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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG-118378-19]

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 -P]

RIN 0938-AU04

Transparency in Coverage

AGENCIES: 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: Proposed rule.

SUMMARY: These 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 (or his or her authorized representative), including an estimate of such individual's cost-sharing liability for covered items or services furnished by a particular provider. Under these proposed rules, plans and issuers would 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 (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. These proposed rules also include 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 insurance 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 proposes amendments to its medical loss ratio program rules to allow issuers offering group or individual health insurance coverage to receive credit in their medical loss ratio calculations for savings they share with enrollees that result from the enrollee's shopping for, and receiving care from, lower-cost, higher-value providers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of display at the Office of the **Federal Register**].

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared with the Department of the Treasury (Treasury Department), Internal Revenue Service (IRS) and the Department of Labor (DOL). Please do not submit duplicates.

All comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the internet exactly as received, and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, please refer to file code CMS-9915-P. Because of staff and resource limitations, the Departments of Labor, HHS, and the Treasury (the Departments) cannot accept comments by facsimile (FAX) transmission.

Comments must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9915-P,
P.O. Box 8010,
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9915-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. The comments are posted on the following website as soon as possible after they have been received <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

FOR FURTHER INFORMATION CONTACT:

Deborah Bryant, Centers for Medicare and Medicaid Services, (301) 492-4293

Christopher Dellana, Internal Revenue Service, (202) 317-5500

Matthew Litton or David Sydlik, Employee Benefits Security Administration, (202) 693-8335

Customer Service Information:

Individuals interested in obtaining information from the 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/ccio) and information on health reform can be found at <http://www.healthcare.gov>.

SUPPLEMENTARY INFORMATION:**I. Background****A. 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.”¹ Section 3(b) of Executive Order 13877 directs the Secretaries of the Departments of Labor, Health and Human Services (HHS), and the Treasury (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 have considered the issue, including by consulting with stakeholders, and have determined that a notice of proposed rulemaking (NPRM), rather than an ANPRM, would allow for more specific and useful feedback from commenters, who would be able to respond to specific proposals. Additionally, increases in health care costs and out-of-pocket liability without transparent, meaningful information about health care pricing have left consumers with little ability to make cost-conscious decisions when purchasing health care items and services. An NPRM, rather than an ANPRM, would enable the Departments to more quickly address this pressing issue.

¹ 84 FR 30849 (June 27, 2019). The Executive Order was issued on June 24, 2019 and was published in the **Federal Register** on June 27, 2019.

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

As explained earlier in this preamble, these proposed rules will fulfill the Departments' responsibility under Executive Order 13877. These proposed rules also would implement legislative mandates under sections 1311(e)(3) of the Patient Protection and Affordable Care Act (PPACA) and section 2715A of the Public Health Service (PHS) Act. The overarching goal of these proposed rules is to support a market-driven health care system by giving consumers the information they need to make informed decisions about their health care and health care purchases. Specifically, the purposes of these proposed rules are to provide consumers with price and benefit information that will enable them to evaluate health care options and to make cost-conscious decisions; reduce surprises in relation to consumers' out-of-pocket costs for health care services; create a competitive dynamic that will begin to narrow price differences for the same services in the same health care markets; foster innovation by providing industry the information necessary to support informed, price-conscious consumers in the health care market; and, over time, potentially lower overall health care costs. The Departments are of the view that this price transparency effort will equip consumers with information to actively and effectively participate in the health care system, the prices for which should be driven and controlled by market forces. For these reasons and those explained in more detail later in this preamble, these price transparency efforts are crucial to providing consumers with information about health care costs and to stabilizing health care spending.

As explained in the report “Reforming America’s Healthcare System through Choice and Competition,”² 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. Most health care consumers rely on third-party payers, including the government and private health insurance, to reimburse health care providers for a large portion of their health care costs. Third-party payers negotiate prices with health care providers and reimburse the providers on the consumer’s behalf, which conceals from consumers the true market price of their care. When consumers seek care, they do not typically know whether they could have received the same service from another provider offering lower prices. Because a large portion of insured consumers’ out-of-pocket financial liability has historically, for many consumers, not been dependent on the provider’s negotiated rate with the third-party payer, there has been little or no incentive for some consumers to consider price and seek out lower-cost care.³ However, as health care spending continues to rise, consumers are shouldering a greater portion of their health care costs.⁴

In the private health insurance market, consumers are responsible for a greater share of

² Azar, A.M., Mnuchin, S.T., and Acosta, A. “Reforming America’s Healthcare System Through Choice and Competition.” December 3, 2018. Available at: <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>.

³ *Id.*

⁴ 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/>.

their health care costs through higher deductibles and shifts from copayments to coinsurance.⁵ A deductible is the amount a consumer pays for covered health services before his or her health plan starts to pay.⁶ Generally, the amount the consumer pays for a specific item or service furnished by a network provider before the deductible is met is the rate the group health plan or health insurance issuer has negotiated with the provider, also referred to as the negotiated rate. A study of large employer health plans found that the portion of payments paid by consumers for deductibles increased from 20 percent to 51 percent between 2003 and 2017.⁷ Furthermore, enrollment in health plans with high deductibles is also increasing. In 2018, the Centers for Disease Control and Prevention estimated that 47 percent of persons under age 65 with private health insurance were enrolled in health plans with high deductibles, up from 25.3 percent in 2010.⁸

Coinsurance is the percentage of costs a participant, beneficiary, or enrollee pays for a covered item or service after he or she has paid his or her deductible.⁹ Copayments (sometimes called "copays") are a fixed amount (\$20, for example) that a consumer pays for a covered item

⁵ 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-contributions-and-cost-sharing-for-families-with-large-employer-coverage/>

⁶ <https://www.healthcare.gov/glossary/deductible/>

⁷ 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/>.

⁸ Cohen, R., Martinez, M., Zammitti, E. "Health insurance Coverage: Early Release of Estimates from the National Health Interview Survey, January-March 2018." August 2018. Available at: <https://www.cdc.gov/nchs/data/nhis/earlyrelease/Insur201808.pdf>.

⁹ <https://www.healthcare.gov/glossary/co-insurance/>.

or service, usually when he or she receives the service. Copays can vary for different items or services within the same plan, like prescription drugs, laboratory tests, and visits to specialists.¹⁰ Copayments are both more predictable for consumers, because the copayment amount is set in advance, and often less expensive for consumers than coinsurance amounts. For instance, assuming an individual has met his or her deductible, if a plan or issuer has negotiated the cost of a procedure with a particular provider to be \$1000, and the plan or issuer has a 20 percent coinsurance requirement, the individual would be responsible for paying a \$200 coinsurance amount toward the cost of the procedure.

In the health care market, where consumers generally are responsible for paying higher deductibles and have more cost sharing in the form of coinsurance, out-of-pocket liability is often directly contingent upon the reimbursement rate a health plan has negotiated with a provider. The fact that more consumers are bearing greater financial responsibility for the cost of their health care provides the opportunity to establish a consumer-driven health care market. 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.¹¹ Currently, however, consumers have little insight into negotiated rates until after services are rendered. As

¹⁰ <https://www.cms.gov/CCIIO/Resources/Files/Downloads/uniform-glossary-final.pdf>

¹¹ Azar, A.M., Mnuchin, S.T., and Acosta, A. "Reforming America's Healthcare System Through Choice and Competition." December 3, 2018. Available at: <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>.

a result, it can be difficult for consumers to estimate potential out-of-pocket costs because of the wide variability in health care prices for the same service.¹²

Without transparency in pricing, there are little to no market forces to drive competition, as demonstrated by significant variations in prices for procedures,¹³ even within a local region. For example, a study of price variation in the San Francisco area showed that, even for a relatively commoditized service such as a lower-back MRI, prices ranged from \$500 to \$10,246.¹⁴ A study on reference pricing in the California Public Employees' Retirement System found a range of \$12,000 to \$75,000 for the same joint replacement surgery, \$1,000 to \$6,500 for cataract removal, and \$1,250 to \$15,500 for arthroscopy of the knee.¹⁵ Variability in pricing, such as in these examples, suggests that there is substantial opportunity for increased transparency to save money by shifting patients from high to lower-cost providers.¹⁶

Many empirical studies have investigated the impact of price transparency on markets, with most research showing that price transparency leads to lower and more uniform prices, consistent with predictions of standard economic theory. One study notes special characteristics

¹² Cooper, Z., Craig, S., Gaynor, M., Reenen J. "The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured." 134. Q. J. of Econ 51. September 4, 2018. Available at: <https://academic.oup.com/qje/article/134/1/51/5090426?searchresult=1>.

¹³ *Id.*

¹⁴ Pinder, J. "Why do MRI prices vary so much? And a note about our data." Clear Health Costs. July 17, 2014. Available at: <https://clearhealthcosts.com/blog/2014/07/prices-vary-much-mini-case-study-mri/>.

¹⁵ Boynton, A., Robinson, J. "Appropriate Use of Reference Pricing Can Increase Value." Health Affairs Blog. July 7, 2015. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20150707.049155/full/>.

¹⁶ 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>.

of the health 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 must serve as their agents; and (3) patients are in a poor position to choose a hospital because they do not have a lot of information about hospital quality and costs.¹⁷ 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.

