use of post-point-of-sale rebates, discounts, and other price concessions that reduce the price that plans and issuers pay for prescription drugs. To address this issue and to introduce greater transparency surrounding prescription drug pricing, in response to comments, the Departments are also finalizing a requirement that plans and issuers must publicly disclose historical net prices, as discussed in detail below.

Prescription Drug Historical Net Price Disclosure

For purposes of the final rules, historical net price means the retrospective average amount a plan or issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. Net price is the price for a prescription drug after discounts are deducted, and is paid at different points in the prescription drug distribution chain (for example, the plan or issuer to the pharmacy, the pharmacy to a wholesaler, and the wholesaler to the manufacturer).[194] For the purposes of the final rules, the Departments are concerned with the price ultimately paid by a plan or issuer to a drug manufacturer.[195] Essentially, rebates, discounts, chargebacks, fees, and other additional price concessions are adjustments made after the point-of-sale that affect the total price paid by the plan or issuer (or through a contract with the PBM) to the manufacturer for a prescription drug product. As a general matter, a price concession is a discount or rebate available to a purchaser of a product or service, wherein the discount or rebate is conditioned upon the purchaser complying with the contractual terms of the rebate or discount offer.[196] More specifically, a rebate is an amount that the prescription drug manufacturer returns to a payer based on utilization by consumers enrolled through a plan or issuer or based on purchases by a provider.[197] A chargeback is a type of discount process through a prescription drug wholesaler where manufactures reimburse wholesalers who offer drugs to purchasers at discounted prices, and the discount negotiation occurs between the manufacturer and the purchaser.[198] Finally, fees include any payment adjustments, incentives, or other discounts that are not included in the negotiated price for a drug (for example, prompt pay discounts, pharmacy network fees, performance-based fees, and incentive fees).[199] The Departments

[192] 42 U.S.C. 1395w–3a(c)(6).

[193] ''National Average Drug Acquisition Cost.'' Centers for Medicare & Medicaid Services. September 15, 2020. Available at: *https://data.medicaid.gov/Drug-Pricing-and-Payment/NADAC-National-Average-Drug-Acquisition-Cost-/a4y5-998d.*

[194] ''AMCP Guide to Pharmaceutical Payment Methods, 2013 Update'' Academy of Managed Care Pharmacy. 2013. Available at: *https://www.amcp.org/sites/default/files/2019-03/Full-Pharmaceutical-Guide-%283.0%29.pdf.*

[195] The Departments note that each plan or issuer (or the PBM acting under contract with the plan or issuer) may utilize a different combination of price concessions.

[196] ''AMCP Guide to Pharmaceutical Payment Methods, 2013 Update. Academy of Managed Care Pharmacy. 2013. Available at: *https://www.amcp.org/sites/default/files/2019-03/Full-Pharmaceutical-Guide-%283.0%29.pdf.*

[197] *Id.*

[198] *Id.*

[199] ''Final Medicare Part D DIR Reporting Requirements for 2017.'' Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-May-30th.*

note that manufacturers also may offer additional price concessions to certain providers or directly to consumers in the form of coupons. The final rules only require disclosure of reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer (or the PBM under contract with the plan or issuer).

As noted earlier, several commenters commented on the nature of the prescription drug pricing information that should be captured to achieve the goals of price transparency. Some commenters noted the net price would be important to price transparency efforts because it would put consumers on notice when the net price is less than their cost-sharing amount and it would capture the actual prices of prescription drugs after the application of price concessions, which would provide transparency regarding actual prescription drug costs. The Departments agree with these commenters that disclosure of information about the net price for prescription drugs (and therefore rebates and other price concessions that are included in the net price) is necessary to achieve the goals of the final rules.

Therefore, the final rules adopt a requirement to make public a historical net price, as defined by the final rules. Furthermore, rather than require disclosure of the actual net price, the final rules establish and adopt a definition of historical net price that balances the need for transparency against concerns expressed by other commenters that release of net prices could affect issuers and PBMs' ability to negotiate drug prices, including rebates and other price concessions. Specifically, the final rules define historical net price as the retrospective average amount a plan or issuer paid an in-network provider, including any in-network pharmacy or other prescription drug dispenser, for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug or prescription drug service. The Departments note that for the purposes of the final rules, the definition of historical net price only includes those price concessions received by the plan or issuer (or under the contract between the PBM and the plan or issuer). Because of timing delays related to application of rebates, discounts, chargebacks, fees, and other price concessions, plans and issuers are required to provide historical or retrospective data, rather than prospective or current pricing data regarding the net price of prescription drugs. In the case prescription drug net prices, historical data will provide valuable information for stakeholders, as the actual prices plans and issuers ultimately pay for prescription drugs cannot be known until after the application of time-delayed rebates, discounts, chargebacks, fees, and other price concessions. As discussed later in this section, plans and issuers will be required to include historical net prices for a 90-day period beginning 180 days before the date a particular Prescription Drug File is published. The final rules also require the historical net price, as defined earlier in this section, to be disclosed through the Prescription Drug File.

As discussed earlier in this preamble, the Departments are aware that an estimated allocation of rebates, discounts, chargebacks, fees, and any other additional price concessions may be necessary to represent the historical net price. Product-specific and non-product specific rebates, discounts, chargebacks, fees, and other price concessions must be allocated by dollar value if the total amount of the price concession is known to the plan or issuer at the time of file publication. It is the Departments' understanding that most discounts, such as those related to market sharing and rebates based on volume, are calculated within time periods as short as one to three months. Therefore, the Departments expect the total amounts for these types of discounts, rebates, and other price concessions will be known at the time of file publication. Where the total amount of a price concession is known at the time of file publication, plans and issuers must allocate the price concession by the total dollar amount.

The Departments also understand that some product-specific and non-product specific price concessions are based upon outcomes- or value-based payment arrangements that calculate rebates over a longer period of time—usually six months to more than three years. Because these price concessions will not be known at the time of file publication, the Departments are requiring plans and issuers to estimate the historical net price using a reasonable allocation and good faith estimate of the total concession amount. Therefore, if the total amount of the price concession is not known to the plan or issuer at the time of file publication, then rebates, discounts, chargebacks, fees, and other price concessions should be reasonably allocated using an estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period.

Rebates may reflect discounts negotiated with drug manufacturers that lower drug prices for the plan or issuer. Rebates may not directly benefit participants, beneficiaries, or enrollees, however, as the decision of whether and how to share savings from rebates is at the discretion of the plan or issuer. Nonetheless, there is evidence that rebates are positively correlated with increased manufacturer list prices for prescription drugs, which is typically the basis for a consumer's cost-sharing liability.[200] A recent analysis found that, on average, from 2015 to 2018, a $1 increase in rebates was associated with a $1.17 increase in manufacturer list prices.[201] Therefore, due to the positive correlation between rebates and manufacturer list prices, a policy that results in a reduction to rebates may result in a reduction in the manufacturer list price (and also overall prescription drug prices). A policy that requires plans and issuers to make public historical net prices could expose the extent of rebates and other price concessions, and this transparency in historical net price could cause a reduction in the use of rebates and other price concessions, and, therefore, a reduction in the manufacturer list price.[202] The resulting reductions in manufacturer list price could lead to lowered out-of-pocket costs for both uninsured consumers who must pay the manufacturer list price and insured consumers with deductibles and coinsurance. Because negotiated rates for prescription drugs are largely based upon the manufacturer list price, the reduction in the manufacturer list price will likely be reflected in the negotiated rate. Further, because negotiated rates are used to determine cost-sharing liability for prescription drugs, a reduction in such rates will likely result in lower consumer costs through a reduction to deductibles and coinsurance.

The Departments are of the view that requiring both the negotiated rate and the historical net price, as defined by the final rules, will produce sufficient transparency regarding prescription drug pricing information to support consumer health care purchasing

[200] Sood, N., et al. ''The Association Between Drug Rebates and List Prices.'' U.S.C. Schaeffer Center for Health Policy and Economics. February 11, 2020. Available at: *https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/*.

[201] *Id.*

[202] *Id.*

decisions and provide other stakeholders insight into actual prescription drug pricing. Inclusion of both the negotiated rate and historical net price addresses the Departments' concern, expressed in the preamble to the proposed rules, that merely requiring disclosure of the rate that is used to determine an individual's cost-sharing liability (that is, as clarified in the final rules, the negotiated rate) could perpetuate the lack of transparency in prescription drug pricing.

Additionally, in the preamble to the proposed rules, the Departments specifically solicited comment on whether and how the public disclosure requirements should account for rebates, discounts, and dispensing fees to ensure individuals have access to meaningful cost-sharing liability estimates for prescription drugs.[203] Upon review of the comments, the Departments are of the view that public disclosure of the historical net price, which takes into account rebates, discounts, dispensing fees, and other price concessions, in addition to the negotiated rate, upon which cost sharing is based, provides the appropriate combination of pricing information to achieve the goals of transparency and ensure that individuals have access to meaningful prescription drug pricing information. First, the negotiated rate will help support consumer health care purchasing decisions. Second, the historical net price will support the public in gaining enhanced knowledge of actual drug prices. Enhanced knowledge of actual drug historical net prices could also support consumer health care purchasing decisions, as consumers could use the information to determine whether their out-of-pocket costs are commensurate with the rebates, discounts, and other price concessions received by their plan or issuer. The historical net price will also make consumers and other stakeholders aware of situations where cost-sharing liability for a prescription drug exceeds the amount their plan or issuer ultimately paid for the prescription drug. In these situations, participants, beneficiaries, and enrollees will be able to make an informed decision regarding whether to utilize their plan or coverage when purchasing the prescription drug. Furthermore, plans and issuers could be incentivized to pass through a larger or more significant share of the rebates and other discounts that they receive from drug manufacturers if those discounts are effectively disclosed via historical net price information.

[203] 84 FR 65464, 65472 (Nov. 27, 2019).

The Departments acknowledge that there are potential adverse consequences of requiring plans and issuers to make public rebates and other price concessions, directly or indirectly, through the historical net price. For instance, stakeholders such as PBMs and prescription drug manufacturers could attempt to find ways to obscure rebates and other price concessions such that they would not be required to be publicly disclosed under the final rules. However, the Departments are of the view that such attempts would likely be discouraged by the nature of the disclosures themselves and would otherwise be unsuccessful if attempted. A benefit of requiring the widespread public disclosure of pricing information for prescription drugs is that the transparency data itself can be used to identify where plans and issuers (or third parties acting on their behalf) may be attempting to circumnavigate disclosure requirements. Researchers and other entities who aggregate and analyze the data will be able to compare pricing data across plans and issuers. This can help identify plans and issuers whose data is an outlier and identify them for further scrutiny by regulators. The current lack of transparency in prescription drug pricing does not allow this type of oversight and monitoring. While it is possible that stakeholders will act in ways that conflict with the intent of the public disclosures, it is also very likely that transparency itself will help state and local regulators to identify these anti-competitive practices. Indeed, it is possible that the public disclosures could help to uncover other unknown anti-competitive business practices that exist today. For these reasons, the Departments are of the view that the benefits of public disclosure of prescription drug pricing information outweigh the potential risk that certain stakeholders may seek to take advantage of the disclosure requirements in ways that would increase prescription drug costs.

A commenter observed that if the Departments were to include the net price, it would be important to clarify that that the information is not necessarily predictive of future transactions because information about rebates is not known with certainty before a drug is dispensed. The Departments recognize that prospective net prices for prescription drugs could be complicated to estimate accurately due to the nature of prescription drug pricing. Nonetheless, the Departments are of the view that the historical net price will be a sufficiently accurate guide for potential prescription drug prices and will fulfill the objectives of the final rules.

The final rules adopt a requirement to include in the Prescription Drug File the historical net price over a 90-day reporting period for each NDC for dates of service within 180 days of the Prescription Drug File publication date. This approach will ensure that data is composed of the historical net price for relatively recent claims (rather than older claims from multiple time periods) and will avoid the conflation of payments from different periods of time. The Departments are of the view that historical net prices from defined periods of time will enable users to make meaningful comparisons across plans and coverages. Additionally, the Departments chose this reporting reference period to be consistent with the period proposed and being finalized through the final rules for reporting of allowed amounts through the Allowed Amounts File. The Departments are of the view that consistency across machine-readable file requirements, where applicable, will reduce potential confusion among file users as well as reduce burdens for plans and issuers. The Departments are of the view that the 180-day lookback period (which is expected to capture many of the market-share and volume rebates and other price concessions) and requirement to make a reasonable allocation will balance the need to be transparent in current prices with the delayed timing of the application of certain rebates and other price concessions.

To reasonably allocate any particular non-product specific or product-specific rebate, discount, chargeback, fee, or other additional price concession by dollar value of the drug where the totals amount is fully known at the time of file publication, plans and issuers should divide the rebate or discount amount by the total dollar value of drugs on which the rebate is calculated, and then apply that percentage to all applicable drugs. For example, if a rebate amount of $20,000 is received during the 3-month file reference period in connection with $100,000 in sales on two drugs during the same period, the rebate is allocated as a 20 percent discount to the prices of those two drugs. Sales for Drug A totaled $60,000 and sales for Drug B totaled $40,000. A rebate of $12,000 ($60,000 multiple by 20 percent) is allocated to Drug A, resulting in a historical net price populated in the Prescription Drug File of $48,000. Similarly, a rebate of $8,000 is allocated to Drug B, resulting in a historical net price populated in the Prescription drug file of $32,000. The Departments are

aware that this allocation methodology will not always perfectly allocate the rebate amounts because of the complexities of rebate calculation, or because of timing issues. However, the Departments are of the view that this simplified approach balances the goal of providing actionable drug pricing information to the public while limiting the burdens on plans and issuers in producing the information.

To reasonably allocate any particular non-product specific or product-specific rebate, discount, chargeback, fee, or other additional price concession where the total amounts are not fully known at the time of file publication, plans and issuers must make a good faith, reasonable estimate of the price concession using an historical adjustment amount. To make this estimate, plans and issuers shall determine the average value of price concessions for the relevant product over a time period prior to the current reporting period and of equal duration to the current reporting period and use that amount to apply an estimated adjustment amount in the current reporting period. For example, Plan X has $100,000 in total sales for 20,000 units—averaging $5 per unit—of Drug A during the current reporting period, which is January 1, 2020, through March 31, 2020. However, Plan X will not know the total amount of product-specific rebate to expect for sales of Drug A for at least another six months. To address this timing issue, Plan X can apply a reasonable estimate to allocate an adjustment to the current reporting period. For instance, Plan X can look back to the total rebates received for the product during a comparable time period. In this example, Plan X reviews its historical data and determines the rebates received for Drug A, from the period between January 1, 2019, and March 31, 2019, totaled $10,000 for sales of 30,000 units totaling $160,000. The average price per unit was $5.33 and the average discount per unit was $0.33 resulting in an average final net price of $5 for Drug A. Plan X then applies this historical rebate percentage to the current reporting period for Drug A. Plan X subtracts $6,250 ($100,000 total sales for the current reporting period multiplied by the estimated 6.25 percent historical rebate percentage) from the $100,000 total sales for a total net price of $93,750 and an average net price for Drug A, rounded to the nearest hundredth, of $4.69. Plan X reports in the Prescription Drug File an average historical net price for Drug A of $4.69 for the current reporting period.

In the discussion of the Allowed Amounts File in the preamble to the proposed rules, the Departments noted that providing the Allowed Amounts information could raise health privacy concerns. The Departments are of the view that similar concerns could be raised regarding the historical net price information in the Prescription Drug File. For example, there may be instances—such as in a small group plan or with respect to an NDC for a rare chronic condition—where, through deduction, disclosure of historical net price information may enable users to identify the participant, beneficiary, or enrollee who received a particular prescription drug because a very small number of claims are used to derive the historical net price of a particular NDC at a particular pharmacy or other prescription drug dispenser. Additionally, as noted in relation to the Allowed Amount File, there may also be instances when the historical net price public disclosure requirement would be inconsistent with Federal or state laws governing health information that are more stringent than HIPAA regarding the use, disclosure, and security of health data that was produced pursuant to a legal requirement, such that plans and issuers would be required to further de-identify data. For example, some of the claims for payment used to derive the historical net price could relate to services provided for substance use disorders, which could implicate disclosure limitations under 42 CFR part 2 governing the confidentiality of patient records related to treating a substance use disorder. The Departments are committed to protecting PHI. To address privacy concerns, the final rules adopt an approach consistent with the out-of-network Allowed Amount File. The final rules do not require plans and issuers to provide historical net price data in relation to a particular pharmacy or other prescription drug dispenser and a particular NDC when compliance would require a plan or issuer to report an historical net price for a particular pharmacy or other prescription drug dispenser calculated with fewer than 20 different claims for payment. Furthermore, the Departments note that disclosure of historical net prices will not be required if compliance would violate applicable health information privacy laws. The Departments are of the view that these mitigation strategies, in addition to the historical net price being an average of amounts paid to a particular provider for a particular NDC during the reference period, are sufficient to protect patients from identification based on information in the Prescription Drug File. The Departments note that the low volume exemption applies only to the requirement to include the historical net price and does not affect the requirement to include the negotiated rates in the Prescription Drug File.

Regarding prescription drugs, the Departments received a comment that requested discounts under section 340B of the PHS Act be included in the applicable machine-readable file, noting that providing this information is important to ensure consumers can access those savings. However, this commenter acknowledged that health plans often do not have access to information about when a section 340B discount is paid and so recommended the Departments develop and implement a process to help health plans identify this information.

Discounts under the section 340B Drug Pricing Program are only available to eligible providers (known as covered entities as outlined in section 340B of the PHS Act) and regulations under section 340B of the PHS Act are outside of the scope of the final rules.

2. Required Method and Format for Disclosing Information to the Public

As explained in section II.C.1.c of this preamble, the final rules adopt the requirement that plans and issuers produce the In-network Rate File, the Allowed Amount File, and the Prescription Drug File. The Departments are finalizing a requirement that the In-network Rates, Allowed Amounts, and Prescription Drug Files must be disclosed as machine-readable files. The final rules define ''machine-readable file'' to mean a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost. The requirement ensures that the machine-readable file can be imported or read by a computer system without those processes resulting in alterations to the ways data and commands are presented in the machine-readable file. The Departments proposed to require each machine-readable file to use a non-proprietary, open format to be identified by the Departments in technical implementation guidance (for example, JavaScript Object Notation (JSON), Extensible Markup Language (XML), or Comma Separate Value(s) (CSV)). A portable document format (PDF) file, for example, would not meet this definition due to its proprietary nature.

Contemporaneous with the proposed rules, the Departments published a PRA package (OMB control number: 0938–1372 (Transparency in Coverage (CMS–

10715)) that further described the specific data elements that would be disclosed in the proposed machine-readable files. Updated cost and burden estimates related to the collection requirements are discussed in the ICR section of this preamble and are included in in the corresponding PRA package, including changes to costs and burdens and additional collection instruments as a result of modifications to the proposed rule made through the final rules.

The Departments proposed requiring group health plans and health insurance issuers to publish their negotiated rates and historical allowed amount data in two machine-readable files, one including required negotiated rate data with in-network providers, and a second including required out-of-network allowed amount data. The Departments proposed requiring plans and issuers to publish the data in two separate machine-readable files to account for the dissimilarity between the negotiated rates paid to in-network providers under contract and the more variable allowed amounts paid to out-of-network providers. The Departments solicited comment on whether building and updating one file could be less burdensome for plans and issuers than maintaining multiple files, and whether having the data in a single file could facilitate use by third-party developers. The Departments were particularly interested in comments regarding whether a single file for disclosure of all the required information would likely be extremely large, making it less than optimal for anticipated users, such as software application developers and health care researchers.

Some commenters supported keeping the In-network Rates File and out-of-network Allowed Amount File separate. One commenter noted the structure would allow quick development of data aggregation efforts and consumer-friendly tools. Additionally, the commenter stated that keeping the files separate would support file ingestion. Another commenter stated that each file would contain fundamentally different data, and the costs associated with storing and maintaining a large combined file would be very large.

The Departments agree that the information being required to be publicly disclosed through the machine-readable files related to negotiated rates and allowed amounts is sufficiently distinct to justify separating the information into separate files. In particular, the out-of-network allowed amounts information must be derived from historical claims data, which is fundamentally different in kind from simply listing applicable rates for each service. Furthermore, the Departments also agree with comments indicating that splitting the files would help reduce the maintenance and storage burdens of the files. Throughout this preamble, the Departments have stressed the importance of ensuring the public disclosures required through the final rules are accessible, especially to internet-based and mobile application developers, to support development of innovative consumer-facing tools, as well as to other entities, such as researchers, and regulators, to support efforts to better understand and support the competitiveness of health care markets.

The requirement to publish more than one machine-readable file which will facilitate the disclosure of data that is different in character, scope, and other factors, which will help facilitate data ingestion for users of the machine-readable files, including third-party developers, researchers, regulators, and other interested parties. This approach will also help facilitate file ingestion, data aggregation, and data analysis by researchers whose projects could lead to important market insights that could inform efforts to further address the wide variation in health pricing, and by regulators who would be able to leverage the data in their oversight activities.

As discussed earlier in this preamble, the final rules adopt a third Prescription Drug File in recognition of the unique pricing attributes of prescription drug products. Prices related to prescription drug products that plans and issuers would have been required to include in the In-network Rate File under the proposed rules will now be required to be publicly disclosed through the third Prescription Drug File. As discussed earlier in this preamble, the Departments estimate that requiring a third file for prescription drugs will not add significantly to the burdens and costs of developing and maintaining the machine-readable files calculated in relation to the final rules because costs and burdens calculated for prescription drugs as included in the In-network Rate File will be transferred to the Prescription Drug File. Additionally, the Departments anticipate that removal of prescription drugs from the In-network Rate File will significantly reduce the size of that file, which could reduce the costs associated with maintenance and storage for the In-network Rate File. The Departments clarify that not all prescription drug pricing information required to be disclosed through the final rules is required to be included in the Prescription Drug File. Rather, the Prescription Drug File is required to include prescription drug pricing information for in-network providers, including pharmacies and other prescription drug dispensers, while the Allowed Amount File is required to include prescription drug pricing information for out-of-network providers, including pharmacies and other prescription drug dispensers. The Departments also clarify that the In-network Rate file may also contain prescription drug information to the extent the prescription drug is a part of a bundled payment arrangement.

Some commenters argued that the method and format for providing information to the public is not feasible. One commenter did not support the policy that the machine-readable files should be provided in a public use file format, claiming the files would be millions of rows long and very difficult to review. Another commenter expressed concern that the volume of data would make it impossible to post all of the information in two files and further stated that there is no single set of codes that describe every item or service, so it would be impossible to post this data without very specific, standard definitions. Given the lack of standard definitions, this commenter argued that there is no systematic way to compile and display the information requested, so claim compilation would have to be done manually. The commenter further stated that, even if there were standard definitions, it would be impossible to provide them in ''plain language.''

Based on consultations with industry and IT development professionals, the Departments do not agree with commenters who stated that development of the machine-readable files would not be feasible as envisioned by the proposed rules. The Departments are aware that these files could be very large and could be difficult for laypersons to navigate. However, the Departments are of the view that the files' primary benefit to health care consumers will be the availability of web-based tools and mobile applications developed for consumer use by third-party developers, aggregation and analysis conducted by researchers, and oversight efforts by regulators. The required machine-readable files will be optimal for ingestion, data aggregation, and data analysis, all of which are functions performed by third-party internet-based developers, researchers, and regulators who use large data sets in a manner that will lead to benefits for consumers. Additionally, notwithstanding that the Departments have designed these

transparency requirements so that it is not necessary that individual consumers use or ingest the data in the machine-readable files, the Departments are of the view that many individual health care consumers do possess the necessary expertise to access and navigate the files. The final rules also impose a requirement to include plain language to identify each item and service included in each file. This requirement will help ensure consumers, third party application developers, researchers, regulators, and other interested parties are able to easily understand the information.

The Departments have determined that the potential benefits for consumers of requiring the disclosure of required data through machine-readable files outweigh the potential for consumer confusion at the individual consumer level. Additionally, the Departments expect that third party application developers, researchers, regulators, and other file users will have the expertise to aggregate, standardize, and interpret the pricing information included in the file and translate the pricing information into products, research, and market oversight and reforms that will ultimately benefit consumers.

The Departments also do not agree that the volume of data would make the machine-readable files too large to post publicly, regardless of whether the data is posted in two or three files. The Departments' rough estimate of file size, based, in part, upon numbers provided by commenters, suggests a file size of approximately 5 gigabytes.[204] CMS currently makes available for download on its website some large public use file (PUF) data sets that are several gigabytes. For example, the Part D Prescriber PUF, [205] available on the CMS website, is over three gigabytes in size. The Departments acknowledge that because of the large file size, file users will likely need to use database or statistical software to download the machine-readable files as importing into Microsoft Excel would result in incomplete loading of data. However, this approach is similar to that used for some of the larger PUF data sets available on the CMS website, including the Part D Prescriber PUF, which must be opened using specialty software.

Assuming that plans' and issuers' negotiated rates are in a digitized format, even if the negotiated rates are not stored in a single database, this information can be systematically compiled and maintained by the plan or issuer. In recognition that there is no single set of billing codes for non-prescription drug services, the Departments are providing flexibility in the final rules by not prescribing which code or set of codes plans and issuers must use to publicly disclose their data. Rather, the Departments are requiring that plans and issuers associate each in-network applicable rate or out-of-network allowed amount with a CPT, HCPCS code, DRG, or other common payer identifier. In the case of prescription drugs, the Departments are requiring plans and issuers to associate each negotiated rate and historical net price with an NDC. The Departments' expectation is that the type of billing code plans and issuers use to populate the machine-readable files will be consistent with the billing codes that plans and issuers use in their operations when actually determining provider reimbursement and cost-sharing liability.

The Departments further note that nothing prevents plans and issuers from including in the files a mixture of billing code types so long as the billing codes included in the file are reflective of the plan's or issuer's operations. To facilitate identification of the billing code type, there will be an indicator in the file format described by the technical implementation guidance that will allow plans and issuers to specify the particular type of billing code entered for each data entry in the machine-readable files. The final rules also require that plans and issuers include plain language descriptions for each billing code. The Departments note that in the case of items and services that are associated with common billing codes (such as the HCPCS codes), plans and issuers are permitted to use the codes' associated short text description.

The final rules further clarify that, in the case of NDCs for prescription drugs, the plain language description must be the proprietary and nonproprietary name assigned to the NDC by the FDA. The Departments have made this change to align with the change to require only the NDC billing code to be used for prescription drugs. Requiring the proprietary and nonproprietary name assigned to the NDC by the FDA further standardized the product identifiers for prescription drugs and will facilitate comparisons across prescription drug pricing information for plans and issuers.

For all other items and services, as the Departments explicitly stated in the proposed rules and elsewhere in this preamble, plans and issuers can meet the ''plain language'' description requirements by using their chosen code's short text description. However, the Departments note that including the short text description for each code is a minimum requirement and nothing in the final rules prevents plans and issuers from providing a more consumer-friendly plain language description for each covered item or service. Plans and issuers may be incentivized to provide more consumer-friendly information in machine-readable files because it may permit them to include disclaimer or clarifying language in the files, where applicable. Furthermore, if a plan or issuer uses plain language descriptions for billing codes in its operations that are more consumer-friendly than the established short text descriptions, the Departments expect plans and issuers to include in the machine-readable files the plain language descriptions they use in their operations.

The Departments received comments that supported the Departments' development of specific technical standards for the files to which plans and issuers must adhere. One commenter recommended the Departments provide guidance to plan sponsors who are able to provide some, but not all, of the file data elements. Another commenter stated that the proposed rules do not make clear how to report items and serviced provided through capitated and bundled payment arrangements in the files; noting that this information is necessary for consumers to measure provider value. One commenter responded positively to the Departments' provision of technical implementation guidance for the files, but requested a robust public comment solicitation far in advance of the applicability date for the rules.

The Departments are of the view that providing specific technical direction in separate technical implementation guidance, rather than in the final rules, will better enable the Departments to respond to technical issues and developments, as well as compliance questions related to novel or rare payment arrangements. Therefore, as proposed, the Departments are developing technical implementation guidance for plans and issuers to assist them in developing the machine-readable files.

The technical implementation guidance will be available online

[204] As a reference point, a typical commercial two-hour Blu-ray film is approximately 15–25 gigabytes. ''White Paper Blue-ray Disc Format General.'' Blue-ray Disc Association. 2018. Available at *http://www.blu-raydisc.com/Assets/Downloadablefile/White_Paper_General_5th_20180216.pdf.*

[205] The Part D Prescriber Public Use File (PUF) is available on the CMS website at the following location: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/PartD2017.*

through GitHub, a website and cloud-based service that helps developers store and manage their code, as well as to track and control changes to their code. The GitHub space offers the Departments the opportunity to collaborate with industry, including regulated entities, and third-party developers to ensure the file format is adapted for reporting of the required public disclosure data for various plan and contracting models. For example, the Departments have updated the schematics of the file formats in response to comments received about and bundled payments and capitated payment arrangements, as well as other alternative contracting models. Plans and issuers will be able to access the GitHub schemas at any time and collaborate with the Departments in real-time.

The Departments' goal in using GitHub is to facilitate this collaborative effort all allow plans and issuers to meet the public disclosure requirements of the final rules while addressing their unique IT system, issuer, and plan attributes. To the extent a plan or issuer's unique attributes (for example, IT system, plan benefit design, or reimbursement model) are not addressed sufficiently through the technical implementation guidance, the Departments intend to provide targeted technical assistance to ensure all plans and issuers are able to meet the public disclosure requirements under the final rules. The technical implementation guidance will provide instructions on how to obtain this technical assistance should the need arise.

The technical implementation guidance hosted on GitHub will include a repository set of schemas describing the data formats (encoded as JSON, XML, and CSV) for all three machine-readable files: The In-network Rate File, the Allowed Amount File, and the Prescription Drug File. The technical implementation guidance will be available as part of the PRA package developed for the ICRs included in the final rules. As part of the PRA process, stakeholders have an additional opportunity to submit comments related to the PRA for 30 days following the publication of the final rules.

In the proposed rules, the Departments requested comment on whether the final rules should adopt a single non-proprietary format for the machine-readable files, specifically JSON files. The Departments understand that this format generally is easily downloadable, and it could simplify the ability of file users to access the data.

The Departments received one comment in support of requiring JSON as the standardized file format for the required machine-readable files. However, the Departments' internal technical experts agreed that the speed of technology developments weighs heavily in favor of maintaining flexibility to adopt a suitable file format as a non-substantive, operational requirement that will be identified in the relevant implementation guidance for the required machine-readable files. Additionally, this flexibility will allow the Departments to adapt the file technical specifications for new and emerging technologies. Therefore, the Departments decline to require in regulation a more specific file format for the machine-readable files.

The Departments reiterate that, as finalized, all machine-readable files must conform to a non-proprietary, open-standards format that is platform-independent and made available to the public without restrictions that would impede the re-use of the information. Therefore, because a PDF file format is proprietary, it would not be an acceptable file format in which to produce the files. A plan or issuer's file will be acceptable so long as it includes all required data elements required for the respective file (that is, all applicable rates in the In-network Rate File, allowed amounts and billed charges in the Allowed Amounts File, and negotiated rates and historical net process in the Prescription Drug File) and is formatted in a manner consistent with the technical implementation guidance the Departments are developing.

The final rules therefore adopt, with modification, the required method and format for disclosure of information through the machine-readable files. The Departments note several non-substantive modifications to the regulatory text, which are being adopted in the final rules to clarify and streamline the text. To further highlight the file technical implementation guidance, the regulation text of the final rules has been modified non-substantively to specify that the machine-readable files must be made available in a form and manner specified in guidance issued by the Departments. In the proposed rules, the regulation text stated more broadly that the machine-readable files must be made available in a form and manner determined by the Departments. Additionally, the proposed rule included two sentences that simply restated what must be publicly disclosed through the two proposed machine-readable files.[206] The Departments have removed these sentences from this this section of the regulatory text because they duplicate language contained in the previous sections of the regulatory text, do not add any additional value to this section of the regulatory text, and could cause confusion.

[206] *See* 84 FR 65464, 65519 (Nov. 27, 2019).

3. Required Accessibility Standards for Disclosure of Information to the Public

The Departments proposed to require a plan or issuer to make available on an internet website the required machine-readable files, and that the files must be accessible free of charge, without having to establish a user account, password, or other credentials, and without having to submit any personal identifying information such as a name, email address, or telephone number. The Departments also proposed to allow plans and issuers flexibility to publish the files in the locations of their choosing based upon their superior knowledge of their website traffic and the places on their website where the machine-readable files would be readily accessible by the intended users. The Departments are finalizing these requirements as proposed. The Departments also considered requiring plans and issuers to submit the internet addresses for the machine-readable files to CMS, and having CMS make the information available to the public. A central location could allow the public to access the information in one centralized location, reducing confusion and increasing accessibility. However, the Departments opted to propose flexible rules allowing plans and issuers to publish the files in the locations they have chosen based upon their determinations regarding where the files will be most easily accessible by the intended users. The Departments also considered that requiring plans and issuers to notify CMS of the internet address for their machine-readable files would increase the burdens on plans and issuers. The Departments requested comment on whether the proposed requirement to allow issuers to display the files in the location of their choice is superior to requiring plans and issuers to report the internet-based addresses of their files to CMS for public display. The Departments were specifically interested in whether the burden associated with reporting file locations to CMS would be outweighed by the risk that members of the public would be unable to easily locate plans' and issuers' machine-readable files.

Several commenters supported the Departments' proposal to make the machine-readable files easily and publicly available. One commenter

supported making the files available free of charge and stated that individuals should not be required to register a user account, password, or enter other credentials, or to submit PII to access the files. Several commenters suggested alternative methods or more stringent requirements for making public the information required to be disclosed through the machine-readable files. One commenter expressed a preference for CMS to maintain a centralized location on the CMS website from which the public can access links to the files. The commenter noted that if the Departments elected not to maintain a centralized database, the Departments should require plans and issuers to prominently display a link to the files in the main menu of the homepage on their respective websites. Similarly, another commenter asserted that the final rules should require issuers to report the location of their files and provide a data dictionary to facilitate oversight and enforcement of plans and issuers.

Other commenters suggested the Departments create a centralized database to house the data required to be disclosed through the machine-readable files. One commenter recommended the information required to be disclosed through the files be loaded into a publicly available searchable database that anyone can access prior to receiving a medical service. Similarly, another commenter recommended that HHS aggregate the data to create a centralized database. By contrast, another commenter recommended the Departments should not create a central location for negotiated rate information and historical data, making the argument that the private sector is best suited to deliver this information to consumers.

As proposed, the machine-readable files must be made publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of PII to access the file. Additionally, the proposed rules specified that the files must be made available in the form and manner specified by the Departments. While the Departments considered comments related to the manner of the public file disclosures (such as prominent display on a plan or issuer's homepage), the Departments are also mindful of the need to provide flexibility to plans and issuers so that they are able to house the files in a location that meets their unique technical specifications. At this time, the Departments are of the view that reporting of the links to the file locations is not necessary to achieve the goals of the final rules. However, the Departments note that nothing in the final rules prevents a Federal or state regulatory body, such as a state Department of Insurance (DOI), from collecting this information from issuers subject to their jurisdiction.

The Departments are aware and understand commenters' interest in HHS aggregating and centralizing all of the data required to be publicly disclosed through the machine-readable files. However, the Departments are of the view that HHS is not best suited for this role. As noted throughout this preamble, the Departments expect making negotiated rate and allowed amount information available through the machine-readable files will spur third-party internet-based developers to innovate, resulting in consumer-facing tools. The Departments anticipate that these consumer-facing tools developed by third parties could act as centralized databases, aggregating the pricing information for many plans and issuers. The Departments are of the view that the private sector is better suited to developing internet-based tools using this information than the Departments, and further, that the competition spurred by several different third parties operating in this space could benefit consumers seeking to find the third-party tool that is best suited to their individual consumer needs.

The final rules adopt, as proposed, the accessibility requirements for the machine-readable files. The final rules clarify that the accessibility requirements apply to all three machine-readable files finalized within the final rules: The In-network Rate File (referred to in the proposed rules as the Negotiated Rate File), the Allowed Amount File, and the Prescription Drug File.

4. Required Timing of Updates of Information To Be Disclosed to the Public

The proposed rules would have required group health plans and health insurance issuers to update the information required to be included in each machine-readable file monthly. The Departments also proposed to require plans and issuers to clearly indicate the date of the last update made to the In-network Rate Files and Allowed Amount Files in accordance with guidance issued by the Departments.

The Departments recognized in the proposed rules that information in In-network Rate Files (referred to in the proposed rules as the Negotiated Rate Files) could change frequently and considered whether to require plans and issuers to update their In-network Rate Files more often than monthly to ensure that consumers have access to the most up-to-date negotiated rate information. Accordingly, the Departments sought comment on whether the final rules should require plans' and issuers' In-network Rate Files to be updated more frequently. The Departments also sought comment on an alternate proposal that would require plans and issuers to update negotiated rate information within 10 calendar days after the effective date of new rates with any in-network provider, and on whether the update timelines for negotiated rate information and historical out-of-network payment data should be the same.

For the reasons discussed elsewhere in this section of this preamble, the final rules adopt, as proposed, the requirement for a plan or issuer to update the information required to be included in each machine-readable file monthly. The final rules clarify that this requirement to update the machine-readable files monthly applies to all three machine-readable files being finalized through the final rules: The In-network Rate File, the Allowed Amount File, and the Prescription Drug File.

Several commenters stated that the requirement to update the In-network Rate Files and Allowed Amount Files monthly is operationally burdensome and the benefits of this requirement are limited because the information will not change significantly on a monthly basis. Some commenters recommended the Departments change the required frequency of updates to every six months, while others suggested that the final rules require updates to the In-network Rate File less frequently than monthly (for example, quarterly or semi-annually), but recommended that the Allowed Amount File should be updated monthly. Another commenter recommended a phased-in approach where the files would be updated twice a year in the first year of implementation and quarterly thereafter. In contrast, one commenter recommended the files be updated in real-time as soon as updates to rates are made.

Based on consultation with government-affiliated IT experts and the design of the file schemas, the Departments are of the view that building the first machine-readable file will facilitate the automation of the process to build future files. In other words, the ability to produce subsequent files should be streamlined after completing initial development. Therefore, the Departments do not find

persuasive the contention that requiring file updates monthly will significantly increase the overall costs and burdens related to producing the files. The Departments, however, do not agree that the files should be updated in real-time as soon as updates are made. With the monthly update requirement, the Departments are seeking to balance the need to ensure the data is current and accurate for consumers with minimizing burdens on plans and issuers.