In Kentucky, public employees are provided with a price transparency tool that allows them to shop for health care services and share in any cost-savings realized by seeking lower-cost care. Over a 3-year period, 42 percent of eligible employees used the program to look up information about prices and rewards and 57 percent of those chose at least one more 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.¹⁸ In 2007, New Hampshire launched a website that allows consumers with private health insurance to compare health care

¹⁷ 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/secretary/RL34101.pdf>.

¹⁸ Rhoads, J. "Right to Shop for Public Employees: How Health Care Incentives are Saving Money in Kentucky." Dartmouth Inst. for Health Pol'y and Clinical Prac. March 8, 2019. Available at: <https://thefga.org/wp-content/uploads/2019/03/RTS-Kentucky-HealthCareIncentivesSavingMoney-DRAFT8.pdf>.

costs and quality.¹⁹ In a recent study of the New Hampshire price transparency tool, researchers found that health care price transparency can shift care to lower-cost providers and save consumers and payers money.²⁰ The study specifically focused on X-rays, CT scans, and MRI scans; determined that the transparency tool reduced the costs of medical imaging procedures by 5 percent for patients and 4 percent for issuers; and estimated savings of \$7.9 million for patients and \$36 million for issuers over a 5-year period. At the end of the 5-year period, out-of-pocket costs for these services in New Hampshire were 11 percent lower than for medical imaging services not included in the transparency tool. Individuals who had not yet satisfied their deductible saw almost double the savings, and prices for services listed in the tool became less dispersed over time.²¹ The Departments are of the view that health care markets could work more efficiently and provide consumers with lower cost health care if individuals could see an estimate of their out-of-pocket liability prior to making their health care purchases.

A study of enrollees in plans with high deductibles found that respondents wanted additional health care pricing information so they could make more informed decisions about

¹⁹ “Compare Health Costs & Quality of Care in New Hampshire.” NH HealthCost. <https://nhhealthcost.nh.gov/>

²⁰ Brown, Z. “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

²¹ *Id.*

where to seek care based on price.²² Another study found that 71 percent of respondents said that out-of-pocket spending was either important or very important to them when choosing a doctor.²³

Currently, the information that consumers need to make informed decisions based on the prices of health care services is not readily available. 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 effectively shop for value.²⁴ The report references a number of barriers that make it difficult for consumers to obtain price estimates in advance for health care services. Such barriers include, for example, the difficulty of predicting health care service needs in advance, a complex billing structure resulting in bills from multiple providers, the variety of insurance benefit structures, and the lack of public disclosure of rates negotiated between providers and third-party payers.

The GAO 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

²² Sinaiko, A., Mehrotra, A., Sood, N. “Cost-Sharing Obligations, High-Deductible Health Plan Growth, and Shopping for Health Care: Enrollees with Skin in the Game.” 176 JAMA Intern. Med. 395. March 2016. Available at: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2482348>.

²³ Ateev, M., Dean, K., Sinaiko, A., Neeraj, S. “Americans Support Price Shopping For Health Care, But Few Actually Seek Out Price Information.” 36 Health Affairs. 1392. August 2017. Available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2016.1471>.

²⁴ <https://www.gao.gov/products/GAO-11-791>

to limits reported by the initiatives in their access or authority to collect certain necessary price data. According to the GAO report, transparency initiatives that provided consumers with a reasonable estimate of their complete costs integrated pricing data from both providers and plans and issuers. The GAO report, therefore, recommended that HHS determine the feasibility, and the next steps, of making estimates of out-of-pocket costs²⁵ for health care services available to consumers.²⁶

States have been at the forefront of transparency initiatives and some have required disclosure of pricing information for years. 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.²⁷ As of early 2012, there were 62 consumer-oriented, state-based health care price comparison websites. Half of these websites were launched after 2006, and most were hosted by a state government agency (46.8 percent) or hospital association (38.7 percent). Most websites reported prices of inpatient care for medical conditions (72.6 percent) or surgeries (71.0 percent). Information about prices of outpatient services such as diagnostic or screening procedures (37.1 percent), radiology studies (22.6 percent), prescription drugs (14.5 percent), or laboratory tests (9.7 percent) were reported less

²⁵ GAO defines an estimate of a consumer's complete health care cost as pricing information on a service that identifies a consumer's out-of-pocket cost, including any negotiated discounts, and all costs associated with a service or services.

²⁶ <https://www.gao.gov/products/GAO-11-791>

²⁷ Frakt, A., Mehrotra, A. "What Type of Price Transparency Do We Need in Health Care?" 170 Ann. Intern. Med. 561. April 16, 2019. Available at: https://mfprac.com/web2019/07literature/literature/Misc/HealthTransparency_Frankt.pdf.

often.²⁸ However, it is important to note that the state efforts directed at plans are not applicable to self-insured group health plans. As a result, the data collected does not include data from self-insured group health plans and a significant portion of consumers would not have access to information on their plans.

States have adopted a variety of approaches to improve price transparency.²⁹ In 2012, Massachusetts began requiring issuers to provide, upon request, the estimated amount insured patients would be responsible to pay for proposed admissions, procedures, or services based upon the information available to the issuer at the time, and also began requiring providers to disclose the charge for the admission, procedure, or service upon request by the patient within 2 working days.³⁰ Sixteen states have implemented all-payer claims databases that include health care prices and quality information; and of these 16 states, 8 states make both price and quality information available to the public through state-based websites.³¹

Health insurance issuers and self-insured group health plans also have moved in the direction of increased price transparency. For example, some group health plans are using price transparency tools to incentivize employees to make cost conscious decisions when purchasing health care services. Most large issuers have embedded cost estimator tools into their enrollee

²⁸ Kullgren, J., Duey, K, Werner, R. “A Census of State Health Care Price Transparency Websites.” 309 JAMA 2437. June 19, 2013. Available at: <https://jamanetwork.com/journals/jama/fullarticle/1697957>.

²⁹ “2017 Price Transparency & Physician Quality Report Card.” Catalyst for Payment Reform. Available at: <https://www.catalyze.org/product/2017-price-transparency-physician-quality-report-card/>.

³⁰ Jenkins, K. “CMS Price Transparency Push Trails State Initiatives.” Nat’l L. Rev. February 8, 2019. Available at: <https://www.natlawreview.com/article/cms-price-transparency-push-trails-state-initiatives>.

³¹ “The State Of State Legislation Addressing Health Care Costs And Quality,” Health Affairs Blog. August 22, 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20190820.483741/full/>.

websites, and some provide their enrollees with comparative cost information, which includes rates that the issuers and plans have negotiated with in-network providers and suppliers.

In the HHS 2020 Notice of Benefit and Payment Parameters (2020 Payment Notice) proposed rule,³² HHS sought input on ways to provide consumers with greater transparency with regard to their own health care data, Qualified Health Plan (QHP) offerings on the Federally-facilitated Exchanges (FFEs),³³ and the cost of health care services. 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 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 out-of-pocket limits, 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

³² 84 FR 227 (Jan. 24, 2019).

³³ The term "Exchanges" means American Health Benefit Exchanges established under section 1311 of PPACA. See section 2791(d)(21) of the PHS Act.

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 group health plans and health insurance 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. Participants included a wide representation of stakeholders from providers, issuers, researchers, and consumer and patient advocacy groups. Participants noted that currently available pricing tools are underutilized, in part because consumers are often unaware that they exist, and even when used, the tools sometimes convey inconsistent and inaccurate information.

Participants also commented that tool development can be expensive, especially for smaller health plans, which tend to invest less in technology because of the limited return on investment. Participants also commented that most tools developed to date do not allow for comparison shopping. Participants stated that existing tools usually use historical claims data, which results in broad, sometimes regional estimates, rather than accurate and individualized prices. In addition, participants noted pricing tools are rarely available when and where consumers are likely to make health care decisions, for example, during interactions with providers. This means that patients are not able to consider relevant cost issues when discussing referral options or the tradeoffs of various treatment options with referring providers. In a national study, there was alignment between patients, employers, and providers in wanting to

know and discuss the cost of care at the point of service.³⁴ 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 treatment options.

In response to this feedback, CMS has pursued initiatives in addition to these proposed rules to improve access to the information necessary to empower consumers to make more informed decisions about their health care costs. These initiatives have included a multi-step effort to implement section 2718(e) of the PHS Act, which was added by section 1001 of PPACA (Pub. L. 111-148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152). Section 2718(e) of the PHS Act requires each hospital operating within the United States to, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) 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 Systems and Long Term Care Hospital Prospective Payment Systems (IPPS/LTCH PPS) final rule,³⁵ 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. 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, and

³⁴ "Let's Talk About Money." University of Utah. <https://uofuhealth.utah.edu/value/lets-talk-about-money.php>.

³⁵ 79 FR 49854, 50146, (Aug. 22, 2014).

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 final rule,³⁶ CMS again reminded hospitals of their obligation to comply with section 2718(e) of the PHS Act and announced an update to its guidelines. 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. The intent of the guidelines is to improve consumer access to important information regarding the cost of their health care through hospital websites. Price transparency and the ability to compare standard charges across hospitals can empower consumers to be more informed and exercise greater control over their purchasing decisions.

In response to stakeholder feedback and Executive Order 13877, 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

³⁶ 83 FR 41144, 41686 (Aug. 17, 2018).

(CMS-1717-F2) final rule (OPPS Price Transparency final rule) by codifying requirements under 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.³⁷ To further improve public access to meaningful hospital charge information, CMS is requiring hospitals to make publicly available their gross charges (as found in the hospital's chargemaster), their payer-specific negotiated charges, their discounted cash prices, and their 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 final rule requires hospitals to display online in a consumer-friendly format the payer-specific negotiated charges, discounted cash prices 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 less than 300 shoppable services, then as many as the hospital provides). CMS defines shoppable services as a service that can be scheduled by a health care consumer in advance, and has further explained that shoppable services are typically those that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient, thus allowing patients to price shop and schedule such services at times that are convenient for them.

³⁷ Published elsewhere in this Federal Register.

The Departments have concluded that the final rules under section 2718(e) of the PHS Act would not result in consumers 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.³⁸ In addition, because section 2718(e) of the PHS Act applies only to items and services provided by hospitals, the final requirements under that section would not improve the price transparency of items and services provided by other health care entities. Accordingly, the Departments have concluded that additional price transparency efforts are necessary 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.

Despite these price transparency efforts, there continues to be a lack of easily accessible pricing information for consumers to use when shopping for health care services. While there are several efforts across states, many still do not require private market plans and issuers to provide real-time, out-of-pocket cost estimates to participants, beneficiaries, and enrollees.³⁹ Furthermore, states do not have authority to require such disclosures to participants and beneficiaries of self-insured group health plans, which compose a significant portion of the private market.⁴⁰ These proposed 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

³⁸ <https://www.gao.gov/products/GAO-11-791>.

³⁹ "2017 Price Transparency & Physician Quality Report Card." Catalyst for Payment Reform. Available at: <https://www.catalyze.org/product/2017-price-transparency-physician-quality-report-card/>.

⁴⁰ Self-Insured Health Benefit Plans 2019: Based on Filings through Statistical Year 2016. 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>.

reforming health care markets by promoting transparency, competition, and choice across the health care industry.

The Departments, therefore, believe that additional rulemaking is necessary and appropriate to ensure consumers can exercise meaningful control over their health care and health care spending. The disclosures that the Departments are proposing to require would ensure consumers have ready access to the information they need to estimate their potential out-of-pocket costs for health care items and services before a service is delivered. These proposed rules would also 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 based on price, which is a fundamental factor in any purchasing decision.

C. Statutory Background and Enactment of PPACA

The Patient Protection and Affordable Care Act was enacted on March 23, 2010 and the Health Care and Education Reconciliation Act of 2010 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 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 plans and issuers providing health insurance 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 shall comply with section 1311(e)(3) of PPACA, except that a plan or coverage that is not offered through an Exchange shall only be required to submit the information required to the Secretary and the state's insurance commissioner, and make such information available to the public. Section 1311(e)(3) of PPACA addresses transparency in health care coverage and imposes certain reporting and disclosure requirements for health plans that are seeking certification as QHPs that may be offered on an Exchange.

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

- 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 this title.

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

Paragraph (C) requires those 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 shall be made available to such individual through an internet website and such other means for individuals without access to the internet.

On March 27, 2012, HHS issued the Exchange Establishment final rule⁴¹ that implemented sections 1311(e)(3)(A) through (C) of PPACA at 45 CFR 155.1040(a) through (c) and 156.220. 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 state insurance commissioner. In the preamble to the Exchange Establishment final rule, HHS noted that "health plan standards set forth under this final rule 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 (MLR)

Section 2718(a) and (b) of the PHS Act, as added by PPACA, generally requires health insurance issuers to submit an annual MLR report to HHS, and provide rebates to enrollees if the

⁴¹ <https://www.govinfo.gov/content/pkg/FR-2012-03-27/pdf/2012-6125.pdf>.

issuers do not achieve specified MLR thresholds. HHS proposes to amend its MLR program rules under section 2718(c) of the PHS Act, under which the 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 proposes to recognize the special circumstances of a different and newer type of plan for purposes of MLR reporting and calculations when that plan shares savings with consumers who choose lower-cost, higher-value providers. HHS proposes to revise 45 CFR 158.221 to add a new paragraph (b)(9) to allow such shared savings, when offered by an issuer, to be factored into an issuer's MLR numerator calculation beginning with the 2020 MLR reporting year.

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

The Departments propose the price transparency requirements set forth in these proposed rules in new 26 CFR 54.9815-2715A, 29 CFR 2590.715-2715A, and 45 CFR 147.210.

Paragraph (a) of the proposed rules sets forth the scope and relevant definitions. Paragraph (b) of the proposed rules includes: (1) a requirement that group health plans and health insurance issuers in the individual and group markets disclose to participants, beneficiaries, or enrollees (or their authorized representatives) upon their 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. Paragraph (c) of the proposed rules would require that plans and issuers disclose to the public, through two machine-readable files, the negotiated rates

for in-network providers, and unique amounts a plan or issuer allowed for items or services furnished by out-of-network providers during a specified time period.

The Departments request comments on all aspects of these proposed rules. In the preamble discussion that follows, the Departments also solicit comments on a number of specific issues related to the proposed rules where stakeholder feedback would be particularly useful in evaluating whether and how to issue final rules.

Sections III and IV of this preamble include requests for information on topics closely related to this rulemaking. Due to the design and capability differences among the information technology systems of plans and issuers, as well as difficulties consumers experience in deciphering information relevant to health care and health insurance, the Departments seek comment on additional price transparency requirements that could supplement the proposed requirements of paragraphs (b) and (c) of these proposed rules. For example, in section III, the Departments seek comment on whether the Departments should require plans and issuers 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).

Section IV of this preamble requests comment on how existing quality data on health care provider items and services can be leveraged to complement the proposals in these proposed rules. Although these proposed rules do not include any health care quality disclosure

requirements, the Departments appreciate the importance of health care quality information in providing consumers the information necessary to make value-based health care decisions.⁴²

A. Proposed Requirements for Disclosing Cost-Sharing Information to Participants, Beneficiaries, or Enrollees

As described earlier in this preamble, the Departments' intention regarding these proposed rules is 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, paragraph (b) of these proposed rules would 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 (or his or her authorized representative).

1. Information Required to be Disclosed to Participants, Beneficiaries, or Enrollees

Based on significant research and stakeholder input, the Departments conclude 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 that might be furnished by particular providers. The Departments, therefore, modeled these proposed price transparency requirements on existing notices that plans and

⁴² "2017 Price Transparency & Physician Quality Report Card." Catalyst for Payment Reform. Available at: <https://www.catalyze.org/product/2017-price-transparency-physician-quality-report-card/>.

issuers generally provide to participants, beneficiaries, or enrollees after health care items and services have been furnished.

Specifically, section 2719 of the PHS Act requires non-grandfathered plans and issuers to provide a notice of adverse benefit determination⁴³ (commonly referred to as an explanation of benefits (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 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. This proposal similarly would require plans and issuers to provide the specific price and benefit information on which an individual's cost-sharing liability is based.

The Departments have concluded that proposing to require plans and issuers to disclose to participants, beneficiaries, or enrollees price and benefit information that is analogous to the information that generally appears on an EOB would be the most effective and reasonable way to present cost-sharing information prior to the receipt of care, in a manner that can be understood by these individuals. Providing individuals with access to information generally included in EOBs before they receive covered items and services would enable individuals to understand their cost-sharing liability for the item or service and consider price when choosing a provider

⁴³ An adverse benefit determination means an adverse benefit determination as defined in 29 CFR 2560.503-1, as well as any rescission of coverage, as described in 29 CFR 2590.715-2712(a)(2) (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time). See 26 CFR 54.9815-2719, 29 CFR 2590.715-2719 and 45 CFR 147.136. Plans subject to the requirements of ERISA (including grandfathered health plans) are also subject to a requirement to provide an adverse benefit determination under 29 CFR 2560.503-1.

from whom to receive the item or service. Cost-sharing liability estimates would be required to be built upon accurate information, including actual negotiated rates, out-of-network allowed amounts, and individual-specific accumulated amounts. This does not mean the Departments would require that the estimate reflect the amount that is ultimately charged to a participant, beneficiary, or enrollee. Instead, the estimate would 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, these proposed rules would not require the cost-sharing liability estimate to include costs for unanticipated items or services the individual could incur due to the severity of the his or her illness or injury, provider treatment decisions, or other unforeseen events.

In designing this price transparency proposal, the Departments also considered stakeholder input regarding the importance of protecting proprietary information. As explained earlier in this preamble, all of the information that would be required to be disclosed under these proposed rules is currently disclosed in EOBs that plans and issuers provide to individuals as a matter of course after services have been furnished and payment has been adjudicated. Therefore, the Departments are of the view that the proposed requirement that plans and issuers disclose this same information, to the same parties, before services are rendered does not pose any greater risk to plan or issuer proprietary information.

Consistent with how the information for an item or service would typically be presented on an EOB, the Departments propose to allow plans and issuers 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 bundles payment, according to how the plan or issuer structures payment for the item or service. Accordingly, these proposed

rules set forth seven content elements that a plan or issuer must disclose, upon request, to a participant, beneficiary, or enrollee (or his or her authorized representative) for a covered item or service, to the extent relevant to the individual's cost-sharing liability for the item or service. These seven content elements generally reflect the same information that is included in an EOB after health care services are provided. The Departments have determined that each of the content elements is 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 under a plan or coverage to learn the amount of their cost-sharing liability for specific items or services under a plan or coverage from a particular provider. The Departments propose 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 processed.

Furthermore, under these proposals, the cost-sharing information would need to be disclosed to the participant, beneficiary, or enrollee in plain language. The proposed 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. 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.

a. First Content Element: Estimated cost-sharing liability

The first content element that plans and issuers would be required to disclose under these proposed rules would be 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 would be required to be computed based on the other relevant cost-sharing information that plans and issuers would be required to disclose, as described later in this section of the preamble.