As noted in the proposed rules, the Departments acknowledge there will be some costs with making updates to the files, including costs to ensure the quality of data and costs associated with posting the information on a public website. The Departments are of the view that requiring plans and issuers to update the files on a monthly basis will sufficiently limit the burden while ensuring that the most current data generally available. However, requiring updates to the files more or less frequently would not adequately balance these interests. Requiring updates to the files more frequently (such as on a daily basis), would add potentially unnecessary burdens for plans and issuers. Requiring updates to the files less frequently would potentially result in consumers relying on outdated information for health care purchasing decisions. While negotiated rates, in particular, may not change frequently for any one contract with a provider or group of providers, the Departments understand that payer-provider contracts are updated on a rolling basis and throughout the year. Therefore, updates throughout the year are needed in order to ensure that the information disclosed remains up-to-date.

The final rules also require that the Prescription Drug File be updated on a monthly basis. The Departments understand the complexities of prescription drug pricing and are aware that drug prices can fluctuate as frequently as daily. However, the Departments have determined that aligning the frequency of updates of all machine-readable files will mitigate the burden associated with maintaining the files for plans and issuers, and will best balance the need for disclosing current and accurate information against that burden. The Departments are aware that the number of pricing updates in the monthly Prescription Drug File will likely be more than the number of monthly pricing updates for medical services in the In-network Rate File. However, the Departments are of the view that if plans and issuers can update their pharmacy claims processing systems in real-time to account for fluctuating prices and adjudicate claims for prescription drugs, then the burden to pull current pricing information into the Prescription Drug File should be manageable.

The Departments will monitor the implementation of the machine-readable file requirements and consider updates in future rulemaking if it is determined that monthly updates are not adequately balancing the need for accurate and current information against the burdens for plans and issuers.

5. Special Rules To Prevent Unnecessary Duplication and Allow for Aggregation

Similar to the proposed cost-sharing information disclosure requirements for participants, beneficiaries, and enrollees, the Departments proposed a special rule to streamline the publication of data that would be included in the proposed machine-readable files. This special rule has three components: One for insured group health plans where a health insurance issuer offering coverage in connection with the plan has agreed to provide the required information, another for plans and issuers that contract with third parties to provide the information on their behalf, and a special rule allowing aggregation of out-of-network allowed amount data.

a. Insured Group Health Plans

The Departments proposed that, to the extent coverage under a group health plan consists of group health insurance coverage, the plan would satisfy the proposed machine-readable file requirements if the issuer offering the coverage were required to provide the information pursuant to a written agreement between the plan and issuer. Accordingly, if a plan sponsor and an issuer enter into a written agreement under which the issuer agrees to provide the information required under the proposed rules, and the issuer fails to provide full or timely information, then the issuer, but not the plan, has violated the final rule's disclosure requirements. This special rule would only apply, however, to insured group health arrangements where the contractually-obligated issuer is independently subject to the final rules.

The Departments received comments expressing strong support of the special rule to streamline public disclosure and avoid unnecessary duplication of disclosures for insured group health insurance coverage. These commenters recommended the policy be retained in the final rules. Accordingly, the final rules retain this special rule as proposed.

b. Use of Third Parties To Satisfy Public Disclosure Requirements

The Departments recognize that self-insured group health plans may rely on written agreements with other parties, such as service providers, to obtain the necessary data to comply with the final rules' disclosure requirements. Furthermore, it is the Departments' understanding that most health care coverage claims in the U.S. are processed through health care clearinghouses and that these entities maintain and standardize health care information, including information regarding negotiated rates and out-of-network allowed amounts.[207] As a result, the Departments noted in the proposed rules that a plan or issuer may reduce the burden associated with making negotiated rates and out-of-network allowed amounts available in machine-readable files by entering a business associate agreement and contracting with a health care claims clearinghouse or other HIPAA-compliant entity to disclose this data on its behalf.[208] Accordingly, the Departments proposed to permit a plan or issuer to satisfy the public disclosure requirement of the proposed rules by entering into a written agreement under which another party (such as a TPA or health care claims clearinghouse) will make public the required information in compliance with this section. However, if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide full or timely information, the plan or issuer will have violated the final rules' disclosure requirements.

Generally, commenters supported the use of clearinghouses or TPAs to store all of the information that must be disclosed under the proposed rules. One commenter suggested that all HIPAA-compliant third parties, not just clearinghouses, be allowed to satisfy the public disclosure requirements. Some commenters raised concerns related to using clearinghouses noting that the feasibility of using clearinghouses is dependent on the clearinghouse receiving all of the necessary data from health insurance issuers and providers who possess the data. The commenter strongly recommended the final rules require entities that possess the data to

[207] The Departments are adopting the definition of health care clearinghouse under 45 CFR 160.103 for purposes of these rules. Under that definition, health care clearinghouse means a public or private entity that performs one of two functions that involve the receiving and processing of health information data from a non-standard format to a standard format or non-standard data elements to standard data elements and vice versa.

[208] 45 CFR 164.502(a)(3) and 164.504(e)(2).

share the information in a timely manner with the relevant clearinghouses. The commenter also noted the costs charged by clearinghouses associated with data storage and noted that the prices must be reasonable and not discriminatory (for example, against smaller plans).

Several commenters recommended the Departments' special rule include protection for plan sponsors if they fail to meet the public disclosure requirements due to an inability, while acting in good faith, to obtain the data from a third-party service provider or when a contracted third-party withholds information or fails to submit information in a timely manner. One of these commenters also requested the Departments establish a policy that liability for failure to comply rests with a contracted third party in the event a plan sponsor can show that, acting in good faith, it is unable to comply with the disclosure requirements due to withholding of information by the third party.

This special rule, as finalized, continues to permit a plan or issuer to satisfy the public disclosure requirements of 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), and, 45 CFR 147.212(b) of the final rules by entering into a written agreement under which another party (such as a TPA or health care claims clearinghouse) will make public the required information in compliance with this section. The final rules identify TPAs and health care claims clearinghouses as examples of the types of parties a plan or issuer may contract with, but these are not the only types of entities that may enter into such arrangements and the Departments expect that they will comply with any applicable privacy protection requirements, including applicable privacy protections under HIPAA.

Plans and issuers are not required to enter into such agreements in order to comply with the public disclosure requirements of the final rules. As the Departments noted in the preamble to the proposed rules, if a plan or issuer chooses to enter into such an agreement it is ultimately the responsibility of the plan or issuer to ensure that the third party provides the information required by the final rules. As noted earlier in this section, the special rule for insured plans is only available to plans that contract with an entity that is an issuer separately subject to final rules. This requirement ensures that the Departments retain a mechanism to enforce the final rules. Accordingly, this special rule relating to the use of third parties to satisfy these requirements continues to provide that the plan or issuer would violate the requirements of the final rules if the third party fails to provide full or timely information.

Another commenter recommended the Departments create a special rule or ''safe harbor'' for plans that are unable to disclose negotiated rate information due to antitrust laws, which prevent the plan from accessing information about its partners' contracts when engaged in a partnership alliance agreement. The commenter described a partnership alliance as shared partner networks in other geographic areas in order to meet the needs of multi-state employer groups.

As discussed earlier in this preamble, the Departments acknowledge that the Sherman Antitrust Act prohibits any contract, combination, or conspiracy in restraint of trade or commerce.[209] Specifically, the law prohibits any ''person'' from entering into any such contract, trust, or similar arrangement.[210] Nothing under the proposed or final rules creates, compels, or endorses agreements or conspiracies between or among persons to form illegal arrangements or trusts in restraint of trade or commerce. Antitrust law does not proscribe or limit action by the Federal Government, to improve competition and lower costs to consumers, even if these actions may involve disclosures that, if made by private parties under a collusive agreement, might invite antitrust scrutiny.[211] Because the Departments are of the view that antitrust law will not prevent plans and issuers from making the public disclosures required under the final rules, there is no need for the Departments to create a special rule for plans that are unable to disclose negotiated rate information due to antitrust laws.

One commenter expressed a concern that multiemployer plans generally do not have access to the rate information needed to provide the cost-sharing disclosures required under the proposed rules, yet plans could be subject to significant penalties for failure to comply. The Departments note that insured multiemployer plans would qualify for the special rule for insured plans under which an issuer providing coverage for a plan enters into an agreement to provide the required information, which is being finalized through the final rules. If a multiemployer plan sponsor enters into a written agreement with an issuer under which the issuer agrees to provide the information required under the final rules, and the issuer fails to provide full or timely information, then the issuer, but not the plan, has violated the transparency disclosure requirements and may be subject to enforcement mechanisms applicable to plans under the PHS Act.[212] Therefore, insured multiemployer plans that contract with an issuer to provide the information required under the final rules would not be subject to enforcement actions under this mechanism; rather, the issuers with whom they have contracted will be subject to enforcement action under the final rules for failure to meet the transparency disclosure requirements.

Under the second special rule, multiemployer plans may also contract with a TPA or other third party (for example, a clearinghouse) to meet the transparency disclosure requirements under the final rules. However, this commenter is correct that if a plan or issuer chooses to enter into such an agreement, and the party with which it contracts fails to provide full or timely information, the plan or issuer would violate the transparency disclosure requirements.

The notion that accountability for compliance rests with a plan or issuer when the issuer or plan enlists a contractor or vendor for a business function is not inconsistent with other applicable regulations.[213] While claims processing is the main function for which an issuer or plan has contracted in this example, other responsibilities, such as responding to Federal audits and report requirements, may fall within the scope of the duties required by contract. The Departments clarify that nothing in the final rules prevents an issuer or plan from ensuring contracts with TPAs or other third parties include clear terms specifying functions required to meet the disclosure requirements of the final rules, as well as establish service level agreements and performance metrics to hold the entities with whom the issuer or plan decides to contract accountable.

Because multiemployer plans may be able to take advantage of the special rules established under the proposed rules, the Departments do not view additional special considerations necessary to address the ability of such

[209] 15 U.S.C. 1.

[210] *Id.*

[211] For example, *see* 84 FR 65464, 65464–65 (Nov. 27, 2019).

[212] Section 2723 of the PHS Act.

[213] For example, plans remain liable for violations of claims regulations under 26 CFR 54.9815–2719 and 29 CFR 2590.715–2719; and QHPs issuers who contract with downstream or delegated entities must maintain compliance with all applicable standards under 45 CFR 156.340(a).

plans to comply with the transparency requirements of the final rules.

c. Aggregation for Allowed Amount Files

In order to further mitigate privacy concerns and to eliminate unnecessary duplication, the Departments proposed to permit plans and issuers to satisfy the public disclosure requirements of the proposed rules by making available out-of-network allowed amount data that has been aggregated to include information from more than one plan or policy. As previously discussed, a plan or issuer may satisfy the disclosure requirement by disclosing out-of-network allowed amounts. Accordingly, under such circumstances, the proposed rules would have permitted plans and issuers to aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract.

To the extent a plan or issuer provided aggregated out-of-network allowed amount information, the Departments proposed to apply the minimum claims threshold to the aggregated claims data set, but not at the plan or issuer level. Based on commenters' requests for clarification, the Departments have determined that the proposed approach to apply the minimum claims threshold to the full aggregated claims data set could undermine the goal of the minimum claims threshold. The out-of-network Allowed Amount File must include a unique plan identifier for each plan or coverage included in the file under 26 CFR 54.9815–2715A3(b)(1)(ii)(A), 29 CFR 2590.715–2715A3(b)(1)(ii)(A), and 42 CFR 147.212(b)(1)(ii)(A). Therefore, even if the data for each plan or coverage were to be aggregated for purposes of determining whether the minimum claims threshold applies to a particular covered item or service, the data in the Allowed Amounts File would be distinguishable at the level of the plan identifier. The Departments are of the view that this could be problematic if all plans or coverage included in an aggregated Allowed Amount File meet the minimum claim threshold for an item or service when combined, but some or all individual plans do not independently meet the minimum claim threshold of 20 claims.

For instance, data for two plans are aggregated in the same Allowed Amount File under this rule. Plan A has 20 claims for Service X, while Plan B only has six claims for Service X. In aggregate, the plans meet the 20-claim threshold with 26 total claims for Service X. However, individually, only Plan A has met the minimum claim threshold. Under the proposal, data for Service X would be required to be included for both Plan A and Plan B, along with both the plan identifiers. The outcome of this requirement would be that Plan B would include data identifiable at the plan level for Service X. The Departments are of the view that allowing Plan B data to be included in the file for Service X would undermine the minimum claim threshold, increasing risk that individual patients' claims histories could be identified. To prevent this outcome, data for each plan or coverage included in an aggregated Allowed Amount File must independently meet the minimum claims threshold for each item or service and for each plan or coverage included in the aggregated Allowed Amount File. To highlight this requirement, the Departments are finalizing this provision of the proposed rules with a minor modification clarifying that the flexibility to aggregate out-of-network allowed amounts for more than one plan or coverage in a single machine-readable file is still subject to the minimum claims threshold applicable to individual plans or coverage as described under paragraph (b)(1)(ii)(C) of the same section.

One commenter requested clarification of a plan's obligation if a third party aggregates the Allowed Amount File. The commenter specifically requested clarification regarding whether the plan or third party would be responsible for posting the file, and whether there will be any special labeling requirements for an aggregated file, including if the file will need to include a disclosure that it includes aggregated data.

Nothing in the final rules prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator from contracting with a third party to post the file. The Departments have added text to the final rules to make clear that this flexibility exists and to provide that if a plan chooses not to also host the file separately on its own public website, it must provide a link on its website to the location where the file is publicly available. The Departments will provide additional information on the form and manner, including labeling, through the file technical implementation guidance.

III. Overview of the Final Rule Regarding Issuer Use of Premium Revenue Under the Medical Loss Ratio Program: Reporting and Rebate Requirements—The Department of Health and Human Services

As stated in the preamble to the proposed rules, consumers with health insurance often lack incentives to seek care from lower-cost providers, for example when consumers' out-of-pocket costs are limited to a set copayment amount regardless of the costs incurred by the issuer. Innovative benefit designs can be used to increase consumer engagement in health care purchasing decisions. HHS proposed to allow issuers that empower and incentivize consumers through the introduction of new or different plans that include provisions encouraging consumers to shop for services from lower-cost, higher-value providers, and that share the resulting savings with consumers, to take credit for such ''shared savings'' payments in their MLR calculations. HHS believes this approach preserves the statutorily-required value consumers receive for coverage under the MLR program, while encouraging issuers to offer new or different plan designs that support competition and consumer engagement in health care.

Formula for Calculating an Issuer's Medical Loss Ratio (45 CFR 158.221)

Section 2718(b) of the PHS Act requires a health insurance issuer offering group or individual health insurance coverage (including grandfathered health insurance plans) to provide rebates to enrollees if the issuer's MLR falls below specified thresholds (generally, 80 percent in the individual and small group markets and 85 percent in the large group market). Section 2718(b) of the PHS Act generally defines MLR as the percentage of premium revenue (after certain adjustments) an issuer expended on reimbursement for clinical services provided to enrollees and on activities that improve health care quality. Consistent with section 2718(c) of the PHS Act, the standardized methodologies for calculating an issuer's MLR must be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.

Several states have considered or adopted legislation over the last few years to promote health care cost transparency and encourage issuers to design and make available plans that ''share'' savings with enrollees who shop for health care services and choose to obtain care from lower-cost, higher-value providers.[214] In addition, at least five states and a number of self-insured group health plans have incorporated such ''shared savings'' provisions into

[214] 24–A Maine Rev. Stat. Ann. Sec. 4318–A (adopted Jun. 19, 2017); Neb. Rev. Stat. Sec. 44–1401 *et seq.* (adopted Apr. 23, 2018); Utah Code Ann. Sec. 31A–22–647 (adopted Mar. 19, 2018); AZ SB 1471 (2018); N.H. HB 1784–FN (2018); MA H2184 (2017).

all or some of their health plans.[215] Under some plan designs, the savings are calculated as a percentage of the difference between the rate charged by the provider chosen by the consumer for a medical procedure and the average negotiated rate for that procedure across all providers in the issuer's network. Under other plan designs, the ''shared savings'' are provided as a flat dollar amount according to a schedule that places providers in one or more tiers based on the rate charged by each provider for a specified medical procedure. Under various plan designs, the ''shared savings'' may be provided in form of a gift card, a reduction in cost sharing, or a premium credit. HHS is of the view that such unique plan designs would motivate consumers to make more informed choices by providing consumers with tangible incentives to shop for care at the best price. As explained elsewhere in the preamble to the proposed rules, there is ample evidence that increased transparency in health care costs would lead to increased competition among providers.[216] HHS is of the view that allowing flexibility for issuers to include savings they share with enrollees in the numerator of the MLR would increase issuers' willingness to undertake the investment necessary to develop and administer plan features that may have the effect of increasing health care cost transparency, which in turn could lead to reduced health care costs.

HHS has in the past exercised its authority under section 2718(c) of the PHS Act to take into account the special circumstances of different types of plans by providing adjustments to increase the MLR numerator for ''mini-med'' and ''expatriate'' plans,[217] student health insurance plans,[218] as well as for QHPs that incurred Exchange implementation costs [219] and certain non-grandfathered plans (that is, ''grandmothered'' plans).[220] This authority has also been exercised to recognize the special circumstances of new plans [221] and smaller plans.[222] Consistent with this approach, HHS proposed to exercise its authority to account for the special circumstances of new and different types of plans that provide ''shared savings'' to consumers who choose lower-cost, higher-value providers by adding a new paragraph 45 CFR 158.221(b)(9) to allow such ''shared savings'' payments to be included in the MLR numerator. HHS made this proposal so that issuers would not be required to pay MLR rebates based on a plan design that would provide a benefit to consumers that is not currently captured in any existing MLR revenue or expense category. HHS proposed that the amendment to 45 CFR 158.221 would become effective beginning with the 2020 MLR reporting year (for reports filed by July 31, 2021). HHS invited comments on this proposal.

After considering the public comments, HHS is finalizing the amendment to 45 CFR 158.221(b) as proposed.

The majority of comments on the proposed amendments to the MLR program rules supported the proposal to add a new paragraph to 45 CFR 158.221(b). Supporters noted that allowing issuers to include ''shared savings'' payments in their MLR calculation aligns issuer and enrollee incentives, aligns with MLR's purposes, is innovative, provides enrollees with value, increases consumer engagement and empowerment, and will promote better enrollee decision-making and reduce total health care costs. Several supportive commenters also noted that the proposal may encourage more issuers to offer such ''shared savings'' programs, as allowing ''shared savings'' payments to be included in the MLR numerator will remove any existing barriers to such programs and facilitate the use of innovative benefit designs that increase consumer engagement in health care purchasing decisions, while disallowing this approach punishes issuers that offer innovative ''shared savings'' programs and disincentivizes issuers from adopting such programs. Several commenters stated that there is evidence that patients are more likely to shop for care when information on prices is coupled with incentives, and that such shopping can generate significant savings for issuers and lead health care providers to lower their prices in order to remain competitive in the marketplace.[223]

HHS agrees with the comments in support of the proposal and is finalizing this amendment as proposed to provide additional flexibility to states and issuers and encourage the economic effects the commenters highlighted.

Some commenters requested clarification regarding certain aspects of the ''shared savings'' plans. Several commenters requested that HHS develop uniform standards and a definition for ''shared savings,'' which according to commenters would, among other things, help prevent fraud and abuse; and that HHS clarify the criteria for low-cost, high-value providers. One commenter asked HHS to provide sub-regulatory guidance to specify in what form the savings can be shared, how issuers will report their ''shared

[215] *See* the State of Kansas' SmartShopper program for state employees enrolled with BCBSKS, available at: *https://healthbenefitsprogram.ks.gov/docs/default-source/site-documents/sehp/vendor-documents/bcbs/smartshopper_state_of_kansas_steps.pdf?sfvrsn=cfa4e44_8;* the state of Kentucky employee member handbook for Livingwell CDHP's SmartShopper program, available at: *https://personnel.ky.gov/KEHP/2020%20LivingWell%20CDHP%20Medical%20Benefit%20Booklet.pdf* and *https://www.smartshopper.com/legacy?utm_expid=.WJ_v45PuTXuo1k6ioPp4tA.1&utm;* the State of Massachusetts employee member handbook for Fallon Health Select Care's SmartShopper program, available at: *https://www.mass.gov/doc/fallon-select-care-handbook-fy21/download;* the State of New Hampshire employee medical benefit, the Site of Service and Vitals SmartShopper Programs, available at: *https://das.nh.gov/riskmanagement/active/medical-benefits/cost-savings-programs.aspx#vitals-smartshopper;* Utah Public Employees Health Program Cost Tools, available at: *https://www.pehp.org/save.*

[216] Austin, D. A., and Gravelle, J. G. ''Congressional Research Service Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' Congressional Research Service. July 24, 2007.''Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf.*

[217] *See* 45 CFR 158.221(b)(3) for ''mini-med'' plans and 45 CFR 158.221(b)(4) for ''expatriate'' plans; *see also* the Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protections and Affordable Care Act; Interim Final Rule; 75 FR 74864, 74872 (Dec. 1, 2010).

[218] *See* 45 CFR 158.221(b)(5); *see also* the Student Health Insurance Coverage; Final Rule, 77 FR 16453, 16458–16459 (Mar. 21, 2012).

[219] *See* 45 CFR 158.221(b)(7); *see also* the Exchange and Insurance Market Standards for 2015 and Beyond; Final Rule; 79 FR 30240, 30320 (May 27, 2014).

[220] *See* 45 CFR 158.221(b)(6); *see also* 79 FR 30240, 30320 (May 27, 2014). *See* 45 CFR 158.221(b)(6); *see also* 79 FR 30240, 30320 (May 27, 2014); *see also* 45 CFR 158.221(b)(6); *see also* 79 FR 30240, 30320 (May 27, 2014). ''Grandmothered'' plans is a term for certain non-grandfathered coverage in the small group and individual health insurance markets. Since 2014, CMS has permitted, subject to applicable State authorities, health insurance issuers to continue certain coverage that could not otherwise remain in place without significant changes to comply with PPACA. Such health insurance coverage would not be treated as out of compliance with sections 2701–2707 and 2709 of the PHS Act and section 1312(c) of PPACA (group health plans must still comply with section 2704 and 270505 of the PHS Act). *See* Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies, available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Limited-Non-Enforcement-Policy-Extension-Through-CY2020.pdf* and *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2021.pdf.*

[221] *See* 45 CFR 158.121; *see also* 75 FR 74864, 74872–74873 (Dec. 01, 2010) and the HHS Notice of Benefit and Payment Parameters for 2018 Final Rule; 81 FR 94058, 94153–94154 (Dec. 22, 2016).

[222] *See* 45 CFR 158.230 and 158.232; *see also* 75 FR 74864, 74880 (Dec. 01, 2010).

[223] For example, one commenter shared that since 2015, its ''shared savings'' program issued over 149,000 incentive reward payments, generating over $85 million in savings. *See https://beta.regulations.gov/document/CMS-2019-0163-14320.*

savings,'' how double-counting can be prevented, and whether ''shared savings'' payments are taxable income. Other commenters suggested that HHS provide maximum flexibility for issuers and states to innovate and develop ''shared savings'' programs they determine are best suited for their populations.

While HHS appreciates these suggestions and is also concerned with preventing fraud and abuse, HHS is of the view that state legislators and regulators are currently in a better position than HHS to work with the issuers in their states to define the ''shared savings'' programs that they support, issue standards and criteria for the programs for their respective constituents, and decide in what form the savings can be made. These considerations include the operational details of any ''shared savings'' program, such as creating standards and definitions, developing acceptable payment methods, and addressing fraud concerns. HHS notes that several issuers have already developed and implemented such programs and that a few states have done the same. The amendment being finalized in this rulemaking is specific to the recognition of ''shared savings'' payments in issuer MLR calculations and is intended to encourage more state and issuer innovation with these types of programs. Accordingly, HHS will provide technical guidance in the MLR Annual Reporting Form Instructions to clarify the reporting of ''shared savings'' payments specifically for MLR purposes. With respect to the comment regarding how double-counting can be prevented, HHS notes that 45 CFR 158.170 prevents double-counting by requiring each expense to be reported in only one category or to be pro-rated between categories for MLR purposes. Finally, whether ''shared savings'' payments to enrollees are taxable will vary based on certain specific facts and circumstances. Some forms of ''shared savings'' may be taxable; however, HHS defers to the Department of the Treasury to address the taxability of such payments as necessary.

Opponents of the proposal stated that it fails to ensure that the savings are actually used for health care or quality improvement activities (QIA), that HHS is subverting the statutory scheme by allowing issuers to spend less on enrollees' care and quality initiatives without returning the premium dollars saved to all enrollees, and that the proposal would allow issuers to further boost profits and diminish the MLR standards and issuer accountability. Some opponents of the proposal argued that since any plan type can offer ''shared savings,'' adding a ''shared savings'' payment component to a policy does not make it a ''different'' type of plan and it should not be treated as such. Others were concerned that the proposal would incentivize issuers to artificially drive down negotiated rates with providers and that these savings may not make their way back to enrollees. One commenter opposed extending ''shared savings'' programs to self-insured ERISA plans. Another commenter pointed out that the National Association of Insurance Commissioners (NAIC) did not mention the proposal in its comments and the MLR statute provides that the NAIC shall establish the definitions and methodologies for MLRs.

HHS agrees that ''shared savings'' are neither an incurred claim nor a QIA. Instead, in support of this amendment to 45 CFR 158.221(b), HHS is relying on the statutory directive under section 2718(c) of the PHS Act that the MLR standardized methodologies shall be designed to take into account the special circumstances of different types of plans and newer plans, such as plans that offer ''shared savings'' payments to enrollees that seek care from lower-cost, higher-value providers. HHS believes that any issuer that includes in its plan design(s) a ''shared savings'' component is offering a ''different'' type of plan and a ''newer'' plan, as a ''shared savings'' program is a new and unique feature. HHS notes that the amendment finalized in these rules helps provide policyholders with value for their premium dollars, as intended by section 2718 of the PHS Act. HHS disagrees that the amendment somehow subverts the statutory scheme as issuers that implement these programs are sharing the savings and returning dollars to enrollees who participate in these programs, and issuers must still otherwise meet the applicable MLR threshold or provide a rebate to enrollees. For the same reasons, HHS does not share certain commenters' view that the amendment weakens the MLR standards and enables issuers to improperly boost profits, as the amendment simply allows issuers to account for the portion of the ''shared savings'' that is passed to participating enrollees and that consequently does not increase issuers' profits. With respect to comments regarding the impact on provider negotiated rates and enrollee access to savings, HHS is unsure how the amendment would incentivize issuers to artificially drive down negotiated rates with providers. However, if as a result of this amendment, provider rates decrease, such a result would in fact benefit enrollees. In addition, because only actual payments made to enrollees can be included in an issuer's MLR calculation under the amendment, issuers will benefit for MLR calculation and reporting purposes only if the savings are actually shared with enrollees. With respect to the comment regarding self-insured ERISA plans, HHS notes that this amendment does not apply to or impact, either self-funded ERISA plans, or self-funded non-ERISA plans, as these plans are not subject to the MLR reporting and rebate requirements under section 2718 of the PHS Act. Last, with respect to comments regarding the NAIC recommendations to HHS, section 2718(c) of the PHS Act directed the NAIC, subject to certification by the Secretary, to establish uniform definitions and standardized methodologies to guide MLR reporting and calculations. The NAIC met its statutory obligation when it provided recommendations to HHS in 2010 in the form of a model regulation.[224] The NAIC's recommendations informed the Secretary's decisions about the Federal definitions and methodologies for calculating MLRs.[225] In this rulemaking, HHS is taking further action to recognize the special circumstances of the different and newer plans that include ''shared savings'' programs with the addition of new paragraph (b)(9) to 45 CFR 158.221.

Some commenters expressed concerns that ''shared savings'' programs in general could actually compromise the quality of care by driving consumer choices based on cost without regard for quality, and that these programs could encumber and curtail medically necessary clinical services in serving the financial interest of the payer. Some commenters requested that HHS only allow ''shared savings'' where there is evidence that the participating enrollees actually receive better care at reduced costs. One commenter stated that the proposal fails to define higher-value, which varies based on each enrollee's circumstances. One commenter questioned the feasibility of measuring whether reward systems generate actual savings.

[224] ''Regulation for Uniform Definitions and Standardized Methodologies for Calculation of the Medical Loss Ratio for Plan Years 2011, 2012, and 2013 per section 2718(b) of the Public Health Service Act,'' MDL–190. Available at: *https://www.naic.org/store/free/MDL-190.pdf?4.*

[225] *See* the Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act; Interim Final Rule, 75 FR 74864 (Dec. 1, 2010); *see also* 45 CFR part 158.

HHS disagrees that programs that reward enrollees for critically examining their options and pursuing cost-effective care interfere with the provision of medically necessary clinical services. However, HHS agrees that quality as well as cost should be determinants of what qualifies for inclusion in any given issuer's ''shared savings'' program. That is why the amendment to 45 CFR 158.221 includes both a cost and quality component; it permits issuers to include in the MLR numerator ''shared savings'' payment made to enrollees choosing to obtain care from a lower-cost and higher-value provider. However, HHS did not propose and is not finalizing elements or criteria issuers must address or otherwise include in their respective ''shared savings'' programs. The amendment finalized in this rulemaking is specific to recognizing ''shared savings'' payments in issuer MLR calculations. As detailed above, HHS believes state legislators and regulators are currently in the best position to work with issuers in their states to develop standards and criteria for ''shared savings'' programs for their respective constituents. HHS further believes that issuers are in the best position to perform the necessary provider credentialing activities that will ensure that network providers that are included in their ''shared savings'' programs are high-value, high-quality providers. Since higher-value can vary by enrollee demographics and provider type, issuers must determine what this means for their enrollees and providers and maintain all documents and other evidence necessary to support that determination consistent with the maintenance of records requirements contained in 45 CFR 158.502. Issuers are sophisticated entities that understand that if their enrollees obtain lower-quality care, their costs over the long-term will increase rather than decrease as their enrollees will likely need additional and possibly corrective medical care. HHS therefore believes that issuers' incentives are aligned with those of their enrollees when it comes to designing ''shared savings'' programs.

HHS received a few comments urging that issuers be allowed to include some or all of the costs of implementing the requirements of these price transparency rules as a QIA in the numerator of the MLR calculation. A few commenters urged HHS to allow issuers to include some or all of the costs of creating the cost estimator tool required by the price transparency aspects of the proposed rules.

Price transparency implementation costs do not constitute an improvement to the quality of health care and thus do not qualify as QIA and cannot be included in the numerator of the MLR calculation.

Lastly, several commenters expressed support for or opposition to the MLR reporting and rebate requirements in general. HHS appreciates these comments but notes that they are outside the scope of the amendments to the MLR program rules contained in the proposed rule.

IV. Applicability

A. In General

1. Entities Subject to the Final Rules

The Departments proposed requiring group health plans, including self-insured plans, and health insurance issuers of individual and group health insurance coverage to disclose pricing information, with certain exceptions as discussed in more detail in this preamble. The Departments are of the view that consumers across the private health insurance market will benefit from the availability of pricing information that is sufficient to support informed health care decisions. Although the Departments considered making the requirements applicable to a more limited segment of the private health insurance market, the Departments are of the view that consumers across the market should receive and benefit from the same access to standardized, meaningful pricing information and estimates. Moreover, applied broadly, these changes have a greater potential to reform health care markets.

Additionally, the preamble to the proposed rules discussed how pricing information related to items and services that are subject to capitation arrangements under a specific plan or contract could meet transparency standards by disclosing only the consumer's anticipated liability. The Departments sought comment on whether there are certain reimbursement or payment models (such as ACOs or staff model HMOs) that should be partially or fully exempt from these requirements or should otherwise be treated differently. Further, the Departments sought comment on how consumers may become better informed about their cost-sharing requirements under these reimbursement or payment models.

The Departments also considered limiting applicability to issuers of individual health insurance coverage and insured group health insurance coverage, but concluded that limiting applicability would be inconsistent with section 2715A of the PHS Act. The Departments are concerned that a more limited approach might encourage plans and issuers to simply shift costs to sectors of the market where the final rules would not apply and where consumers have diminished access to pricing information. Additionally, the Departments are concerned that a more limited approach may distort the health care market by creating perverse incentives for plans and issuers to avoid participating in certain markets that require compliance with these requirements.

The Departments are aware that certain plans and health coverage are not subject to the transparency provisions under section 2715A of the PHS Act and, therefore, are not be subject to the final rules. This includes grandfathered health plans, excepted benefits, health care sharing ministries, and short-term, limited-duration insurance (STLDI).

Grandfathered health plans are health plans that were in existence as of March 23, 2010, the date of enactment of PPACA, and that are only subject to certain provisions of PPACA, as long as they maintain their status as grandfathered health plans under the applicable rules.[226] Under section 1251 of PPACA, section 2715A of the PHS Act does not apply to grandfathered health plans. Therefore, the proposed rules would not have applied to grandfathered health plans (as defined in 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140).

In accordance with sections 2722 and 2763 of the PHS Act, section 732 of ERISA, and section 9831 of the Code, the requirements of title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code do not apply to any group health plan (or group health insurance coverage offered in connection with a group health plan) or individual health insurance coverage in relation to its provision of excepted benefits. Excepted benefits are described in section 2791 of the PHS Act, section 733 of ERISA, and section 9832 of the Code. Section 2715A of the PHS Act is contained in title XXVII of the PHS Act, and, therefore, the proposed rules would not have applied to a plan or coverage consisting solely of excepted benefits.

The Departments also proposed that the rules would not apply to STLDI. Under section 2791(b)(5) of the PHS Act, STLDI is excluded from the definition of individual health insurance coverage and is therefore exempt from section 2715A of the PHS

[226] 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140.

Act.[227] Therefore, the proposed rules would not have applied to STLDI coverage.

The Departments also proposed that the rules would not apply to health reimbursement arrangements, or other account-based plans, as defined in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), that simply make reimbursements subject to a maximum fixed dollar amount for a period, with the result that cost-sharing concepts are not applicable to those arrangements.

In contrast, the Departments proposed that the final rules would apply to grandmothered plans, meaning certain non-grandfathered health insurance coverage in the individual and small group markets with respect to which CMS has announced it will not take enforcement action even though the coverage is out of compliance with certain specified market requirements.[228] The Departments sought comment on whether grandmothered plans may face special challenges in complying with these transparency reporting provisions and whether the proposed rules should apply to grandmothered plans.

The final rules adopt these provisions as proposed. The final rules apply these requirements to group health plans, and health insurance issuers offering non-grandfathered group or individual health insurance coverage, with certain exceptions. Thus, the final rules apply to grandmothered plans. The Departments are finalizing, as proposed, that these requirements will not apply to certain plans and coverages that are not subject to the transparency provisions under section 2715A of the PHS Act, including grandfathered health plans, excepted benefits, and STLDI. Additionally, the final rules will not apply to health reimbursement arrangements, or other account-based plans, as defined in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), as these account-based arrangements simply make certain dollar amounts available, with the result that cost-sharing and price setting concepts are not applicable to those arrangements.

The majority of commenters supported applying these requirements to issuers of individual health insurance coverage and group health insurance coverage, as well as group health plans. Commenters supported allowing consumers across the market to access important pricing information. Some commenters suggested additional plans and coverages that should be required to comply with these requirements, as discussed later in this preamble. The Departments did not receive comments regarding application of the final rules to grandmothered plans.

One commenter stated that the proposed rules would create an uneven playing field that would unfairly advantage plans and issuers offering stand-alone dental or vision coverage over plans that incorporate such benefits into major medical coverage. For example, the commenter stated that a plan offering essential health benefits would have to include in a machine-readable file negotiated rates for pediatric dental services. However, a plan offering stand-alone dental coverage would not have to publish pricing information. For these reasons, the commenter recommended that vision, dental, and hearing benefits, if offered as part of a plan or coverage subject to the transparency requirements, should be excluded from information disclosed through the internet-based self-service tool and machine-readable files.

In response to this comment, the Departments note that section 2721(b), (c)(1) through (3) of the PHS Act provides an exemption from title XXVII of the PHS Act for ''any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) *in relation to its provision of excepted benefits.*'' (*See also* section 732 (b), (c) of ERISA, and section 9831(b), (c) of the Code) (emphasis added).[229] To the extent that a plan or issuer provides a participant, beneficiary, or enrollee with the opportunity to opt out of limited scope dental or vision benefits, those benefits are considered as not an integral part of the plan and, accordingly, are considered excepted benefits.[230] Therefore, under the final rules, plans and issuers that offer excepted benefits, such as limited scope dental or vision benefits, along with their major medical coverage are not required to disclose the information required by the final rules regarding their provision of those excepted benefits. Accordingly, the final rules do not create an uneven playing field that would unfairly advantage plans and issuers offering stand-alone dental or vision coverage over plans that incorporate such benefits into major medical coverage.

The Departments received a mix of comments regarding whether the final rules should apply to alternative contracting and alternative payment model structures, such as ACOs or HMOs. One commenter recommended a narrower scope for ACOs and other capitated payment arrangements, including only requiring transparency tools to display amounts that are not service dependent (for example, flat copayments), as well as accumulator information about deductibles and out-of-pocket maximums. As discussed elsewhere in this preamble, some commenters expressed concern regarding how the final rules would apply to reference-based pricing models, direct primary care, bundled or capitated payment arrangements, and value-based insurance design. Additionally, some commenters expressed concern regarding how the final rules would apply to plans with rental networks and quality-adjusted and risk-adjusted contracts (under which prices can only be calculated after the fact). These commenters recommended that these kinds of arrangements be exempt from the final rules' requirements.

On the other hand, other commenters suggested that there is no justification for excluding plans that reimburse their providers based on capitation from the requirements of the final rules as this would result in an incomplete data set, and issuers of risk adjustment-covered plans already assign values to services to administer benefits with deductibles and co-insurance, for risk adjustment purposes under 45 CFR 153.710(c), and for internal reporting. One commenter recommended that the final rules should apply to ACOs and other capitated arrangements and that these arrangements should be required to disclose their underlying financial incentive arrangements, not just consumer's anticipated liability. The commenter also noted that any exemptions may incentivize plans to move to these pricing models, which the commenter characterized as opaque and potentially consumer-unfriendly. Several commenters agreed that pricing information related to items and services subject to capitation arrangements could meet transparency standards only through the disclosure of the consumer's anticipated liability.

Some commenters raised the concern that the proposed rules would have a particularly negative impact on smaller entities that are less likely to have the financial reserves and technological

[227] *See* 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103.

[228] Pate, R. ''Insurance Standards Bulletin Series.'' Centers for Medicare & Medicaid Services. January 31, 2020. Available at: *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2021.pdf.*

[229] *See also* section 2763 of the PHS Act.