The proposed rules define “cost-sharing liability” to mean 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. Cost-sharing liability calculations must consider all applicable forms of cost sharing, including deductibles, coinsurance requirements, and copayments. The term cost-sharing liability does not include premiums, balance billing amounts for 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.

The proposed rules define “items or services” to mean all encounters, procedures, medical tests, supplies, drugs, durable medical equipment, and fees (including facility fees), for which a provider charges a patient in connection with the provision of health care. This proposed definition of items or services is intended to be flexible enough to allow plans and issuers to disclose cost-sharing information for either discrete items or services for which an individual is seeking cost-sharing information, or, if the issuer bundles payment for items or

services associated with a treatment or procedure, for a set of items or services included in the bundle. These proposed rules further define “covered items or services” to mean items or services for which the costs are payable, in whole or in part, under the terms of a plan or coverage. The Departments solicit comment on 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 or providers. The Departments also solicit comment on these definitions.

b. Second Content Element: Accumulated amounts

The second content element would be a participant’s, beneficiary’s, or enrollee’s accumulated amounts. These proposed rules define “accumulated amounts” to mean the amount of financial responsibility that a participant, beneficiary, or enrollee has incurred at the time the request for cost-sharing information is made, either with respect to a deductible or an out-of-pocket limit (such as the annual limitation on cost sharing provided in section 2707(b) of the PHS Act, as incorporated into ERISA and the Code, or a maximum out-of-pocket amount the plan or issuer establishes that is lower than the requirement under the PHS Act). In the case where an individual is enrolled in a family plan or coverage (or 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.⁴⁴ For this purpose, 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).

The Departments understand that certain cumulative treatment limitations 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, plans and issuers would be required to provide cost-sharing information with respect to an accumulated amount for a cumulative treatment limitation that reflects the status of the

⁴⁴ The Departments read section 2707(b) as requiring non-grandfathered group health plans to comply with the maximum annual limitation on cost sharing promulgated under section 1302(c)(1) of PPACA, including the HHS clarification that the self-only maximum annual limitation on cost sharing 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 annual limitation on cost sharing applies to an individual who is enrolled in family coverage or other coverage that is not self-only coverage under a group health plan. See 80 FR 10749, 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>.

individual's progress toward meeting the limitation, and would 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 visits to 10 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 has been made at that time.

c. Third Content Element: Negotiated rate

The third content element under these proposed rules would be 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. These proposed rules define "negotiated rate" to mean the amount a plan or issuer, or a third party (such as a third-party administrator (TPA)) on behalf of a plan or issuer, has contractually agreed to pay an in-network provider for a covered item or service pursuant to the terms of an agreement between the provider and the plan, issuer, or third party on behalf of a plan or issuer. The Departments understand 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, these proposed rules would require disclosure of the rate that results from using such a formula, which would be required to be expressed as a dollar amount.

Negotiated rates generally are an essential input for the calculation of a participant's, beneficiary's, or enrollee's cost-sharing liability. For example, cost-sharing liability for a covered service with a 30 percent coinsurance requirement cannot be determined without knowing the negotiated rate of which an individual must pay 30 percent. Additionally, if an individual has not met an applicable deductible and the cost for a covered item or service from an in-network provider is less than the remaining deductible, then the cost-sharing liability will in fact be the negotiated rate. The Departments acknowledge, however, 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, 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 propose that disclosure of a negotiated rate would not be required under these proposed rules if it is not relevant for calculating an individual's cost-sharing liability for a particular item or service. The Departments seek comment on whether there are any reasons disclosure of negotiated rates should nonetheless be required under these circumstances.

Under these proposed rules, plans and issuers would be required to disclose to participants, beneficiaries, or enrollees an estimate of cost-sharing liability for items and services, including prescription drugs. This would allow individuals to request cost-sharing information for a specific billing code (as described later in this preamble) associated with a prescription drug or by descriptive term (such as the name of the prescription drug), which will permit individuals 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 individuals to obtain

cost-sharing information by using a billing code or descriptive term, the rules would also permit individuals 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. The proposed rules define the term “bundled payment” to mean a payment model under which a provider is paid a single payment for all covered items or services provided to a patient for a specific treatment or procedure. However, the Departments acknowledge 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 average wholesale price or wholesale acquisition cost, which frequently differs from the price the plan or issuer has negotiated for the prescription drug.⁴⁵ In these instances, providing the individual with a rate that has been negotiated between the issuer or plan and its pharmacy benefit manager 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 individual has not met his or her deductible. However, arguably, requiring the issuer to disclose only the rate upon which the individual’s cost-sharing liability estimate is based would perpetuate the lack of transparency around drug pricing.

The Departments seek comment regarding 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 individuals have access to meaningful cost-sharing liability estimates for prescription drugs. The Departments also solicit comment as to whether there are certain scenarios in which drug pricing

⁴⁵ “Follow the Dollar: How the pharmaceutical distribution and payment system shapes the prices of brand medicines.” PhRMA. November 2017. Available at <https://www.phrma.org/report/follow-the-dollar-report>.

information should not be included in an individual's estimated cost-sharing liability. For example, would the cost to an individual for a drug outside of a bundled payment arrangement be so impacted by factors beyond the negotiated rate for the drug, and not reasonably knowable by the plan or issuer, that the cost-sharing liability estimate for that drug would not be meaningful for the individual and should not be provided outside of a cost-sharing liability estimate for a bundled payment? Alternatively, should drug costs be required to be included in a cost-sharing liability estimate in all scenarios, including when the consumer searches for cost-sharing information for a particular drug by billing code or descriptive term in connection with items and services for which the plan or issuer does not bundle payment? The Departments also seek comment on whether the relationship between plans or issuers and pharmacy benefit managers⁴⁶ allows plans and issuers to disclose rate information for drugs, or if contracts between plans and issuers and pharmacy benefit managers 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 seek comment on the time that would be needed to make those changes.

d. Fourth Content Element: Out-of-network allowed amount

The fourth content element would be the out-of-network allowed amount for the requested covered item or service. 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. These proposed rules define "out-of-network allowed amount" to mean the maximum amount a plan or issuer would pay for a covered item or service furnished by

⁴⁶ Pharmacy benefit managers are third-party companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, self-insured group health plans, and other payers.

an out-of-network provider. Under these proposed rules, plans and issuers would be required to disclose an estimate of cost-sharing liability for a participant, beneficiary, or enrollee. Therefore, when disclosing an estimate of cost-sharing liability for an out-of-network item or service, the 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 instance, 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.

Because the proposed 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), 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. Nonetheless, under section 1311(e)(3)(A)(vii) of PPACA and section 2715A of the PHS Act, Congress intended that participants, beneficiaries, enrollees, and other members of the public have access to accurate and timely information on 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 if they request

additional information from an out-of-network provider about how much the provider would charge for a particular item or service.

e. Fifth Content Element: Items and services content list

The fifth content element would be a list of those covered items and services for which cost-sharing information is disclosed. This requirement would be relevant 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, rather than one discrete item or service. This requirement would not apply when an individual requests cost-sharing information for an item or service not subject to a bundled payment arrangement. 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. In the Departments' view, in order to support consumers' ability to shop for services, consumers need to know precisely what items and services are included in the cost-sharing information provided.

f. Sixth Content Element: Notice of prerequisites to coverage

The sixth content element would be a notice, 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 define 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, prerequisites include concurrent review, prior authorization, and step-therapy or fail-first protocols. The definition of prerequisite in these proposed rules is intended 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. Accordingly, the proposed definition of prerequisite does not include medical necessity determinations generally, or other forms of medical management techniques that do not require action by the participant, beneficiary, or enrollee. The Departments solicit comment on whether there are any additional medical management techniques that should be explicitly included as prerequisites in the final rules.

g. Seventh Content Element: Disclosure notice

The seventh and final content element would be a notice that communicates certain information in plain language and includes several specific disclosures. First, 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 plan or issuer and the amount collected from the patient 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. The Departments understand that there are numerous state laws that address balance-billing practices such that the notice described in this 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 request 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 notice would 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 notice would 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, under these proposed rules, plans and issuers would be permitted to include any additional information, including other disclaimers that the plan or issuer determines appropriate, as long as the additional information does not conflict with the information required to be provided. Plans and issuers would be 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. For example, plans and issuers may 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 may also 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, and seek comment on whether a disclaimer indicating the expiration of the cost estimate should be required. Furthermore, 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 consumer.

The Departments have 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 is being proposed contemporaneously with, but separate from, these proposed rules. The Departments seek comment on the proposed model language and any additional information that stakeholders believe should be included in the proposed model notice or any information that should be omitted from the proposed model notice. As noted later in the preamble, to obtain copies of the proposed model notice, please visit CMS's Website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410-786-1326. If you wish to comment, please submit your comments electronically as specified in the ADDRESSES section of these proposed rules and identify the rule (CMS-9915-P), the ICR's CFR citation, CMS ID number, and OMB control number.

The Departments further clarify that this proposed 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, notwithstanding 45 CFR 156.130(c), 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 annual limitation on cost sharing or provide a notice to the enrollee that additional costs may be incurred for an EHB, including balance billing charges.

The Departments request comment on the proposed notice disclaimers and whether any additional disclaimers would be necessary or beneficial to consumers' learning about their potential cost-sharing liability for covered items and services. For example, should the Departments require a notice that explains that the cost-sharing information provided may not account for claims an individual has submitted that the plan or issuer has not yet processed? The Departments are also considering 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 individual 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.

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, these proposed rules would require that group health plans and health insurance issuers disclose to participants, beneficiaries, or enrollees (or their authorized representatives) 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 these 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.

In order for plans and issuers to provide accurate cost-sharing information, the Departments understand that the participant, beneficiary, or enrollee will have to input certain data elements into the tool. Therefore, 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, 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. With respect to a request for cost-sharing information for all in-network providers, 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 each tier. 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. The Departments request comment on whether there are any scenarios under which plans and issuers may not be able to ascertain the in-network facilities at which an in-network provider furnishes services.

As stated previously, the Departments acknowledge that plans and issuers may not have sufficient information on providers outside of their network to provide the participant, beneficiary, or enrollee a complete estimate of out-of-pocket expenses, since the plan or issuer may not know what the out-of-network provider will bill for an item or service. However, if the plan or issuer provides coverage for out-of-network items or services, the plan or issuer generally will have established an out-of-network allowed amount that the participant, beneficiary, or enrollee could use, in conjunction with information he or she may request from the out-of-network provider about what the total bill for services may be, to compute an estimate of his or her out-of-pocket expenses. It is 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 out-of-network provider's allowed amount for a covered item or service (such as by zip code or state). Therefore, plans and issuers 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 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 and the amount of estimated cost-sharing liability to the beneficiary, participant, or enrollee. The Departments solicit 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.

It is the Departments' intention that these proposed rules would require plans and issuers to create a user-friendly internet-based self-service tool, but these proposed rules do not include a definition for "user-friendly" since there are a variety of ways a tool can be designed to be user-friendly. The Departments want to preserve plan and issuer flexibility to create tools that are best for their participants, beneficiaries, or enrollees, 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 paragraph (b)(1) of these proposed rules efficiently and effectively, without unnecessary effort. The Departments are of the view that plans and issuers can look to federal plain language guidelines,⁴⁷ the requirements for a Summary Plan Description's method of presentation at 29 CFR 2520.102-2(a), and general industry standards for guidance when

⁴⁷ <https://www.plainlanguage.gov/guidelines>

designing and developing their consumer tools. The Departments solicit comment on whether there is different or additional guidance that should be consulted.

These proposed rules require that the self-service tool be made available on an internet website to provide consistency with section 1311(e)(3)(C) of PPACA, which uses the term “internet website.” However, the Departments seek 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 acknowledge that there may be technical differences between a website and other methods of viewing internet-based content, such as mobile applications. However, 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.

Mobile applications also may provide additional benefits beyond those of traditional websites. Due to the portability of mobile devices, a self-service tool that is similar to the kind required for an internet website under these proposed rules 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 understand that mobile applications may, in certain cases, offer greater privacy and security protections than an internet website for the information protected by applicable privacy and security requirements, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rules (45 CFR parts 160

and 164) (HIPAA Rules) that would be accessible through the proposed tool. Accordingly, the Departments seek 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 seek comment on the relative resources required for building an internet website versus an internet-based mobile application.

b. Second Delivery Method: Paper form

With respect to a delivery method that would not require a participant, beneficiary, or enrollee (or his or her authorized representative) to have access to the internet, plans and issuers would have to furnish, at the request of the of the participant, beneficiary, or enrollee (or his or her authorized representative), without a fee, all of the information required to be disclosed under paragraph (b)(1) of these proposed rules, as outlined earlier in this preamble, in paper form. A plan or issuer would be required to provide the information in accordance with the requirements under paragraph (b)(2)(i) of these proposed rules 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.

This information would be required to be mailed to a participant, beneficiary, or enrollee no later than 2 business days after a participant's, beneficiary's, or enrollee's request is received. This would mean that cost-sharing information must be mailed via the U.S. Postal Service or some other delivery system within 2 business days of receipt of an individual's request. Nothing in these proposed rules prohibits a plan or issuer from providing individuals with the option to request disclosure of the information required under paragraph (b)(1) of these proposed rules through other methods (such as, over the phone, through face-to-face encounters, by facsimile, or by email).

The Departments request comment on these proposed disclosure methods, including whether additional methods of providing information should be required, rather than permitted. The Departments are 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.

The Departments also are considering requiring all plans and issuers to allow individuals to seek cost-sharing information by inputting a description of a treatment or procedure (such as knee replacement) that often involves the provision of multiple items and services. The Departments are interested in feedback on whether it would be feasible for plans and issuers to allow individuals to request cost-sharing information by such a treatment or procedure if the plan or issuer makes payments based on a discrete billing code for each item and service associated

with a treatment or procedure, and not as a bundled payment for all items and services associated with the treatment or procedure. For instance, if an individual requests cost-sharing information for a knee replacement, and the plan or issuer does not bundle payment for multiple items and services provided in connection with a knee replacement, would it be unduly burdensome for a plan or issuer to disclose meaningful cost-sharing information for items and services typically provided in connection with a knee replacement?

3. Special Rule to Prevent Unnecessary Duplication

These proposed rules include a special rule to streamline the provision of the required disclosures and avoid unnecessary duplication of the disclosures with respect to group health coverage. The proposed special rule is similar to the one that applied with respect to the requirement for group health plans and health insurance issuers to provide certificates of creditable coverage before that requirement was generally superseded by PPACA.⁴⁸

The special rule provides that to the extent coverage under a plan consists of group health insurance coverage, the plan would satisfy the requirements of these proposed rules if the issuer offering the coverage is required to provide the information pursuant to a written agreement between the plan and issuer. Accordingly, for example, if there were a plan and an issuer that

⁴⁸ As of December 31, 2014, group health plans are generally no longer required to provide HIPAA certificates of creditable coverage. See 26 CFR 9801-5 and 29 CFR 2590.701-5. An exception to this general rule is expatriate health plans, which must satisfy the provisions of title XXVII of the PHS Act, Chapter 100 of the Code, and part 7 of subtitle B of title I of ERISA that would otherwise apply if PPACA had not been enacted. See section 3(d)(2)(G) of the Expatriate Health Coverage Clarification Act (EHCCA), enacted as Division M of the Consolidated and Further Continuing Appropriations Act of 2015.

enter into a written agreement under which the issuer agrees to provide the information required under these proposed rules, and the issuer failed to provide full or timely information, then the issuer, but not the plan, would violate the transparency disclosure requirements.⁴⁹

4. Privacy, Security, and Accessibility

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

The Departments also expect that plans and issuers will follow existing applicable state and federal laws regarding persons who must be allowed to access and receive the information that would be disclosed under these proposed rules. These proposed rules refer to such persons as "authorized representatives" and do not establish any new class of persons or entities who are authorized to access the information that would be provided through the proposed internet-based, self-service tool. Accordingly, the Departments expect plans and issuers to follow existing laws

⁴⁹ Under section 4980D(d)(1) of the Code, the excise tax for group health plans failing to satisfy these proposed 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.

with regard to persons who may or must be allowed to access the cost-sharing information that would be required to be disclosed under these proposed rules.

B. Proposed Requirements for Public Disclosure of Negotiated Rates and Historical Allowed Amount Data for Covered Items and Services from Out-of-Network Providers

The Departments take the position that health care spending cannot be curbed without more competition in the market, and competition cannot be achieved without greater price transparency. As explained earlier in this preamble, section 2715A of the PHS Act and section 1311(e)(3)(A) of PPACA require group health plans and health insurance issuers to make public certain specified information, as well as other information the Secretary of HHS determines to be appropriate to provide transparency in health coverage. Thus, these provisions evidence Congress' intent that members of the public play a role in using health coverage transparency information to promote consumer interests. Consistent with this authority, the Departments have determined that it would be appropriate to require plans and issuers to make public negotiated rates with in-network providers and data outlining the different amounts a plan or issuer has allowed for covered items or services furnished by out-of-network providers.

The Departments have concluded that public availability of such information would create price transparency for persons who are uninsured, as well as insured persons who are considering coverage alternatives. The proposal would also support meaningful comparisons between plan coverage options and issuer options for all consumers, comparisons that would not be supported through the internet-based consumer tool proposed earlier in this rule. In proposing requirements for public disclosure of negotiated rates and historical out-of-network allowed amounts, the Departments are exercising 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), which requires plans and issuers to disclose other information the Secretary of HHS determines to be appropriate to create transparency in health coverage.

As explained later in this preamble, the proposed disclosure requirements would provide consumers, including third-party software developers and health care researchers, information about health care prices that is necessary to make informed health care purchasing decisions. These requirements would also help to expose price differences so that consumers can judge the reasonableness of provider prices and shop for care at the best price. Accordingly, it is the Departments' view that public availability of negotiated rates and historical out-of-network allowed amounts 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.

1. Public disclosure of negotiated rates and historical out-of-network allowed amounts is necessary to create price transparency for all consumers and payers of health care items and services, as well as of benefit to state and federal regulators

First, public availability of negotiated rates and historical out-of-network allowed amounts would empower the nation's 28.5 million uninsured consumers⁵⁰ to make more informed health care decisions. Uninsured consumers often must pay full cost for health care items and services, such that pricing information is critical to their ability to evaluate their

⁵⁰ Keith, K. "Two New Federal Surveys Show Stable Uninsured Rate." Health Affairs Blog. September 13, 2018. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180913.896261/full/>

service options and control their health care spending. Uninsured consumers could use publicly-available pricing information to find affordable service providers or providers who offer the lowest price, depending on the consumer's personal needs and priorities. Provider lists of standard charges often do not reflect the true cost of particular items and services.⁵¹ Although a provider's negotiated rates with group health plans and health insurance 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, which could inform their own negotiations with that provider for the same item or service.