[230] 26 CFR 54.9831–1(c)(3)(ii), 29 CFR 2590.732(c)(3)(ii), and 45 CFR 146.145(b)(3)(ii).

resources to build and maintain systems to operationalize disclosure requirements. Some commenters requested that the final rules be optional or that smaller plans and TPAs be exempted from the requirements. For example, a few commenters recommended providing an exception to the price transparency requirement for small issuers, TPAs, and plans with revenue below the $41.5 million small entity threshold or with 100,000 commercial participants, beneficiaries, and enrollees or fewer. They suggested that an exception to the final rules would allow small issuers to adopt elements of the requirements of most relevance to their participants, beneficiaries, and enrollees while not forcing them to create a much more expensive option that may be of limited appeal.

In considering these concerns, the Departments weighed the competing goals of ensuring that consumers have access to pricing information, the burden on plans, including self-insured plans, and issuers of individual health insurance coverage and group health insurance coverage, and encouraging innovative plan design. As finalized, all issuers of non-grandfathered individual and group health insurance coverage and self-insured plans (that are not account-based plans), are required to comply with the final rules. Finalizing these rules to be applicable to plans as proposed is the most straightforward approach as it is impossible to define and predict all possible modifications, plans, or models. Furthermore, doing so mitigates creating incentives to adopt certain plan designs over others. The Departments believe that this is not likely to stifle innovation. Rather, the Departments are of the view that this approach creates a level playing field for non-grandfathered individual and group health insurance coverage and self-insured plans (that are not account-based plans) to create innovative plan designs and increase consumers' access to pricing information that is sufficient to support informed health care decisions. The Departments are of the view that exempting plan designs, such as alternative contracting and alternative payment model structures, would create an opportunity for plans and issuers to avoid sharing important pricing information with consumers. The Departments maintain the view that consumers across the market should come to expect and receive the same access to standardized, meaningful pricing information and estimates for all plans affected by the final rules. In addition, as detailed earlier in this preamble, issuers of risk adjustment-covered plans that include capitation arrangements are required under the final rules to submit a derived amount, potentially using the same internal methodology the issuer uses to assign a price value to the item or service for purposes of submitting risk adjustment data under 45 CFR 153.710(c).

A few commenters supported exempting grandfathered health plans, HRAs or other account-based plans, excepted benefits, and STLDI from the proposed rules. However, a majority of commenters were concerned that the final rules, as proposed, would not apply to plans or arrangements that may have the highest potential cost-sharing obligations, such as STLDI and health care sharing ministries. These commenters were concerned that STLDI plans often have dollar limits on covered benefits, limits on prescription drug coverage and covered doctor visits, and excluded benefits, which often means consumers enrolled in these plans can face higher cost-sharing liability when seeking medical care than patients covered by individual health insurance coverage, as defined under section 2791(b)(5) of the PHS Act. They stated that it is even more important for these patients to have access to their cost-sharing liability under the final rules before receiving care or even signing up for a STLDI plan, so they are aware of their coverage limits and are prepared to receive bills from the hospital and other health care providers for amounts that exceed their coverage. One commenter stated that whether such plans are considered ''individual health insurance'' is not relevant for such a determination, as the proposed rules would not apply to just individual health insurance, but would also apply to group coverage and grandmothered plans.

The Departments appreciate the concerns raised by commenters regarding these plans. However, the final rules adopt these policies as proposed. As noted earlier in this section of this preamble, certain types of coverage and arrangements such as STLDI, excepted benefits and health care sharing ministries, are not subject to the transparency provisions under section 2715A of the PHS Act and, therefore, are not subject to the final rules. However, the Departments encourage all plans that are not subject to the final rules to work to increase the transparency and availability of pricing information, to enable consumers to make informed health care decisions.

One commenter sought clarification of the liability of individual employers concerning Multiple Employer Welfare Arrangements (MEWAs) and Taft-Hartley plans. Section 715 of ERISA incorporates section 2715A of the PHS Act into part 7 of ERISA. Generally, employers are only responsible for ensuring compliance with the requirements of ERISA for a Taft-Hartley plan (also known as a multi-employer plan), if they are a member of the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or are otherwise a fiduciary of the plan. For MEWAs that are employee welfare benefit plans, the bona fide group or association that sponsors the MEWA assumes and retains responsibility for operating and administering the MEWA, including ensuring compliance with Part 7 of ERISA. In cases where the MEWA itself is not a plan, each employer that provides benefits through a MEWA and, therefore, maintains its own plan, is separately responsible for compliance with ERISA requirements, and thus with the requirements of the final rules.

Some commenters recommended adding additional plans and coverages to the list of health coverage not subject to these transparency requirements. One commenter recommended adding expatriate health plans because the Expatriate Health Coverage Clarification Act of 2014 exempts expatriate health plans from most of the provisions of PPACA, including sections 1311(e)(3) of PPACA and section 2715A of the PHS Act, both of which the Departments cite in asserting statutory authority to propose these transparency requirements. Another commenter recommended that Denominational Health Plans be specifically exempted from the final rules. This commenter noted that Denominational Health Plans can only offer coverage to a limited segment of the population—eligible employees in the denomination—based on church requirements, beliefs, and polity. Therefore, most of the individuals to which this information would be disclosed would not be eligible to enroll in these plans even if they wished to do so. Other commenters recommended extending the final rules to health coverage to which 2715A of the PHS Act does not apply. For example, a commenter recommended that the Departments add Medicaid Managed Care Organization plans and Medicare-Medicaid Plans to the list of health plans not subject to the transparency requirements. The commenter noted that the combination of Medicaid payment rates and low cost-sharing requirements limit the

usefulness of this information in the Medicaid context.

The Departments are finalizing the final rules as proposed and, therefore, all plans subject to section 2715A of the PHS Act must comply with these requirements. The Departments agree with commenters that sections 1311(e)(3) of PPACA and 2715A of the PHS Act do not apply to expatriate health plans [231] and, therefore, such plans are not subject to the requirements in the final rules. Furthermore, the Departments' authority for the final rules derive from section 2715A of the PHS Act, which only applies to group health plans and health insurance issuers offering group or individual health insurance coverage, and not Medicaid Managed Care Organization plans, Medicare-Medicaid Plans, and Denominational Health Plans.

Interaction of Final Rules With 45 CFR 156.220

The Departments recognize that health insurance issuers offering group or individual health insurance coverage as QHPs through an Exchange are already subject to reporting requirements under 45 CFR 156.220 that implement the transparency in coverage requirements of section 1311(e)(3) of PPACA. Pursuant to 45 CFR 156.220, issuers of QHPs offered through an individual market Exchange or a Small Business Health Options (SHOP) Exchange, including stand-alone dental plans, must submit specific information about their plans' coverage to the appropriate Exchange, HHS, and the state insurance commissioner, as well as make the information available to the public in plain language.

The Departments acknowledge the similar purposes served by 45 CFR 156.220 and the final rules. The Departments, however, note the final rules do not alter requirements under 45 CFR 156.220. Accordingly, QHP issuers must comply with both rules' requirements. If necessary and to the extent appropriate, HHS may issue future guidance to address QHP issuers' compliance with both 45 CFR 156.220 and the final rules.

2. Applicability Dates

Except as otherwise provided for in the proposed MLR requirements,[232] the Departments proposed that all the proposed requirements would become applicable for plan years (or in the individual market, policy years) beginning on or after one year after the finalization of the final rules. The Departments requested feedback about this proposed timing. In particular, the Departments were interested in information regarding the time necessary to develop cost estimation tools and machine-readable files. The Departments are finalizing a modified applicability timeline for the machine-readable files at 26 CFR 54.9815–2715A3, 29 CFR 2590.715–54.9815–2715A3, and 45 CFR 147.212. The requirements to publish the machine-readable files will become effective for plan years (or in the individual market, for policy years) beginning on or after January 1, 2022. The Departments, in response to comments, are finalizing an applicability date that is generally one-year later than the proposed applicability date for complying with the internet-based self-service tool requirements. Specifically, plans and issuers will be allowed to phase in the requirements at 26 CFR 54.9815–22715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 regarding the items and services included in the internet-based self-service tool. Plans and issuers will be required to provide pricing information for a minimum of 500 items and services identified by the Departments beginning with plan years (or in the individual market, policy years) on or after January 1, 2023. Plans and issuers will be required to provide the pricing information through the internet-based self-service tool for all items and services by plan years (or in the individual market, policy years) beginning on or after January 1, 2024.

The Departments are finalizing applicability dates that do not tie applicability timelines to the beginning of plan years (or in the individual market policy years) that begin one year after the effective date of the rules, as proposed. Because most plan and policy years begin on January 1st, the Departments are of the view that this change in the applicability date likely will not shorten the amount of time plans and issuers have to comply with the machine-readable file requirements, as it has been the Departments' intent, including under the proposed rules, to require calendar year plans and policies to come into compliance with the final rules by January 1, 2022. The changed timeline is therefore unlikely to lead to increased burdens or costs. The Departments are finalizing a 3-year applicability timeline for the internet-based self-service tool requirements. Under the proposed rules, plans and issuers would have had to comply with all relevant proposed requirements beginning with plan or policy years beginning on or after January 1, 2023. Under the final rules, full compliance with all requirements associated with the internet-based self-service tool will not be required until plan or policy years beginning on or after January 1, 2024. For these reasons, the final rule's applicability dates for the self-service tool requirements are also unlikely to lead to increased burdens or costs.

Many commenters submitted comments regarding the proposed applicability date of the proposed rules. The majority of commenters strongly recommended delaying the proposed applicability date for the internet-based self-service tool and machine-readable file requirements of the rules for at least one year and up to five years from publication of the final rules.

Commenters recommended delaying the applicability date of the final rules because complying with the requirements will require negotiations with administrative service providers, and the design, building, and testing of websites. Other commenters cited the challenges in accessing some of the required information from third parties and the technical challenges plans will likely face as additional reasons to delay the applicability dates of these requirements. Additionally, commenters noted that the proposed rules would require disclosure of large volumes of data, which will have to be coordinated among various parties and for which systems will need to be put into place to ensure timely, accurate disclosure. Some commenters noted that a delay would be needed due to complex operational and compliance issues related to contracting with TPAs, ownership of data, and building and operating new IT systems.

Commenters also cited vendor supply/demand challenges; extensive technology design, development, and deployment work; amending agreements with third parties; financing required to meet the requirements of the final rules; and time needed to test the tools for consumer use as reasons to delay the applicability date. One commenter noted that their current price estimator tools took considerable time and resources to develop, and large portions of a tool's underlying logic or feature set may not be compatible with the approach envisioned in the proposed rules. Moreover, testing, evaluating, and resolving these types of issues will require significant investment in IT development, numerous iterations of quality assurance and consumer testing, extensive education and training for plan staff, and development of new consumer-facing materials, among other

[231] 42 U.S.C. 18014.

[232] As noted above, HHS proposed and finalized that the amendment to the MLR regulation will become effective beginning with the 2020 MLR reporting year (for reports filed by July 31, 2021).

challenges. Another commenter recommended that employers/plan sponsors should not have to comply with the final rules until the first day of the first plan year that is two years after the date on which the rules are published. Similarly, commenters requested a lengthy phase-in period to give employers, third parties, issuers, and health care providers time to modify their contractual agreements to provide all of the data the proposed rules would require to be disclosed.

A few commenters stated the Departments severely underestimated the time needed to implement the machine-readable files. The commenter noted that the timeline to implement the machine-readable files is very short, which could compromise the integrity of the files and lead to unintended consequences for consumers. Another commenter noted that, if not eliminated, the requirement to make machine-readable files available should be applicable no earlier than plan or policy years beginning three years after the date the rules are finalized.

As discussed in the economic impact analysis, the Departments are of the view that developing the machine-readable files should be straightforward for most plans and issuers and that plans and issuers will incur limited additional administrative burdens or costs after the one-time initial file development. The development activities needed to establish the machine-readable files involve gathering, formatting, and making publicly available already existing data that plans and issuers use in their everyday operations. Plans and issuers need to keep this information current for operational purposes, and the additional costs and burdens of ensuring that the machine-readable files are updated monthly is expected to decrease in subsequent years and ultimately become minimal, as the Departments expect plans and issuers to automate the updating and verification processes in the years following initial development.

The Departments are of the view that providing for a phased-in approach with regard to the number of items and services required for the internet-based self-service tool will provide more time for plans and issuers to plan for any increased costs, work with various vendors, perform user testing, and build appropriate technology to handle the disclosure of data through the internet-based self-service tool. Therefore, the final rules require plans and issuers to include in the internet-based self-service tool (and by request, through the paper method) 500 items and services identified by the Departments for plan years (in the individual market, for policy years) beginning on or after January 1, 2023, and all items and services for plan years (in the individual market, for policy years) beginning on or after January 1, 2024. The Departments are of the view that providing more time to implement the internet-based self-service tool while generally maintaining the timeline for the machine-readable files, strikes the appropriate balance between minimizing burdens for issuers and maximizing price transparency for the public. Providing information to the public through the machine-readable files sooner will also accelerate researchers' and third-party developers' access to pricing information and potentially provide additional resources and incentives for plans to build out their own consumer-tools.

Many commenters also encouraged the Departments to allow for a phased-in approach for the internet-based self-service tool and machine-readable files. Some commenters suggested finalizing a rule that allows for a phased-in approach for different group health plans and health insurance issuers of individual and group health insurance coverage to come into compliance with the final rules. Some commenters recommended finalizing a rule that allows for a phased-in approach by allowing smaller entities an extended implementation timeframe (*that is,* an additional 3 to 5 years) due to the disproportionate IT burden that will be placed on these smaller entities. Additionally, commenters were concerned that the rules may create a competitive advantage for larger issuers and TPAs.

A few commenters recommended that the rules be implemented in a more gradual fashion by requiring a price transparency tool that covers a narrower data set initially, for example, one that includes only the most common shoppable services. These commenters asserted that, over time, this scope could be broadened to be fully inclusive, but an initial narrow focus could increase the chance that patients have critical, actionable information as soon as possible.

Other commenters recommended a phased approach that would focus first on the functionality providing the most value to consumers to establish a baseline standard of price transparency across plans, while allowing time for the industry to solve more difficult technical challenges. Another commenter recommended allowing employers that have highly customized benefit structures additional time to implement the internet-based self-service tool. One commenter recommended allowing for a transition period for issuers and plans to use their current tools to meet the requirements.

A few commenters recommended including quality metrics. These commenters noted that requiring quality information in the disclosures would take additional time. In particular, one commenter was concerned that in the absence of quality data, price transparency could actually increase spending. The commenter therefore recommended delaying the implementation of the final rules until quality information, such as information related to patient satisfaction and experience, adherence to clinical standards and evidence-based medicine, and patient safety and clinical outcomes, could be incorporated. Another commenter stated that, if pharmacy quality information could be included, the Departments would need to provide for several years to transform existing consensus-based processes to identify appropriate quality metrics to include health plans serving different populations. Another commenter urged the Departments to perform a study on the effects of price transparency and the potential consequences on consumers seeking care to better understand how best to integrate quality information alongside prices to allow consumers to evaluate the services that best respond to their individual needs.

As the Departments explain in section II.C.1 of this preamble, government and private sector actors are working to develop and implement reliable and reasonable quality measures that can be applied to produce quality rating information that consumers may access and consider alongside pricing. As commenters acknowledged, delaying the final rules for the purpose of requiring the integration of quality information with price information would require several additional years. While the Departments appreciate the value of quality information to informed health care decision-making, the Departments are of the view that price transparency in health coverage must not be delayed for years when some quality information is already available or under development. Indeed, the Departments expect that the ready availability of pricing information will create greater consumer interest in quality information and other data relevant to health care decision-making, and that the market will respond to provide such information through innovative resources such as online tools and mobile applications. The Departments anticipate that innovators will seek ways to best present and

integrate pricing and quality data. However, the Departments also will consider what next steps are appropriate and feasible within the Departments' current authorities, including the possibility of conducting a study to evaluate how to best integrate quality information alongside prices. For these reasons and those noted earlier in this preamble, the Departments decline to require plans and issuers to include quality information in the disclosures required by the final rules.

The Departments are finalizing the applicability dates of the final rules as described earlier in this preamble. The Departments are of the view that the additional time and flexibility regarding the internet-based self-service tool will help address the concerns commenters raised regarding smaller entities' ability to comply with these requirements.

B. Enforcement and Good Faith Special Applicability

The preamble to the proposed rules did not discuss how the proposed rules would be enforced. State regulators, in their comments to the proposed rules, sought greater clarity on how the proposed rules' requirements would be enforced as specifically applied to health issuers in the individual and group markets. Section 1311(e)(3) is located in title I of PPACA and, under section 1321(c)(2) of PPACA is subject to the enforcement scheme set forth in section 2723 of the PHS Act. Similarly, section 2715A of the PHS Act is subject to the enforcement scheme set forth in section 2723 of the PHS Act. Therefore, states will generally be the primary enforcers of the requirements imposed upon health insurance issuers by the final rules.[233] The Departments expect to work closely with state regulators to design effective processes and partnerships for enforcing the final rules.

The proposed rules included a special applicability provision to address circumstances in which a group health plan or health insurance issuer, acting in good faith, makes an error or omission in its disclosures. Specifically, a plan or issuer would not fail to comply with the proposed rules solely because it, acting in good faith and with reasonable diligence, made an error or omission in a disclosure, provided that the plan or issuer corrects the information as soon as practicable. Additionally, to the extent such an error or omission was due to good faith reliance on information from another entity, the proposed rules included a special applicability provision under which, to the extent compliance would require a plan or issuer to obtain information from any other entity, the plan or issuer would not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knew, or reasonably should have known, that the information was incomplete or inaccurate. Under the proposed rules, if a plan or issuer had knowledge that such information was incomplete or inaccurate, the plan or issuer would be required to correct the information as soon as practicable.

Furthermore, the proposed rules also included a special applicability provision to account for circumstances in which a plan or issuer fails to make the required disclosures available due to its internet website being temporarily inaccessible. Accordingly, the proposed rules provided that a plan or issuer would not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

The Departments solicited comments regarding whether, in addition to these special applicability provisions, additional measures should be taken to ensure that plans and issuers that have taken reasonable steps to ensure the accuracy of required information disclosures are not exposed to liability by virtue of providing such information as required by the proposed rules.

In general, commenters supported the good faith special applicability provisions (also referred to as ''safe harbors'') and recommended certain clarifications. One commenter requested clarification regarding how the Departments would determine whether a plan or issuer acted in ''good faith'' and with ''reasonable diligence.'' Another commenter requested additional guidance on what it would mean to ''correct'' information, and specifically whether this requirement would apply on a prospective or retrospective basis. Another commenter recommended the Departments allow health plans 30 days to update accumulated amounts in the internet-based self-service tool.

The Departments are finalizing the ''good faith'' safe harbor as proposed. While ''good faith'' is not explicitly defined in the final rules, it is an established legal and business term that is generally understood to involve honesty in fact and the observance of reasonable commercial standards of fair dealing, according to the Uniform Commercial Code.[234] Efforts to correct omitted or erroneous information should proceed promptly after the plan or issuer is informed of the error. At a minimum, correcting information should include replacing the incorrect information, and may include notifying those affected of the error and the correction, using digital or written communications to notify affected participants, beneficiaries, and enrollees, and posting a notice on the internet website of the expected time before the error will be corrected.

The Departments received few comments on the good faith special applicability provision to account for circumstances in which a plan or issuer fails to make the required disclosures available due to its internet website being temporarily inaccessible. One commenter recommended that the website inaccessibility safe harbor be expanded to cover situations in which the internet-based self-service tool or machine-readable files are temporarily inaccessible, including because the internet website is inaccessible. This clarification would cover other technical issues, for example, that may affect only these resources, even though the remainder of the issuer's or plan's website is accessible.

Several commenters recommended that the Departments expand the ''safe harbor'' to account for additional circumstances. Commenters recommended that a safe harbor be created for plans that do not have direct access to negotiated in-network rates and allowed amounts, or information regarding reference based re-pricing in real time, and that may be unable to obtain some of the required information despite good faith efforts. For example, commenters recommended exempting employers, plan sponsors, and self-insured plans that rely on TPAs from liability if they have made good faith efforts to obtain the required data but have failed to do so. Commenters also recommended exempting plan sponsors that have been unable to procure third-party vendors from liability if these plans sponsors have acted in good faith. One commenter recommended that the Departments finalize a good faith special applicability provision to protect

[233] DOL has jurisdiction to enforce the final rules as they apply to group health plans subject to ERISA. Treasury has jurisdiction over certain church plans. HHS has jurisdiction over non-Federal governmental plans and over health insurance issuers where the HHS Secretary determines that a state has failed to substantially enforce the requirements. OPM has jurisdiction over the Federal Employees Health Benefits Plans.

[234] ''Uniform Commercial Code. General Definitions.'' Cornell Law School Legal Information Institute. Available at: *https://www.law.cornell.edu/ucc/1/1-201#Goodfaith.*

health plans and issuers that provide cost estimates that meet the requirements of the final rules if the estimates do not match the amounts actually paid by participants, beneficiaries, or enrollees. This commenter also requested that this safe harbor be extended to the cost-sharing estimate requirements.

Commenters also recommended that the Departments consider a safe harbor provision for covered entities that clearly provides that issuers and plans are not responsible for the downstream privacy and security of PHI shared by a participant, beneficiary, or enrollee with a third-party application consistent with the recent guidance issued by the HHS OCR.[235] Another commenter recommended the creation of additional safe harbor provisions to allow and encourage health care organizations to share threat information about security risks and incidents linked to third-party applications.

One commenter noted that disclosure of pricing information through the machine-readable files and cost-sharing tool raises concerns for plan sponsors about the potential for increased litigation under ERISA based on the release of payer-specific negotiated rates. The commenter encouraged DOL to effectively and expressly address this issue so that any disclosure requirement is crafted in a way that does not increase fiduciary liability for employer plan sponsors. The commenter recommended that DOL consider proposing a ''safe harbor'' to protect employers from downstream litigation risk related to the public disclosure of negotiated rates and disclosure of negotiated rates through the cost-sharing tool. Such a ''safe harbor'' could provide that so long as an employer can demonstrate it ''considered'' negotiated rates as part of its decision-making process in selecting an administrative service organization (ASO) for its plan, so that it would not be deemed to have acted imprudently as a fiduciary for purposes of ERISA with respect to the selection of the ASO by virtue of the negotiated rates. While the Departments appreciate this comment regarding increased litigation under ERISA, this request is beyond the scope of this rulemaking.

Finally, several commenters requested a deemed compliance standard for employers or plans that already offer transparency tools designed to assist participants with cost estimates and obtaining up-to-date cost-sharing information or for plans and issuers that voluntarily submit their data to multi-payer claims databases. Other commenters noted that some existing state laws require plans to provide the ability for enrollees to look up their out-of-pocket costs for several hundred procedures online or by phone. These commenters recommended—to reduce burden on issuer implementation and avoid duplication of effort—that health plans that comply with existing state laws requiring treatment cost-estimator functionality be deemed in compliance with any similar Federal requirements. Another commenter recommended this safe harbor be extended to the machine-readable files.

The Departments understand that states have been at the forefront of transparency initiatives and some have required disclosure of pricing information for years. However, it is important to note that states do not have authority to require such disclosures by plans subject to ERISA, which compose a significant portion of the private market.[236] As a result, a significant portion of consumers do not have access to information on their plans, even in states that have implemented transparency requirements. The Departments are also aware that many plans and issuers have moved in the direction of increased price transparency. Despite these price transparency efforts, the Departments understand that there continues to be a lack of easily accessible pricing information for consumers to use when shopping for health care services. The final rules are meant, in part, to address this lack of easily accessible pricing information, and represent a critical part of the 'Departments' overall strategy for reforming health care markets by promoting transparency, competition, and choice.

The Departments will take these additional safe harbor recommendations into consideration for future rulemaking. The Departments are not including in the final rules any safe harbor rule that would substitute the offering of existing tools or compliance with existing state transparency laws. The Departments have concluded that additional price transparency efforts are necessary to empower consumers, promote competition in the health care industry, and reduce the overall rate of growth in health care spending. The additional safe harbors recommended by commenters would not allow for the consistent baselines and standards that the Departments seek to establish with the final rules. As noted above, one of the goals of the final rules is to empower plans and issuers in the commercial health care market to innovate and compete in an industry where innovation and competition currently appear to be limited. By requiring public disclosure of pricing data a year after the effective date of the rules, the final rules will encourage issuers, TPAs, and third-party developers and innovators to create or enhance their shopping tools, including the self-service tools also required by these final rules. The development of these tools in turn will create additional consumerism, which will lead to lower prices throughout the health care market. This impact is only achievable, however if all applicable plans and issuers are held to the same standards and timelines. Furthermore, limiting the applicability of the final rules would undermine the Departments' overall strategy for reforming health care markets by promoting transparency, competition, and choice across the health care industry.

The Departments are of the view that, ultimately, plans and issuers are responsible for complying with the requirements outlined in the final rules. The Departments understand that plans may have to make adjustments to their contracts and as such, the Departments have factored that into the burden estimates and timing requirements for implementation explained elsewhere in the final rules. As plans and issuers are responsible for complying with the requirements outlined in the final rules, they should carefully examine the capacity of any partners they may contract with to provide the required information. Finally, as discussed earlier in this preamble, the Departments recognize the privacy concerns raised by commenters, but are of the view that the final rules, which include an exemption for providers with fewer than 20 different claims for payment and do not require any disclosure of PII or PHI through an API, and the continuing obligation of plans and issuers to comply with applicable privacy requirements, do not raise sufficient privacy concerns to require an additional privacy-related safe harbor.

V. Economic Impact Analysis and Paperwork Burden

A. Summary/Statement of Need

This regulatory action is taken, in part, in light of Executive Order 13877

[235] ''HHS FAQ.'' United States Department of Health and Human Services. Available at: *https://www.hhs.gov/hipaa/for-professionals/faq/3009/does-a-hipaa-covered-entity-bear-liability.html.*

[236] Panis, C. W. A., and Brien, M. J. ''Self-Insured Health Benefit Plans 2019: Based on Filings through Statistical Year 2016.'' Deloitte. January 7, 2019. Available at: *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2019-appendix-b.pdf.*

directing the Departments to issue an ANPRM, soliciting comments consistent with applicable law, requiring providers, health insurance issuers, and self-insured group health plans to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care. As discussed previously in this preamble, in response to Executive Order 13877, the Departments published the proposed rules entitled ''Transparency in Coverage.'' Despite the growing number of initiatives and the growing consumer demand for, and awareness of, the need for pricing information, there continues to be a gap in easily accessible pricing information for consumers to use to shop for health care items and services. The final rules add new requirements to 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 147 aimed at addressing this gap, and are a critical part of the Administration's overall strategy for reforming health care markets by promoting transparency and competition, creating choice in the health care industry, and enabling consumers to make informed choices about their health care. As discussed later in the RIA, the Departments acknowledge that more than 90 percent of plans, issuers, and TPAs currently provide some form of internet-based self-service tool to their consumers. However, as stated in section I.B of the final rules, the Departments understand that utility and accuracy among existing issuer cost estimator tools varies widely. Based on issuer demonstrations of their tools given to the Departments, some estimators reflect a combined range of possible costs; others give estimates based off historical pricing or claims data from various sources, while others are restricted in the types of procedures they include. Moreover, some existing issuer tools do not take into account a participant's, beneficiary's, or enrollee's accumulators.[237] The Departments are of the view that it is important to establish a minimum set of standards of what is acceptable so that consumers can take advantage of the information market-wide. Consistency will give consumers confidence that the information presented by these tools will not change arbitrarily. Reliability assures consumers that information in these tools accurately reflects plans' and issuers' best estimates of costs. The availability of these tools across all markets will ensure that no participant, beneficiary, or enrollee is denied access to the benefits of this rule and the Departments are of the view that this consistency is vital for success and utilization. As discussed previously in section I.B, state transparency requirements are generally not applicable to self-insured group health plans, and as a result, a significant portion of consumers may not have access to information on their plans and their health care costs. The Departments encourage additional functionality and innovation to be built around the requirements of the final rules, but believe a baseline is required to give the participant, beneficiary, or enrollee some confidence that no matter which plans tool they used, it would at least offer the same basic information. By requiring group health plans and health insurance issuers to disclose to participants, beneficiaries, or enrollees such individual's cost-sharing information for covered items or services furnished by a particular provider, the final rules provide them sufficient information to determine their potential out-of-pocket costs related to needed care and encourages them to consider price when making decisions about their health care.

B. Overall Impact

The Departments have examined the impact of the final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order. An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). The Departments have concluded that the final rules are likely to have economic impacts of $100 million or more in at least 1 year, and, therefore, meet the definition of ''economically significant rule'' under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with the final rules. OMB reviewed this regulation in accordance with the provisions of Executive Order 12866.

Two commenters suggested that the proposed rules failed to comply with Executive Order 12866. Executive Order 12866 defines rules likely to have an economic impact in excess of $100 million as ''significant'' and requires that the agencies conduct an assessment of potential costs. The commenters suggested that the economic impact analysis and cost assessment the agencies provided for the proposed rules were short of the concrete, well-founded analysis required of the economic analysis directed by Executive Order 12866 that must accompany a proposed rulemaking as far-reaching, and potentially costly, as the proposed rules. One commenter suggested that the proposed rules were inconsistent with

[237] *See also* ''Are healthcare's cost estimate tools making matters worse for patients?'' Becker's Hospital CFO Report. Available at *https://www.beckershospitalreview.com/finance/are-healthcare-s-cost-estimate-tools-making-matters-worse-for-patients.html* (citing Gordon, E. ''Patients Want To Price-Shop For Care, But Online Tools Unreliable.'' NPR. November 30, 2015. Available at *https://www.npr.org/sections/health-shots/2015/11/30/453087857/patients-want-to-price-shop-for-care-but-online-tools-unreliable*) (''Some estimators reflect a combined range of possible costs, while others are based off historical pricing or claims data from various sources. Many online estimate tools are restricted in the types of procedures they include. . . .'').

both Executive Order 12866 and Executive Order 13563, both of which direct agencies to carefully consider alternatives to regulations an agency has deemed necessary, and to select the least burdensome approach available. The commenter maintained that the agencies did not adequately consider alternatives and are proposing an unnecessarily and excessively burdensome approach.

After consideration and discussion of the comments related to proposed cost estimates received in response to the proposed rules, the Departments chose to reevaluate the cost estimates associated with the provisions in the final rules. The Departments also consulted with internal and external IT professionals to gain a better insight into what individuals and tasks would be needed to design, develop, and deploy the internet-based self-service tool and the three machine-readable files required by the final rules. Based on this consultation and additional research, the Departments have chosen to increase the cost estimates to account for the updated understanding of the costs posed by the final rules, as well as the additional requirements included in the final rules. The Departments further discuss changes to the final cost estimates later in this preamble and in the associated ICR sections.

The final rules will enable participants, beneficiaries, and enrollees to obtain information about their potential cost-sharing liability for covered items and services that they might receive from a particular provider by requiring plans and issuers to disclose cost-sharing information as described at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211. As discussed earlier in section I.B. of the final rules, there has been a shift in the health care market from copayments to coinsurance. Coupled with increases in plans and coverages with high deductibles, generally requiring sizeable out-of-pocket expenditures prior to receiving coverage under the terms of the plan or policy, participants, beneficiaries, and enrollees are now shouldering a greater portion of their health care costs than before. For example, over the period from 2008 to 2018, the average health care costs incurred by families covered by large employers—including premium contributions and out-of-pocket spending on health care services—have increased 67 percent from $4,617 to $7,726 annually. Over the same period, the average out-of-pocket costs alone have increased from $1,779 to $3,020 annually.[238] The Departments are of the view that disclosure of pricing information is crucial for participants, beneficiaries, or enrollees to engage in informed health care decision-making and believe that with greater price transparency and access to more accurate and actionable pricing information, participants, beneficiaries, and enrollees will be able to consider the value of an item or service when making decisions related to their health care.

In addition, as described at 26 CFR 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3, 29 CFR 2590.715–2715A1, 2590.715–2715A2, and 2590.715–2715A3, and 45 CFR 147.210, 147.211 and 147.212, the final rules require group health plans and health insurance issuers to make public in-network rates, including amounts in underlying fee schedules, negotiated rates, and derived amounts for in-network providers; historical allowed amounts paid to out-of-network providers and billed charges for all covered items and services; and negotiated rates and historical net prices for prescription drugs. The Departments are of the view that these requirements, through providing greater transparency and access to pricing information, will provide consistency and confidence across all internet-based self-service tools. Access to data provided by the three machine-readable files will ensure that all consumers have the pricing information they need in a readily accessible format, which could inform their choices, in addition to potentially impacting cost disparities and improvements to the overall functioning of the health care market. The Departments are of the view that greater price transparency and the availability of price information to the public will empower the 26.1 million uninsured consumers [239] to make more informed health care decisions and allow consumers who wish to shop among plans and coverage options to better understand the potential cost of their care. Public availability of this information will also allow third-party IT developers to provide consumers with more accurate information on provider, plan, and issuer value, as well as prescription drug pricing information, ensuring that such information is available to consumers where and when it is needed. Furthermore, providing the in-network rates along with out-of-pocket costs will also show what future costs could be for a participant, beneficiary, or enrollee for the same service, depending on the progress of his or her deductible. This information will help consumers make informed decisions related to their health care needs now and in the future.

The Departments received many comments regarding the underlying economic principles of the proposed rules. Many commenters were concerned the rules as proposed could disrupt contract negotiations between providers and health plans and result in providers acting in anticompetitive ways (such as collusion, consolidation, or price fixing), resulting in increased rates (a so-called ''race to the top''). Some of these commenters were particularly concerned with the potential of the Departments' proposals to spur anticompetitive behavior in highly concentrated markets. Several of these commenters cited the FTC's concerns about the potential negative impacts of price transparency on competition in the health insurance markets, including the possibility that providers (or sellers) will coordinate their behavior or bid less aggressively, leading to higher prices. Commenters also cited similar concerns expressed by the Department of Justice (DOJ) and the Congressional Budget Office (CBO) about the unintended consequences of releasing competitive proprietary information such as the in-network rates of plans and issuers. Commenters further stated increased costs would negatively impact consumer choice and reduce the affordability of health insurance coverage of low- and middle-income consumers. One commenter expressed concern that plans and issuers could also coordinate to reduce provider payment levels below market competitive rates, which could negatively impact patient access to quality care. In contrast, one commenter suggested that concerns about potential collusion among providers are unfounded as local markets are currently populated by a limited number of providers who tend to have knowledge of each other's rates and

[238] Rae, M., Copeland, R., and Cox, C. ''Tracking the rise in premium contributions and cost-sharing for families with large employer coverage.'' Peterson-KFF. August 14, 2019. Available at: *https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/?utm_campaign=KFF-2019-Health-Costs&utm_medium=email&_hsenc=p2ANqtz-_72_RHB9Twe8BpbqOg28rdlGqxq_SBgV6rB-kbC4PuYMItIOSxHQLmh_D3OH4GOnUKZXa8&utm_source=hs_email&hsCtaTracking=04848753-3235-436e-a0de-ae8238ad00ad%7Cc1097ae0-0521-4e9a-8e45-e5a87f67af4a.*

[239] ''Income, Poverty and Health Insurance Coverage in the United States: 2019.'' United States Census Bureau. September 15, 2020. Available at: *https://www.census.gov/newsroom/press-releases/2020/income-poverty.html.*

consumers currently receive pricing information through EOBs. The commenter also expressed the opinion that the argument put forth by issuers that in-network rates are trade secrets is self-serving and benefits them at the expense of consumers and the public.

One issuer stated that its experience in state markets where health care price transparency was implemented (Massachusetts, New Hampshire, and Maine) do not provide evidence that transparency efforts produce reduced health care prices and that state price transparency efforts negatively affected issuers' ability to negotiate lower rates. However, another commenter cited a study of the New Hampshire transparency initiative that found ''a significant reduction in negotiated prices.'' [240]

Some commenters suggested that the Departments should ensure that strong protections are in place to prevent price fixing or unsustainably low reimbursement for care before requiring public disclosure of in-network and out-of-network rates. For example, to address concerns about price fixing, one commenter suggested working closely with the FTC and other appropriate Federal and state authorities to monitor health care provider markets for any incidence of collusion, potentially leading to the prosecution of entities for violations that raise costs for patients and plan sponsors.

By contrast, several commenters expressed the view that the public disclosure of payer-specific in-network rates and transparency would promote competition in the health insurance markets and will drive down costs, which could result in lower, more reasonable health care prices. One commenter cited a paper that reviewed outcomes after the implementation of price transparency efforts and found evidence for behavioral changes that could place pressure on providers to lower rates.[241] Specifically, the paper found evidence of shopping activity among consumers, especially younger consumers, evidence of development activity by third-party application developers using this information, and evidence that employers will use the data to negotiate better rates. Another commenter noted that employers and health plans would be able to leverage the information to negotiate rates that are more reasonable and encourage patients to access higher-value providers.

As noted previously in sections I.B and I.C of this preamble, the Departments are of the view that greater price transparency and the public disclosure of pricing information is necessary to enable consumers to use and understand pricing data in a manner that will increase competition, improve markets, reduce disparities in health care prices, and potentially lower health care costs. The Departments continue to be of the view that effective downward pressure on health care pricing cannot be fully achieved without increased price transparency and the public disclosure of pricing information. As discussed in section E.3 of this preamble, the Federal Government maintains laws and processes to investigate reports of collusive or other anticompetitive practices.

Section 1311(e)(3) of PPACA and section 2715A of the PHS Act, as well the authority vested in the Departments, grant participants, beneficiaries, enrollees, and the public the right to know the prices of health care items and services, which will enable them make informed health care purchasing decisions. Without access to price information, consumers are unable to accurately assess and choose the least costly care and coverage options among all available options, and choice cannot be meaningful without adequate information about those choices. Currently, insured participants, beneficiaries, or enrollees, as well as uninsured consumers, do not have access to adequate and accessible pricing information related to care and coverage. The potential benefit of consumer access to this information is enormous. Furthermore, the Departments are aware of consumer demand for this information. According to a May 2019 poll conducted by the Harvard Center for American Political Studies, 88 percent of U.S. registered voters (out of a sample of 1,295) stated they would support an initiative by the government to mandate issuers, hospitals, doctors and other providers to disclose the cost of their services and discounted or negotiated rates between these groups.[242] Furthermore, 65 percent of these individuals would favor these initiatives even if in the short term they lead to an increase in prices by some providers.[243] The vast majority of comments the Departments received in response to the proposed rules were from individuals who expressed general support for the transparency proposals and expressed frustration at the lack of information available about health care pricing and a desire to have access to this information.