Second, information on 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. The proposed requirements that plans and issuers disclose negotiated rates and out-of-network allowed amounts to their participants, beneficiaries, or enrollees (or their authorized representatives) through an internet self-service tool or in paper form will make critical pricing information available to consumers with health insurance coverage. However, the Departments are of the view that both insured and uninsured consumers need access to data on negotiated rates and out-of-network allowed amounts across plans and issuers to be able to shop most effectively for their health care coverage.

Public disclosure of plan and issuer negotiated rates and out-of-network allowed amounts would create and promote price transparency in the health care market for all consumers and

⁵¹ Arora, V., Moriates, C., Shah, N. "The Challenge of Understanding Health Care Costs and Charges." 17 AMA J. Ethics. 1046. November 2015. Available at: <https://journalofethics.ama-assn.org/article/challenge-understanding-health-care-costs-and-charges/2015-11>.

payers, including insured consumers, uninsured consumers, sponsors of self-insured and fully-insured group health plans, as well as government sponsors and regulators of local, state, and federal health care programs. For any consumer, insured or uninsured, who wishes to evaluate available options for group or individual market coverage, pricing information is also essential.

Specifically, for those uninsured consumers who wish to purchase coverage and become insured, pricing information for different plans or coverage and their in-network providers would be key to consumers' ability to effectively shop for coverage that best meets their needs at prices they can afford. The same is true for insured or uninsured consumers who wish to evaluate coverage options under their employer's plan or shop for coverage in the individual market. 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 maximum out-of-pocket limits – all factors directly determined by a plan's or issuer's negotiated rates or out-of-network allowed amounts. 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, the Departments understand that plans and issuers often place limitations on benefits for specialized services. This causes many specialists to reject insurance, making it difficult, if not impossible, for consumers 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 limitations may include exclusions from coverage for speech issues that are developmental in nature, and are not due to a

specific illness or injury.⁵² Moreover, many plans and issuers that do provide coverage for developmental speech issues place annual visit limits on speech therapy services. Accordingly, consumers who have a need for such specialized services often 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 compare out-of-network benefits among different plans and issuers.

Third, public disclosure of pricing information is necessary to enable consumers to use and understand price transparency data in a manner that will increase competition, reduce disparities in health care prices, and potentially lower health care costs. The Departments are of the view that true downward pressure on health care pricing cannot be fully achieved without public disclosure of pricing. General economic theory holds that markets work best when there is price competition.⁵³ When consumers can shop for services and items based on price, providers and suppliers compete to lower price and improve quality.⁵⁴

One of the recognized impediments to increased competition through health care consumerism is widespread knowledge gaps most consumers have when it comes to evaluating health care options. Making this information public would facilitate and incentivize the design, development, and offering of consumer tools and support services that are necessary to address

⁵² <https://www.asha.org/practice/reimbursement/private-plans/PrivatePlansCoverageSLP/>.

⁵³ https://www.consumer.ftc.gov/sites/default/files/games/off-site/youarehere/pages/pdf/FTC-Competition_How-Comp-Works.pdf

⁵⁴ Kessler, D., McClellan, M. "Is Hospital Competition Socially Wasteful?" 115 Q. J. of Econ. 577. May 2, 2000. Available at: <https://www.nber.org/papers/w7266>.

the general inability of consumers to use or otherwise make sense of health care pricing information. The Departments' proposal to make this information publicly available would allow health care software application developers and other innovators to compile, consolidate, and present this information to consumers in a manner that supports meaningful comparisons between different coverage options and providers, and that assists consumers in making informed health care and coverage decisions.⁵⁵ One of the primary purposes of these proposals to make price information publicly available is to put price information in the hands of those best equipped to use it in a manner that will support greater consumerism in the health care market (for example, information technology developers who build tools to help consumers make informed health care decisions).

In developing these proposed rules, the Departments considered that, due to the complexity of our health care system and the data that drives plan and issuer payments for health care services, such data is unlikely to be usable by the average consumer. Put plainly, consumers would not (or could not) effectively use pricing information they do not understand or cannot decipher. The Departments understand many consumers do not fully comprehend the basics of health coverage, much less the more complex facets of our 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

⁵⁵ The Departments recognize that implementation of the API discussed in Section III, Request for Information, could go further toward the goal of empowering application developers and other innovators to support price transparency in the health care market.

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 (bundled payment arrangements, for example).⁵⁶ As a result, the Departments have determined that the proposal to make public negotiated rates with in-network providers and historical payment data outlining out-of-network allowed amounts is appropriate because it would encourage innovation that could help consumers understand and effectively use price transparency information. The more consumers use transparent price data effectively to find quality services they need at the best available prices, the greater the rise in consumerism and competition, as well as downward pressure on the costs of health care items and services.

The Departments assume that market actors 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. The Departments further assume that technology developers will be incentivized to design and make available web tools and mobile applications that can guide consumers in accessing available price information, increasing the likelihood that consumers will use the information to make informed health care purchasing decisions. Ultimately, improved access and usability of this information has the potential to increase health insurance literacy, consumerism, and competition, resulting in more reasonable,

⁵⁶ See <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)).

controlled costs for health care items and services. Additionally, the information would provide industry researchers and experts with baseline data to assist them with identifying, designing, and testing new or existing health care delivery and coverage models.

Fourth, along with consumers, sponsors of self-insured and fully-insured group health plans are also disadvantaged by the lack of price transparency. Group health plans bear the increasing cost of their participants' and beneficiaries' health care. Without information related to what other plans or issuers are actually paying for particular items and services, plans currently lack the pricing information necessary to shop or effectively negotiate for the best coverage for their participants and beneficiaries. 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 pricing information will also assist plans that contract with TPAs or issuers to provide a network of physicians. That information would provide valuable data a plan could use to assess the reasonableness of network access prices offered by TPAs and issuers by evaluating the specific prices members of a TPA's or issuer's network are accepting for their services. Given that, as of 2017, more than 55 percent of the nation's population received coverage from their employers,⁵⁷ the ability of group health plans to effectively negotiate pricing for coverage and services would be a boon to competition in the health care market.

⁵⁷ As of 2017, employer-based coverage was the most common, covering 56.0 percent of the population for some or all of the calendar year. Berchick, E., Hood, E. Barnett, J. "Health Insurance Coverage in the United States: 2017." U.S. Government Printing Office. September 2018. Available at: <https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-264.pdf>.

Fifth, public disclosure of price transparency information is also appropriate because it would assist health care regulators in carrying out their duties to oversee health insurance issuers in their states, as well as in designing and maintaining sustainable health care programs. Public disclosure of pricing information would enable state regulators to monitor actual trends in prices for health care items and services. States would be able to assess whether the trend rates issuers use in their rate filings are reasonable in order to assess whether the rates should be approved. 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 would inform their price negotiations with issuers. The Departments understand, however, that some government agencies may already have access to the information proposed to be made public. The Departments, thus, are specifically interested in comments from government stakeholders regarding whether and how the price transparency proposed to be created under these proposed rules would benefit government regulators and health care programs.

For these reasons, the Departments propose, in paragraph (c), to require plans and issuers to make available two machine-readable files (as defined later in this preamble) that include information regarding negotiated rates with in-network providers, allowed amounts for covered items or services furnished by particular out-of-network providers, and other relevant information as defined in accordance with specific method and format requirements. These proposed rules would also require plans and issuers to update this information on a monthly basis to ensure it remains accurate.

2. Information Required to be Disclosed to the Public

The Departments are of the view 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, creating 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 these 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. For convenience, these are respectively referred to as the Negotiated Rate File and the Allowed Amount File in this preamble. The files would include the following content elements.

a. First Content Element: Name or identifier for each plan option or coverage

The first content element that plans and issuers would be required to include in both the Negotiated Rate File and the Allowed Amount File would be the name and identifier for each plan option or coverage offered by a plan or issuer. For the identifier, the Departments propose that plans and issuers use their Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) IDs, as applicable. The Departments seek comment on whether EINs and HIOS IDs are the appropriate identifiers for this purpose. The Departments also seek comment on whether there are other plan or issuer identifiers that should be considered and adopted.

b. Second Content Element: Billing codes

The second content element that plans and issuers would be required to include in both files would be any billing or other code used by the plan or issuer to identify items or services for

purposes of claims adjudication, or accounting or billing for the item or service, including but not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), the National Drug Code (NDC), or other common payer identifier used by a plan or issuer, such as hospital revenue codes, as applicable.

The Departments propose to require that plans and issuers associate each negotiated rate or out-of-network allowed amount with a CPT or HCPCS code, DRG, NDC, or other common payer identifier, as applicable, because plans, issuers, and providers uniformly understand them and commonly use them for billing and paying claims (including for both individual items and services and service packages). The Departments also propose 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 plan or issuer could use the codes' associated short text description.

c. Third Content Element: Negotiated rates or out-of-network allowed amounts

Negotiated Rate File

The third content element that plans and issuers would be required to include in the Negotiated Rate File would be negotiated rates under a plan or coverage with respect to each covered item or service 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 plan or issuer would be required to provide the calculated dollar amount of the negotiated rate for each provider. Negotiated rates would have to be associated with the provider's National Provider Identifier (NPI), which is accessible by providers, plans, and issuers.

The Departments understand 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 plan or issuer must 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 plan must identify the bundle of items and services by the relevant code.

Plans and issuers would also be required to include in the Negotiated Rate File 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).

Allowed Amount File

The third content element plans and issuers would be required to include in the Allowed Amount File would be historical out-of-network allowed amounts for covered items and services. These 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 Negotiated 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, which is accessible by providers, plans, and issuers.

When disclosing an out-of-network allowed amount under this requirement, the plan or

issuer would disclose the aggregate of 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 is \$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, 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).

As an example, assume Group Health Plan A intends to publish a machine-readable file on July 1 reporting the out-of-network historical allowed amount data the Departments propose to require. Under these proposed requirements, Group Health Plan A's Allowed Amount File must detail each discrete out-of-network allowed amount the plan calculated in connection with a covered item or service furnished by an out-of-network provider between January 1 and April 1. During this 90-day time period, Group Health Plan A paid 23 claims from Provider Z seeking compensation for rapid flu tests (CPT Code 87804), a service covered under the group health plan. Group Health Plan A calculated out-of-network allowed amounts of \$100 for three claims, \$150 for 10 claims, and \$200 for the remaining 10 claims. Under these proposed rules, Group Health Plan A would report in the file published on June 30, that it calculated three different out-of-network allowed amounts of \$100, \$150, and \$200 for rapid flu tests (CPT Code 87804) in connection with covered services furnished by Provider Z from January 1 to April 1. On July 30, Group Health Plan A would update the file to show the unique out-of-network allowed amounts for CPT Code 87804 for Provider Z's services rendered from February through April. On

August 30, Group Health Plan A would update the file to show such payments for services rendered from March through May, and so on.

The Departments specifically seek comment on whether the required disclosures of historical out-of-network allowed amounts will provide useful information that can assist consumers in locating services at an affordable cost, or whether there is additional information that is both useful to anticipated users and practical for plans and issuers to disclose for this purpose. For instance, the Departments considered requiring plans and issuers to disclose in the Allowed Amount File amounts out-of-network providers charged participants, beneficiaries, and enrollees for covered services. We understand that such charge amounts would be included in any claim for out-of-network benefits and could be helpful to consumers shopping for services based on price. We seek comment on this data element and other information that would support the transparency goals of these proposed rules.

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 assume these amounts will provide payment data that is useful to consumers because it is reflective of current reimbursements. Specifically, the Departments propose 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 different periods of time. Payment data from defined periods of time will enable users to make meaningful comparisons across plans and coverage options.

The 90-day reporting period ensures that the public has access to reasonable volumes of payment data from which users can make useful and accurate inferences about how much a

service would cost if furnished by a particular provider. The Departments are concerned, however, that out-of-network providers may not provide services to participants, beneficiaries, or enrollees on a sufficiently frequent basis during a 90-day period to yield a useful amount of payment data. The Departments seek comment generally on these issues and on whether the Departments should require that reporting of out-of-network allowed amounts cover a longer period of time, such as 120 days, 180 days, or more.

Similarly, the Departments propose 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 machine-readable file. The Departments are of 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. The Departments also understand, however, that claims processing times may vary between plans and issuers, and that external factors may increase processing timelines. For example, the Departments understand that many out-of-network providers do not send claims directly to plans and issuers, but require patients 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 seek comment on 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. For instance, the Departments seek comment on whether the

Departments should require that more time elapses between the end of the reporting period and publication of the data, such as 120 days, 180 days, or more, to increase the likelihood that out-of-network claims from the relevant reporting period have been adjudicated and paid by the time they must be published.

The Departments are aware that providing this information could raise health privacy concerns. For example, there may be instances (such as in a small group health plan or with respect to an item or service for a rare chronic condition) where, through deduction, disclosing the required payment information may enable users to identify the patient who received the service. There may also be instances when this public disclosure requirement would be inconsistent with federal or state laws governing health information that are more stringent than HIPAA Rules with regard to 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 to the extent a patient could be identified through deduction. For example, some of the claims for payment from an out-of-network provider could relate to services provided for substance use disorder, which could implicate disclosure limitations under 42 CFR part 2 governing the confidentiality of substance use disorder patient records. Thus, some of the out-of-network allowed amounts that the Departments propose to make public could be subject to disclosure rules and limitations under 42 CFR part 2.

To address privacy concerns, the Departments propose 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. Furthermore, the Departments note that disclosure of such information

would not be required if compliance would violate applicable health information privacy laws. The Departments are committed to protecting sensitive patient health information. For this reason, in addition to proposing this exemption, the Departments propose under paragraph (c)(1)(ii) to require only unique out-of-network allowed amounts to mask the total episodes of care for a particular provider and item or service. The Departments believe these mitigation strategies, in addition to flexibilities proposed to allow the aggregation of reported data (as described later in this preamble), are sufficient to protect patients from identification based on information in the Allowed Amount File. The Departments solicit comment on whether additional privacy protections are required.

The Departments specifically solicit 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 seek comment on additional approaches that could decrease the potential for aggregated health information that would be disclosed under these proposed rules to be identified, especially with respect to smaller group health plans.

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

The Negotiated Rate and Allowed Amounts Files would be required to be disclosed as machine-readable files. These proposed 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. This means that the machine-readable file can be imported or read by a computer system without those processes resulting in alterations to the ways the data and the commands are presented in the machine-readable file. These proposed rules would require each machine-readable file to use

a non-proprietary, open format to be identified by the Departments in technical implementation guidance (for example, JSON, XML, CSV). A PDF file, for example, would not meet this definition due to its proprietary nature.

The Departments considered proposing that group health plans and health insurance issuers post negotiated rates and historical out-of-network allowed amount data for all covered items and services using a single standardized, non-proprietary file format, specifically JSON. The Departments understand that this format generally is easily downloadable, and it could simplify the ability of price transparency tool developers to access the data. The Departments seek comment on whether the final rule should require group health plans and health insurance issuers to make the Negotiated Rate and Allowed Amounts Files available as JSON files.

These machine-readable files would also be required to comply with technical, non-substantive implementation guidance to be published following the finalization of these proposed rules. The guidance will provide technical direction that identifies the specific open, non-proprietary file format in which plans and issuers should produce the machine-readable files. It will, among other things, provide the schema for the file, which is a description of the manner in which the data should be organized and arranged. The guidance would ensure consistent implementation of the machine-readable file requirements across all plans and issuers, and would ensure stability, predictability, and reliability for users of the proposed machine-readable file.

The Departments believe that providing such specific technical direction in separate guidance, rather than in this rule, would better enable the Departments to update these specific requirements to keep pace with and respond to technological developments. The Departments will publish a PRA package that will further describe the specific data elements that would be disclosed in the proposed machine-readable files.

The Departments propose to require plans and issuers to publish their negotiated rates and historical allowed amount data in two machine-readable files, one reporting required negotiated rate data with in-network providers, and a second reporting required out-of-network allowed amount data. The Departments considered allowing plans and issuers to have flexibility to publish this information in either one or two machine-readable files. The Departments solicit 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 market innovators.

The Departments are specifically 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. The Departments propose to require plans and issuers to publish data on negotiated in-network rates and data on historical out-of-network allowed amounts in separate machine-readable files to account for the dissimilarity between the static rates paid to in-network providers under contract and the more variable amounts paid to out-of-network providers. The Departments seek comment on the benefits and challenges to providing all the required data in two separate files, as proposed.

4. Required Accessibility Standards for Disclosure of Information to the Public

These proposed rules include provisions intended to address potential barriers that could inhibit the public's ability to access and use the information should it become available. For example, some plans and issuers require consumers to set up a username and password, or require consumers to submit various types of other information, including their email address, in order to access data offered by plans and issuers. The Departments are concerned that these

requirements might deter the public from accessing negotiated rate and allowed amount information. Accordingly, these proposed rules would require a plan or issuer to make available on an internet website the information described earlier in this preamble in two machine-readable files that 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 or email address.

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 negotiated rate information and historical data for out-of-network allowed amounts 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 location plans and issuers determine 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 burden on plans and issuers. The Departments request comment on whether the proposed requirement to allow issuers to display the flat files in the location of their choice is superior to requiring plans and issuers to report the web addresses of their machine-readable files to CMS for public display. The Departments are specifically interested in whether the burden associated with reporting file locations to CMS is outweighed by the risk that members of the public will be unable to easily locate plans' and issuers' machine-readable files.

5. Required Timing of Updates of Information to be Disclosed to the Public

These proposed rules would require a group health plan or health insurance issuer to update monthly the information required to be included in each machine-readable file. The

Departments recognize, however, that information in Negotiated Rate Files may change frequently and are considering whether to require plans and issuers to update their Negotiated Rate Files more often than proposed to ensure that consumers have access to the most up-to-date negotiated rate information. Accordingly, the Departments also seek comment on whether the final rules should require plans' and issuers' Negotiated Rate Files to be updated more frequently. For instance, the Departments considered requiring plans and issuers to update negotiated rate information within 10 calendar days after the effective date of new rates with any in-network provider, including rates for in-network providers newly added to a plan's provider network and updates made necessary by a provider leaving the plan's or issuer's network. The Departments seek comment on this alternate proposal and on whether the update timelines for negotiated rate information and historical out-of-network payment data should be the same.