As noted in the preamble to the proposed rules and earlier in this preamble, the belief that greater price transparency will reduce health care costs by encouraging providers to offer more competitive rates is consistent with the predictions of standard economic theory and a number of empirical studies regarding price transparency in other markets. The Departments agree, however, that the health care market presents unique challenges. The Departments reviewed a study that notes certain special characteristics of the health care market, including that: (1) Diseases and treatments affect each patient differently, making health care difficult to standardize and making price dispersion difficult to monitor; (2) patients cannot always know what they want or need, and physicians effectively must serve as their agents (for example, by recommending specialists and determining whether a patient is admitted to a hospital); and (3) patients are typically in a poor position to choose a hospital because they do not have sufficient information about hospital quality and costs.[244] This study suggests that these special characteristics of the health care market, among other relevant factors, make it difficult to draw conclusions based on empirical evidence gathered from other markets. Nevertheless, the same study concluded that despite these complications, greater price transparency, such as access to posted prices, might lead to more efficient outcomes and lower prices.

Another study evaluated hospital discharge information following the publication of prices.[245] Hospital

[240] Brown Z. Y. ''Equilibrium Effects of Health Care Price Information.'' 101 Review of Economics & Stat. 699 (2019). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.*

[241] Blase, B. ''Transparent Prices Will Help Consumers and Employers Reduce Health Spending.'' Texas Public Policy Foundation. September 27, 2019. Available at: *https://galen.org/assets/Blase_Transparency_Paper_092719.pdf.*

[242] ''The CAPS Harris Poll.'' Harvard Center for American Political Studies, 45. May 2019. Available at: *https://harvardharrispoll.com/wp-content/uploads/2019/06/HHP_May19_vF.pdf?utm_source=hs_email&utm_medium=email&_hsenc=p2ANqtz--NgSdTYgg GUP4tWyR2IEQ7i8TCg1s3DcHuQyhErIgkX3KFUi3SFgl9OZKm4-JUOOi9tmMQ.*

[243] *Id.*at 46.

[244] Austin, A. D., and Gravelle, J. G. ''Congressional Research Service Report to Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' Congressional Research Service. July 24, 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf.*

[245] Kim, M. ''The effect of hospital price transparency in health care markets.'' University of

utilization increased for hospitals that priced below the mean market price, while hospital utilization decreased for hospitals that priced above the mean market price.

In a recent study of the New Hampshire price transparency tool, researchers found that health care price transparency could shift care to lower-cost providers and save consumers and payers money.[246] The study specifically focused on X-rays, CT scans, and MRI scans; it determined that the transparency tool reduced the costs of medical imaging procedures by five percent for patients and four percent for issuers; and estimated savings of $7.9 million for patients and $36 million for issuers over a 5-year period.

In another example, in Kentucky, public employees were provided with a price transparency tool that allowed them to shop for health care services and share in any cost-savings realized by seeking lower-cost care.[247] Over a 3-year period, 42 percent of eligible employees used the program to research information about prices and rewards.[248] The study found that 57 percent of those that used the transparency tool chose at least one cost-effective provider, saving state taxpayers $13.2 million and resulting in $1.9 million in cash benefits paid to public employees for seeking lower cost care.[249]

The Departments recognize the transparency efforts in New Hampshire and Kentucky are not necessarily generalizable nationwide and provide only some empirical data to support the overarching goal of these final rules that transparency in health care can lead to savings for consumers and issuers by putting downward pressure on prices. The Departments are of the view that consumers equipped with information about the cost of their medical options prior to receiving care will allow them to be able to make more informed decisions that will put additional downward pressure on health care costs. While the often-unequal relationship between patients and providers can sometimes mean that patients are not always best equipped to determine their care, there are many health care purchasing decisions that could and should take into account a patient's financial concerns. For instance, physician providers may also be able to provide health care transparency information when referring patients to specialists for in- or out-of-network care, such as for elective procedures. The pricing information, combined with the physician's advice, could help health care consumers evaluate options along the cost and quality spectrums and help guide them to high-value options. The Departments are of the view that health care pricing transparency may increase the impact of economic market forces on the health care markets, despite the health care market's unique characteristics. The Departments anticipate that once issuers, plans, and providers are aware that consumers can engage with the markets in an informed manner, they may adjust their costs to potentially be more competitive in their pricing of items and services.

1. Impact Estimates of the Transparency in Coverage Provisions and Accounting Table

The final rules set forth requirements for group health plans and health insurance issuers to disclose to a participant, beneficiary, or enrollee, his or her cost-sharing information for covered items or services from a particular provider or providers. The final rules also include requirements for plans and issuers to disclose in-network rates (including negotiated rates, amounts in underlying fee schedules and derived amounts) for in-network providers, historical allowed amounts and billed charges for covered items and services provided by out-of-network providers, and negotiated rates and historical net prices for prescription drugs through machine-readable files posted on a public internet website. In accordance with OMB Circular A–4, Table 2 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action.

The Departments are unable to quantify all benefits and costs of the final rules. The effects in Table 2 reflect non-quantified impacts and estimated direct monetary costs and transfers resulting from the provisions of the final rules for plans, issuers, beneficiaries, participants, enrollees, and state and the Federal Governments.

TABLE 2—ACCOUNTING TABLE

Intended Outcomes:

- Provides consumers with a tool to determine their estimated out-of-pocket costs, potentially becoming more informed on the cost of their health care, which could result in lower overall costs if consumers choose lower-cost providers or items and services.
- Potential increase in timely payments by consumers of medical bills as a result of knowing their estimated overall costs prior to receiving services and having the ability to budget for expected health care needs.
- Potential profit gains by third-party mobile application developers by selling and exchanging consumer health data and potential benefits to consumers through the development of mobile applications that may be more user-friendly and improve consumer access to cost information, potentially resulting in reductions in out-of-pocket costs.
- Potentially enable consumers shopping for coverage to understand the in-network rates for providers and the negotiated rates and historical net prices for prescription drugs in different group and individual health plans available to them and choose a plan that could minimize their out-of-pocket costs.
- States could potentially use the In-network Rate and Prescription Drugs Files to determine if premium rates are set appropriately.
- Potential reduction in cross-subsidization, which could result in lower prices as prices become more transparent.
- Public posting of in-network rates (including negotiated rates, amounts in underlying fee schedules, and derived amounts), negotiated rates, and historical net prices for prescription drugs could facilitate the review of anti-trust violations and potential collusion.
- Potential for the disclosure of in-network rates to apply pressure on providers to bill less aggressively.
- Strengthening of stakeholders' ability to support consumers.

Benefits:

- Potential societal resource savings (non-quantified efficiency portion of any overall reduction in consumer health care expenditures).
- Potential to reduce the cost of surprise billing to consumers.

Pennsylvania. 2011. Available at: *https://repository.upenn.edu/dissertations/AAI3475926.*

[246] Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. Econ. & Stat. 1. (2018). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.*

[247] Rhoads, J. ''Right to Shop For Public Employees: How health care incentives are saving money in Kentucky.'' The Dartmouth Institute for Health Policy and Clinical Practice. March 8, 2019. Available at: *https://thefga.org/wp-content/uploads/2019/03/RTS-Kentucky-HealthCareIncentivesSavingMoney-DRAFT8.pdf.*

[248] *Id.*

[249] *Id.*

Costs:	Low estimate (million)	High estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	$4,080.2	$5,472.4	2020	7	2021–2025
	4,047.7	5,392.9	2020	3	2021–2025

Quantitative:

- Cost to plans, issuers and TPAs to plan, develop, and build the required internet-based self-service tool and machine-readable files, to provide in-network rates for in-network providers and out-of-network allowed amounts, and negotiated rates and historical net prices for prescription drugs, maintain appropriate security standards and update and maintain the machine-readable files per the final rules.
- Increase operating costs to plans and issuers as a result of training staff to use the internet-based self-service tool, responding to consumer inquiries, and delivering consumer's cost-sharing information and required notices.
- Cost to plans and issuers to review all the requirements in the final rules.

Non-Quantified:

- Potential cost incurred by plans and issuers that wish to develop a mobile accessible version of their internet-based self-service tool.
- Potential exposure of consumers to identity theft as a result of breaches and theft of PII.
- Potential increase in cyber security costs by plans and issuers to prevent data breaches and potential loss of PII.
- Potential increase in out-of-pocket costs for consumers if providers or prescription drug manufacturers increase prices for items and services or plans and issuers shift those costs to consumers in the form of increased cost sharing other than increased deductibles.
- Potential costs to states to review and enforce provisions of the final rules.
- Potential increase in consumer costs if reductions in cross-subsidization are for uncompensated care, as this could require providers finding a new way to pay for those uncompensated care costs.
- Potential increase in health care costs if consumers confuse cost with quality and value of service.
- Potential costs to inform and educate consumers on the availability and functionality of an internet-based self-service tool.
- Potential consumer confusion related to low health care literacy and the potential complexity of internet-based self-service tools.
- Potential cost to plans and issuers to conduct quality control reviews of the information in the in-network rate, out-of-network allowed amounts, and prescription drug machine-readable files.
- Potential costs to plans, issuers, and TPAs if they are required to renegotiate contracts in order to remove gag clauses in order to meet the requirements of the final rules.
- Potential costs to plans, issuers, and TPAs if they incur use cases per user CPT licensure charges.
- Potential increase in costs to consumers and issuers if providers or prescription drug manufacturers engage in anticompetitive behaviors.
- Potential state and Federal costs associated with any changes in prescription drug prices resulting from the prescription drug machine-readable file release that may impact state Medicaid, CHIP, and Basic Health Plan programs and Federal health care programs.

Transfers:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Federal Annualized Monetized ($/year)	$425.2	2020	7	2021–2025
	423.0	2020	3	2021–2025
Other Annualized Monetized ($/year)	274	2020	7	2021–2025
	274	2020	3	2021–2025

Quantitative:

- Transfers from the Federal Government to consumers in the form of increased premium tax credits by approximately $1,047 million in 2022, $623 million in 2023, $216 million in 2024, and $218 million in 2025 as a result of estimated premium increases by issuers in the individual market to comply with the final rules.
- Transfer from consumers to issuers in the form of reduced MLR rebate payments in the individual and group markets by approximately $120 million per year by allowing issuers to take credit for ''shared savings'' payments in issuers' MLR calculations.
- Transfers from providers to consumers and issuers of approximately $154 million per year as a result of lower medical costs for issuers and consumers by allowing issuers to share with consumers the savings that result from consumers shopping for care from lower-cost providers.

Non-Quantified:

- Potential transfer from providers to consumers facing collections to reduce the overall amounts owed to providers if they are able to use competitor pricing as a negotiating tool.
- Potential transfer from providers to consumers if there is an overall decrease in health care costs due to providers reducing prices to compete for customers.
- Potential transfer from issuers to consumers if there is an overall decrease in prescription drug costs due to potential reductions in prescription drug prices.
- Potential transfer from consumers to issuers or prescription drug manufacturers if drug manufacturers increase prescription drug prices.
- Potential transfer from consumers to providers if there is an increase in health care costs if providers and services increase their in-network rates to match those of competitors.
- Potential transfer from issuers to consumers if premiums decrease and potential transfer from consumers to issuers if premiums increase.
- Potential transfer from issuers to consumers and the Federal Government in the form of decreased premiums and premium tax credits as a result of issuers adopting provisions encouraging consumers to shop for services from lower-cost providers and sharing the resulting savings with consumers.
- Potential Transfers from the Federal Government to drug manufacturers, PBMs, and retail pharmacies for any change in prescription drug costs, which could impact prices paid by Federal health care programs should prescription drug costs increase.
- Potential Transfers from drug manufacturers, PBMs, and retail pharmacies to the Federal Government to for any change in prescription drug costs, which could impact prices paid by Federal health care programs should prescription drug costs decrease.

Table 2 provides the anticipated benefits and costs (quantitative and non-quantified) to plans and issuers to disclose cost-sharing information as described at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, 45 CFR 147.211, and at 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, 45 CFR 147.212, and make public in-

network rates, amounts in underlying fee schedules, or derived amounts of in-network providers, out-of-network allowed amounts paid for covered items and services, and negotiated rates and historical net prices for prescription drugs. The following information describes the benefits and costs—qualitative and non-quantified—to plans and issuers separately for these three requirements. Some commenters stated that the Departments attempted analysis of the economic impact of the proposed rules was wholly inadequate and demonstrated that the Departments had not performed the basic fact-gathering and analysis that agencies are expected to undertake before undertaking notice-and-comment rulemaking. These comments stated that the material the Departments presented under section VII, ''Economic Impact Analysis and Paperwork Burden'' was a patchwork of speculation and assumptions without any grounding in empirical data or analysis. The commenters further stated: The Departments listed 10 specific cost elements that they did not attempt to quantify; failed to include any consideration of regulatory familiarization costs; omitted consideration of training costs for both government employees who will be charged with enforcing the regulation and for the staff of regulated issuers and plan sponsors who will be responsible for compliance; and failed to account for the impact of the litigation burden on regulated issuers, plan sponsors, and the public judicial system. Another commenter suggested that the Departments failed to conduct an adequate cost-benefit analysis because they failed to consider and quantify regulatory alternatives, failed to quantify potentially knowable costs, and failed to quantify benefits or offer additional evidence supporting such benefits. Similarly, another commenter stated that the Departments' analysis was lacking in any quantitative assessment of benefits and did not credibly demonstrate that quantification of benefits might be difficult.

The Departments consulted with various stakeholders in an effort to develop the economic analysis associated with the final rules, including the estimated costs. Additionally, the Departments requested comment on the estimates presented in the proposed rules to obtain more information and input with respect to the unquantified costs and benefits. The Departments received a number of comments related to the cost estimates, which are discussed later in the RIA and ICR sections. However, the Departments did not receive any comments providing actionable information as it relates to a number of the unquantifiable aspects of the proposed rules.

As previously discussed in sections II.B.2.C and V.B.1 in this preamble, the Departments received comments related to the lack of estimated costs associated with the renegotiation of provider contracts, litigation expenses, and the removal of gag clauses. However, none of the comments received provided any information that would aid the Departments in estimating such costs. The Departments recognize that there are numerous aspects associated with the final rules that they are unable to estimate due to an overall lack of knowledge and information with regard to the actions that issuers, providers, or TPAs may be required to take to meet the requirements of the final rules. As discussed in sections V.C and D, the Departments have sought to provide estimates to account for the regulatory familiarization costs and other estimates related to the alternatives considered in the development of the final rules. For the final rules, the Departments have updated the regulatory review costs to include familiarization costs for each state DOI (including the District of Columbia), issuers, and TPAs.

2. Requirements for Disclosing Cost-Sharing Information to Participant, Beneficiaries, or Enrollees Under 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211

Costs

Under 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b) of the final rules group health plans and health insurance issuers must disclose required cost-sharing information in accordance with prescribed method and format requirements upon the request of a participant, beneficiary, or enrollee. The required cost-sharing information includes seven content elements, which are described in paragraph (b)(1) of the regulations and discussed earlier in section II.B.1 in this preamble. The quantitative costs associated with this requirement are detailed in the section VI.A.2—of the ICR later in this preamble.

In addition to the costs described later in the corresponding ICR, the Departments recognize there may be other costs associated with this requirement that are difficult to quantify given the lack of information and data. For example, while the Departments are of the view that the overall effect of the final rules will lower health care costs, the Departments recognize that price transparency may have the opposite effect because in some markets where pricing is very transparent, price ranges can narrow in response to greater transparency, and costs can increase.[250] In section II.B.2.C in this preamble, the Departments addressed comments related to the potential for unintended consequences related to the public disclosures required through the In-network Rate. The Departments note that the current lack of pricing information means that health care consumers are generally not able to include price in their health care purchasing decisions. The Departments are of the view that making pricing information available will begin to ameliorate distortions resulting from consumer decision-making not taking costs sufficiently into account. Additionally, the Departments recognize that states may incur additional costs to enforce the requirements in the final rules.

As described in section VI, the Departments assume most self-insured group health plans will work with a TPA to meet the requirements of the final rules. The Departments estimated costs in the high-range estimate by assuming that all issuers and TPAs (for self-insured group health plans) will need to develop and build their internet-based self-service tool.

As described in section VI.A.1 of the ICR, the Departments assume most self-insured group health plans will work with a TPA to meet the requirements of the final rules. The Departments estimated cost in the high-end estimate by assuming that all issuers and TPAs (for self-insured group health plans) will need to develop and build their internet-based self-service tools from scratch. However, the Departments also provide a low-end estimate by assuming that over 90 percent of plans, issuers, or TPAs currently provide an internet-based self-service tool and will only be required to modify an existing internet-based self-service tool which may already meet some (if not all) the requirements in the final rules.[251] The

[250] Kutscher, B. ''Report: Consumers demand price transparency, but at what cost?'' Modern Healthcare. June 2015. Available at: *https://www.modernhealthcare.com/article/20150623/NEWS/150629957/consumers-demand-price-transparency-but-at-what-cost.*

[251] Sharma, A., Manning, R., and Mozenter, Z. ''Estimating the Burden of the Proposed Transparency in Coverage Rule.'' Bates White Economic Consulting. January 22, 2020. Available at: *https://www.bateswhite.com/media/publication/183_Estimating%20Burden%20of%20Proposed%20TCR.pdf.* In order to determine our estimates in determining the low-

Continued

Departments recognize that some plans, issuers, or TPAs might also voluntarily elect to develop or enhance a mobile application, if one is already available or in some stage of planning and implementation, which will result in additional costs. Additionally, TPAs generally work with multiple self-insured group health plans, and as a result, the costs for each TPA and self-insured group health plan may be lower to the extent they are able to coordinate their efforts and leverage any resulting economies of scale.

Moreover, health care data breach statistics show there has been an upward trend in data breaches over the past 10 years, with 2019 having more reported data breaches than any other year since records first started being published. Between 2009 and 2019 there have been 3,054 health care data breaches involving more than 500 records; resulting in the loss, theft, exposure, or impermissible disclosure of 230,954,151 health care records, equating to more than 69.78 percent of the United States population. Health care data breaches are now being reported at a rate of more than one per day.[252] Based on this information, the Departments recognize the requirements of the final rules provide additional opportunities for health care data breaches. Although privacy and security costs have been imbedded into the development and implementation cost estimates discussed in the section VI.A.1 and further discussed in section II.B.4 of this preamble, the Departments expect that plans and issuers will follow existing applicable state and Federal laws regarding persons who may or must be allowed to access and receive the information. The Departments recognize that some plans and issuers may incur additional expenses to ensure a consumers' PHI and PII are secure and protected. Additionally, as consumers accessing the internet-based self-service tool may be required to input personal data to access the consumer-specific pricing information, consumers may be exposed to increased risk and experience identity theft as a result of breaches and theft of PII. As noted previously in section II.B.4 of this preamble, the Departments are finalizing a provision that reminds plans and issuers of their duty to comply with requirements under other applicable state or Federal laws, including requirements governing the accessibility, privacy, or security of information, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

One commenter stated that since multiemployer plans do not directly control the process of negotiations or the resulting information, these plans do not have access to the information necessary to satisfy the final rules and plans could be subject to significant penalties for failure to comply. Another commenter, that surveyed employers who sponsor self-insured ERISA-covered plans, noted that respondents would likely contract with a TPA to comply with the final rules because employers do not have all the necessary data nor the capability to collect that data. Employers indicated that contracting with a TPA for these requirements would come at a significant compliance cost to them. Commenters noted that they rent networks from issuers and contract with those issuers as TPAs to administer plan benefits. It is the issuer that holds the pricing information for medical services, facilities, and providers, not the self-insured employer. Another commenter stated that the burden incurred by plans, issuers, and TPAs would be crippling for smaller TPAs and health plans, and that burden would ultimately be passed along to employers, and, therefore, to consumers. Another commenter expressed concern that all of the data aggregation and collection required under the regulations—along with the need to contract with a third-party developer to create an on-line cost-sharing liability service tool that is capable of providing customized cost-sharing information to a particular participant, beneficiary, or enrollee—may be overly costly to plans. The commenter further suggested that there may also be significant costs associated with data storage.

The Departments appreciate the comments received in response to the proposed rules and recognize that not all plans will be the source of the material information required to meet the requirements of the final rules, and that many plans will ultimately seek out third-party assistance in the development of their internet-based self-service tool and machine-readable files, thus avoiding any potential penalties for noncompliance. As noted in section II.B.5 of this preamble, multiemployer plans may contract with a TPA or other third party (for example, a clearinghouse) to meet the requirements under the final rules. The Departments note that it is possible that obtaining third-party assistance to meet the requirements of the final rules could result in additional costs. The Departments expect, however, that TPA, or other third party, assistance will help alleviate some of the cost concerns expressed by commenters as a result of economies of scale. As noted above, commenters noted that many self-insured ERISA plans rent networks from issuers and contract with issuers as TPAs to administer plan benefits. By leveraging their relationships with their issuer-TPA, self-funded plans may be able to reduce their overall costs by using any tools developed by those issuers. The Departments also recognize that in order to meet the requirements of the final rules, some smaller TPAs and issuers could face disproportionate increases in costs. However, the Departments anticipate that a number of TPAs and issuer-TPAs will seek to coordinate their efforts and take advantage of any resulting economies of scale to reduce their overall costs, and that this approach can be leveraged in order to reduce concerns related to the development of both the internet-based self-service tool as well as the required machine-readable files. The Departments recognize that issuers and TPAs will incur potential costs associated with data storage and providing access to the internet-based self-service tool. These costs can be generally broken down into two sections: Bandwidth pricing and disc space. Bandwidth Pricing accounts for the amount of traffic going to a site, the size of the information that is transferred from the server to the user's browser, and the speed in which that happens. Provided that 99 percent of websites do not exceed 5 gigabytes of bandwidth per month,[253] this means if an issuer's or TPA's self-service tool, hosted on Microsoft's cloud product, would be free or minimal if beyond five gigabytes.[254] Disk Space Pricing accounts for the size of the hard drives necessary to host a website. Assuming that each issuer or TPA would need an estimated 351 gigabytes of storage this would translate to approximately $8 per month. Thus, assuming that each issuer or TPA will not require five gigabytes of bandwidth for their internet-based self-service tool, the Departments are of the

range cost estimate, the Departments estimated that only 90 percent of plans, issuers, and TPAs provided an online tool that would meet the assumptions used in developing the estimated costs.

[252] ''Healthcare Data Breach Statistics.'' HIPAA Journal. Available at: *https://www.hipaajournal.com/healthcare-data-breach-statistics/*.

[253] ''How Much Bandwidth and Disk Space Do I Really Need?'' Hosting Manual. Available at: *https://www.hostingmanual.net/bandwidth-disk-space-need/*.

[254] ''Bandwidth Pricing Details.'' Microsoft Azure. Available at: *https://azure.microsoft.com/en-us/pricing/details/bandwidth/*.

view that the overall costs to store and provide data through the internet-based self-service tool will be minimal. The Departments recognize that the final rules will impose significant costs on plans, issuers, and TPAs, and that some of these costs may be transferred to consumers in the form of higher premiums or changes in the cost-sharing structure of plans.

Intended Outcomes

Informed Consumers. Through increased price transparency, consumers armed with pricing information will have greater control over their own health care spending, which can foster competition among providers, resulting in less disparity in health care prices or an overall reduction in health care prices. Consumers who use the internet-based self-service tool will be able to access their cost-sharing amount paid to date; their progress toward meeting their accumulators, such as deductibles and out-of-pocket limits; their estimated cost-sharing liability for an identified item or service; negotiated rates for in-network providers for covered items and services, and the out-of-network allowed amounts for covered items and services. Additionally, consumers will know how much health care services will cost for a particular treatment-, and, and if applicable, whether coverage of a specific item or service is subject to a prerequisite. As discussed previously in section II.B.1.a of this preamble, section 2713 of PPACA requires group health plans and health insurance issuers to provide certain recommended preventive items and services without cost-sharing. However, if the same items or services are furnished as non-preventive actions or by an out-of-network provider, the participant, beneficiary, or enrollee may be subject to the cost-sharing terms of his or her plan. If a plan or issuer cannot determine whether the request is for a preventive item or service, the plan or issuer must display the non-preventive cost-sharing liability, along with a note that the item or service may not be subject to cost-sharing if it is billed as a preventive service. Pricing information also gives consumers the ability to plan ahead for any known items and services they may require in the near future. The Departments are of the view that access to this information is essential to enable consumers to make informed decisions regarding specific services or treatments, budget appropriately to pay any out-of-pocket expenses, and determine what impact any change in providers, items, or services will have on the cost of a particular service or treatment.

Several consumers stated that they want the opportunity to shop for the best price when seeking out medical care and expressed that this information is critical when deciding whether to proceed with a test or procedure. Other consumers expressed the desire to shop for items and services and stated that shopping for health care would give them more control over their personal health care decisions and spending. Some consumers felt strongly that they should be able to compare prices to find the best deal for non-life-threatening care. Some other consumers also expressed frustration when describing their own experiences of trying and failing to obtain pricing information before receiving a particular service.

The Departments agree that providing the information required in the final rules will provide consumers with tools and information they can use to determine and evaluate the potential costs associated with their particular health care needs, thus providing them the opportunity to obtain the care they need at a cost they find acceptable.

Consumers may become more cost conscious. The Departments are of the view that with increased price transparency consumers may begin to focus more carefully on the costs of services. Currently, consumers may be aware they have a coinsurance of 20 percent for an item or service, but they may be unaware of what dollar amount they will ultimately be responsible for paying. Knowing that dollar amount may motivate consumers to seek lower-cost providers and services or seek needed care they did not obtain because of uncertainty or concerns about the costs. As discussed in sections I.E.3, II.C, and V.B.2–4 in this preamble, there has been recent evidence in New Hampshire and Kentucky that supports the Departments' view that having access to pricing information, along with currently available information on provider quality and incentives to shop for lower prices, can result in consumers choosing providers with lower costs for items and services, thus potentially lowering overall health care costs.[255] The Departments acknowledge that this may only hold true if cost and cost sharing varies between services and providers. Depending on the degree of cost variation between specific items and services, there could be large variations in the degree to which prices change per item or service resulting in wide variations in health care costs and associated out-of-pocket costs.[256] Cost sharing in some alternative contracting models, such as HMOs and Exclusive Provider Organizations (EPO), generally occurs through fixed copayment amounts regardless which provider furnishes a covered item or service and, therefore, the internet-based self-service tool will provide little incentive for consumers to choose less costly providers in this context.

Timely Payment of Medical Bills. The Departments anticipate that consumers with access to the information provided in response to the final rules will be more likely to pay their medical bills on time. A recent Transunion survey found that 79 percent of respondents said they would be more likely to pay their bills in a timely manner if they had price estimates before obtaining care.[257] In addition, a non-profit hospital network found that the more information they shared with patients, the better prepared those patients were for meeting their responsibilities. The hospital network reported that providing price estimates to patients resulted in increased point of service cash collections from $3 million in 2010 to $6 million in 2011.[258] However, the Departments recognize that consumers may not be aware of any potential balance billing charges, where not prohibited by state law, and other potential costs associated with their

[255] Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. of Econ. and Stat. 1. July 16, 2018. Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf*; *see also* Rhoads, J. ''Right to Shop for Public Employees: How health care incentives are saving money in Kentucky.'' The Dartmouth Institute for Health Policy and Clinical Practice. March 8, 2019. Available at: *https://thefga.org/wp-content/uploads/2019/03/RTS-Kentucky-HealthCareIncentivesSavingMoney-DRAFT8.pdf.*

[256] The evidence cited in this RIA yields per-capita annual savings estimates ranging from between $3 and $5 (=$2.8 million + $1.3 million + $7.0 million + $2.3 million two-year savings, across 1.3 million California public employees and their family members, per Boynton and Robinson (2015)), to $6.50 (=$7.9 million + $36 million five-year savings found by Brown (2018), divided across the 1.36 million residents of New Hampshire), to $17 (=$13.2 million three-year savings across 0.26 million beneficiaries, per Rhoads (2019)). If these results were extrapolated to the entire U.S. population, the estimate of rule-induced reductions in annual consumer expenditures could range from $0.98 billion to $5.5 billion, with the median result across the three studies at $2.1 billion. This range has a tendency toward overestimation, in that effects of the Hospital Price Transparency final rule and existing non-Federal transparency programs have not been subtracted off.

[257] Kutscher, B. ''Report: Consumers demand price transparency, but at what cost?'' Modern Healthcare. June 2015. Available at: *https://www.modernhealthcare.com/article/20150623/NEWS/150629957/consumers-demand-price-transparency-but-at-what-cost.*

[258] ''Reimagining Patient Access.'' Insurancenewsnet. December 29, 2015. Available at: *https://insurancenewsnet.com/oarticle/reimagining-patient-access*#.

health care such as facility fees etc. While these consumers will have a better idea of the costs they will incur when obtaining health care, they will likely be unaware of any additional charges they could incur as a result of obtaining care resulting in higher than expected out-of-pocket costs. Additionally, consumers may not fully be aware of their costs due to potential medical complications that might arise during the course of treatment or while obtaining a specific service.

Increased Competition Among Providers. Studies have found that state price transparency regulations have resulted in hospitals decreasing their charges and a decrease in mean price and price variability for queried procedures. One study found the publication of chargemaster data resulted in a decrease in mean price and price variability for queried procedures.[259] However, another study attributed the reduction in charges to the ''reputational costs of perceived overcharging,'' yet also noted that reductions in charges were associated with decreases in discounts leading to no consumer savings.[260] Another issuer-initiated price transparency program, designed to encourage the selection of high-value providers, provided consumers with price differences among MRI facilities.[261] Those patients provided pricing information saw an 18.7 percent reduction in the cost per test and a decrease in the use of hospital-based facilities.[262] The study also found that price variations between hospital and non-hospital facilities were reduced by 30 percent.[263] As discussed in sections I.B in this preamble, the Departments recognize that requiring hospitals to display payer-specific negotiated charges, discounted cash prices, and de-identified minimum and maximum negotiated charges for as many of the 70 CMS selected shoppable services and additional hospital-selected shoppable services for a combined total of at least 300 shoppable services may play a role in decreasing mean prices and price variability.[264] However, the Departments are of the view that the Hospital Price Transparency final rule does not, in itself, result in reduced prices and price variability as the rule does not result in consumers receiving complete price estimates for health care items and services from both hospitals and issuers. Further, the Hospital Price Transparency final rule does not provide price transparency with respect to items and services provided by other health care providers. Therefore, the Departments are of the view that the requirements of the final rules will provide the additional price transparency necessary to empower a more price-conscious and responsible health care consumer and lead to increased competition among providers as consumers will be aware of and have the ability to compare the out-of-pocket cost of a covered item or service prior to receiving an item or service, which could force higher-cost providers to lower their prices in order to compete for the price sensitive consumer.

3. Requirements for Public Disclosure of In-Network Provider Rates for Covered Items and Services, Out-of-Network Allowed Amounts and Prescription Drug Pricing Information Through Machine-Readable Files Under 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212

Costs

Under 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), and 45 CFR 147.212(b) of the final rules, group health plans and health insurance issuers are required to make available to the public, on an internet website, three digital files in a machine-readable format. The first file (the In-network Rate File) must include information regarding all applicable rates, which may include negotiated rates, underlying fee schedules, or derived amounts, to the extent they may be used for purposes of determining provider reimbursement or cost-sharing for in-network providers. The Departments note that prescription drug products may be included in the In-network Rate File only to the extent they are included as part of an alternative payment arrangement, such as a bundled payment arrangement. The second file (the Allowed Amount File) must provide data showing the allowed amounts and billed charges with respect to covered items and services, including prescription drugs, furnished by out-of-network providers over a 90-day period beginning 180 days prior to the publication date of the machine-readable file. The third file (the Prescription Drug File) must include information for negotiated rates and historical net prices for prescription drugs, organized by NDC. Plans and issuers are required to make the information available in accordance with certain method and format requirements described at paragraph (b)(2) and update these files monthly as required under paragraph (b)(3). The quantitative costs associated with meeting these requirements are detailed in section VI.2 of the ICR section.

Some commenters stated that the requirement to use billing codes would be very costly and potentially cost-prohibitive. One commenter indicated this is because use of CPT codes, the most commonly used billing codes, requires licensure by the American Medical Association (AMA). According to the commenter, the AMA charges licensing fees based on use cases per user. Another commenter noted that some self-funded plans rent networks and do not have real-time access to network pricing, and there are fees charged to plans to access the negotiated discounts with the provider network the plan has rented. As a result, the commenter suggested that plans will have to pay the network access fees twice—once the information required under the final rules and a second time when the actual claim is received and processed through an intermediary—to meet the requirements of the final rules.

The Departments understand that the use of CPT codes may represent an additional cost for some plans and issuers. Generally, the Departments anticipate that if a plan or issuer currently has the capability or licensure to record CPT codes on EOBs mailed to consumers, the plans or issuers should also be able to use that CPT code to make the public disclosures required through the final rules without, or with minimal, additional costs. The Departments also have concluded that, as plans and issuers would already include licensing costs for using CPT codes in the cost of doing business, they would not incur additional costs to use the CPT codes to populate the machine-readable files. The Departments acknowledge that some plans and issuers could face instances where they could incur additional costs in order to access the required CPT or network information based on the structure of licensing agreements to which they are currently parties. However, due to an overall lack of specific information and knowledge associated with the number of plans and issuers that currently have

[259] Ward, C., and Reeder, T. ''The Evolution and Impact of Hospital Price Transparency in North Carolina.'' North Carolina Medical Journal. Volume 81. Issue 2. April 2020. Available at: *https://www.ncmedicaljournal.com/content/81/2/95.short.*

[260] Christensen, H.B., Floyd, E., and Maffett, M. ''The Only Prescription is Price Transparency: The Effect of Charge-Price-Transparency Regulation on Healthcare Prices.'' Management Science. February 21, 2019. Available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2343367.*

[261] Wu, S.J., et al. ''Price transparency for MRIs increased use of less costly providers and triggered provider competition.'' Health Affairs. August 2014. Available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0168.*

[262] *Id.*

[263] *Id.*

[264] 84 FR 65524 (Nov. 27, 2019).

such licensing agreements, the structure of those agreements, and the alternatives available to those plans and issuers, the Departments are unable to accurately estimate any associated costs that might be incurred under these circumstances.

One commenter stated that for many employer-sponsored health plans, in-network rates usually belong to a network administrator, not the health plan, and, in the event network administrators were to update their contractual agreements to permit plans to receive and share pricing information, it is likely they will charge fees or request financial concessions from plans, which will increase administrative burdens on group health plans.

The Departments understand that requiring release of this pricing information will affect certain commercial arrangements and expectations that prevail in parts of the health care industry today, which could result in certain one-time and ongoing administrative costs. However, the Departments are of the view that making this information available to consumers and the public will serve consumers' long-term interests in facilitating a consumer-oriented, information-driven, more competitive market. Additionally, as discussed previously in section II.C in this preamble, the Departments are finalizing several special rules to streamline the provision of the public disclosures required through the final rules. These special rules were designed to reduce the overall compliance costs of the disclosures required by the final rules and to support smaller issuers and plans in meeting the requirements of the final rules by permitting certain contractual arrangements and the aggregation of allowed amount data in some circumstances.

The Departments also recognize that a certain amount of data storage will be required to post the machine-readable files on a publicly available internet website. Through the efficiencies of cloud computing and data storage, the cost to host large files dramatically decreased in price in the past several years. Popular services such as Simple Storage Service from Amazon Web Services and Standard Storage from the Google Cloud Platform can host files for roughly $0.026 per gigabyte. The Departments' size estimates of roughly 5 gigabytes for each machine-readable file would incur a monthly data storage cost of approximately $0.39 for all of the machine-readable files.

Non-Quantified Costs for Public Disclosure of In-Network Rates. In addition to the costs described in section VI.A.2, the Departments recognize there may be other costs associated with the requirement to make in-network rates publicly available that are difficult to quantify given the current lack of information and data. While the Departments are of the view that the overall effect of the final rules will be to provide greater price transparency and potentially lower health care prices, there are instances in very transparent markets where price ranges can narrow and average costs can increase as a result of price transparency.[265] The Departments also recognize that plans and issuers may experience ongoing additional costs (for example, the cost of quality control reviews) to ensure they comply with the requirements of the final rules. In addition, the Departments are aware that information disclosures allowing competitors to determine the rates their competitors are charging may dampen each competitor's incentive to offer a lower price or result in a higher price equilibrium.[266] While plans and issuers with the highest in-network rates may see a decrease in their in-network rates, as their providers respond to consumer and smaller issuers' concerns regarding paying more for the same item and service, plans and issuers with the lowest in-network rates may see their lower cost providers adjust their rates upward. However, most research suggests that when better price information is available, prices for goods sold to consumers fall. For example, in an advertising-related study, researchers found that the act of advertising the price of a good or service is associated with lower prices.[267]

A potential additional non-quantified cost could be the cost to remove gag clauses from contracts between plans, issuers, and providers. Contracts between plans, issuers, and providers often include a gag clause, which prevents plans and issuers from disclosing in-network rates. The Departments recognize that plans, issuers and providers may incur a one-time expense for their attorneys to review and update their provider contracts to remove any relevant gag clauses. Comments received regarding gag clauses and contract negotiations are further discussed in section VI.A.2 later in this preamble.

Another potential cost concerns the final rules' impact on a plan's or issuer's ability or incentive to establish a robust network of providers. A health insurance provider network is a group of providers that have contracted with a plan or issuer to provide care at a specified price the provider must accept as payment in full. Many times, plans and issuers want consumers to use the providers in their network because these providers have met the plan's or issuer's quality standards and agreed to accept an in-network rate for their services in exchange for the patient volume they will receive by being part of the plan's or issuer's network.[268] Some plans and issuers offer a narrow network: These networks operate with a smaller number of providers, meaning a consumer will have fewer choices when it comes to in-network providers, but often offer lower monthly premiums and out-of-pocket costs.[269] The Departments recognize that making in-network rates public may create a disincentive for plans and issuers to establish a contractual relationship with a provider (including in narrow networks) because providers may be unwilling to give a discount to plans and issuers when that discount will be made public. As addressed further in section VI.C later in this preamble, the requirements of the final rules could result in a reduction in revenue for those smaller plans and issuers that are unable to pay higher rates to providers and may require them to narrow their provider networks, which could affect access to care for some consumers. Due to smaller plans' and issuers' potential inability to pay providers with higher rates, smaller plans and issuers may further narrow their networks to include only providers with lower rates, possibly making it more difficult for smaller plans and issuers to fully comply with network adequacy standards described at 45 CFR 156.230 or other applicable state network adequacy requirements.

Some commenters stated that public disclosure of in-network rates could affect the sustainability and affordability

[265] Kutscher, B. ''Report: Consumers demand price transparency, but at what cost?'' Modern Healthcare. June 2015. Available at: *https://www.modernhealthcare.com/article/20150623/NEWS/150629957/consumers-demand-price-transparency-but-at-what-cost.*

[266] Koslov, T., and Jex, E. ''Price transparency or TMI?'' United States, Federal Trade Commission. Available at: *https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.*

[267] Austin, D. A, and Gravelle, J. G. ''Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector.'' Congressional Research Service. June 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf.*

[268] Davis, E. ''Health Insurance Provider Network Overview.'' Verywell Health. August 2019. Available at: *https://www.verywellhealth.com/health-insurance-provider-network-1738750.*

[269] Anderman, T. ''What to Know About Narrow Network Health Insurance Plans.'' Consumer Reports. November 23, 2018. Available at: *https://www.consumerreports.org/health-insurance/what-to-know-about-narrow-network-health-insurance-plans/.*

of QHPs offered through the Exchanges by placing upward pressure on rates and by placing provider participation in networks at risk. One commenter stated that the potential negative effects on QHPs would especially harm unsubsidized consumers and consumers in rural areas where provider consolidation is most common and could impact overall marketplace stability and the risk pool. Furthermore, commenters asserted that increased premiums for QHPs could result in increased Federal spending in the form of higher premium tax credit (PTC) payments, which could substantially increase the Federal deficit over 10 years. One commenter stated that the Departments should not finalize the release of in-network rates until they fully evaluate the impact on affordable plan options on the Exchanges and the effects on Federal spending.

As discussed later in section V.B.5 of this preamble, the Departments estimate premiums for the fully-insured markets will be $471 billion for 2022, including the individual, small group, and large group markets. The Departments estimate that the cost for 2022 represents approximately 2.4 percent of projected commercial insured premiums for the fully-insured market, 1.4 percent in 2023, 0.5 percent in 2024, and 0.5 percent in 2025. Assuming this level of premium increase in the individual market, PTC outlays are estimated to increase by about $1,047 million in 2022, $623 million in 2023, $216 million in 2024, and $218 million in 2025. Given that the 2021 President's Budget estimates that PTC outlays are expected to be $43.8 billion in 2022, $44.8 billion in 2023, $45.875 billion in 2024, and $48.2 billion in 2025,[270] the Departments expect the estimated increase of $1,047 million in 2022, $623 million in 2023, $216 million in 2024, and $218 million in 2025 to have minimal impacts on anticipated enrollment and are not of the view that this increase will result in any widespread negative effects on market stability. Additionally, the Departments have determined that enrollment impacts will be minimal, as estimated premium impacts are relatively small, and rate increases for subsidized enrollees in the individual market will be largely mitigated. Additionally, participants, beneficiaries, and enrollees currently make health insurance coverage decisions based on their particular health and financial situations, and it is not predictable how information provided as a result of the final rules will significantly impact those health insurance coverage decisions. Thus, the Departments do not expect the final rules to significantly increase the selection risk beyond the levels that currently exist. The Departments do acknowledge that the estimated increases in premiums could result in minor harm to unsubsidized consumers as they could be faced with increased premiums that would not be negated by any increases in PTC and this could impact those consumers' decisions related to obtaining health insurance coverage.

The Departments received several comments from issuers, providers, and employers stating that the requirement to publicly disclose in-network rates would threaten the viability of their business models or business models upon which they rely. One commenter stated that the proposal to release in-network rates could affect the viability of individual and small group market health plans sold by small issuers. The commenter further suggested that ''safety net'' health plans (which serve individuals and families that do not have access to other sources of coverage in markets that other issuers find unprofitable) currently may be able to access more favorable contract terms with providers, and these types of arrangements would be at risk if the in-network rate information were required to be made public. The commenter expressed particular concern that exposure of the rates of safety net hospitals may uniquely disadvantage them in negotiations with plans and issuers because they may have to raise rates on certain services to support safety net activities. Similarly, a hospital system stated that publishing in-network rates would negatively impact its ability to contain costs and threaten its current participation in the networks of nearly all area health plans. Another commenter indicated that providers would leave plans' and issuers' networks if plans' and issuers' attempts to achieve more favorable rates using public in-network rate information proved unsuccessful. Another commenter argued that the policy requiring disclosure of in-network rates could also result in the collapse of the network administrator business model, which would result in significantly increased administrative costs for health plans that would need to contract separately with each participating provider.

The Departments understand that requiring the release of this pricing information will upset certain commercial arrangements and expectations that prevail in parts of the health care industry today, which could result in certain one-time and ongoing administrative costs. However, the Departments have concluded that providing increased price transparency and making this information available to the public will serve the public's long-term interests in facilitating a consumer-oriented, information-driven, more competitive market potentially leading to reduced overall health care costs.

Some commenters suggested that, by using publicized in-network rate information, plans and issuers could also coordinate to reduce provider payment levels below market competitive rates, a so-called ''race to the bottom.'' Some of these commenters stated that this ''race to the bottom'' could also potentially hurt access to, and quality of, care. For example, one commenter stated that if provider reimbursement rates were set too low, patient access to care would be negatively impacted because providers will not have the resources to invest in technology, training, and equipment.

One commenter suggested that plans and issuers would likely want to re-negotiate rates once they learn local prices and that dominant issuers could use payer specific in-network rate information to deter and punish hospitals that lower their rates or enter into value-based arrangements with the dominant issuer's competitors.

Several commenters stated that required disclosure of in-network rates could result in an increase in health care prices. Others specifically expressed concerns that making payer-specific in-network rates available would disrupt contract negotiations between providers and health plans and result in providers changing their rates in anticompetitive ways (''race to the top'') and could promote an environment that could support collusion between providers, resulting in increased prices. Other commenters suggested that required disclosures would lead to the consolidation of providers and even greater consolidation in the commercial health insurance industry, and expressed concerns that disclosures could particularly harm small health plans and TPAs who may have been able to get discounted rates by offering health plans in a limited service area.

One commenter noted that other states' transparency systems used several distinguishable features to mitigate the risks of publicizing rates, but noted that, despite these efforts, the data was still used in contract negotiations.

[270] OMB 2021 President's Budget. Available at: *https://www.whitehouse.gov/wp-content/uploads/2020/02/budget_fy21.pdf.*

The Departments recognize that there is the potential for adverse market outcomes as a result of the final rules. As noted previously, the Departments are aware of the potential that plans and issuers could seek to use the public availability of in-network rates or underlying fee schedules in attempts to lower prices in what certain commenters called a ''race to the bottom.'' As noted previously in this section, the Departments recognize the potential for anticompetitive behaviors and increased consolidation that may occur should providers use the in-network rate or fee schedule data to increase their rates or should smaller plans and issuers struggle to comply. The Departments recognize that provider collusion could result in increased prices, and also recognize that this sort of behavior could result in distinct coverage areas or agreements where providers choose not to compete for consumers. As discussed previously in this preamble, the Departments nonetheless have concluded that providing increased price transparency and making this information available to the public will serve the public's long-term interests in facilitating a consumer-oriented, information-driven, more competitive health care market.[271] Should the market become more competitive, as the Departments anticipate, the reduction in prices may provide more options for those providers that function as ''safety-net providers'' to expand their networks or enhance the services they currently provide by organizing and delivering a significant level of health care and other related services to uninsured, Medicaid, and other vulnerable populations. The Departments also reason that the likelihood of price and other forms of collusion will be mitigated to some extent by the actions of state and Federal regulatory and antitrust enforcement authorities and the enforcement of current market laws and regulations. The Departments are of the view that enforcement actions taken to reduce the likelihood of price collusion will further reduce the chances that issuers will seek to reduce the size of their networks.

Although consumer education is not a requirement of the final rules, plans, issuers and TPAs may face additional costs if they chose to inform and educate their consumers about the options available to them, how to use these tools, increase their general health care knowledge. Providing educational opportunities to participants, beneficiaries, or enrollees could encourage those participants, beneficiaries, or enrollees to seek lower cost services, providing plans, issuers and TPAs the potential to realize a return on the investments incurred to comply with the final rules.

Non-Quantified Cost for Public Disclosure of out-of-network allowed amounts. In addition to the costs described in section VI.A.2 and the previous analysis related to the public disclosure of in-network rates, the Departments recognize that there may be other costs associated with the requirement to make historical payments of out-of-network allowed amounts and billed charges publicly available that are difficult to quantify, given the current lack of information and data.

Furthermore, while plans and issuers must de-identify data (such as claim payment information for a single provider) and ensure certain sensitive data are adequately protected, unauthorized disclosures of PHI and PII may increase as a result of manual preparation and manipulation of the required data. The potential disclosures of PHI and PII may require plans, issuers, and TPAs to obtain additional cyber-security insurance that could lead to additional costs.

Non-Quantified Cost for Public Disclosure of Prescription Drug Pricing Information. In addition to the costs described in section VI.A.2 and the previous analysis related to the public disclosure of in-network rates and allowed amounts, the Departments recognize that there are other costs associated with the requirement to make negotiated rates and historical net prices for prescription drugs publicly available that are difficult to quantify, given the current lack of information and data. For example, as a result of the availability of consolidated negotiated rates and historical net prices, drug manufacturers may seek to restructure their rebate and discount programs and could potentially cease providing rebates to plans and issuers, PBMs, or pharmacies, which could then result in less savings being passed on to consumers.

Intended Outcomes

The Departments are of the view that providing greater price transparency by requiring group health plans and health insurance issuers to make information regarding all applicable rates publicly available, which may include negotiated rates, amounts in underlying fee schedules, or derived amounts for in-network provider rates; 90-days of historical allowed amount and billed charges data for out-of-network providers; and prescription drug negotiated rates and historical net prices will ultimately benefit plans and issuers, regulatory authorities, consumers, and the overall health care market.

Group Health Plans and Health Insurance Issuers. Plans and issuers may benefit from these requirements because under the final rules a plan or issuer would have a better understanding of other plans' or issuers' in-network rates. This may allow plans and issuers paying higher rates for the same items or services to negotiate with certain providers to lower their rates, thereby lowering provider reimbursement rates, reducing price variation, and potentially resulting in an overall decrease in health care costs. The Departments acknowledge, however, as noted in the ''costs'' section (V.B.3) earlier in this preamble, that knowledge of other providers' in-network rates could also drive up rates if a provider discovers they are currently being paid less than other providers by a plan or issuer and, therefore, seek to negotiates higher rates.

In addition, the final rules may result in more plans and issuers using a reference pricing structure. Under this structure, participants, beneficiaries, or enrollees who select a provider charging above the reference price (or contribution limit) must pay the entire difference and these differences do not typically count toward that individual's deductible or out-of-pocket limit. Plans and issuers may want to use a reference pricing structure to pass on any potential additional costs associated with what they can identify as higher-cost providers to the participant, beneficiary, or enrollee. The Departments recognize that reference pricing might not impact every consumer. For example, the California Public Employees' Retirement System (CalPERS) provides exceptions from reference pricing when a member lives more than 50 miles from a facility that offers the service below the price limit. It also exempts the patient if the patient's physician gives a clinical justification for using a high-priced facility or hospital setting. Another example is a business with a self-insured group health plan that exempts laboratory tests for patients with a diagnosis of cancer from its reference pricing program. However, reference pricing has generally been shown to result in price reductions, as opposed to mere slowdowns in the rate of price

[271] Gudiksen K.L., Chang, S.M., and King, J.S. ''The Secret of Health Care Prices: Why Transparency Is in the Public Interest.'' California Health Care Foundation. July 2019. Available at: *https://www.chcf.org/wp-content/uploads/2019/06/SecretHealthCarePrices.pdf.*

growth. For example, in the first two years after implementation, reference pricing saved CalPERS $2.8 million for joint replacement surgery, $1.3 million for cataract surgery, $7.0 million for colonoscopy, and $2.3 million for arthroscopy.[272]

Regulatory Authorities. In many states, issuers must obtain prior approval for rate changes from the state's DOI. Regulatory authorities such as state DOIs might benefit from the final rules because knowledge of provider in-network rates and out-of-network allowed amounts paid to out-of-network providers could support determinations of whether premium rates, including requests for premium rate increases, are reasonable and justifiable.

Consumers. Access to the in-network rates between plans and issuers and in-network providers, the amount plans and issuers have paid to out-of-network providers, and prescription drug pricing information will allow consumers to understand the impact of their choice of health insurance coverage option and their choices of providers on the cost of a particular service, item, or treatment. Giving consumers access to this information as part of their health care decision-making process may facilitate a greater degree of control over their own health care costs. Furthermore, having access to publicly available out-of-network allowed amounts will provide consumers who are shopping for health insurance coverage the ability to compare the different rates plans and issuers ultimately pay for items and services, including items and services from providers that might be out-of-network. While the Departments are of the view that consumers will benefit from the final rules, the Departments recognize that utilizing the required information will not be practical or reasonable in an emergency situation. Similarly, some consumers may need assistance in understanding complex terms or other associated mechanisms in order to utilize this information.

The Departments recognize that beneficiaries and enrollees in state and Federal health care programs (including Medicare, Medicaid, CHIP, Basic Health Program and coverage provided by the Department of Defense and Veterans Administration) will be impacted by spillover effects related to any reductions or increase in prices for individual items and services and prescription drugs as a result of the final rules. For example, Medicare Part B has historically reimbursed physicians for physician-administered drugs using a formula that is based off the average sales price (ASP). To the extent the final rules drive changes in prescription drug prices, that will change the Federal reimbursement rates under Medicare Part B and may impact Medicare beneficiaries' out-of-pocket costs for their prescriptions. In addition, by law, Medicaid programs in every state receive the lowest negotiated rate for prescription drugs. To the extent the final rules drive changes in prescription drug prices, this will impact the amount all states, the Federal Government, and some beneficiaries pay for prescription drugs. Similarly, if providers start increasing (or decreasing) their in-network rates, there could also be spillover effects for Medicare Advantage or Medicaid Managed Care Organizations (MCO), particularly for issuers and plans that use the same network for both private plans, Medicare Advantage Plans and Medicaid MCOs. These changes will impact the amount the Federal Government, states, and beneficiaries will need to pay for their Medicare and/or Medicaid.

Overall Health Insurance Market. The price transparency required by the final rules may also induce an uninsured person to obtain health insurance coverage. Depending on premium rates, an uninsured individual might select health insurance coverage after learning the actual dollar difference between the usual and customary rates that he or she pays for items and services and the in-network rates and out-of-network allowed amounts under the terms of a plan or issuer's policy. In addition, the final rules might force providers to lower their rates for certain items and services in order to compete for the price sensitive consumer, plan, or issuer. Although the immediate payment impact would be categorized as a transfer, any accompanying health and longevity improvements would be considered benefits (and any accompanying increases in utilization would, thus, be considered additional costs). As discussed in section V.B in this preamble, a study of New Hampshire's HealthCost initiative found that the availability of pricing information resulted in a five percent reduction in costs for medical imaging procedures. The study further found that patients saved approximately $7.5 million dollars on X-Ray, CT, and MRI scans over the five-year study period (dollars are stated in 2010 dollars).[273]

Some commenters suggested that the biggest impact on health care spending and costs would come from self-insured employers who would now be able to access and use in-network rate data to negotiate lower rates on behalf of plan participants; improve their provider networks; make more informed decisions about plan offerings; help steer enrollees to higher-quality, lower-cost providers; and more meaningfully implement value-based payment designs. Other commenters stated that the proposed rules would help create more efficient and value-based health care systems by encouraging issuers to design innovative benefit designs that push patients toward lower-cost care. Another commenter stated that requiring plans and issuers to share publicly their in-network rates and the allowed amounts paid to out-of-network providers had the potential to increase competition among plans and issuers.

The Departments are of the view that the requirements in the final rules will provide providers, plans, and issuers the ability to provide quality health care services at lower costs to participants, beneficiaries, or enrollees through enhanced provider and payer competition.

4. Medical Loss Ratio (45 CFR 158.221)

''Shared savings'' programs allow issuers to share with enrollees any savings that result from enrollees shopping for, and receiving care from, lower-cost, higher-value providers. In the final rules, HHS is amending 45 CFR 158.221(b) to allow health insurance issuers that elect to offer ''shared savings'' programs to take credit for such ''shared savings'' payments in their MLR calculations. For this impact estimate, HHS is assuming that only relatively large issuers (with at least 28,000 enrollees) that have consistently reported investment costs in health IT on the MLR Annual Reporting Form of at least $10.50 per enrollee, which represents issuers with 70 percent of total reported commercial market health IT investment or issuers that operate in states that currently or may soon support ''shared savings'' plan designs,[274] will initially choose to offer plan designs with a ''shared savings''

[272] Boynton, A., and Robinson, J. ''Appropriate Use of Reference Pricing Can Increase Value.'' Health Affairs Blog. July 7, 2015. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20150707.049155/full/.*

[273] Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. Econ. & Stat. 1. (2018). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.*

[274] The states that supported ''shared savings'' plan designs at the time the estimate was developed and therefore were included in the estimate are Maine, Massachusetts, New Hampshire, and Utah.

component. HHS assumes that such issuers will share, on average, 50 percent of the savings with enrollees (which will increase the MLR numerator under the final rules), and that issuers whose MLRs were previously below the applicable MLR standards will use their retained portion of the savings to lower enrollees' premiums in future years (which will reduce the MLR denominator). Based on 2017–2019 MLR data, HHS estimates that this will reduce MLR rebate payments from issuers to enrollees by approximately $120 million per year, while facilitating savings that will result from lower medical costs of approximately $154 million per year for issuers and enrollees (some of which will be retained by issuers, shared directly with enrollees, or used by issuers to reduce future premium rates).

5. Summary of Estimated Transfers

The Departments are assuming that because 2021 premium rates are nearly finalized, health insurance issuers will not be able to charge for the expenses incurred to implement the requirements of the final rules in their 2021 rates. Because issuers will not have the opportunity to reflect the 2021 development costs in the 2021 premium rates, some issuers may apply margin to the ongoing expenses as they develop premium rates for 2022 and after. The Departments estimate premiums for the fully-insured markets will be $471 billion for 2022, $494 billion in 2023, $516 billion in 2024, and $539 billion in 2025, which includes the individual, small group, and large group markets.[275] The Departments estimate that the ongoing expense represents approximately 2.4 percent of projected commercial insured premiums for the fully-insured market in 2022, 1.4 percent in 2023, and 0.5 percent in 2024 and 2025 (an average of 1.2 percent per year). Assuming this level of premium increase in the individual market, PTC outlays are estimated to increase by about $1,047 million in 2022, $623 million in 2023, $216 million in 2024, and $218 million in 2025. Given that 2022 PTC outlays are expected to be $44 billion,[276] the Departments expect that the estimated premium impacts will be relatively small, and rate increases for subsidized enrollees in the individual market will largely be mitigated. Therefore, the Departments expect enrollment impacts to be minimal. The Departments note that any impact of the final rules on provider prices has not been estimated as limited evidence has generally shown no predictable impact on provider prices. As a result, the Departments are assuming that the overall impact will be minimal. However, there is a large degree of uncertainty regarding the effect on prices, so actual experience could differ.

The Departments received comments stating that the broader impact to premiums was not considered in the proposed rules. Several commenters stated that increased health care prices could be passed along to consumers, patients, and taxpayers in the form of higher premiums. Some commenters specifically observed that the cost of developing and maintaining the required machine-readable files on a monthly basis would likely be passed on to consumers in the form of higher premiums. Another commenter noted that employers, TPAs, and issuers might incur increased costs relative to the rules regarding potential data breaches, increased liability, and cyber-coverage costs (liability insurance designed to cover financial losses that result from data breaches and other cyber events) that could also impact plan premiums.

Other commenters suggested that use of information in the In-network Rate File could be used by consumers to engage in practices that would lead to adverse selection and potentially higher premiums. One commenter asserted that the proposed rules would allow individuals to enter the insurance pool for specific costly treatments or procedures and then drop coverage or switch coverage at the end of the contract year for a plan with lower premiums, which would result in higher premiums for all consumers because there is no ability for health plans to spread the risk across a reliable and long-term customer base.

By contrast, one commenter observed that premium increases could be mitigated if low-deductible participants, beneficiaries, or enrollees were given information about the cost of the health care they utilize, and that over time price transparency could create lower health care costs.

The Departments recognize that many issuers and TPAs will likely transfer the costs associated with meeting the requirements in the final rules to consumers in the form of increased premiums. However, the Departments do not currently have enough information or evidence to determine the overall effects the final rules will have on premiums and therefore have not estimated how the final rules will impact an individual's premium. The Departments also note that adverse selection risk currently exists in the individual market; individuals already make health care coverage decisions based on their particular health and financial situations. It is not clear how the price information contained in the In-network Rate, Allowed Amount, and Prescription Drug Files will significantly impact an individual's health care coverage decisions. The Departments do not expect the final rules to significantly increase the selection risk beyond the levels that currently exist.

Also, it is questionable how much the final rules will lower health care costs for low deductible participants, beneficiaries, or enrollees because cost-sharing amounts are usually much less than the cost of the services, so that the participants, beneficiaries, or enrollee have no economic incentive to seek lower cost services. Additionally, evidence is limited but generally does not show significant differences in insured participant, beneficiary, or enrollee behavior as a result of price transparency.

C. Regulatory Review Costs

Affected entities will need to understand the requirements of the final rules before they can comply. Group health plans and health insurance issuers are responsible for ensuring compliance with the final rules. However, as assumed elsewhere, it is expected that issuers and TPAs (for self-insured group health plans) will incur this cost and burden for most group health plans, and only the largest self-insured plans may incur this cost and burden directly. Thus, issuers and TPAs (and possibly some of the largest self-insured plans) will be responsible for providing plans with compliant services. The Departments are currently not aware of any specific number of large self-insured plans that will seek to meet the requirements of the final rules without third-party assistance and are thus unable to accurately account for those plans, however, those plans will incur similar costs and burdens as TPAs and issuers in order to develop the required tools and to review and understand the final rules. Therefore, the cost and burden for the regulatory review is estimated to be incurred by the 1,959 issuers and TPAs. The Departments also are of the view that each state DOI, 50 states plus the District of Columbia, will need to review and understand the final rules in order to be able to provide the appropriate level of oversight and enforcement.

[275] 2017 earned premium data was taken from amounts reported for MLR, and trended forward using overall Private Health Insurance trend rates from the NHE projections.

[276] OMB 2021 President's Budget. Available at: *https://www.whitehouse.gov/wp-content/uploads/2020/02/budget_fy21.pdf.*

If regulations impose administrative costs on private entities, such as the time needed to read and interpret the final rules, the Departments should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review and interpret the final rules, the Departments are assuming that the total number of issuers, TPAs, and state DOIs will be required to comply with the final rules.

Nonetheless, the Departments acknowledge that this assumption may understate or overstate the costs of reviewing the final rules. It is possible that not all affected entities will review the final rules in detail, and some entities may seek the assistance of outside counsel to read and interpret them. For these reasons, the Departments are of the view that the number of issuers, TPAs, and DOIs would be a fair estimate of the number of reviewers of the final rules.

Using the wage information from the Bureau of Labor Statistics (BLS) [277] for a Computer and Information Systems Manager (Code 11–3021), a Lawyer (Code 23–1011) and a state Compliance Officer (Code 13–1041).[278] The Departments estimate that the cost for each issuer or TPA to review the final rules will be $285.66 per hour, including overhead and fringe benefits, and each state DOI will incur a cost of approximately $55.58 per hour.[279] Assuming an average reading speed, the Departments estimate that it will take approximately two hours for each staff member to review and interpret the final rules; therefore, the Departments estimate that the cost of reviewing and interpreting the final rules for each issuer and TPA will be approximately $571.32 and $111.16 for each state DOI, including the District of Columbia. Thus, the Departments estimate that the overall cost for the estimated 1,959 issuers and TPAs and each state DOI will be $1,124,885.04 (($571.32 × 1,959 (total number of estimated issuers and TPAs)) + ($111.16 × 51 (total number of DOIs))).

D. Regulatory Alternatives Considered

In developing the policies contained in the final rules, the Departments considered alternatives to the final rules. In the following paragraphs, the Departments discuss the key regulatory alternatives the Departments considered.

1. Limiting Cost-Sharing Disclosures to Certain Covered Items and Services, and Certain Types of Group Health Plans and Health Insurance Issuers

The final rules require group health plans and health insurance issuers to disclose cost-sharing information for any requested covered item or service. The Departments considered limiting the number of items or services for which plans and issuers would be required to provide cost-sharing information to lessen the costs on these entities. However, limiting disclosures to a specified set of items and services reduces the breadth and availability of useful cost estimates to determine anticipated cost-sharing liability and limits the impact of price transparency efforts by reducing the incentives to lower prices and provide higher-quality care. The Departments assumed that plans (or TPAs on their behalf) and issuers, whether for a limited set of covered items and services or for all covered items and services, would be deriving these data from the same data source. Because the data source would be the same, the Departments assumed that any additional costs to produce the information required for all covered items and services, as opposed to a limited set of covered items and services, would be minimal. The Departments are of the view that this limited additional cost is outweighed by the potentially large benefit to consumers of having access to the required pricing information for the full scope of items and services covered by their plan or issuer. For these reasons, in order to allow consumers to estimate their out-of-pocket costs for all services and items covered under their plan or coverage, and to achieve lower health care costs and reduce spending through increased price transparency, the final rules are requiring cost-sharing information be disclosed for all covered items and services. However, in recognition of commenters' concerns regarding the implementation timetable for the internet-based self-service tool, the final rules include a staggered implementation schedule for the disclosure of cost-sharing information through the internet-based self-service tool.

The Departments also considered implementing a more limited approach by imposing requirements only on individual market plans and fully-insured group coverage. However, the Departments are concerned that this limited approach might encourage plans to simply shift costs to sectors of the market where these requirements would not apply and where consumers would have less access to pricing information. The Departments are of the view that all consumers should be able to access the benefits of greater price transparency and that a broader approach will have the greatest likelihood of controlling the cost of health care industry-wide. Indeed, if the requirements of the final rules were limited to only individual market plans, the Departments estimate only 9,716,000 individuals would receive the intended benefits of the final rules. In contrast, under the final rules, a total of 212,314,000 participants, beneficiaries, and enrollees may receive the intended benefits.[280] The Departments acknowledge that limiting applicability of the requirements of the final rules to the individual market would likely reduce the overall cost estimates identified in section V.B.2, but the overall cost estimates per covered life would likely increase. Further, there is a great deal of overlap in issuers that offer coverage in both the individual and group markets. Issuers offering coverage in both markets would be required to comply with the requirements of the final rules even if the Department limited the applicability to only the individual market. Because TPAs provide administrative functionality for self-insured group health insurance coverage, those non-issuer TPA entities would not incur any costs because they do not have any overlap between the individual and group markets. The Departments are of the view that the benefits of providing consumer pricing information to an estimated total 212,314,000 participants, beneficiaries, and enrollees outweigh the increased costs that a subset of plans, issuers, and TPAs, that are not active participants in the individual market, would incur. The Departments have determined that the benefits of the final rules being widely applicable will not only provide access to health care pricing information to a greater number of individuals, but that any developed economies of scale will have a much

[277] Wage information available at *https://www.bls.gov/oes/current/oes_nat.htm.*

[278] Wages obtained for State Government, excluding schools and hospitals at *https://www.bls.gov/oes/current/naics4_999200.htm.*

[279] Adjusted hourly wages are determined by multiplying the mean hourly rate by 100 percent to account for fringe benefits and overhead costs.

[280] ''Health Insurance Coverage in the United States: 2019'' (Appendix A). United States Census Bureau/September 15, 2020. Available at: *https://www2.census.gov/programs-surveys/demo/tables/p60/271/table1.pdf.* The number of covered individuals in the individual market and the total number of covered individuals have been updated from those estimated in the proposed rule. The numbers provided in this final rule are based on more recent data and more accurately reflect the number of covered individuals in the private market (excluding those enrolled in Tricare coverage). The data provided is for 2019, whereas the data presented in the proposed rule was derived from multiple sources for multiple years (2016 and 2019).

greater likelihood of achieving the goal of controlling the cost of health care industry-wide.

As noted in section I.B of this preamble, in the summer and fall of 2018, HHS hosted listening sessions in which attendees stated that existing tools usually use historical claims data, which results in broad, sometimes regional, estimates, rather than accurate and individualized prices. The Departments considered allowing plans and issuers to use rate information from historical claims data to calculate price estimates. The Departments recognize that many plans and issuers use historical claims data to inform and determine cost-sharing estimates, but the Departments are of the view that using pricing information such as negotiated rates will provide for a more accurate and reliable estimate. Providing more accurate estimates of consumer prices will provide more benefit to consumers, allowing them to better estimate their potential out-of-pocket costs and search for items and services they feel are more affordable.

2. Requirement To Make Available Machine-Readable Files of In-Network Rates, Historical Data for Out-of-Network Allowed Amount Payments Made to Out-of-Network Providers, and Prescription Drug Pricing Information on a Public Website

In proposing the requirement that group health plans and health insurance issuers post in-network rates, historical data for out-of-network allowed amount payments made to out-of-network providers, and negotiated rates and historical net prices for each prescription drug on a publicly accessible website, the Departments considered requiring plans and issuers to submit the internet addresses for the machine-readable files to CMS. CMS would then make the information available to the public from CMS's website. A central location could allow the public to access in-network rate information, out-of-network allowed amounts, and prescription drug information for all plans and issuers in one place, potentially reducing confusion and increasing accessibility. Posting in-network rates, out-of-network allowed amounts, and prescription drug information in a central location might also make it easier to post available quality information alongside price information. However, to provide flexibility and reduce costs, the Departments are of the view that plans and issuers should determine where to post the in-network rate, out-of-network allowed amount, and prescription drug information rather than prescribing the location where the information is to be disclosed. Further, requiring plans and issuers to submit internet addresses for their machine-readable files to CMS would result in additional costs to the extent plans and issuers already post this information in a different location.

3. Frequency of Updates to Machine-Readable Files

In developing 26 CFR 54.9815–2715A3(b)(3), 29 CFR 2590.715–2715A3(b)(3), and 45 CFR 147.212(b)(3) of the final rules, the Departments considered requiring more frequent updates (*i.e.,* within 10 calendar days of new rate finalization) to the in-network rates, out-of-network allowed amounts, and prescription drug information. More frequent updates would provide a number of benefits for patients, providers, and the public at large. Specifically, such a process would ensure that the public has access to the most up-to-date rate information so that consumers can make the most meaningful, informed decisions about their health care utilization. Requiring group health plans, health insurance issuers, and TPAs (or other entity acting on a plan or issuers behalf) to update the machine-readable files more frequently would result in increased costs for those affected entities, however. With respect to the In-network Rate File, the Departments estimate that requiring updates within 10 calendar days of rate finalization would result in each plan, issuer, or TPA incurring a burden of 4,428 hours, with an associated equivalent cost of $635,112 in the second year after implementation of the final rules and an annual burden of 1,116 hours, with an associated equivalent cost of $162,828 in subsequent years. Based on recent data the Departments estimate a total 1,959 entities—1,754 issuers [281] and 205 TPAs [282]—will be responsible for implementing the final rules. For all 1,959 issuers and TPAs, the total burden, in the second year of implementation of the final rules, would be 8,674,452 hours, with an associated equivalent cost of $1,244,184,408 and an annual ongoing burden of 2,186,244 hours, with an associated ongoing annual costs of $318,980,052 in subsequent years. As discussed in section VI.A.2, requiring a less frequent 30 calendar day update will reduce the burden, in year two, for each entity to 1,476 hours with an associated equivalent cost of $211,704. The burden and associated costs, in subsequent years, will be reduced to 372 hours, with an associated cost of $54,276. For all 1,959 issuers and TPAs, the total burden, in year two, is reduced to 2,891,484 hours, with and associated equivalent cost of $414,728,136. For subsequent years, the total burden is reduced to 728,748 hours, with an associated equivalent cost of $106,326,684. With respect to the Allowed Amount File, the Departments estimate that requiring updates within 10 calendar days of rate finalization would result in each plan, issuer, or TPA incurring a burden of 1,908 hours, with an associated equivalent cost of $290,628 in the second year and an annual ongoing burden of 468 hours, with an associated equivalent cost of $61,452 in subsequent years. For all 1,959 issuers and TPAs, the total burden, in year two, would be 3,737,772 hours with and associated equivalent cost of $569,340,252. For subsequent years, the total ongoing burden would be 916,812 hours, with an associated equivalent cost of $120,384,468. As further discussed in section VI.A.2, requiring a less frequent update will reduce the year two burden for each issuer and TPA to 636 hours, with an associated equivalent cost of $96,876. For subsequent years, the total ongoing burden will be reduced to 156 hours, with an associated equivalent cost of $20,848. For all 1,959 issuers and TPAs, the total burden for year two is reduced to 1,245,924 hours, with an associated equivalent cost of $189,780,084. For subsequent years, the total ongoing burden will be reduced to 305,604 hours, with an associated equivalent cost of $40,128,156. With respect to the Prescription Drug File, the Departments estimate that requiring updates within 10 calendar days of rate finalization would result in each plan, issuer, or TPA incurring a burden of 2,700 hours, with an associated equivalent cost of $416,664 in the second year and an annual ongoing burden of 1,116 hours, with an associated equivalent cost of $162,828 in subsequent years. For all 1,959 issuers and TPAs, the total burden, in year two, would be 5,289,300 hours with and associated equivalent cost of $816,244,776. For subsequent years, the total ongoing burden would 2,186,244 hours, with an associated equivalent cost of $318,980,052. As discussed in section VI.A.2, requiring a less frequent update will reduce the year two burden for each issuer and TPA to 900 hours, with an associated equivalent cost of $138,888. For subsequent years, the total ongoing burden will be reduced to 372 hours,

[281] 2018 MLR Data Trends.

[282] Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

with an associated equivalent cost of $54,276. For all 1,959 issuers and TPAs, the total burden for year two is reduced to 1,763,100 hours, with an associated equivalent cost of $272,081,592. For subsequent years, the total ongoing annual burden will be reduced to 728,748 hours, with an associated equivalent cost of $106,326,684. By requiring monthly updates to the machine-readable files, rather than updates every 10 calendar days, the Departments have chosen to strike a balance between placing a significant burden on issuers (and their service providers) and assuring the availability of accurate information.

4. File Format Requirements

In 26 CFR 54.9815–2715A3(b)(2), 29 CFR 2590.715–2715A3(b)(2), and 45 CFR 147.212(b)(2), the final rules require group health plans and health insurance issuers to post information in three machine-readable files. A machine-readable file is defined as a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost. The final rules require each machine-readable file to use a non-proprietary, open format. The Departments considered requiring issuers and TPAs to post in-network rates, allowed amounts paid for out-of-network services, and prescription drug information using a specific file format, namely JSON. However, the Departments are of the view that being overly prescriptive regarding the file type will impose an unnecessary costs on issuers and TPAs despite the advantages of JSON, namely that JSON files are downloadable and readable for many health care consumers, and the potential for JSON to simplify the ability of price transparency tool developers to access the data. Therefore, the Departments are requiring that issuers and TPAs post the in-network rate, allowed amount, and prescription drug pricing information in three distinct machine-readable files using a non-proprietary, open format. The Departments will provide additional guidance regarding the file format in future technical implementation guidance.

In addition, the Departments considered requiring plans and issuers to provide the specific out-of-network allowed amount methodology needed for consumers to determine out-of-pocket liability for services by providers not considered in-network by the plan or issuer, rather than historical data on paid out-of-network claims. However, the Departments understand providing a formula or methodology for calculating a provider's out-of-network allowed amount does not provide the data users need in an easy-to-use machine-readable format. The Departments determined that providing monthly data files on allowed amounts by plans and issuers over a 90-day period for items and services provided by out-of-network providers will enable users to more readily determine what costs a plan or issuer may pay toward items or services obtained out-of-network. Because a plan or issuer does not have a contract with an out-of-network provider that establishes negotiated rates, the plan or issuer cannot anticipate what that provider's charges will be for any given item or service; therefore, the Departments, as discussed previously in this preamble, are requiring the inclusion of billed charges in the Allowed Amounts File.

Providing data on the billed charge in connection with each unique allowed amount on the out-of-network Allowed Amount File will provide consumer with information related to what their plan or issuer will likely contribute to the costs of items or services obtained from out-of-network providers and the billed charges associated with those item or services. This information will provide the consumer with a reasonably accurate estimate of the amount of additional liability a consumer could be required to pay for a particular item or service received from an out-of-network provider. Out-of-network allowed amount and billed charges data will provide increased price transparency for consumers, and the costs related to producing these data are not considered to be significantly higher than that associated with producing the methodology for determining allowed amounts for payments to out-of-network providers. Given these circumstances, the final rules are requiring that payers provide allowed amount data for out-of-network covered items or services furnished by a particular out-of-network provider during the 90-day time period that begins 180 days prior to the publication date of the Allowed Amount File, and billed charges rather than requiring plans and issuers to report their methodology or formula for calculating the allowed amounts for out-of-network items and services.

5. Requiring Disclosure of Cost-Sharing Information to Participants, Beneficiaries, and Enrollees and Publicly-Posted Machine-Readable Files With In-Network Rates, Out-of-Network Allowed Amounts, and Prescription Drug Pricing Information

The Departments considered whether it would be duplicative to require group health plans and health insurance issuers to disclose cost-sharing information through an internet-based self-service tool or in paper form to participants, beneficiaries, or enrollees so that they may obtain an estimate of their cost-sharing liability for covered items and services and publicly-posted machine-readable files containing data on in-network rates, out-of-network allowed amounts, and prescription drug pricing information. The requirement to disclose cost-sharing information to participants, beneficiaries, or enrollees in the final rules require plans and issuers to provide consumer-specific information on potential cost-sharing liability to enrolled consumers, complete with information about their deductibles, copays, and coinsurance. However, cost-sharing information for these plans and coverage would not be available or applicable to consumers who are uninsured or shopping for plans pre-enrollment. Data disclosed to participants, beneficiaries, or enrollees would also not be available to third parties who are interested in creating internet-based self-service tools to assist both uninsured and insured consumers with shopping for the most affordable items or services. Limiting access to data to a subset of consumers would not promote the transparency goals of the final rules and would reduce the potential for the final rules to drive down health care costs by increasing competition.

As discussed in more detail in section VI.A.1 in this preamble, the Departments have estimated the high-end three-year average annual cost to develop only the internet-based self-service tool, including the initial tool build and maintenance, customer service training, customer assistance, and mailing costs. The Departments estimate the three-year average total burden per issuer, or TPA will be approximately 23,338 hours, with an associated equivalent average annual cost of approximately $3,262,262. For all 1,959 issuers and TPAs, the Departments estimate the total three-year average annual burden will be 45,718,171 hours with an associated equivalent total average annual cost of approximately $6,390,770,952.

Additionally, the Departments estimated that for implementation of the required internet-based self-service tool in conjunction with the out-of-network allowed amount, in-network and prescription drug machine-readable files, the Departments estimate that the annual high-end three-year average annual costs and burden for each issuer or TPA will be approximately 28,958 hours, with an associated equivalent cost of approximately $4,040,142. For all 1,959 issuers and TPAs, the Departments estimate the total three-year average annual burden and cost to be 56,727,751 hours with an associated equivalent total average annual cost of approximately $7,914,635,260.

In contrast, and as discussed in more detail in section VI.A.1, the Departments estimate that the low-end three-year average burden and cost to develop and maintain only the internet-based self-service tool, including the initial tool build and maintenance, customer service training, customer assistance, and mailing costs. The Departments estimate the total three-year average cost and burden per issuer or TPA will be approximately 15,475 hours, with an associated equivalent average annual cost of approximately $2,150,169. For all 1,959 issuers and TPAs, the Departments estimate the total three-year average annual burden to be 30,315,730 hours with an associated equivalent total average annual cost of approximately $4,212,181,157.

Finally, the Departments estimated that for implementation of the required internet-based self-service tool in conjunction with the out-of-network allowed amount, in-network rate, and prescription drug machine-readable files, the Departments estimate that the three-year average annual low-end cost and burden for each issuer or TPA will be approximately 21,095 hours, with an associated equivalent average annual cost of approximately $2,928,048. For all 1,959 issuers and TPAs, the Departments estimate the total three-year average annual low-end burden and cost will be 41,325,310 hours with an associated equivalent total average annual cost of approximately $5,736,045,465. While the Departments recognize that requiring disclosures through all mechanisms will increase the costs for issuers and TPAs required to comply with the final rules, the Departments are of the view that the additional costs associated with greater price transparency are outweighed by the benefits that will accrue to the broader group of consumers (such as the uninsured and individuals shopping for coverage) and other individuals who would benefit directly from the additional information provided through the machine-readable files. Additionally, the Departments are of the view that the final rules have the potential to reduce the cost of surprise billing to consumers. The Departments further believe that the final rules will, with the disclosure of in-network rates, potentially apply pressure on providers to bill less aggressively. Consumer advocacy groups could also use the wide price dispersion of the same CPT level service or NDC level drug by the same providers with different negotiated rates, depending upon issuer or TPA contract, to further place downward pressure on health care costs. In addition, as noted earlier in section II.C.1–2 of this preamble, researchers and third-party developers will also be able to use the data included in the machine-readable files in a way that could create even more benefits to consumers, including those consumers not currently enrolled in a particular plan or coverage. For these reasons, the Departments have concluded that, in addition to requiring plans and issuers to disclose cost-sharing information to participants, beneficiaries, or enrollees through an internet-based self-service tool, requiring plans and issuers to publicly disclose information regarding in-network rates, out-of-network allowed amounts, and prescription drug pricing will further the goals of price transparency and create benefits for all potentially affected stakeholders.

6. Requiring an Internet-Based Self-Service Tool and Machine-Readable Files in Lieu of an API

The Departments considered whether to require group health plans and health insurance issuers to make the information required by the final rules available through a standards-based API, instead of through the proposed internet-based self-service tool and machine-readable files. Access to pricing information through an API could have a number of benefits for consumers, providers, and the public at large. This information could ensure the public has access to the most up-to-date rate information. Providing real-time access to pricing information through a standards-based API could allow third-party innovators to incorporate the information into applications used by consumers or combined with electronic medical records for point-of-care decision-making and referral opportunities by clinicians for their patients. Additionally, being able to access this data through a standards-based API would allow consumers to use the application of their choice to obtain personalized, actionable health care price estimates, rather than being required to use one developed by their plan or issuer (or a service provider), although those consumers may be required to pay for access to those applications.

While there are many benefits to a standards-based API, it is the Departments' view that both an internet-based tool and machine-readable files are the first iterative steps towards developing price transparency standards-based APIs. It is the Departments' view that standards-based API would be a natural next technological step. The Departments also recognize that the majority of issuers have an existing internet-based tool that could be enhanced to meet the disclosure requirements in the final rules. The burden associated with updating existing tools to standardize data attributes is going to be less than building a standards-based API. Looking at the average cost over a 3-year period for the API for all 1,959 issuers and TPAs, the Departments estimate an average annual cost that would significantly exceed the estimated annual cost of implementing the internet-based self-service tool and machine-readable files. The Departments recognize that the development of an API may be streamlined by leveraging existing APIs currently used by plans, issuers, or TPAs for their own applications. Additionally, any requirements for an API would build on the requirements finalized in CMS's Interoperability & Patient Access final rule [283] requiring certain entities, such as Federally-facilitated Exchange QHP issuers and companies that participate in both Medicare and the individual or group market, to provide certain data through a standards-based API. Building on the Interoperability & Patient Access final rule could result in significantly lower costs for issuers and TPAs as it relates to the development and implementation of a standards-based API. Nonetheless, while the Interoperability & Patient Access final rule focuses on the disclosure of information regarding post care and clinical data, the rules finalized here require plans and issuers to provide information related to a participant's, beneficiary's, or enrollee's individual's cost-sharing, allowed amounts for covered items and services from out-of-network providers, and negotiated rates and historical net prices for each prescription drug prior to seeking or obtaining care. The Departments are therefore of the view

[283] 85 FR 25510 (May 1, 2020).

that plans, issuers, and TPAs would incur significant and distinct costs if required to us a standards-based API to comply with the final rules.

Although not estimated here, the Departments expect any associated maintenance costs would also decline in succeeding years as plans, issuers, and TPAs gain additional efficiencies or undertake similar procedures to maintain any currently used internal APIs. Nonetheless, weighing the costs of providing the required information using an internet-based self-service tool and machine-readable files against the potential costs of using a standards-based API, particularly given the timeframes required by the final rules, the Departments are of the view that, at least in the short-term, requiring an internet-based self-service tool and machine-readable files is the more sensible approach.

Even though the Departments are of the view that an internet-based self-service tool and machine-readable files are appropriate in the short-term, as discussed earlier in this preamble, the Departments recognize that a standards-based API format in the long-term may be more beneficial to the public, as it would provide access to the most up-to-date rate information; would allow health care consumers to use the application of their choice to obtain personalized, actionable health care service price estimates; and would allow third-party developers to use the collected data to develop internet-based self-service tools. Therefore, the Departments are considering future rulemaking to further expand access to pricing information through standards-based APIs, including individuals' access to estimates about their own cost-sharing liability and information about in-network rates, historical payment data for out-of-network allowed amounts, and negotiated rates and historical net prices for prescription drugs.

VI. Collection of Information Requirements

The final rules contain ICRs that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 24.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Departments solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of each of the Departments.
- the accuracy of the Departments' estimate of the information collection burden.
- the quality, utility, and clarity of the information to be collected.
- recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The Departments solicited comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, the Departments generally use data from the BLS to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with ICRs.[284] One commenter noted that the markup rates for labor, fringe benefits, and overhead are underestimated at 100 percent, while the conventional standard is 200 percent to 300 percent. The commenter further stated that if the Departments were to update the burden estimates with the conventional standard for overhead markup, the total of annual quantified costs would increase to over $500 million per year.

The Departments acknowledge that there are various methodologies used to determine and estimate fringe benefits and other overhead costs; however, the commenter did not provide any source recognizing or supporting their assertion that the conventional standard is to use 200 percent to 300 percent increases. The Departments agree that if a higher percentage were used to estimate hourly wages and overhead, then the estimated costs for the final rules could potentially be significantly higher. However, the Departments note that the use of 100 percent is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. The Departments are of the view that doubling the hourly wage to estimate total cost is a reasonably acceptable estimation method.

The Departments recognize that the maturity of technology will vary from organization to organization. An independent study by Bates White Economic Consulting (Bates White), commissioned by one commenter, developed an assessment of the costs of the proposed rules by interviewing a mix of 18 large and small health insurance issuers covering about 78 million lives. They reported various degrees of existing tools' compliance with the requirements of the proposed rules. The Departments reevaluated its initial burden estimates developed for the proposed rules based on feedback from commenters and the Bates Whites study. Because the Departments could not make an estimate for any specific issuer, an independent government cost estimate (IGCE) was conducted for each of the machine-readable files and the internet-based self-service tool to aid the Departments in conducting the burden and cost estimates for the final rules. The goals of an IGCE are to aid the government acquisition process in determining a project's cost estimates based on project requirements or objectives that are typically found in a performance work statement or statement of work. IGCEs are developed by the government without contractor influence and are based on market research. The estimated skill sets required to build both the internet based self-service tool and machine-readable files can be found in TABLE 3 below. The Departments based the IGCE cost estimates on the rule's requirements and each IGCE has baseline assumptions that are built into the final estimate.

The IGCE assumptions for the internet-based self-service tool included things such as research, engineering development, and design and were not based on any existing tools. There was an assumption that product development would be done in the cloud to take advantage of economies of scale or with on-premise infrastructure that allows for the development of ''infrastructure as code.'' The IGCE assumptions for the machine-readable files included that all items and services for a specific plan have a negotiated price, that all price numbers are digitized, that pricing information is stored in many locations (not in a single database), that pricing information is accessible through internal systems, that building the first machine-readable file will facilitate automation for building future machine-readable files, and that there is an ability to run queries against claims data.

Based on comments discussed later sections VI.A.1–2, the Departments have chosen to use the Contract Awarded Labor Category (CALC) [285] database tool, managed by the General Services Administration (GSA), to derive the

[284] May 2018 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at: *https://www.bls.gov/oes/current/oes_stru.htm.*

[285] CALC information and wage rates are available at: *https://calc.gsa.gov/about/.*

hourly rates for the burden and cost estimates in the final rules. The CALC tool was built to assist acquisition professionals with market research and price analysis for labor categories on multiple U.S. GSA & Veterans Administration (VA) contracts. Wages obtained from the CALC database are fully burdened to account for fringe benefits and overhead costs. The Departments chose to use wages derived from the CALC database because, even though the BLS data set is valuable to economists, researchers, and others that would be interested in larger, more macro-trends in parts of the economy, the CALC data set is meant to help market research based on existing government contracts in determining how much a project/product will cost based on the required skill sets needed. The CALC data set also factors in the fully-burdened hourly rates (base pay + benefits) into wages whereas BLS rates do not. CALC occupations and wages provide the Departments with data that aligns more with, and provides more detail related to, the occupations required for the implementation of the requirements in the final rules. As discussed earlier, after consideration and discussion of comments, the Departments chose to further reevaluate the cost and burden estimates. Based on the Departments consultation with internal and external IT professionals and additional research, the Departments have chosen to increase our overall costs and burden estimates to account for our updated understanding of the burdens associated with the final rules and the additional requirements included in the final rules. The Departments further discuss changes to the final cost and burden estimates in the corresponding ICR sections.

While the following estimates for the internet-based self-service tool assume that entities are either iterating on an existing tool or building a brand new tool from the ground up, the Departments are of the view that it is highly likely that third-party developers will take this opportunity to build white-label products that meet the requirements of the final rules and that they will reduce costs through economies of scale by doing so. As such, the Departments' cost estimates may have some tendency towards over-estimation.

Table 3 presents the fully burdened hourly wage and job descriptions used in the Departments' estimates.

TABLE 3—HOURLY WAGES USED IN BURDEN ESTIMATES

CALC occupation title	Mean hourly wage ($/hour)
Project Manager/Team Lead	$153.00
Scrum Master	105.00
Technical Architect/Sr. Developer	149.00
Application Developer, Senior	143.00
Business Analyst	120.00
UX Researcher/Service Designer	154.00
Designer	116.00
DevOps Engineer	181.00
Customer Service Representative	40.00
Web Database/Application Developer IV	152.00
Service Designer/Researcher	114.00

1. ICR Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees (26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211)

The Departments add 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b), requiring group health plans and health insurance issuers of individual and group health insurance coverage to disclose, upon request, to a participant, beneficiary, or enrollee, such individual's cost-sharing information for items; negotiated rates and underlying fee schedule rates for in-network providers; and allowed amounts for covered items and services from out-of-network providers. As discussed previously in section II.B.1 of this preamble, in paragraphs 26 CFR 54.9815–2715A2(b)(1)(i), 29 CFR 2590.715–2715A2(b)(1)(i), and 45 CFR 147.211(b)(1)(i) through (vii) the final rules require plans and issuers to make this information available through an internet-based self-service tool on an internet website and, if requested, in paper form or other format agreed upon between the plan, issuer, or TPA and participant, beneficiary, or enrollee.

The final rules require plans and issuers to disclose, upon request, certain information relevant to a determination of a participant's, beneficiary's, or enrollee's cost-sharing liability for a particular health care item or service from a particular provider, to the extent relevant to the individual's cost-sharing liability for the item or service, in accordance with seven content elements: The individual-specific estimated cost-sharing liability; the individual-specific accumulated amounts; the in-network rate; the out-of-network allowed amount for a covered item or service, if applicable; the items and services content list when the information is for items and services subject to a bundled payment arrangement; a notice of prerequisites to coverage (such as prior authorization); and a disclosure notice. However, as discussed earlier in this section II.B.1 of this preamble, in instances where items or services, generally considered preventive, are furnished as non-preventive items or services, the participant, beneficiary, or enrollee may be subject to the cost-sharing terms of his or her plan. If a plan or issuer cannot determine whether the request is for a preventive item or service, the plan or issuer must display the non-preventive cost-sharing liability, along with a note that the item or service may not be subject to cost-sharing if it is billed as a preventive service. The final rules also require the disclosure notice to include several statements, written in plain language, which include disclaimers relevant to the limitations of the cost-sharing information disclosed, including: A statement that out-of-network providers may balance bill participants, beneficiaries, or enrollees, a statement that the actual charges may differ from those for which a cost-sharing liability estimate is given, and a statement that the estimated cost-sharing liability for a covered item is not a guarantee that coverage will be provided for those items and services. In addition, plans and issuers will be permitted to add other disclaimers they determine appropriate so long as such information is not in conflict with the disclosure requirements of the final rules. The Departments have developed model language that plans and issuers will be able to use to satisfy the requirement to provide the notice statements described earlier in section II.B.1 of this preamble.

As discussed in section II.B.1 of this preamble, the final rules require plans and issuers to make available the information described in 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b) of the final rules through an internet-based self-service tool. The information is required to be provided in plain-language through real-time responses. Plans and issuers will be required to allow participants, beneficiaries, or enrollees to search for cost-sharing information for covered items and services by billing code, or by descriptive term, per the user's request, in connection with a specific in-network provider, or for all in-network providers. In addition, the internet-based self-service tool must allow users to input information necessary to determine the out-of-network allowed amount for a covered item or service

provided by an out-of-network provider (such as zip code). The internet-based self-service tool is required to have the capability to refine and reorder results by the geographic proximity of in-network providers, and the estimated amount of cost-sharing liability to the beneficiary, participant, or enrollee.

As discussed in sections II.B.1 and 2 earlier in this preamble, the final rules require plans and issuers to furnish upon request, in paper form, the information required to be disclosed under 26 CFR 54.9815–2715A2(b)(1), 29 CFR 2590.715–2715A2(b)(1), and 45 CFR 147.211(b)(1) of the final rules to a participant, beneficiary, or enrollee. As discussed in sections II.B.1 and 2 in this preamble, a paper disclosure is required to be furnished according to the consumer's filtering and sorting preferences and mailed to the participant, beneficiary, or enrollee within two business days of receiving the request. Plans or issuers may, upon request, provide the required information through other methods, such as over the phone, through face-to-face encounters, by facsimile, or by email.

The Departments assume fully-insured group health plans will rely on issuers to develop and maintain the internet-based self-service tool and provide any requested disclosures in paper form. While the Departments recognize that some self-insured plans might independently develop and maintain the internet-based self-service tool, at this time the Departments assume that self-insured plans will rely on TPAs (including issuers providing administrative services and non-issuer TPAs) to develop the required internet-based self-service tool. The Departments make this assumption because the Departments understand that most self-insured group health plans rely on TPAs for performing most administrative duties, such as enrollment and claims processing. For those self-insured plans that choose to develop their own internet-based self-service tools, the Departments assume that they will incur a similar cost and burden as estimated for issuers and TPAs, as discussed in section VI.A.1 later in this preamble. In addition, 26 CFR 54.9815–2715A2(b)(3), 29 CFR 2590.715–2715A2(b)(3), and 45 CFR 147.211(b)(3) of the final rules provide for a special rule to prevent unnecessary duplication of the disclosures with respect to health insurance coverage, which provides that a plan may satisfy the disclosure requirements if the issuer offering the coverage is required to provide the information pursuant to a written agreement between the plan and issuer. Thus, the Departments have used issuers and TPAs as the unit of analysis for the purposes of estimating required changes to IT infrastructure and administrative costs and burdens. The Departments estimate approximately 1,754 issuers and 205 TPAs will be affected by the final rules.

The Departments acknowledge that the costs described in these ICRs may vary depending on the number of lives covered, the number of providers and items and services for which cost-sharing information must be disclosed, and the fact that some plans and issuers already have robust tools that can be easily adapted to meet the requirements of the final rules. In addition, plans and issuers may be able to license existing cost estimator tools offered by third-party vendors, obviating the need to establish and maintain their own internet-based self-service tools. The Departments assume that any related vendor licensing fees would be dependent upon complexity, volume, and frequency of use, but assume that such fees would be lower than an overall initial build and associated maintenance costs. Nonetheless, for purposes of the estimates in these ICRs, the Departments assume all 1,959 issuers and TPAs will be affected by the final rules. The Departments also developed the following estimates based on the mean average size, by covered lives, of issuers or TPAs. As noted later in this section, the Departments sought comment on the inputs and assumptions that were used to develop these cost and burden estimates, particularly regarding existing efficiencies that would reduce the cost and burden estimates.

High Range Estimate for Internet-Based Self-Service Tool From Start-Up to Operational Functionality

The Departments estimate that the one-time costs and burden each issuer or TPA will incur to complete the one-time technical build; including activities such as planning, assessment, budgeting, contracting, building and systems testing, incorporating any necessary security measures, incorporating disclaimer and model notice language, or development of the model and disclaimer notice materials for those that choose to make alterations. The Departments assume that this one-time cost and burden will be incurred in 2022 to develop and build the internet-based self-service tool and provide information for the 500 required items and services, and additional one-time costs will be incurred in 2023 in order to fully meet the requirements of the final rules. As mentioned earlier in section V.A.2 of this preamble, the Departments acknowledge that a number of issuers and TPAs have previously developed some level of internet-based self-service tool similar to, and containing some functionality related to, the requirements in the final rules. The Departments thus seek to estimate a burden and cost range (high-end and low-end) associated with the final rules for those issuers and TPAs. In order to develop the high-end hourly burden and cost estimates, the Departments assume that all issuers and TPAs will need to develop and build their internet-based self-service tool from start-up to operational functionality. The Departments estimate that for each issuer or TPA it will take a Project Manager/Team Lead 4,160 hours (at $153 per hour), a Scrum Master 4,160 hours (at $105 per hour), a Technical Architect/Sr. Developer 4,160 hours (at $149 per hour), an Application Developer, Senior 4,160 hours (at $143 per hour), a Business Analyst 4,160 hours (at $120 per hour), a UX Researcher/Service Designer 4,160 hours (at $154 per hour), a Designer 4,160 hours (at $116 per hour), a DevOps Engineer 4,160 hours (at $181 per hour), and a Web Database/Application Developer IV 4,160 hours to complete this task. The Departments estimate the total burden per issuer or TPA will be approximately 37,440 hours, with an equivalent cost of approximately $5,295,680. For all 1,959 issuers and TPAs, the total first year one-time total burden is estimated to be 73,344,960 hours, with an equivalent total cost of approximately $10,374,237,120. The Departments' estimates are higher-bound estimates that do not consider potential cost savings that could be realized should issuers and TPAs buy or lease an internet-based self-service tool from a third-party vendor or other issuer. However, the Departments are of the view that issuers or TPAs that choose to buy or rent an internet-based self-service tool from another entity could incur significantly less costs and burdens.

TABLE 4A—TOTAL HIGH-END FIRST YEAR ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR EACH ISSUER OR TPA

CALC occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	4,160	$153.00	$636,480.00
Scrum Master	4,160	105.00	436,800.00
Technical Architect/Sr. Developer	4,160	149.00	619,840.00
Application Developer, Senior	4,160	143.00	594,880.00
Business Analyst	4,160	120.00	499,200.00
UX Researcher/Service Designer	4,160	154.00	640,640.00
Designer	4,160	116.00	482,560.00
DevOps Engineer	4,160	181.00	752,960.00
Web Database/Application Developer IV	4,160	152.00	632,320.00
Total per respondent	37,440	.....	5,295,680.00

TABLE 4B—TOTAL HIGH-END FIRST YEAR ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ALL ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	37,440.0	73,344,960	$10,374,237,120

Several commenters stated that the Departments grossly underestimated the cost burden of implementation on plans and issuers. One commenter stated that surveyed issuers estimated an average cost of $6.2 million to build, develop or modify, implement, test, and launch an internet-based self-service tool. This is 28 times greater than the Departments' proposed estimate for an issuer that needs to build a new tool and 112 times greater than the Departments' estimate for an issuer that has an existing tool. Furthermore, this commenter noted that surveyed issuers estimated average annual maintenance costs of $1.4 million per issuer—over 100 times greater than those anticipated by the Departments. Surveyed issuers also estimated set-up costs that averaged about $5.53 million (ranging from $1,000,000 to $15,000,000) compared to the Departments' proposed estimate of $221,029. This is more than 25 times what the Departments estimated as the cost for a full build of the internet-based self-service tool. Although most of the issuers surveyed had an existing internet-based self-service tool meeting many of the required elements of the final rules, several issuers expressed significant concern about the cost and feasibility of complying with the requirements of the proposed rules. Specifically, the issuers surveyed expressed concerns noting that the requirements may necessitate a complete rebuild of their consumer tool. The surveyed issuers further indicated that the proposed rules would be costlier than implementing real-time claims adjudication, in which the claim for the medical service is adjudicated at the time the service is provided. They stated that they would need to effectively adjudicate the claim before it actually happens—to provide estimates for every conceivable type of medical item or service while integrating this information with various benefits. The surveyed issuers also noted that condensing all of the detail required in the final rules into a user-friendly format for use by enrollees would be a considerable and possibly even infeasible challenge. They further stated that the Departments' assumption that issuers with an existing internet-based self-service tool would face a lower hour burdens and costs to comply with the proposed rules was incorrect.

The Departments have considered the comments submitted in response to the cost and burden estimates related to the internet-based self-service tool. In response, the Departments have adjusted the costs and burden estimates to better reflect and align with the values submitted by commenters. In addition, the Departments have developed the estimates above, and in other ICR sections, using CALC wage rates as discussed in section VI.A of this preamble.

Low Range Estimate for Internet-Based Self-Service Tool Requiring Partial Build

The Departments recognize that a significant number of issuers and TPAs may already have some form of internet-based self-service tool that allows for comparison shopping of different plans and that a large number of issuers and TPAs may currently provide participants, beneficiaries, or enrollees with the ability to obtain some estimated out-of-pocket costs.[286] For those issuers and TPAs that currently have some level of functional internet-based self-service tool that would meet some (or all) of the requirements of the final rules, the Departments recognize that these entities may incur lower burdens and costs overall, as the Departments are of the view that these entities may require an overall lower level of effort and capital expenditure to meet the requirements of the final rules. Thus, the Departments have estimated a low-end burden and cost to comply with the final rules. Assuming that over 90 percent of issuers and TPAs currently provide an internet-based self-service tool and will only be required to make changes to their current system in order to meet the requirements in the final rules, the Departments estimate that 175 issuers and 21 TPAs will be required to develop an internet-based self-service tool from start-up to operational functionality. The Departments also estimate that each of those 196 entities will incur a first-year one-time cost and burden of approximately 37,440 hours, with an

[286] *See* AHIP release dated August 2, 2019. ''AHIP Issues Statement on Proposed Rule Requiring Disclosure of Negotiated Prices.'' America's Health Insurance Providers. August 2, 2019. Available at: *https://www.ahip.org/ahip-issues-statement-on-proposed-rule-requiring-disclosure-of-negotiated-prices/; see also* Higgins, A., Brainard, N., and Veselovskiy, G. ''Characterizing Health Plan Price Estimator Tools: Findings from a National Survey.'' 22 Am. J. Managed Care 126. 2016. Available at: *https://ajmc.s3.amazonaws.com/_media/_pdf/AJMC_02_2016_Higgins%20(final).pdf.*

equivalent cost of approximately $5,295,680 (as discussed previously in this ICR). For those 196 entities, the total first year one-time burden is estimated to be 7,334,496 hours with an equivalent total cost of approximately $1,037,423,712.

TABLE 5A—LOW-RANGE FIRST YEAR ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ISSUERS AND TPAS REQUIRING A COMPLETE BUILD

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
196	196	37,440	7,334,496	$1,037,423,712.00

The Departments estimate that those issuers and TPAs that will only be required to make changes to their existing systems will already have operational capabilities that meet approximately 70 percent of the requirements in the final rules and will only incur costs and burdens related to changes needed to fully meet the requirements of the final rules. Based on this assumption, the Departments estimate that 1,579 issuers and 184 TPAs will incur a first-year one-time hour burden of 11,232 hours, with an associated cost of $1,588,704.00 to fully satisfy the initial requirements of the final rules. For all 1,763 issuers and TPAs, the Departments estimates the total first year one-time burden will be 19,803,139 hours, with an equivalent total cost of approximately $2,801,044,022.40. The Departments recognize that issuers and TPAs may currently have some form of internet-based self-service tool that may provide greater functionality that could meet a greater proportion of the requirements in the final rules. In those cases, issuers and TPAs could see lower costs and burdens. The Departments also recognize that there are likely a number of issuers and TPAs that currently provide some form of internet-based self-service tool that would require more development to meet the requirements of the final rules. In those instances, those issuers and TPAs could incur greater costs and burdens. The Departments' estimates are higher-bound estimates that do not consider potential cost savings that could be realized should issuers and TPAs buy or lease an internet-based self-service tool from a third-party vendor or other issuer. However, the Departments are of the view that issuers or TPAs that choose to buy or rent an internet-based self-service tool from another entity could incur significantly less costs and burdens.

TABLE 5B—LOW-END FIRST YEAR ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ISSUERS AND TPAS REQUIRING ONLY A PARTIAL BUILD

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,763	1,763	11,232	19,803,139	$2,801,044,022.40

TABLE 5C—TOTAL LOW-END FIRST YEAR ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ALL ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	13,853	27,137,635	$3,838,467,734.40

In addition to the range of one-time costs and burdens estimated in Tables 4B, 5B, 5C, 6A, and 6B, issuers and TPAs will incur annual costs such as those related to ensuring cost estimation accuracy, providing quality assurance, conducting website maintenance and making updates, and enhancing or updating any needed security measures. The Departments estimate that for each issuer and TPA, it will take a Project Manager/Team Lead 1,040 hours (at $153 per hour), a Scrum Master 1,300 hours (at $105 per hour), an Application Developer, Senior 1,560 hours (at $143 per hour), a Business Analyst (at $120.00 per hour) 520 hours, a Designer (at $116.00 per hour) 1,040 hours, a DevOps Engineer (at $181.00 per hour) 520 hours, a Web Database/Application Developer IV (at $152.00 per hour) 1,560 hours, and a UX Researcher/Service Designer 520 hours (at $154 per hour) to perform these tasks. The total annual burden for each issuer or TPA will be 8,060 hours, with an equivalent cost of approximately $1,113,060. For all 1,959 issuers and TPAs, the total annual maintenance burden is estimated to be 15,789,540 hours, with an equivalent associated total cost of approximately $2,180,484,540.00. The Departments recognize that issuers and TPAs will likely have varying levels of IT capabilities and experience in maintaining and internet-based tool and could incur higher or lower costs and burdens depending on those capabilities. The Departments expect maintenance costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing their internet-based self-service tool.

TABLE 6A—ESTIMATED YEAR TWO IMPLEMENTATION COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR EACH ISSUER OR TPA

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	3,120	$153.00	$477.360.00
Scrum Master	3,120	105.00	327,600.00
Technical Architect/Sr. Developer	3,120	149.00	464,880.00
Application Developer, Senior	4,160	143.00	594,880.00
Business Analyst	2,080	120.00	249,600.00
UX Researcher/Service Designer	2,080	154.00	320,320.00
Designer	1,560	116.00	180,960.00
DevOps Engineer	2,080	181.00	376,480.00
Web Database/Application Developer IV	3,120	152.00	
Total per Respondent	24,440	.....	3,446,320.00

TABLE 6B—ESTIMATED YEAR TWO IMPLEMENATION COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ALL ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	24,440.0	47,877,960	$6,611,791,830.97

In addition to the range of one-time costs and burdens estimated in Tables 4B, 5B, 5C, 6A, and 6B, issuers and TPAs will incur annual costs such as those related to ensuring cost estimation accuracy, providing quality assurance, conducting website maintenance and making updates, and enhancing or updating any needed security measures. The Departments estimate that for each issuer and TPA, it will take a Project Manager/Team Lead 1,040 hours (at $153 per hour), a Scrum Master 1,300 hours (at $105 per hour), an Application Developer, Senior 1,560 hours (at $143 per hour), a Business Analyst (at $120.00 per hour) 520 hours, a Designer (at $116.00 per hour) 1,040 hours, a DevOps Engineer (at $181.00 per hour) 520 hours, a Web Database/Application Developer IV (at $152.00 per hour) 1,560 hours, and a UX Researcher/Service Designer 520 hours (at $154 per hour) to perform these tasks. The total annual burden for each issuer or TPA will be 8,060 hours, with an equivalent cost of approximately $1,113,060. For all 1,959 issuers and TPAs, the total annual maintenance burden is estimated to be 15,789,540 hours, with an equivalent associated total cost of approximately $2,180,484,540.00. The Departments recognize that issuers and TPAs will likely have varying levels of IT capabilities and experience in maintaining and internet-based tool and could incur higher or lower costs and burdens depending on those capabilities. The Departments expect maintenance costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing their internet-based self-service tool.

TABLE 7A—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR MAINTENANCE OF INTERNET-BASED SELF-SERVICE TOOL FOR EACH ISSUER OR TPA

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	1,040	$153.00	$159,120.00
Scrum Master	1,300	105.00	136,500.00
Application Developer, Senior	1,560	143.00	223,080.00
Business Analyst	520	120.00	62,400.00
Designer	1,040	116.00	120,640.00
DevOps Engineer	520	181.00	94,120.00
Web Database/Application Developer IV	1,560	152.00	237,120.00
UX Researcher/Service Designer	520	154.00	80,080.00
Total per Respondent	8,060	.....	1,113,060.00

TABLE 7B—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR MAINTENANCE OF INTERNET-BASED SELF-SERVICE TOOL FOR ALL ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	8,060.0	15,789,540	$2,180,484,540.00

As noted previously in this ICR section, commenters stated that the Departments grossly underestimated the cost burden of implementation on plans and issuers. Additionally, commenters stated that the Departments had underestimated the maintenance costs associated with the internet-based self-service tool. Issuers estimated the annual maintenance costs to be on average, about $3.78 million per issuer or TPA (ranging from $375,000 to $10,000,000). As noted previously in this ICR section, based on comments received, the Departments have adjusted the costs and burden estimates to better reflect and align with the values submitted by commenters. The Departments estimate the high-end three-year average total hour burden, for all issuers and TPAs to develop, build, and maintain an internet-based self-service tool will be 45,670,820 hours annually, with an average annual total equivalent cost of $6,388,837,830.

The Departments acknowledge that the costs described earlier in this section may vary depending on the number of covered lives and the number of providers and items and services incorporated into the internet-based self-service tool. Recognizing that many issuers and TPAs currently have some form of internet-based self-service tool in operation that meets some aspects of the requirements of the final rules, the Departments estimate the low-end average three-year annual total burden, for all issuers and TPAs to develop, build, and maintain an internet-based self-service tool will be 30,268,378 hours annually, with an average annual total equivalent cost of $4,210,248,035. The Departments recognize that plans, issuers, and TPAs may be able to license existing internet-based self-service tools offered by vendors, obviating the need to establish, upgrade, and maintain their own internet-based self-service tools, and that vendor licensing fees, dependent upon complexity, volume, and frequency of use, could be lower than the burden and costs estimated here.

TABLE 8—ESTIMATED HIGH-END THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE INTERNET-BASED SELF-SERVICE TOOL

Year	Estimated number of health insurance issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2022	1,959	1,959	37,440.0	73,344,960	$10,374,237,120
2023	1,959	1,959	24,440.0	47,877,960	6,611,791,830.97
2024	1,959	1,959	8,060.0	15,789,540	2,180,484,540.00
3 year Average	1,959	1,959	23,313	45,670,820	6,388,837,830.32

TABLE 9—ESTIMATED LOW-END THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE INTERNET-BASED SELF-SERVICE TOOL

Year	Estimated number of health insurance issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2022	1,959	1,959	13,853	27,137,635	$3,838,467,734.40
2023	1,959	1,959	24,440	47,877,960	6,611,791,830.97
2024	1,959	1,959	8,060	15,789,540	2,180,484,540.00
3 year Average	1,959	1,959	15,451	30,268,378	4,210,248,035.12

In addition to the one-time and annual maintenance costs estimated in Table 8 and Table 9, issuers and TPAs will also incur an annual burden and costs associated with customer service representative training, consumer assistance and education, and administrative and distribution costs related to the disclosures required in the final rules. The Departments estimate that, to understand and navigate the internet-based self-service tool and provide the appropriate assistance to consumers, each customer service representative will require approximately two hours (at $40 per hour) of annual consumer assistance training at an associated cost of $80 per hour. The Departments estimate that each issuer and TPA will train, on average, 10 customer service representatives annually, resulting in a total annual burden of 20 hours, with an associated total cost of $800. For all 1,959 issuers and TPAs, the total annual burden is estimated to be 39,180 hours, with an equivalent total annual cost of approximately $1,567,200. The Departments recognize that some issuers or TPAs may require varying levels of training to acquaint their customer service representatives with the functionalities of their internet-based self-service tool depending on the degree of changes required to comply with the final rules, in which case some issuers could incur higher costs and burdens to appropriately train personnel.

TABLE 10A—ESTIMATED ANNUAL COST AND HOUR BURDEN PER ISSUER OR TPA TO TRAIN CUSTOMER SERVICE REPRESENTATIVES TO PROVIDE ASSISTANCE TO CONSUMERS RELATED TO THE INTERNET-BASED SELF-SERVICE TOOL

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Customer Service Representatives	2	$40.00	$80.00
Total per Respondent	2	.....	80.00

TABLE 10B—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS TO TRAIN CUSTOMER SERVICE REPRESENTATIVES TO PROVIDE ASSISTANCE TO CONSUMERS RELATED TO THE INTERNET-BASED SELF-SERVICE TOOL

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	20	39,180	$1,567,200.00

The Departments assume that the greatest proportion of beneficiaries, participants, or enrollees that will request disclosure of cost-sharing information in paper form will do so because they do not have access to the internet. However, the Departments acknowledge that some consumers with access to the internet will contact a plan or issuer for assistance with using the internet-based self-service tool and may request to receive cost-sharing information in paper form.

Recent studies have found that approximately 20 million households do not have an internet subscription.[287] Further, approximately 19 million Americans (6 percent of the population) lack access to fixed broadband services that meet threshold levels.[288] Additionally, a recent Pew Research Center analysis found that 10 percent of U.S. adults do not use the internet, citing the following major factors: difficulty of use, age, cost of internet services, and lack of computer ownership.[289] Additional research indicates that an increasing number, 17 percent, of individuals and households are now considered ''smartphone only'' and that 37 percent of U.S. adults mostly use smartphones to access the internet and that many adults are forgoing the use of traditional broadband services.[290] Further research indicates that younger individuals and households, including approximately 93 percent of households with householders aged 15 to 34, are more likely to have smartphones compared to those aged over 65.[291] The Departments are of the view that the population most likely to use the internet-based self-service tool would generally consist of younger individuals, who are more comfortable using technology and are more likely to have internet access via broadband or smartphone technologies.

The Departments note that there are 212.3 million beneficiaries, participants, or enrollees enrolled in group health plans or with health insurance issuers required to comply with the requirements of the final rules for at least part of the year.[292] On average, it is estimated that each issuer or TPA would annually administer the benefits for 108,379 beneficiaries, participants, or enrollees.

A recent study noted that only one to 12 percent of consumers that have been offered internet-based or mobile application-based price transparency tools use them.[293] Taking that into account, and assuming that six percent of covered individuals lack access to fixed broadband services, the Departments estimate that on average six percent of participants, beneficiaries, or enrollees will seek customer support (a mid-range percentage of individuals that currently use available cost estimator tools) and that an estimated one percent of those participants, beneficiaries, or enrollees will request any pertinent information be disclosed to them in in a non-internet manner—resulting in an estimated 0.06 percent of participants, beneficiaries, or enrollees requesting information. As discussed in section V.D.1 of this preamble, the Departments have adjusted the estimates related to customer service and mailed requests in order to account for more recent data related to the number of participants, beneficiaries, and enrollees. The Departments estimate that each issuer or TPA, on average, will require a customer service representative to interact with a beneficiary, participant, or enrollee approximately 65 times per year on matters related to cost-sharing information disclosures required by the final rules. The Departments estimate that each customer service representative will spend, on average, 15 minutes (at $40 per hour) for each interaction, resulting in a cost of approximately $10 per interaction. The Departments estimate that each issuer or TPA will incur an annual burden of 16 hours, with an associated equivalent cost of approximately $650; resulting in a total annual burden of 31,847 hours, with an associated cost of approximately $1,273,884 for all issuers and TPAs.

The Departments assume that all beneficiaries, participants, or enrollees that contact a customer service representative will request non-internet disclosure of the internet-based self-service tool information. Of these, the Departments estimate that 54 percent of the requested information would be transmitted via email or facsimile at negligible cost to the issuer or TPA and that 46 percent will request the information be provided by mail. The Departments estimate that, on average, each issuer or TPA will send approximately 30 disclosures by mail annually. Based on these assumptions, the Departments estimate that the total number of annual disclosures sent by mail for all issuers and TPAs will be 58,599. The Departments recognize that the numbers of per issuer and TPA mailings may represent a low-end estimate and the number of requests may vary amongst each issuer or TPA depending on the demographics of their beneficiaries, participants, or enrollees. The Departments are of the view that although more individuals will contact customer support for cost information the vast majority of those individuals will likely obtain this information over the phone or have it emailed rather than have it mailed to them.

The Departments assume, on average, the length of the printed disclosure will be approximately nine single-sided pages in length, assuming two pages of

[287] ''2017 American Community Survey Single-Year Estimates.'' United States Census Bureau. September 13, 2018. Available at: *https://www.census.gov/newsroom/press-kits/2018/acs-1year.html*.

[288] ''Eight Broadband Progress Report.'' United States Federal Communications Commission. December 14, 2018. Available at: *https://www.fcc.gov/reports-research/reports/broadband-progress-reports/eighth-broadband-progress-report*. In addition to the estimated 19 million Americans that lack access, they further estimate that ''in areas where broadband is available, approximately 100 million Americans still do not subscribe.''

[289] Anderson, M. et al. ''10% of Americans don't use the internet. Who are they?'' Pew Research Center. April 22, 2019. Available at: *https://www.pewresearch.org/fact-tank/2019/04/22/some-americans-dont-use-the-internet-who-are-they/*.

[290] Anderson, M. ''Mobile Technology and Home Broadband 2019.'' Pew Research Center. June 13, 2019. Available at: *https://www.pewinternet.org/2019/06/13/mobile-technology-and-home-broadband-2019/* (finding that overall 17 percent of Americans are now ''smartphone only'' internet users, up from 8 percent in 2013. They study also shows that 45 percent of non-broadband users cite their smartphones as a reason for not subscribing to high-speed internet).

[291] Ryan, C. ''Computer and internet Use in the United States: 2016.'' American Community Survey Reports: United States Census Bureau. August 2018. Available at: *https://www.census.gov/content/dam/Census/library/publications/2018/acs/ACS-39.pdf*.

[292] *Id.* at 283.

[293] Mehrotra, A., Chernew, M., and Sinaiko, A. ''Health Policy Report: Promises and Reality of Price Transparency.'' April 5, 2018. 14 N. Eng. J. Med. 378. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMhpr1715229*.

information (similar to that provided in an EOB) for three providers (for a total of six pages) and an additional three pages related to the required notice statements, with a printing cost of $0.05 per page. Therefore, including postage costs of $0.55 per mailing, the Departments estimate that each issuer or TPA will incur a material and printing costs of approximately $1.00 ($0.45 printing plus $0.55 postage costs) per mailed request. Based on these assumptions, the Departments estimate that each issuer or TPA will incur an annual printing and mailing cost of approximately $30, resulting in a total annual printing and mailing cost of approximately $58,599 for all issuers and TPAs.

TABLE 11A—ESTIMATED ANNUAL COST AND HOUR BURDEN PER RESPONSE PER ISSUER OR TPA TO ACCEPT AND FULFILL REQUESTS FOR A MAILED DISCLOSURES

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Customer Service Representatives	0.25	$40.00	$10
Total per Respondent	0.25		10

TABLE 11B—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS TO ACCEPT AND FULFILL REQUESTS FOR MAILED DISCLOSURES

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total labor cost of reporting	Printing and materials cost	Total cost
1,959	1132,509	16	31,847	$1,273,884.00	$58,598.66	$1,332,482.66

The Departments solicited comment on the overall estimated costs and burdens related to this collection of information request. The Departments also sought comment on the technical and labor requirements or costs that may be required to meet the requirements of the proposed rules: For example, what costs may be associated with any potential consolidation of information needed for the internet-based self-service tool functionality. The Departments sought comment on the estimated number of issuers and TPAs currently in the group and individual markets and the number of self-insured group health plans that might seek to independently develop an internet-based self-service tool, the percentage of consumers who might use the internet-based self-service tool, and the percentage of consumers who might contact their plan, issuer, or TPA requesting information via a non-internet disclosure method. The Departments sought comment on any other existing efficiencies that could be leveraged to minimize the burden on plans, issuers, and TPAs, as well as how many or what percentage of plans, issuers, and TPAs might leverage such efficiencies. The Departments sought comment on the proposed model notice and any additional information that stakeholders thought should be included, removed, or expanded upon and its overall adaptability.

All comments received with regard the topics above have been noted and addressed in their corresponding ICR sections.

In conjunction with the final rules, CMS is seeking approval for this information collection (OMB control number: 0938–1372 (Transparency in Coverage (CMS–10715)). CMS is requiring the following information collections to include the following burden. DOL and the Department of the Treasury will submit their burden estimates upon approval.

2. ICRs Regarding Requirements for Public Disclosure of In-network Rates, Historical Allowed Amount Data for Covered Items and Services from Out-of-Network Providers and Prescription Drug Pricing Information under 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212.

The Departments are adding 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), and 45 CFR 147.212(b) to the final rules requiring group health plans and health insurance issuers to make public in-network rates for covered items and services, out-of-network allowed amounts for covered items or services, and negotiated rates and historical net prices for each prescription drug NDC through three machine-readable files that must conform to guidance issued by the Departments. The list of required data elements that must be included for each file for each covered item or service are discussed in section II.C previously in this preamble and enumerated under paragraph (b)(1)(i) for the In-network Rate File, paragraph (b)(1)(ii) for the Allowed Amount File, and paragraph (b)(1)(iii) for the Prescription Drug File of the final rules. Under paragraphs (b)(2) and (3) of the final rules, the machine-readable files must be posted on a public internet site accessible to any person free of charge and without conditions and must be updated monthly.

For the In-network Rate File, the final rules require the negotiated rates, underlying fee schedules, or derived amounts under a plan or coverage regarding each covered item or service be furnished for in-network providers. As discussed in section II.C earlier in this preamble, the Departments expect plans and issuers to make public the negotiated rate, fee schedule, or derived amount that is used to adjudicate claims for the purpose of reconciling a provider's payment to determine a participant's, beneficiary's, or enrollee's cost-sharing liability. As discussed in the previous ICR section, the Departments assume fully-insured group health plans will rely on issuers and most self-insured group health plans will rely on issuers or TPAs to develop and update the machine-readable files. The Departments recognize that there may be some self-insured plans that wish to individually comply with the final rules and will thus incur a similar burden and cost as described in the following paragraphs.

Many commenters stated the costs associated with the technical build and maintenance of the machine-readable files will be significant, and many commenters strongly suggested that the costs and burden of implementing the files would be significantly higher than those estimated in the proposed rules. Some commenters stated that the final rules would unreasonably burden

issuers with administrative costs and could be especially burdensome for small issuers and self-insured plans. One commenter noted that a significant amount of burden would be placed on out-of-network providers to provide information regarding costs to plans and issuers. Another commenter, a hospital association, stated that the proposed rules would be an administrative burden for hospitals as they would require a massive investment by hospitals to provide data to comply and that these resources would be diverted from patient care support.

The Departments recognize that the requirements in the final rules could result in instances where small issuers and self-insured plans face a disproportionate burden due to their size; however, as noted earlier in this preamble, the Departments expect that small issuers, plans, and TPAs will combine their efforts and seek to take advantage of any resulting economies of scale.

An independent study by Bates White Economic Consulting (Bates White), commissioned by one commenter, developed an assessment of the costs of the proposed rules by interviewing a mix of 18 large and small health insurance issuers covering about 78 million lives; Bates White assessed the average issuer cost to implement the In-network Rate File as $2,139,167 with a range from $85,000 to $10,000,000. Bates White reported that commercial issuers estimated an average cost of $2.1 million per issuer to develop and implement the In-network Rates File. Per the study, issuers view the In-network Rate File as about 20 times costlier to implement than the Departments' proposed estimate. In addition, Bates White assessed the average annual issuer cost to maintain the In-network Rate Files would be $467,000 with a range from $15,000 to $1,000,000. Another commenter noted that commercial issuers estimated annual costs of $600,000 per issuer to maintain the In-network Rate File. Issuers viewed the In-network Rate File as about 13 times costlier to maintain than the Departments' proposed estimate.

In another attempt to quantify this burden, one commenter emphasized that the potential universe of prices that would need to be disclosed on the files is enormous and could be in the hundreds of billions (more than 94,000 codes multiplied by the number of unique practitioners, which in the large issuer's system alone could exceed 2 million).

One commenter noted that the effort to comply would involve an immense amount of data aggregation, de-identification, and application development work, and these tasks would be especially difficult for small issuers and self-insured plans who are more likely to rely on ''rented'' networks. The commenter stated that to comply with the final rules, issuers would need a team with data expertise and knowledge of plan design and medical service billing to aggregate data, build re-pricing engines, and assure accuracy.

Due to the belief that the burden estimate in the proposed rules and related PRA grossly underestimated the burden of implementation on plans and issuers, one commenter suggested the Departments should retract the PRA and work with stakeholders to develop a less burdensome transparency solution. Other commenters stated the burden estimates included in the proposed rules violate the spirit and express provision of the PRA.

The Departments recognize the concerns and issues noted by commenters. As noted in section VI.A in this preamble, the Departments have reviewed comments related to the costs and burdens associated with the requirements of the final rules and devised updated estimates using CALC derived wage rates. The Departments note that the conclusions of the Bates White study referenced earlier in this preamble were based on interviews with issuers in which issuers described the steps they viewed as necessary to establish the required internet-based self-service tool and the machine-readable files, and provided related costs estimates associated with the estimated initial set-up of the internet-based self-service tool and machine-readable files. These estimates, however, did not provide the level of detail necessary for the Departments to assess how those initial cost estimates differ from the Departments' estimates.

The Bates White study also recognized the difficulty associated with assessing issuer estimates reported from issuer study participants. The study recognized that issuers interviewed varied widely in size, had different levels of experience, and had engaged in different levels of analysis of the impacts in the proposed rules. The study further noted the differences in the extent to which issuers evaluated the costs and feasibility of complying with the proposed rules. The study also recognized that issuers interviewed made different assumptions about the degree of support from vendors or trade associations that may have affected issuers' perception of the administrative and operational costs of implementation, and that issuers did not provide details of the varied operational and implementation costs and activities underlying their stated estimates for complying with the proposed rules. Specifically, the study provided no insight regarding the labor categories, wages, or hourly burdens that were considered to produce these cost estimates. Accordingly, the Bates White study did not provide details sufficient to allow those estimates to be compared to the Departments' estimates in the proposed rules.

Given the limited utility of information offered by the Bates White study, the Departments took additional steps to ensure the reasonableness and accuracy of the cost estimates associated with compliance with the final rules. In developing the updated estimates, the Departments took into account the potential aggregation of data and the potential likelihood that the data required to meet the requirements of the final rules would need to be obtained from multiple sources. The Departments recognize that the size and complexity of the machine-readable files will result in data files that are large. However, the Departments do not anticipate that data storage would impose a significant burden for issuers or TPAs due to the relatively inexpensive costs associated with storage methods such as cloud storage.

The Departments estimate a one-time first year burden and cost to issuers and TPAs to make appropriate changes to IT systems and processes, to develop, implement and operate the In-network Rate File in order to meet the requirements of the final rules. The Departments estimate that each health or TPA will require a Project Manager/Team Lead 364 hours (at $153 per hour), a Scrum Master 1,404 hours (at $105 per hour), a Technical Architect/Sr. Developer 2,080 hours (at $149 per hour), an Application Developer, Senior 1,716 hours (at $143 per hour), a Business Analyst 1,404 hours (at $120 per hour), a Service Designer/Researcher 520 hours (at $114 per hour) and a DevOps Engineer 260 hours (at $181 per hour) to complete this task. The total one-time first year burden for each issuer or TPA is estimated to be approximately 7,748 hours, with an equivalent associated cost of approximately $1,033,240. For all 1,959 issuers and TPAs, the Departments estimate the total one-time first year burden will be 15,178,332 hours with an associated cost of approximately $2,024,117,160. The Departments emphasize that these are upper bound estimates that are meant to be sufficient to cover substantial, complex activities

that may be necessary for some plans, issuers, or TPAs to comply with the final rules due to the manner in which their current systems are designed. Such activities may include such significant activities as the design and implementation of databases that will support the production of the In-network Rate Files.

TABLE 12A—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE IN-NETWORK RATE FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	364	$153.00	$55,692.00
Scrum Master	1,404	105.00	147,420.00
Technical Architect/Sr. Developer	2,080	149.00	309,920.00
Application Developer, Senior	1,716	143.00	245,388.00
Business Analyst	1,404	120.00	168,480.00
Service Designer/Researcher	520	114.00	59,280.00
DevOps Engineer	260	181.00	47,060.00
Total per Respondent	7,748		1,033,240.00

TABLE 12B—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE IN-NETWORK RATE FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	7,748	15,178,332	$2,024,117,160.00

In addition to the one-time year one costs estimated in Tables 12A and 12B, issuers or TPAs will incur an additional year two burden and cost to update the In-network Rate File monthly as required in the final rules. The Departments estimate that for each month each issuer or TPA it will require a Project Manager/Team Lead 22 hours (at $153 per hour), a Scrum Master 22 hours (at $105 per hour), a Technical Architect/Sr. Developer 22 hours (at $149 per hour), an Application Developer, Senior 22 hours (at $143 per hour), a Business Analyst 13 hours (at $120 per hour) and a DevOps Engineer 22 hours (at $181 per hour) to make the required updates and needed adjustments to the In-network Rate File. The Departments estimate that each issuer or TPA will incur a monthly year two burden of 123 hours, with an associated monthly cost of approximately $17,642 to adjust and update the In-network Rate File. Each issuer or TPA will need to update the In-network Rate File 12 times during a given year, resulting in a year two burden of 1,476 hours, with an associated equivalent cost of approximately $211,704. The Departments estimate the total year two burden for all 1,959 issuers and TPAs will be 2,891,484 hours, with an associated equivalent cost of approximately $414,728,136. The Departments consider this estimate to be an upper-bound estimate and expect ongoing update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the In-network Rate File.

TABLE 13A—ESTIMATED MONTHLY YEAR TWO COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE IN-NETWORK RATE FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	22	$153.00	$3,366.00
Scrum Master	22	105.00	2,310.00
Technical Architect/Sr. Developer	22	149.00	3,278.00
Application Developer, Senior	22	143.00	3,146.00
Business Analyst	13	120.00	1,560.00
DevOps Engineer	22	181.00	3,982.00
Total per Respondent	123		17,642.00

TABLE 13B—ESTIMATED YEAR TWO COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE IN-NETWORK RATE FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	1,476	2,891,484	$414,728,136.00

In addition to the one-time year one and monthly year two costs estimated Tables 12A, 12B, 13A, and 13B, in subsequent years, issuers and TPAs will incur an ongoing monthly burden and cost to update and maintain the In-network Rate File on a monthly basis as required by the final rules. The Departments estimate that for each issuer or TPA it will require a Project Manager/Team Lead 9 hours (at $153 per hour) and an Application Developer, Senior 22 hours (at $143 per hour) to make the required updates to the In-network Rate File. The Departments estimate that each issuer or TPA will incur a monthly burden of 31 hours, with an associated cost of approximately $4,523 to update the In-network Rate File. Each issuer or TPA will need to update the In-network Rate File 12 times during a given year, resulting in an ongoing annual hour burden of 372 hours, with an associated equivalent cost of approximately $54,276. The Departments estimate the total annual burden for all 1,959 issuers and TPAs will be 728,748 hours, with an associated equivalent cost of approximately $106,326,684. The Departments consider this estimate to be an upper-bound estimate and expect ongoing update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the In-network Rate File.

TABLE 14A—ESTIMATED MONTHLY ONGOING COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE IN-NETWORK RATE FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	9	$153.00	$1,377.00
Application Developer, Senior	22	143.00	3,146.00
Total per Respondent	31		4,523.00

TABLE 14B—ESTIMATED ANNUAL ONGOING COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE IN-NETWORK RATE FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	372	728,748	$106,326,684.00

The Departments estimate the total one-time year one burden for all issuers and TPAs will be 15,178,332 hours, with an associated equivalent cost of approximately $2,024,117,160 to develop and build the In-network Rate File in a machine-readable format. In year two, the Departments estimate the burden and costs to update and maintain the In-network Rate file for all issuers and TPAs will be 2,891,484 hours, with an associated equivalent cost of approximately $414,728,136. In subsequent years, the Departments estimate the total annual burden to maintain and update the In-network Rate File will be 728,748 hours, with an annual associated equivalent cost of approximately $106,326,684. The Departments estimate the three-year average annual total burden, for all issuers and TPAs, will be 6,266,188 hours, with an average annual associated equivalent total cost of $848,390,660.

TABLE 15—ESTIMATED THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE IN-NETWORK RATE FILE

Year	Estimated number of health insurance issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2021	1,959	1,959	7,748	15,178,332	$2,024,117,160.00
2022	1,959	23,508	1,476	2,891,484	414,728,136.00
2023	1,959	23,508	372	728,748	106,326,684.00
3 year Average	1,959	16,325	3,199	6,266,188	848,390,660.00

As mentioned in sections V.B in this preamble, the Departments understand that plans and issuers may include gag clauses in their provider contracting agreements, which prevent disclosure of in-network rates. The Departments sought comment on whether such agreements would need to be renegotiated to remove such clauses, and, if so, sought comment regarding any costs and burden associated with this action.

One commenter stated the Departments have not sufficiently accounted for costs associated with updating legal agreements (with physicians, hospitals, drug manufacturers, and device manufacturers, for example), updating and integrating data from multiple systems, and establishing processes for making updates to files in the ordinary course of business. Another commenter observed the Departments have not adequately accounted for the time, resources, and cost burdens of renegotiating contracts to remove gag clauses or confidentiality clauses, which prevent disclosure of in-network rates. One commenter provided examples of these costs: Printing and paper, mailing, attorney drafting initial amendments and review of non-standard language requests, costs for employees charged with negotiation and administration, and costs paid to vendors.

Due to the potential complexities and time involved in contract negotiations, the Departments recognize that should contracts require renegotiation, all associated parties will face additional costs and burdens. However, the Departments do not have insight into these complexities or knowledge of how these contracts are structured, and they are thus not able to quantify the costs and burdens associated with these tasks. Also, as addressed earlier in this preamble, it is not uncommon for new or modified regulatory requirements or new statutory provisions to alter private contract arrangements. The Departments note that the possibility of new or modified regulatory requirements or new statutory provisions altering such contracts often is contemplated in the contracts themselves; for example, drafters may include contract language indicating that terms may be altered by changes in law or regulation. Such language would obviate the need for updates outsides of the regular contracting schedule and any associated costs and burden.

For the Allowed Amount File, the final rules require plans and issuers to make available a machine-readable file showing the unique out-of-network allowed amounts and billed charges for covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days before the publication date of the file. As discussed earlier in this preamble, to the extent that a group health plan or health insurance issuer has paid multiple bills for an item or service to a particular out-of-network provider at the same allowed amount, the final rules will only require a plan or issuer to list the allowed amount once. Additionally, if the plan or issuer would only display allowed amounts in connection with 20 or fewer claims for a covered item or service for payment to a provider during any relevant 90-day period, the plan or issuer will not be required to report those unique allowed amounts.

As previously noted, an independent study by Bates White, commissioned by one commenter, assessed the average issuer cost to implement the Allowed Amount File as $1,071,167 with a range from $42,000 to $5,000,000 and estimated the cost to implement the Allowed Amount File as about 9 times costlier to implement than the Departments' proposed estimate. This commenter also argued that the average annual issuer cost to maintain the Allowed Amount File would be $643,000 with a range from $12,000 to $1,500,000. Another commenter argued that the cost to maintain the Allowed Amount File would be about 44 times costlier than the Departments' proposed estimate.

As noted above regarding the In-network Rate File cost and burdens, the Departments have devised updated estimates for the Allowed Amounts File using CALC derived wage rates. In developing the updated estimates, the Departments took into account the potential aggregation of data and the potential likelihood that the data required to meet the requirements of the final rules would need to be obtained from multiple sources.

The Departments estimate a one-time year one burden and cost to issuers and TPAs to make appropriate changes to IT systems and processes, to develop, implement, and operate the Allowed Amount File in order to meet the requirements of the final rules. The Departments estimate that each issuer or TPA will require a Scrum Master 520 hours (at $105 per hour), a Technical Architect/Sr. Developer 780 hours (at $149 per hour), an Application Developer, Senior 2,080 hours (at $143 per hour), a Business Analyst 520 hours (at $120 per hour), and a DevOps Engineer 260 hours (at $181 per hour) to complete this task. The Departments estimate the total one-time first year burden for each issuer or TPA will be approximately 4,160 hours, with an equivalent associated cost of approximately $577,720. For all 1,959 issuers and TPAs, the Departments estimate the total one-time year one burden will be 8,149,440 hours, with an equivalent associated cost of approximately $1,131,753,480.

TABLE 16A—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE ALLOWED AMOUNT FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Scrum Master	520	$105.00	$54,600.00
Technical Architect/Sr. Developer	780	149.00	116,220.00
Application Developer, Senior	2,080	143.00	297,440.00
Business Analyst	520	120.00	62,400.00
DevOps Engineer	260	181.00	47,060.00
Total per Respondent	4,160	.....	577,720.00

TABLE 16B—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE ALLOWED AMOUNT FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	4,160	8,149,440	$1,131,753,480.00

In addition to the one-time year one costs estimated in Tables 16A and 16B, issuers and TPAs will incur additional monthly burdens and costs in year two to update the Allowed Amount File. The Departments estimate that, in year two, each issuer or TPA will require a Scrum Master 9 hours (at $105 per hour), an Application Developer, Senior 22 hours (at $143 per hour), and a DevOps Engineer 22 hour (at $181) to make the required monthly Allowed Amount File updates. The Departments estimate that each issuer or TPA will incur a monthly burden of 53 hours, with an equivalent associated cost of approximately $8,073 to update the Allowed Amount File. The Departments estimate that each issuer or TPA will need to update the Allowed Amount File 12 times during a given year, resulting in a year two annual burden of approximately 636 hours, with an equivalent associated cost of

approximately $96,876. The Departments estimate the total year two burden for all 1,959 issuers and TPAs will be 1,245,924 hours, with an equivalent associated cost of approximately $189,780,084. The Departments consider this estimate to be an upper-bound estimate and expect ongoing Allowed Amount File update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the Allowed Amount File.

TABLE 17A—ESTIMATED YEAR TWO MONTHLY COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE ALLOWED AMOUNT FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Scrum Master	9	$105.00	$945.00
Application Developer, Senior	22	143.00	3,146.00
DevOps Engineer	22	181.00	3,982.00
Total per Respondent	53	.....	8,073.00

TABLE 17B—ESTIMATED YEAR TWO COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE ALLOWED AMOUNT FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	636	1,245,924	$189,780,084.00

In addition to the one-time year one, monthly and total year two costs estimated in Tables 16A, 16B, 17A and 17B, in subsequent years, issuers and TPAs will incur additional ongoing monthly burdens and costs to update the required Allowed Amount File. The Departments estimate that for each issuer or TPA it will require a Scrum Master 4 hours (at $105 per hour), and an Application Developer, Senior 9 hours (at $143 per hour) to make the required monthly Allowed Amount File updates. The Departments estimate that each issuer or TPA will incur a monthly burden of 13 hours, with an equivalent associated cost of approximately $1,707 to update the Allowed Amount File. The Departments estimate that each issuer or TPA will need to update the Allowed Amount File 12 times during a given year, resulting in an ongoing annual burden of approximately 156 hours, with an equivalent associated cost of approximately $20,484. The Departments estimate the total burden for all 1,959 issuers and TPAs will be 305,604 hours, with an equivalent associated cost of approximately $40,128,156. The Departments consider this estimate to be an upper-bound estimate and expect ongoing Allowed Amount File update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the Allowed Amount File.

TABLE 18A—ESTIMATED MONTHLY ONGOING COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE ALLOWED AMOUNT FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Scrum Master	4	$105.00	$420.00
Application Developer, Senior	9	143.00	1,287.00
Total per Respondent	13	.....	1,707.00

TABLE 18B—ESTIMATED ANNUAL ONGOING COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE ALLOWED AMOUNT FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	156	305,604	$40,128,156.00

The Departments estimate the one-time year one burden for all issuers and TPAs will be 8,149,440 hours, with an equivalent associated cost of approximately $1,131,753,480 to develop and build the Allowed Amount File to meet the requirements of the final rules. In year two, the Departments estimate the total annual burden of 1,245,924 hours to maintain and update the Allowed Amount File, with an equivalent associated cost of approximately $189,780,084. In subsequent years, the Departments estimate the total annual burden to maintain and update the Allowed Amount File will be 305,604 hours, with an annual equivalent associated cost of approximately $40,128,156. The Departments estimate the three-year average annual total burden for all issuers and TPAs will be 3,233,656 hours, with an average annual total

equivalent associated cost of approximately $453,887,240.

TABLE 19—ESTIMATED THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE ALLOWED AMOUNT FILE

Year	Estimated number of issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2021	1,959	1,959	4,160	8,149,440	$1,131,753,480.00
2022	1,959	23,508	636	1,245,924	189,780,084.00
2023	1,959	23,508	156	305,604	40,128,156.00
3 year Average	1,959	16,325	1,651	3,233,656	453,887,240.00

The Departments sought comment for this collection of information request related to all aspects of the estimated burdens and costs. Specifically, the Departments sought comments related to any technical or operational difficulties associated with maintaining current and up-to-date provider network information or any out-of-network allowed amounts for covered items and services. The Departments also sought comments related to the technical and labor requirements or costs that may be required to meet the requirements in the final rules; specifically, any factors that could minimize the frequency of updates that issuers or TPAs would be required to make to the Allowed Amount File.

The Departments also solicited comments for this collection of information request related to all aspects of the estimated burdens and costs. Specifically, the Departments sought comments related to any technical or operational difficulties associated with collecting data and maintaining any out-of-network allowed amounts for covered items and services, including, any difficulties associated with the adjudication of paid claims and incorporating covered items or services furnished by a particular out-of-network provider during the 90-day time period that begins 180 days prior to the publication date of the Allowed Amount File. The Departments also sought comments related to the technical and labor requirements or costs that may be required to meet the requirements in the proposed rules: Specifically, any factors that could minimize the burdens and costs associated with updates that issuers or TPAs would be required to make to the Allowed Amount File.

As addressed in section II.C in this preamble, the use of a HIPAA-compliant clearinghouse is permitted, but not required, in order to make the required information public. Plans and issuers are permitted to use HIPAA-compliant clearinghouses to meet the disclosure requirements and the Departments anticipate they may do so if this method is more efficient and cost-effective.

The Departments acknowledge that as many as 95 percent of group health plans and health insurance issuers may already contract with claims clearinghouses that currently collect some or all of the information required to be disclosed under the final rules and might be able to meet the requirements in the final rules easily, potentially obviating the need for the plan, issuer, or TPA to invest in IT system development. The Departments assume that these plans, issuers, and TPAs will still incur burdens and costs, albeit reduced, related to oversight and quality assurance regarding any associated clearinghouse activities. The Departments sought comments on existing efficiencies, such as the use of clearinghouses that could be leveraged by plans, issuers, and TPAs related to the development and updating of the required machine-readable files and how many issuers, TPAs, or self-insured plans may already contract with clearinghouses that collect the information required. Comments received are discussed earlier in the Use of Third Parties to Satisfy Public Disclosure Requirements section of this preamble.

For the Prescription Drug File, the Departments estimate one-time first-year burdens and costs to issuers and TPAs to make appropriate changes to IT systems and processes to develop, implement, and operate the Prescription Drug File in order to meet the requirements in the final rules. The Departments estimate that each issuer or TPA will require a Project Manager/Team Lead 260 hours (at $153 per hour), a Scrum Master 260 hours (at $105 per hour), an Application Developer, Senior 520 hours (at $143 per hour), a Business Analyst 520 hours (at $120 per hour), and a DevOps Engineer 260 hours (at $181 per hour) to complete this task. The total one-time first year burden for each issuer or TPA is estimated to be approximately 1,820 hours, with an equivalent associated cost of approximately $250,900. For all 1,959 issuers and TPAs, the Departments estimate the total one-time first year burden will be 3,565,380 hours, with an associated estimated cost of approximately $491,513,100. The Departments emphasize that these are upper bound estimates that are meant to be sufficient to cover substantial, complex activities that may be necessary for some plans and issuers to comply with the final rules due to the manner in which their current systems are designed. Such activities may include such significant activity as the design and implementation of databases that will support the production of the Prescription Drug File.

TABLE 20A—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE PRESCRIPTION DRUG FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	260	$153.00	$39,780.00
Scrum Master	260	105.00	27,300.00
Application Developer, Senior	520	143.00	74,360.00
Business Analyst	520	120.00	62,400.00

TABLE 20A—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE PRESCRIPTION DRUG FILE—Continued

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
DevOps Engineer	260	181.00	47,060.00
Total per Respondent	1,820		250,900.00

TABLE 20B—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE PRESCRIPTION DRUG FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	1,820	3,565,380	$491,513,100.00

In addition to the one-time year one costs estimated in Tables 20A and 20B, issuers and TPAs will incur additional year two burdens and costs to update the required Prescription Drug File monthly. The Departments estimate that for each month, each issuer or TPA will require a Project Manager/Team Lead 22 hours (at $153 per hour), an Application Developer, Senior 22 hours (at $143 per hour), a Business Analyst 9 hours (at $120 per hour) and a DevOps Engineer 22 hours (at $181 per hour) to make the required updates and needed adjustments to the Prescription Drug File. The Departments estimate that each issuer or TPA will incur a monthly, year two, burden of 75 hours, with an associated monthly cost of approximately $11,574 to update the Prescription Drug File. Each issuer or TPA will need to update the Prescription Drug File 12 times during a given year, resulting in a year two burden of 900 hours, with an associated equivalent cost of approximately $138,888. The Departments estimate the total year two burden for all 1,959 issuers and TPAs will be 1,763,100 hours, with an associated equivalent cost of approximately $272,081,592. The Departments consider this estimate to be an upper-bound estimate and expect ongoing update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the Prescription Drug File.

TABLE 21A—ESTIMATED MONTHLY YEAR TWO COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE PRESCRIPTION DRUG FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	22	$153.00	$3,366.00
Application Developer, Senior	22	143.00	3,146.00
Business Analyst	9	120.00	1,080.00
DevOps Engineer	22	181.00	3,982.00
Total per Respondent	75		11,574.00

TABLE 21B—ESTIMATED YEAR TWO COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE PRESCRIPTION DRUG FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	900	1,763,100	$272,081,592.00

In addition to the one-time year one and monthly year two costs estimated in Tables 20A, 20B, 21A and 21B, in subsequent years, issuers and TPAs will incur ongoing monthly burdens and costs to update and maintain the Prescription Drug File on a monthly basis. The Departments estimate that each issuer or TPA will require a Scrum Master 9 hours (at $153 per hour) and an Application Developer, Senior 22 hours (at $143 per hour) to make the required updates to the Prescription Drug File. The Departments estimate that each issuer or TPA will incur a monthly burden of 31 hours, with an associated cost of approximately $4,523, to update the Prescription Drug File. An issuer or TPA will need to update the Prescription Drug File 12 times during a given year, resulting in an ongoing annual burden of 372 hours, with an associated equivalent cost of approximately $54,276. The Departments estimate the total annual burden for all 1,959 issuers and TPAs will be 728,748 hours, with an associated equivalent cost of approximately $106,326,680. The Departments consider this estimate to be an upper-bound estimate and expect ongoing update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing Prescription Drug File.

TABLE 22A—ESTIMATED MONTHLY ONGOING COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE PRESCRIPTION DRUG FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Scrum Master	9	$153.00	$1,377.00
Application Developer, Senior	22	143.00	3,146.00
Total per Respondent	31		4,523.00

TABLE 22B—ESTIMATED ANNUAL ONGOING COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE PRESCRIPTION DRUG FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	372	728,748	$106,326,684.00

The Departments estimate the total one-time year one burden for all issuers and TPAs will be 3,565,380 hours, with an associated equivalent cost of approximately $491,513,100 to develop and build the Prescription Drug File in a machine-readable format. In year two, the Departments estimate the burden and costs to update and maintain the Prescription Drug File, on a monthly basis, for all issuers and TPAs to be 1,763,100 hours, with an associated equivalent cost of approximately $272,081,592. In subsequent years, the Departments estimate the total annual burden of 728,748 hours to maintain and update the Prescription Drug File, with an annual associated equivalent cost of approximately $106,326,684. The Departments estimate the three-year average annual total burden, for all issuers and TPAs, will be 2,019,076 hours with an average annual associated equivalent total cost of $289,973,792.

TABLE 23—ESTIMATED THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE PRESCRIPTION DRUG FILE

Year	Estimated number of issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2021	1,959	1,959	1,820	3,565,380	$491,513,100.00
2022	1,959	23,508	900	1,763,100	272,081,592.00
2023	1,959	23,508	372	728,748	106,326,684.00
3 year Average	1,959	16,325	1,031	2,019,076	289,973,792.00

Due to comments received in response to the proposed rules, the Departments have made changes to the final rules and the ICR sections discussed above. The Departments seek comment regarding the changes associated with these ICR sections. The Departments also seek comment on the use of the CALC database, as discussed in section VI.A, to determine occupational descriptions and hourly wage rates. The Departments seek comment on the revised costs and burdens discussed in section VI.A.1 as they relate to the required internet-based self-service tool. The Departments also seek comment on model language developed by the Departments, as discussed in section II.B.1.g of this preamble, to meet the requirements of the final rule. The Departments also seek comment on the revised costs and burdens, as discussed in section VI.A.2, related to the requirements for the public disclosure of In-network Rate, Allowed Amount, and Prescription Drug Files. Additionally, the Departments seek comment on the data element changes associated with those collection instruments. For the In-network Rate File, the Departments seek comment regarding the data elements added to the collection instrument; specifically, addition of data elements including the TIN, Place of service code, derived amount, underlying fee schedule rates, payment arrangement indicator, the use of base negotiated rates (for certain reimbursement models), and other data elements discussed in section C.1.c of this preamble. The Departments also seek comment on the Allowed Amount File regarding the addition of data elements including the TIN, NPI, and billed charges associated with allowed amounts. The Departments seek comment on all data elements discussed in section C.1.c of this preamble as they relate to the Prescription Drug File, as well as the estimated costs and burdens estimated above.

In association with amendments made to the final rules, CMS is seeking OMB approval for the information collection requirements associated with OMB control number 0938–1372 (CMS–10715—Transparency in Coverage). Comments will be solicited through a 60-day **Federal Register** notice, in accordance with Section 3506(c)(2)(A) of the Paperwork Reduction Act. Data collection requirements associated with the internet-based self-service tool, In-network Rate, Allowed Amount, and Prescription Drug Files will not be effective until OMB approval is sought. The Department of Labor and the Department of the Treasury will submit their burden estimates upon approval.

2. ICRs Regarding Medical Loss Ratio (45 CFR 158.221)

HHS is finalizing its proposal to amend 45 CFR 158.221(b) to allow health insurance issuers offering group or individual health insurance coverage to include in the MLR numerator ''shared savings'' payments made to

enrollees as a result of the enrollee choosing to obtain health care from a lower-cost, higher-value provider. HHS does not anticipate that implementing this provision will require significant changes to the MLR Annual Reporting Form or will significantly change the associated burden. The burden related to this collection is currently approved under OMB Control Number 0938–1164 (Exp. 10/31/2020); Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS–10418).

3. Summary of Annual Burden Estimates for Requirements

TABLE 24—ESTIMATED THREE YEAR AVERAGE PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control number	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Mailing cost ($)	Total cost ($)
§§ 54.9815–2715A2(b)(2)(i); 2590.715–2715A2(b)(2)(i); and 147.211(b)(2)(i).	0938–1372*	1,959	1,959	23,313	45,670,820	$6,388,837,830.32	$0	$6,388,837,830.32
§§ 54.9815–2715A2(b)(2)(ii); 2590.715–2715A2(b)(2)(ii); and 147.211(b)(2)(ii).	0938–1372	1,306	84,926	11	21,231	849,256.00	39,065.78	888,321.78
§§ 54.9815–2715A3(b)(i); 2590.715–2715A3(b)(i); and 147.212(b)(1)(i).	0938–1372	1,959	16,325	3,199	6,266,188	848,390,660.00	0	848,390,660.00
§§ 54.9815–2715A3(b)(1)(ii); 2590.715–2715A3(b)(1)(ii); and 147.212(b)(1)(ii).	0938–1372	1,959	16,325	1,651	3,233,656	453,887,240.00	0	453,887,240.00
§§ 54.9815–2715A3(b)(1)(iii); 2590.715–2715A3(b)(1)(iii); and 147.212(b)(1)(iii).	0938–1372	1,959	16,325	1,031	2,019,076	289,973,792.00	0	289,973,792.00
Total			135,860	29,204	57,210,971	7,981,938,778.32	39,065.78	7,981,977,844.10

*High-end three year estimated values are represented in the table and used to determine the overall estimated 3-year average.

For PRA purposes, the Departments are splitting the burden: CMS will account for 50 percent of the associated costs and burdens and the Departments of Labor and the Department of the Treasury will each account for 25 percent of the associated costs and burdens. The burden for CMS will be 28,605,486 hours, with an equivalent associated cost of approximately $3,990,969,389 and a cost burden of $19,533. For the Departments of Labor and the Treasury, each Department will account for a burden of 14,302,743 hours with an equivalent associated cost of approximately $1,995,484,695 and a cost burden of $9,766.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare a final regulatory flexibility analysis to describe the impact of proposed rules on small entities, unless the head of the agency can certify that the rule would not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.''

HHS uses a change in revenues of more than three to five percent as its measure of significant economic impact on a substantial number of small entities.

The final rules require that group health plans and health insurance issuers disclose to a participant, beneficiary, or enrollee such individual's cost-sharing information for covered items or services from a particular provider or providers; to make public in-network rates, including amounts in underlying fee schedules, negotiated rates, and derived amounts for in-network providers; historical allowed amounts paid to out-of-network providers and billed charges for all covered items and services; and negotiated rates and historical net prices for prescription drugs. The Departments are of the view issuers generally exceed the size thresholds for ''small entities'' established by the SBA, so the Departments are not of the view that an initial regulatory flexibility analysis is required for such firms. ERISA-covered plans are often small entities, however. While the Departments are of the view that these plans would rely on the larger issuers or TPAs to comply with the final rules, they would still experience increased costs because the costs of complying with these requirements will likely be passed on to them. However, as discussed in more detail later in this section of this preamble, the Departments are not of the view that the additional costs meet the significant impact requirement. In addition, while the requirements of the final rules do not apply to providers, providers may experience a loss in revenue as a result of the demands of price sensitive consumers and plans, and because smaller issuers may be unwilling to continue paying higher rates than larger issuers for the same items and services. The Departments are of the view that issuers would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $41.5 million or less would be considered small entities under North American Industry Classification System codes. Issuers could possibly be classified under code 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $35 million or less.[294] The Departments are of the view that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report submissions for the 2017 MLR reporting year, approximately 90 out of 500 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less. [295] This estimate likely overstates the actual

[294] ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes.'' United States Small Business Administration. Available at: *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf.*

[295] ''Medical Loss Ratio Data and System Resources.'' CCIIO. Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

number of small health insurance issuers that may be affected, since over 72 percent of these small issuers belong to larger holding groups, and most, if not all, of these small issuers are likely to have non-health lines of business that will result in their revenues exceeding $41.5 million. The Departments are of the view that these same assumptions also apply to the TPAs that would be affected by the final rules. The Departments do not expect any of these 90 potentially small entities to experience a change in rebates under the amendments to the MLR provisions of the final rules in 45 CFR part 158. The Departments acknowledge that it may be likely that a number of small entities might enter into contracts with other entities in order to meet the requirements in the final rules, perhaps allowing for the development of economies of scale. Due to the lack of knowledge regarding what small entities may decide to do in order to meet these requirements and any costs they might incur related to contracts, the Departments sought comment on ways that the final rules will impose additional costs and burdens on small entities and how many would be likely to engage in contracts to meet the requirements.

The Departments received a number of comments related to the potential additional costs, burdens, and other effects the final rules could have on small entities. These comments have been noted and addressed in the RIA and ICR sections titled Regarding Requirements for Public Disclosure of In-network Rates, Historical Allowed Amount Data for Covered Items and Services from Out-of-Network Providers and Prescription Drug Pricing Information; Requirements for Disclosing Cost-sharing information to Participant, Beneficiaries, or Enrollees; and the Applicability Date section of this preamble.

For purposes of the RFA, the DOL continues to consider a small entity to be an employee benefit plan with fewer than 100 participants.[296] Furthermore, while some large employers may have small plans, most small plans are maintained by small employers.

Thus, the Departments are of the view that assessing the impact of the final rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the SBA (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631, *et seq.*). Therefore, EBSA requested comments on the appropriateness of the size standard used in evaluating the impact of the final rules on small entities. Using the DOL definition of small, about 2,160,743 of the approximately 2,327,339 plans are small entities. Using a threshold approach, if the total costs of the final rules are spread evenly across all 1,754 issuers, 205 TPAs, and 2,327,339 ERISA health plans, without considering size, using the three-year average costs, the per-entity costs could be $3,426.77 ($7,981,977,844.10/2,329,298). If those costs are spread evenly across the estimated 212.3 million beneficiaries, participants, or enrollees[297] enrolled in plans or issuers required to comply with the requirements then the average cost per covered individual would be $37.60 ($7,981,977,844.102/212.3 million). Neither the cost per entity nor the cost per covered individual is a significant impact. Further, the costs estimated in section VI in this preamble may be overstated as it is assumed that all of issuers and TPAs will build the internet-based self-service tool and the machine-readable files, compile the appropriate data, and perform the required updates themselves rather than using common third parties such as clearinghouses, as discussed in section II.C in this preamble. If private health insurance transactions are processed through clearinghouses, with at least the fields required in the machine-readable files, there could be an unaccounted for source of savings, as clearinghouses may already process much of the data that issuers and TPAs would be required to collect under the final rules.

In addition, section 1102(b) of the SSA (42 U.S.C. 1302) requires the Departments to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the SSA, the Departments define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds.

As noted and addressed in section II.B.2.C in this preamble, commenters expressed concerns that exposure of in-network rates could have various unintended consequences on the health care industry, group health plans and health insurance issuers, and providers. Also as discussed in the sections VI.A.2, one commenter stated that the proposed rules would create administrative burdens for hospitals as hospitals would be required to make massive investments to provide the data required under the final rules. The Departments note that the final rules do not explicitly apply to hospitals and do not agree that hospitals will require massive investments to comply with the final rules, as opposed to the potential costs they could incur in order to comply with the Hospital Price Transparency final rule. Furthermore, the Departments recognize that while the requirements of the final rules do not apply to providers, including hospitals, some providers may experience a loss in revenue as a result of the demands of price sensitive consumers. The Departments also recognize that while the requirements in the final rules may result in instances where small rural hospitals face additional costs and burdens due to their size and the market dynamics in their areas, the generally reduced competition amongst rural hospitals, due to the overall lower number of hospitals in these areas, will provide them more leverage when negotiating with issuers. Nonetheless, some rural hospitals may see their costs increase if the lack of competition results in these hospitals being unable to negotiate more favorable terms with plans and issuers. This dynamic could result in some small rural hospitals seeing their revenue decrease as reimbursement rates decline and overall costs increase, though rural hospitals could also see reduced costs and burdens if they are able to successfully negotiate more favorable network contracts. Due to a lack of information and overall knowledge, the Departments are not able to confidently estimate the effects the final rules will have on small rural hospitals; however, the Departments are of the view that the final rules will not have a significant impact on the operations of a substantial number of small rural hospitals.

Impact of Regulations on Small Business—Department of the Treasury

Pursuant to section 7805(f) of the Code, the proposed rules that preceded the final rules were submitted to the Chief Counsel for Advocacy of the SBA for comment on their impact on small businesses, and no comments were received.

C. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated

[296] The basis for this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans that cover fewer than 100 participants.

[297] *Id.* at 272.

costs and benefits and take certain actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million.

State, local, or tribal governments may incur costs to enforce some of the requirements of the final rules. The final rules include instructions for disclosures that would affect private sector firms (for example, issuers offering health insurance coverage in the individual and group markets, and TPAs providing administrative services to group health plans). The Departments acknowledge that state governments could incur costs associated with enforcement of sections within the final rules and, although the Departments have not been able to quantify all costs, the Departments expect the combined impact on state, local, and tribal governments to be below the threshold. The costs incurred by the private sector have been previously discussed in Collection of Information Requirements sections.

One commenter contended that due to the requirement to make the machine-readable files publicly available, issuers would also be required to post files with complete negotiated payment amount information, and that these files would be very complex, with thousands of procedure codes and many different plans and networks offered by issuers. The commenter further contended that due to the complexity and size of the files significant state resources would be required to review these files in order to ensure their accuracy, completeness, and timeliness. They contended that without funding states will be challenged in maintaining effective enforcement and urged the Departments to consider providing grants to states to cover the cost of enforcing any final rules.

The Departments recognize that due to size and complexity of the machine-readable files required some states will incur increased burdens and costs to review and ensure compliance with the requirements in the final rules. However, at this time, the Departments do not have available funding to provide grants to assist states in their efforts. The Departments will take it under consideration and evaluate the potential necessity to provide grants to assist states in their efforts should a significant need arise. The Departments expect that a number of states with the requisite authority to enforce the provisions of the final rules may defer enforcement to Federal regulators because of lack of funds.

D. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. Federal agencies promulgating regulations that have federalism implications must consult with state and local officials and describe the extent of their consultation and the nature of the concerns of state and local officials in this preamble to the regulation.

In the Departments' view, the final rules may have federalism implications, because they would have direct effects on the states, the relationship between national governments and states, and on the distribution of power and responsibilities among various levels of government relating to the disclosure of health insurance coverage information to the public.

Under the final rules, all group health plans and health insurance issuers, including self-insured, non-Federal governmental group health plans as defined in section 2791 of the PHS Act, will be required to develop an internet-based self-service tool to disclose to a participant, beneficiary, or enrollee, the consumer-specific estimated cost-sharing liability for covered items or services from a particular provider and also to provide this information by mail upon request. The final rules also require plans and issuers to disclose provider in-network rates, historical data on out-of-network allowed amounts, and negotiated rates and historical net prices for prescription drugs through digital files in a machine-readable format posted publicly on an internet website. Such Federal standards developed under section 2715A of the PHS Act preempt any related state standards that require pricing information to be disclosed to the participant, beneficiary, or enrollee, or otherwise publicly disclosed, to the extent the state disclosure requirements would provide less information to the consumer or the public than what is required under the final rules.

The Departments are of the view that the final rules may have federalism implications based on the required disclosure of pricing information, as the Departments are aware of at least 28 states that have passed some form of price-transparency legislation, such as all-payer claims databases, consumer-facing price comparison tools, and the right to shop programs.[298] Under these state provisions, state requirements vary broadly in terms of the level of disclosure required.[299] Some states list the price for each individual service, whereas some states list the aggregate costs across providers and over time to measure the price associated with an episode of illness. States also differ in terms of the dissemination of the information. For example, California mandates that uninsured patients receive estimated prices upon request. In contrast, other states use websites or software applications that allow consumers to compare prices across providers. Only seven states have published the pricing information of issuers on consumer-facing public websites.[300] Therefore, the final rules may require a higher level of disclosure by plans and issuers than some state laws.

One commenter asked that the Departments clarify their intentions regarding Federal preemption with respect to state laws that conflict with the final rules. Congress passed PPACA to improve the health insurance markets on a nationwide basis. *King.* v. *Burwell,* 135 S. Ct. 2480, 2496 (2015). Under section 1321(d) of PPACA and section 2724(a) of the PHS Act, nothing in these regulations would preempt state law unless such state law prevents the application of the applicable Federal requirement. Based on this legal context, the Departments intend the implementation of the rules to preempt state law to the extent enforcement of state law would prevent the application of PPACA.[301] To the extent the final rules preempt state law, they do so under well-settled law.

In general, through section 514, ERISA supersedes state laws to the extent that they relate to any covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. Furthermore, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act

[298] ''Transparency of Health Costs; State Actions.'' National Conference of State Legislatures. March 2017. Available at: *https://www.ncsl.org/research/health/transparency-and-disclosure-health-costs.aspx.*

[299] Mehrotra, A., Chernew, M., and Sinaiko, A. ''Promise and Reality of Price Transparency.'' 14 N. Engl. J. Med. 378. April 5, 2018. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMhpr1715229.*

[300] Evans, M. ''One State's Effort to Publicize Hospital Prices Brings Mixed Results.'' Wall Street Journal. June 26, 2019. Available at: *https://www.wsj.com/articles/one-states-effort-to-publicize-hospital-prices-brings-mixed-results-11561555562.*

[301] *See* section 1321(d) of PPACA (''Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.)

(implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the HIPAA requirements (including those of PPACA) are not to be ''construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a 'requirement' of a federal standard.'' The conference report accompanying HIPAA indicates that this preemption is intended to be the ''narrowest'' preemption of states laws (See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018). States may therefore continue to apply state law requirements to issuers except to the extent that such requirements prevent the application of PPACA requirements that are the subject of this rulemaking. Accordingly, states have significant latitude to impose requirements on issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, the Departments have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of NAIC, and consulting with state insurance officials on an individual basis. The Departments intend to act in a similar fashion in enforcing PPACA, including the provisions of section 2715A of the PHS Act. While developing the final rules, the Departments attempted to balance the states' interests in regulating issuers with Congress' intent to provide an improved level of price transparency to the public in every state. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to the final rules, the Departments certify that the Department of the Treasury, Employee Benefits Security Administration, and the CMS have complied with the requirements of Executive Order 13132 for the final rules in a meaningful and timely manner.

E. Congressional Review Act

The final rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information. Therefore, the final rules have been transmitted to the Congress and the Comptroller General. Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs designated the final rules as ''major rules'' as that term is defined in 5 U.S.C. 804(2), because it is likely to result in an annual effect on the economy of $100 million or more. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

F. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

The final rules are considered an Executive Order 13771 regulatory action. The Departments estimate that these rules will generate $3,489.71 million in costs in 2021, $10,761.15 million in 2022, $6,569 million in 2023, and annual costs of approximately $2,330 million thereafter. Discounted at 7 percent relative to year 2016, over a perpetual time horizon the annualized value of these costs is $2,413.54 million. Details on the estimated costs of the final rules can be found in the preceding analyses.

VII. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1135, 1185d, and 1191c; and Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 1311 of PPACA, 2701 through 2763, 2791, 2792, and 2794 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–94), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

Sunita Lough,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: October 28, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

Signed at Washington DC, this 30th day of October, 2020.

Jeanne Klinefelter Wilson,

Acting Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 8, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 20, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Amendments to the Regulations

For the reasons set forth in this preamble, the Department of the Treasury amends 26 CFR part 54 as set forth below:

PART 54—PENSION EXCISE TAXES

■ **Par. 1.** The authority citation for part 54 is amended by adding an entry for §§ 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

Sections 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3 are also issued under 26 U.S.C. 9833;

* * * * *

■ **Par. 2.** Sections 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3 are added to read as follows:

§ 54.9815–2715A1 Transparency in coverage—definitions.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth definitions for the price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage established in this section and §§ 54.9815–2715A2 and 54.9815–2715A3.

(2) *Definitions.* For purposes of this section and §§ 54.9815–2715A2 and 54.9815–2715A3, the following definitions apply:

(i) *Accumulated amounts* means:

(A) The amount of financial responsibility a participant or beneficiary has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts shall include the financial responsibility a participant or beneficiary has incurred toward meeting his or her individual deductible or out-of-pocket limit, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or out-of-pocket limit, as applicable. Accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or out-of-pocket limit (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant or beneficiary, has used within that time period).

(ii) *Beneficiary* has the meaning given the term under section 3(8) of the Employee Retirement Income Security Act of 1974 (ERISA).

(iii) *Billed charge* means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iv) *Billing code* means the code used by a group health plan or health insurance issuer or provider to identify health care items or services for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, National Drug Code (NDC), or other common payer identifier.

(v) *Bundled payment arrangement* means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant or beneficiary for a specific treatment or procedure.

(vi) *Copayment assistance* means the financial assistance a participant or beneficiary receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vii) *Cost-sharing liability* means the amount a participant or beneficiary is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost-sharing liability generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(viii) *Cost-sharing information* means information related to any expenditure required by or on behalf of a participant or beneficiary with respect to health care benefits that are relevant to a determination of the participant's or beneficiary's cost-sharing liability for a particular covered item or service.

(ix) *Covered items or services* means those items or services, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(x) *Derived amount* means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers, or submitting data in accordance with the requirements of 45 CFR 153.710(c).

(xi) *Historical net price* means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non-product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the historical net price in a machine-readable file in accordance with § 54.9815–2715A3. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under § 54.9815–2715A3(b)(1)(iii)(D)(*3*).

(xii) *In-network provider* means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary.

(xiii) *Items or services* means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care.

(xiv) *Machine-readable file* means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xv) *National Drug Code* means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xvi) *Negotiated rate* means the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvii) *Out-of-network allowed amount* means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider.

(xviii) *Out-of-network provider* means a provider of any item or service that does not have a contract under a participant's or beneficiary's group health plan or health insurance coverage to provide items or services.

(xix) *Out-of-pocket limit* means the maximum amount that a participant or beneficiary is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xx) *Plain language* means written and presented in a manner calculated to be understood by the average participant or beneficiary.

(xxi) *Prerequisite* means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite does not include medical necessity determinations generally or other forms of medical management techniques.

(xxii) *Underlying fee schedule rate* means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's or beneficiary's cost-sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount.

(b) [Reserved]

§ 54.9815–2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage for the timely disclosure of information about costs related to covered items and services under a group plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 54.9815–2715A1 apply.

(b) *Required disclosures to participants and beneficiaries.* At the request of a participant or beneficiary who is enrolled in a group health plan, the plan must provide to the participant or beneficiary the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section.

(1) *Required cost-sharing information.* The information required under this paragraph (b)(1) is the following cost-sharing information, which is accurate at the time the request is made, with respect to a participant's or beneficiary's cost-sharing liability for covered items and services:

(i) An estimate of the participant's or beneficiary's cost-sharing liability for a requested covered item or service furnished by a provider or providers that is calculated based on the information described in paragraphs (b)(1)(ii) through (iv) of this section.

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While group health plans and health insurance issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a group health plan or health insurance issuer may allow a participant or beneficiary to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as ''preventive'', ''non-preventive'' or ''diagnostic'' as a means to request the most accurate cost-sharing information.

(ii) Accumulated amounts.

(iii) In-network rate, comprised of the following elements, as applicable to the group health plan's or health insurance issuer's payment model:

(A) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service; this rate must be disclosed even if it is not the rate the plan or issuer uses to calculate cost-sharing liability; and

(B) Underlying fee schedule rate, reflected as a dollar amount, for the requested covered item or service, to the extent that it is different from the negotiated rate.

(iv) Out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider; provided, however, that in circumstances in which a plan or issuer reimburses an out-of-network provider a percentage of the billed charge for a covered item or service, the out-of-network allowed amount will be that percentage.

(v) If a participant or beneficiary requests information for an item or service subject to a bundled payment arrangement, a list of the items and services included in the bundled payment arrangement for which cost-sharing information is being disclosed.

(vi) If applicable, notification that coverage of a specific item or service is subject to a prerequisite.

(vii) A notice that includes the following information in plain language:

(A) A statement that out-of-network providers may bill participants or beneficiaries for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participant or beneficiary in the form of a copayment or coinsurance amount (the difference referred to as balance billing), and that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for these potential

additional amounts. This statement is only required if balance billing is permitted under state law;

(B) A statement that the actual charges for a participant's or beneficiary's covered item or service may be different from an estimate of cost-sharing liability provided pursuant to paragraph (b)(1)(i) of this section, depending on the actual items or services the participant or beneficiary receives at the point of care;

(C) A statement that the estimate of cost-sharing liability for a covered item or service is not a guarantee that benefits will be provided for that item or service;

(D) A statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's or beneficiary's deductible and out-of-pocket maximum;

(E) For items and services that are recommended preventive services under section 2713 of the PHS Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or non-preventive item or service; and

(F) Any additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the additional information does not conflict with the information required to be provided by this paragraph (b)(1).

(2) *Required methods and formats for disclosing information to participants and beneficiaries.* The methods and formats for the disclosure required under this paragraph (b) are as follows:

(i) *Internet-based self-service tool.* Information provided under this paragraph (b) must be made available in plain language, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request. Group health plans and health insurance issuers must ensure that the self-service tool allows users to:

(A) Search for cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers by inputting:

(*1*) A billing code (such as CPT code 87804) or a descriptive term (such as ''rapid flu test''), at the option of the user;

(*2*) The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and

(*3*) Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

(B) Search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by out-of-network providers by inputting:

(*1*) A billing code or descriptive term, at the option of the user; and

(*2*) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's or beneficiary's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.

(ii) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant or beneficiary. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant or beneficiary;

(B) Provide the cost-sharing information in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section; and

(C) Mail the cost-sharing information in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants or beneficiaries request disclosure other than by paper (for example, by phone or email), plans and issuers may provide the disclosure through another means, provided the participant or beneficiary agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(3) *Special rule to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years beginning on or after January 1, 2024.

(2) As provided under § 54.9815–1251, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 54.9815–2711(d)(6) or short-term, limited-duration insurance as defined in § 54.9801–2.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized

representatives to access participant or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 54.9815–2715A3 Transparency in coverage—requirements for public disclosure.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage for the timely disclosure of information about costs related to covered items and services under a group plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 54.9815–2715A1 apply.

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (b)(1) of this section in three machine-readable files, in accordance with the method and format requirements described in paragraph (b)(2) of this section, and that are updated as required under paragraph (b)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (b) that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate machine-readable file that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. The in-network rate machine-readable file must include:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) All applicable rates, which may include one or more of the following: negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the group health plan or health insurance issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(*1*) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant or beneficiary-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant or beneficiary-specific characteristics;

(*2*) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider;

(*3*) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(*4*) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(ii) An out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) Unique out-of-network allowed amounts and billed charges with respect to covered items or services, furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file (except that a group health plan or health insurance issuer must omit such data in relation to a particular item or service and provider when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 20 different claims for payments under a single plan or coverage). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(*1*) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(*2*) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

(iii) A prescription drug machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-

digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) The NDC and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration (FDA) for each covered item or service that is a prescription drug under each coverage option offered by a plan or issuer;

(C) The negotiated rates which must be:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC; and

(D) Historical net prices that are:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when compliance with this paragraph (b)(1)(iii)(D) would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for payment). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(iii)(D) requires the disclosure of information that would violate any applicable health information privacy law.

(2) *Required method and format for disclosing information to the public.* The machine-readable files described in this paragraph (b) must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services. The machine-readable files must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

(3) *Timing.* A group health plan or health insurance issuer must update the machine-readable files and information required by this paragraph (b) monthly. The group health plan or health insurance issuer must clearly indicate the date that the files were most recently updated.

(4) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Aggregation permitted for out-of-network allowed amounts.* Nothing in this section prohibits a group health plan or health insurance issuer from satisfying the disclosure requirement described in paragraph (b)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described in paragraph (b)(1)(ii)(C) of this section is independently met for each item or service and for each plan or coverage included in an aggregated Allowed Amount File. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or issuer has contracted may aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract. Additionally, nothing in this section prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available.

(c) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after January 1, 2022.

(2) As provided under § 54.9815–1251, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 54.9815–2711(d)(6) or short term limited duration insurance as defined in § 54.9801–2.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that

the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF LABOR

For the reasons set forth in this preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 3. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 4. Sections 2590.715–2715A1, 2590.715–2715A2, and 2590.715–2715A3 are added to read as follows:

§ 2590.715–2715A1 Transparency in coverage—definitions.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth definitions for the price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage established in this section and §§ 2590.715–2715A2 and 2590.715–2715A3.

(2) *Definitions.* For purposes of this section and §§ 2590.715–2715A2 and 2590.715–2715A3, the following definitions apply:

(i) *Accumulated amounts* means:

(A) The amount of financial responsibility a participant or beneficiary has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts shall include the financial responsibility a participant or beneficiary has incurred toward meeting his or her individual deductible or out-of-pocket limit, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or out-of-pocket limit, as applicable. Accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or out-of-pocket limit (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant or beneficiary, has used within that time period).

(ii) *Billed charge* means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iii) *Billing code* means the code used by a group health plan or health insurance issuer or provider to identify health care items or services for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, National Drug Code (NDC), or other common payer identifier.

(iv) *Bundled payment arrangement* means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant or beneficiary for a specific treatment or procedure.

(v) *Copayment assistance* means the financial assistance a participant or beneficiary receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vi) *Cost-sharing liability* means the amount a participant or beneficiary is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost-sharing liability generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(vii) *Cost-sharing information* means information related to any expenditure required by or on behalf of a participant or beneficiary with respect to health care benefits that are relevant to a determination of the participant's or beneficiary's cost-sharing liability for a particular covered item or service.

(viii) *Covered items or services* means those items or services, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(ix) *Derived amount* means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers, or submitting data in accordance with the requirements of 45 CFR 153.710(c).

(x) *Historical net price* means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non-product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the historical net price in a machine-readable file in accordance with § 2590.715–2715A3. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under § 2590.715–2715A3(b)(1)(iii)(D)(*3*).

(xi) *In-network provider* means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which

a relevant item or service is provided to a participant or beneficiary.

(xii) *Items or services* means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care.

(xiii) *Machine-readable file* means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xiv) *National Drug Code* means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xv) *Negotiated rate* means the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvi) *Out-of-network allowed amount* means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider.

(xvii) *Out-of-network provider* means a provider of any item or service that does not have a contract under a participant's or beneficiary's group health plan or health insurance coverage to provide items or services.

(xviii) *Out-of-pocket limit* means the maximum amount that a participant or beneficiary is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xix) *Plain language* means written and presented in a manner calculated to be understood by the average participant or beneficiary.

(xx) *Prerequisite* means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite does not include medical necessity determinations generally or other forms of medical management techniques.

(xxi) *Underlying fee schedule rate* means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's or beneficiary's cost-sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount.

(b) [Reserved]

§ 2590.715–2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage for the timely disclosure of information about costs related to covered items and services under a group plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 2590.715–2715A1 apply.

(b) *Required disclosures to participants and beneficiaries.* At the request of a participant or beneficiary who is enrolled in a group health plan, the plan must provide to the participant or beneficiary the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section.

(1) *Required cost-sharing information.* The information required under this paragraph (b)(1) is the following cost-sharing information, which is accurate at the time the request is made, with respect to a participant's or beneficiary's cost-sharing liability for covered items and services:

(i) An estimate of the participant's or beneficiary's cost-sharing liability for a requested covered item or service furnished by a provider or providers that is calculated based on the information described in paragraphs (b)(1)(ii) through (iv) of this section.

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While group health plans and health insurance issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a group health plan or health insurance issuer may allow a participant or beneficiary to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as ''preventive'', ''non-preventive'' or ''diagnostic'' as a means to request the most accurate cost-sharing information.

(ii) Accumulated amounts.

(iii) In-network rate, comprised of the following elements, as applicable to the group health plan's or health insurance issuer's payment model:

(A) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service; this rate must be disclosed even if it is not the rate the plan or issuer uses to calculate cost-sharing liability; and

(B) Underlying fee schedule rate, reflected as a dollar amount, for the requested covered item or service, to the extent that it is different from the negotiated rate.

(iv) Out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider; provided, however, that in circumstances in which a plan or issuer reimburses an out-of-network provider a percentage of the billed charge for a covered item or service, the out-of-network allowed amount will be that percentage.

(v) If a participant or beneficiary requests information for an item or service subject to a bundled payment arrangement, a list of the items and

services included in the bundled payment arrangement for which cost-sharing information is being disclosed.

(vi) If applicable, notification that coverage of a specific item or service is subject to a prerequisite.

(vii) A notice that includes the following information in plain language:

(A) A statement that out-of-network providers may bill participants or beneficiaries for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participant or beneficiary in the form of a copayment or coinsurance amount (the difference referred to as balance billing), and that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for these potential additional amounts. This statement is only required if balance billing is permitted under state law;

(B) A statement that the actual charges for a participant's or beneficiary's covered item or service may be different from an estimate of cost-sharing liability provided pursuant to paragraph (b)(1)(i) of this section, depending on the actual items or services the participant or beneficiary receives at the point of care;

(C) A statement that the estimate of cost-sharing liability for a covered item or service is not a guarantee that benefits will be provided for that item or service;

(D) A statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's or beneficiary's deductible and out-of-pocket maximum;

(E) For items and services that are recommended preventive services under section 2713 of the PHS Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or non-preventive item or service; and

(F) Any additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the additional information does not conflict with the information required to be provided by this paragraph (b)(1).

(2) *Required methods and formats for disclosing information to participants and beneficiaries.* The methods and formats for the disclosure required under this paragraph (b) are as follows:

(i) *Internet-based self-service tool.* Information provided under this paragraph (b) must be made available in plain language, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request. Group health plans and health insurance issuers must ensure that the self-service tool allows users to:

(A) Search for cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers by inputting:

(*1*) A billing code (such as CPT code 87804) or a descriptive term (such as ''rapid flu test''), at the option of the user;

(*2*) The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and

(*3*) Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

(B) Search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by out-of-network providers by inputting:

(*1*) A billing code or descriptive term, at the option of the user; and

(*2*) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's or beneficiary's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.

(ii) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant or beneficiary. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant or beneficiary;

(B) Provide the cost-sharing information in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section; and

(C) Mail the cost-sharing information in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants or beneficiaries request disclosure other than by paper (for example, by phone or email), plans and issuers may provide the disclosure through another means, provided the participant or beneficiary agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(3) *Special rule to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan

years beginning on or after January 1, 2024.

(2) As provided under § 2590.715–1251, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 2590.715–2711(d)(6) or short term limited duration insurance as defined in § 2590.701–2.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 2590.715–2715A3 Transparency in coverage—requirements for public disclosure.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage for the timely disclosure of information about costs related to covered items and services under a group plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 2590.715–2715A1 apply.

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (b)(1) of this section in three machine-readable files, in accordance with the method and format requirements described in paragraph (b)(2) of this section, and that are updated as required under paragraph (b)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (b) that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate machine-readable file that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. The in-network rate machine-readable file must include:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) All applicable rates, which may include one or more of the following: Negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the group health plan or health insurance issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(*1*) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant or beneficiary-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant or beneficiary-specific characteristics;

(*2*) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider;

(*3*) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(*4*) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(ii) An out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) Unique out-of-network allowed amounts and billed charges with respect to covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file (except that a group health plan or health insurance issuer must omit such data in relation to a particular item or service and provider when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 20 different claims for payments under a single plan or coverage). Consistent with paragraph

(c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(*1*) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(*2*) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

(iii) A prescription drug machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) The NDC, and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration (FDA), for each covered item or service under each coverage option offered by a plan or issuer that is a prescription drug;

(C) The negotiated rates which must be:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC; and

(D) Historical net prices that are:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when compliance with this paragraph (b)(1)(iii)(D) would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for payment). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(iii)(D) requires the disclosure of information that would violate any applicable health information privacy law.

(2) *Required method and format for disclosing information to the public.* The machine-readable files described in this paragraph (b) must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services. The machine-readable files must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

(3) *Timing.* A group health plan or health insurance issuer must update the machine-readable files and information required by this paragraph (b) monthly. The group health plan or health insurance issuer must clearly indicate the date that the files were most recently updated.

(4) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Aggregation permitted for out-of-network allowed amounts.* Nothing in this section prohibits a group health plan or health insurance issuer from satisfying the disclosure requirement described in paragraph (b)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described in paragraph (b)(1)(ii)(C) of this section is independently met for each item or service and for each plan or coverage included in an aggregated Allowed Amount File. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or issuer has contracted may aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract. Additionally, nothing in this section prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available.

(c) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after January 1, 2022.

(2) As provided under § 2590.715–1251, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 2590.715–2711(d)(6) or short term limited duration insurance as defined in § 2590.701–2.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph

(b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in this preamble, the Department of Health and Human Services amends 45 CFR parts 147 and 158 as set forth below:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 5. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 6. Sections 147.210, 147.211 and 147.212 are added to read as follows:

§ 147.210 Transparency in coverage—definitions.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth definitions for the price transparency requirements for group health plans and health insurance issuers in the individual and group markets established in this section and §§ 147.211 and 147.212.

(2) *Definitions.* For purposes of this section and §§ 147.211 and 147.212, the following definitions apply:

(i) *Accumulated amounts* means:

(A) The amount of financial responsibility a participant, beneficiary, or enrollee has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts shall include the financial responsibility a participant, beneficiary, or enrollee has incurred toward meeting his or her individual deductible or out-of-pocket limit, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or out-of-pocket limit, as applicable. Accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or out-of-pocket limit (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant, beneficiary, or enrollee has used within that time period).

(ii) *Billed charge* means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iii) *Billing code* means the code used by a group health plan or health insurance issuer or provider to identify health care items or services for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, National Drug Code (NDC), or other common payer identifier.

(iv) *Bundled payment arrangement* means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant, beneficiary, or enrollee for a specific treatment or procedure.

(v) *Copayment assistance* means the financial assistance a participant, beneficiary, or enrollee receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vi) *Cost-sharing liability* means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost-sharing liability generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(vii) *Cost-sharing information* means information related to any expenditure required by or on behalf of a participant, beneficiary, or enrollee with respect to health care benefits that are relevant to a determination of the participant's, beneficiary's, or enrollee's cost-sharing liability for a particular covered item or service.

(viii) *Covered items or services* means those items or services, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(ix) *Derived amount* means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers or submitting data in accordance with the requirements of § 153.710(c) of this subchapter.

(x) *Enrollee* means an individual who is covered under an individual health insurance policy as defined under section 2791(b)(5) of the Public Health Service (PHS) Act.

(xi) *Historical net price* means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non-product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the historical net price in a machine-readable file in accordance with § 147.212. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price

concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under § 147.212(b)(1)(iii)(D)(*3*).

(xii) *In-network provider* means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee.

(xiii) *Items or services* means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care.

(xiv) *Machine-readable file* means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xv) *National Drug Code* means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xvi) *Negotiated rate* means the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvii) *Out-of-network allowed amount* means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider.

(xviii) *Out-of-network provider* means a provider of any item or service that does not have a contract under a participant's, beneficiary's, or enrollee's group health plan or health insurance coverage to provide items or services.

(xix) *Out-of-pocket limit* means the maximum amount that a participant, beneficiary, or enrollee is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xx) *Plain language* means written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee.

(xxi) *Prerequisite* means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite does not include medical necessity determinations generally or other forms of medical management techniques.

(xxii) *Underlying fee schedule rate* means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount.

(b) [Reserved]

§ 147.211 Transparency in coverage—required disclosures to participants, beneficiaries, or enrollees.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 147.210 apply.

(b) *Required disclosures to participants, beneficiaries, or enrollees.* At the request of a participant, beneficiary, or enrollee who is enrolled in a group health plan or health insurance issuer offering group or individual health insurance coverage, the plan or issuer must provide to the participant, beneficiary, or enrollee the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section.

(1) *Required cost-sharing information.* The information required under this paragraph (b)(1) is the following cost-sharing information, which is accurate at the time the request is made, with respect to a participant's, beneficiary's, or enrollee's cost-sharing liability for covered items and services:

(i) An estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for a requested covered item or service furnished by a provider or providers, which must reflect any cost-sharing reductions the enrollee would receive, that is calculated based on the information described in paragraphs (b)(1)(ii) through (iv) of this section.

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While group health plans and health insurance issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a group health plan or health insurance issuer may allow a participant, beneficiary, or enrollee to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as ''preventive'', ''non-preventive'' or ''diagnostic'' as a means to request the most accurate cost-sharing information.

(ii) Accumulated amounts.

(iii) In-network rate, comprised of the following elements, as applicable to the group health plan's or health insurance issuer's payment model:

(A) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service; this rate must be disclosed even if it is not the rate the plan or issuer uses to calculate cost-sharing liability; and

(B) Underlying fee schedule rate, reflected as a dollar amount, for the requested covered item or service, to the

extent that it is different from the negotiated rate.

(iv) Out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider; provided, however, that in circumstances in which a plan or issuer reimburses an out-of-network provider a percentage of the billed charge for a covered item or service, the out-of-network allowed amount will be that percentage.

(v) If a participant, beneficiary, or enrollee requests information for an item or service subject to a bundled payment arrangement, a list of the items and services included in the bundled payment arrangement for which cost-sharing information is being disclosed.

(vi) If applicable, notification that coverage of a specific item or service is subject to a prerequisite.

(vii) A notice that includes the following information in plain language:

(A) A statement that out-of-network providers may bill participants, beneficiaries, or enrollees for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participant, beneficiary, or enrollee in the form of a copayment or coinsurance amount (the difference referred to as balance billing), and that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for these potential additional amounts. This statement is only required if balance billing is permitted under state law;

(B) A statement that the actual charges for a participant's, beneficiary's, or enrollee's covered item or service may be different from an estimate of cost-sharing liability provided pursuant to paragraph (b)(1)(i) of this section, depending on the actual items or services the participant, beneficiary, or enrollee receives at the point of care;

(C) A statement that the estimate of cost-sharing liability for a covered item or service is not a guarantee that benefits will be provided for that item or service;

(D) A statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's, beneficiary's, or enrollee's deductible and out-of-pocket maximum;

(E) For items and services that are recommended preventive services under section 2713 of the PHS Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or non-preventive item or service; and

(F) Any additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the additional information does not conflict with the information required to be provided by this paragraph (b)(1).

(2) *Required methods and formats for disclosing information to participants, beneficiaries, or enrollees.* The methods and formats for the disclosure required under this paragraph (b) are as follows:

(i) *Internet-based self-service tool.* Information provided under this paragraph (b) must be made available in plain language, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request. Group health plans and health insurance issuers must ensure that the self-service tool allows users to:

(A) Search for cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers by inputting:

(*1*) A billing code (such as CPT code 87804) or a descriptive term (such as ''rapid flu test''), at the option of the user;

(*2*) The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and

(*3*) Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

(B) Search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by out-of-network providers by inputting:

(*1*) A billing code or descriptive term, at the option of the user; and

(*2*) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's, beneficiary's, or enrollee's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.

(ii) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant, beneficiary, or enrollee. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant, beneficiary, or enrollee;

(B) Provide the cost-sharing information in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section; and

(C) Mail the cost-sharing information in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants, beneficiaries, and enrollees request disclosure other than by paper (for example, by phone or email), plans and issuers may provide the disclosure through another means, provided the participant, beneficiary, or enrollee agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(3) *Special rule to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) *Applicability.* (1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

(2) As provided under § 147.140, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 147.126(d)(6) or short term limited duration insurance as defined in 45 CFR 144.103.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 147.212 Transparency in coverage—requirements for public disclosure.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 147.210 apply.

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (b)(1) of this section in three machine-readable files, in accordance with the method and format requirements described in paragraph (b)(2) of this section, and that are updated as required under paragraph (b)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (b) that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate machine-readable file that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. The in-network rate machine-readable file must include:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) All applicable rates, which may include one or more of the following: Negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the group health plan or health insurance issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(*1*) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant, beneficiary, or enrollee-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant, beneficiary, or enrollee-specific characteristics;

(*2*) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider;

(*3*) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(*4*) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(ii) An out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health

insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) Unique out-of-network allowed amounts and billed charges with respect to covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file (except that a group health plan or health insurance issuer must omit such data in relation to a particular item or service and provider when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 20 different claims for payments under a single plan or coverage). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(*1*) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(*2*) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

(iii) A prescription drug machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) The NDC, and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration (FDA), for each covered item or service that is a prescription drug under each coverage option offered by a plan or issuer;

(C) The negotiated rates which must be:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC; and

(D) Historical net prices that are:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when compliance with this paragraph (b)(1)(iii)(D) would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for payment). Consistent with paragraph (b)(3) of this section, nothing in this paragraph (b)(1)(iii)(D) requires the disclosure of information that would violate any applicable health information privacy law.

(2) *Required method and format for disclosing information to the public.* The machine-readable files described in this paragraph (b) must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services. The machine-readable files must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

(3) *Timing.* A group health plan or health insurance issuer must update the machine-readable files and information required by this paragraph (b) monthly. The group health plan or health insurance issuer must clearly indicate the date that the files were most recently updated.

(4) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Aggregation permitted for out-of-network allowed amounts.* Nothing in this section prohibits a group health plan or health insurance issuer from satisfying the disclosure requirement described in paragraph (b)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described in paragraph (b)(1)(ii)(C) of this section is independently met for each item or service and for each plan or coverage included in an aggregated Allowed Amount File. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or issuer has contracted may aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract. Additionally, nothing in this section prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available.

(c) *Applicability.* (1) The provisions of this section apply for plan years (in the

individual market, for policy years) beginning on or after January 1, 2022.

(2) As provided under § 147.140, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 147.126(d)(6) or short term limited duration insurance as defined in § 144.103 of this subchapter.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 7. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 8. Section 158.221 is amended by adding paragraph (b)(9) to read as follows:

§ 158.221 Formula for calculating an issuer's medical loss ratio.

* * * * *

(b) * * *

(9) Beginning with the 2020 MLR reporting year, an issuer may include in the numerator of the MLR any shared savings payments the issuer has made to an enrollee as a result of the enrollee choosing to obtain health care from a lower-cost, higher-value provider.

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