The proposed rules would also require plans and issuers to clearly indicate the date of the last update made to the Negotiated Rate and Allow Amount Files in accordance with guidance issued by the Departments. The Departments seek comment on this proposal.

6. 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 propose a special rule to streamline the provision of the required disclosures 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 propose that, to the extent coverage under a group health plan consists of group health insurance coverage, the plan would satisfy the proposed file requirement if the health insurance issuer offering the coverage is 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 these proposed rules, and the issuer fails to provide full or timely information, then the issuer, but not the plan, would violate the transparency disclosure requirements and be subject to enforcement mechanisms applicable to group health plans under the PHS Act.⁵⁸

b. Use of Third Parties to Satisfy Public Disclosure Requirements

Plans and issuers may wish to engage other entities to assist them in complying with the disclosure requirements under these proposed rules. In particular, it is the Departments' understanding that most health care insurance and coverage claims in the U.S. are processed through health care claims clearinghouses⁵⁹ and that these entities maintain and standardize health care information, including information on negotiated rates and out-of-network allowed

⁵⁸ Section 2723 of the PHS Act.

⁵⁹ The Departments propose to adopt the definition of health care clearinghouse under 45 CFR 160.103 for purposes of these proposed rules. Under that definition, health care clearinghouse means a public or private entity, including billing services, repricing companies, community health management information systems or community health information systems, and "value-added" networks and switches, that does either of the following functions: (1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction. (2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

amounts. As a result, plans and issuers 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 these data on their behalf.⁶⁰ Accordingly, these proposed rules would permit a plan or issuer to satisfy the public disclosure requirement of paragraph (c) 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 would violate the transparency disclosure requirements.

c. Aggregation permitted for Allowed Amount Files

In order to further mitigate privacy concerns and to eliminate unnecessary duplication, the Departments propose to permit plans and issuers to satisfy the requirement of paragraph (c)(1)(ii) of these 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 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. Accordingly, under such circumstances, these proposed rules would permit issuers, service providers, or other parties with which the plan or issuer has contracted to aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract. To the

⁶⁰ See 45 CFR 164.502(a)(3) and 164.504(e)(2).

extent a plan or issuer is providing out-of-network allowed amount information in the aggregate, the Departments propose to apply the 10 minimum claims threshold to the aggregated claims data set, and not at the plan or issuer level.

7. Additional Comment Solicitation on the Negotiated Rate and Allowed Amount Files

As discussed earlier in this preamble, the Departments assume that some group health plans and health insurance issuers may store data in different systems, including dated legacy systems, which could make it difficult to accurately and efficiently populate a file as required by these proposed rules. The Departments understand that clearinghouses may provide a solution to plans and issuers in this situation, as many clearinghouses already possess the data that would be required to be disclosed in these proposed rules. The Departments seek feedback on the ways plans and issuers may be able to use a health care claims clearinghouse to fulfill the requirements of this rule and the impact this may have in reducing the burden of satisfying these proposed requirements. The Departments further seek comment on whether plans and issuers similarly could use TPAs to reduce the costs and burden of complying with these proposed requirements.

Although the Departments propose in these rules to require plans and issuers to make price and payment information public through machine-readable files, the Departments considered proposing to require plans and issuers to provide rate information through a publicly accessible API that would comply with standards defined by the Departments. The Departments note that there is currently no standard HIPAA transaction applicable to data that will be made available to members of the public who are not covered entities.⁶¹ The Departments also

⁶¹ See generally 45 CFR part 162, subparts K-S (describing standard HIPAA transactions).

understand that issuer and plan systems could be designed in a manner that providing API access to information that would be disclosed under these proposed rules could be more efficient and less burdensome than maintaining the information in machine-readable files. The Departments are concerned, however, that many plans and issuers could face significant technical issues in complying with such a requirement. The Departments, therefore, seek comment on whether plans and issuers should have the flexibility to provide access to negotiated rates and out-of-network allowed amounts through a publicly accessible API that conforms to defined standards.

Finally, the Departments recognize that the precise impact of making pricing information public cannot be predicted. As discussed in section VII of the preamble to these proposed rules, the Departments are aware that price transparency could have negative unintended consequences in markets where pricing will become very transparent, including narrowing of prices and increases in average costs. The Departments also recognize that information disclosures allowing competitors to know the rates plans and issuers are charging may dampen incentives for competitors to offer lower prices, potentially resulting in higher prices. Some stakeholders also have expressed concern that without additional legislative or regulatory efforts public availability of negotiated rates may have the unintended consequence of increasing costs for services in highly concentrated markets or result in anticompetitive behaviors. Notwithstanding these concerns, the Departments remain confident that the release of the data will help reduce pricing disparities and potentially drive down health care costs, as discussed earlier in this preamble. The Departments seek comment on these potential concerns and what additional rules would help to mitigate risk of these potential consequences.

Interaction of Proposed Requirements with 45 CFR 156.220

The Departments recognize that group and individual market health insurance issuers that

offer 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 these proposed rules. The Departments, however, do not intend for these proposed rules, if finalized, to alter requirements under section 45 CFR 156.220. Accordingly, if these proposed rules are finalized as proposed, QHP issuers would need to comply with requirements under both rules. If necessary and to the extent appropriate, HHS may issue future guidance to address QHP issuers' compliance with both section 45 CFR 156.220 and these proposed rules once they are finalized.

III. Request for Information: Disclosure of Pricing Information through a Standards-based API

The Departments are considering further expanding access to pricing information – both individuals' access to estimates about their own cost-sharing liability, and information about negotiated in-network rates and data for out-of-network allowed amounts in future rulemaking. Specifically, the Departments are considering whether to require, through future rulemaking, that group health plans and health insurance issuers make available as discrete data elements through a standards-based API the cost-sharing information that would be disclosed through the proposed internet-based self-service tool, as well as the in-network negotiated rates and out-of-network allowed amounts that this rule proposes to be publicly disclosed through machine-readable files.

Standards-based APIs are also sometimes referred to as “open” APIs to convey that certain technical information for the API is openly published to facilitate uniform use and data sharing in a secure, standardized way.

The availability of patient cost-sharing information prior to the ordering and delivery of services can enable both patients and clinicians to make more informed decisions about the course of treatment and the cost to the patient. Requiring such access through a standards-based API could have a number of benefits for patients, providers, and the public at large. It would help promote the Departments’ goal of allowing technology innovators to compile, consolidate and present pricing data in a usable format for consumers, thereby helping to make that data more relevant for consumers. For example, providing real-time access to the pricing information as discrete data elements through this mechanism would enable this information to be incorporated into third-party applications used by health care consumers or into electronic medical records for point-of-care decision-making and referral opportunities by clinicians. Additionally, being able to access these data elements through standards-based APIs would allow health care consumers to use a third-party application of their choice to obtain personalized, actionable health care service price estimates, rather than being required to use a specific application or online tool developed or identified by their plan or issuer. Widespread adoption of published, common, technical, content, and vocabulary standards are an important factor in fostering an environment in which third-party vendors can tailor products and services to better serve consumers through making health information accessible and actionable, including information that can support better financial decisions about their health care.

APIs are messengers or translators that work behind the scenes to ensure that software programs can talk to one another.⁶² An API can be thought of as a set of commands, functions, protocols, or tools published by one software developer (“A”) that enable other software developers to create programs (applications or “apps”) that can interact with A’s software without the other software developer needing to know the internal workings of A’s software, all while maintaining consumer data privacy standards. This is how API technology enables the seamless user experiences associated with applications familiar from other aspects of many consumers’ daily lives, such as travel and personal finance. Standardized, transparent, and procompetitive API technology can similarly benefit consumers of health care services. A standards-based, transparent API’s technical requirements are consistent with other system APIs that have been developed to the same standards and are openly published, supporting interoperability. Technical consistency is fundamental to scale API-enabled interoperability and reduce the level of custom development and costs necessary to access, exchange, and use health information. Publishing specific technical and business information, such as how to demonstrate authorization to access specific data, necessary for applications to interact successfully with an API in production, is commonplace in many other industries and has fueled innovation, growth, and competition. In addition, a standards-based API does not allow any and all applications or application developers unfettered access to sensitive information within a database or data system. Instead, a standards-based API can enable an application to securely access a specific set of data based on established technical specifications and authentication and access controls. These controls can be implemented consistent with the organization’s identity authentication or

⁶² For more information on APIs, see https://www.healthit.gov/api-education-module/story_html5.html.

access authorization verification processes that comply with all applicable privacy and security laws and regulations.

On March 4, 2019, HHS Office of the National Coordinator for Health Information Technology (ONC) published a proposed rule, “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” (ONC 21st Century Cures Act proposed rule), which proposed updates to the standards, implementation specifications and certification criteria as well as Condition and Maintenance of Certification requirements for health information technology (health IT) under the ONC Health IT Certification Program. The ONC 21st Century Cures Act proposed rule specifically describes the requirements health IT developers must meet to comply with the API Condition of Certification as established by the 21st Century Cures Act and to be certified as meeting API-focused certification criteria under the ONC Health IT Certification Program. In the proposed rule, ONC proposed a set of technical API standards including the HL7 Fast Healthcare Interoperability Resources (FHIR) standard and complementary security and app registration protocols, OAuth 2.0 and OpenID Connect Core, for adoption by HHS at 45 CFR 170.215. ONC also proposed the adoption of a standard called the “United States Core Data for Interoperability (USCDI)” at 45 CFR 170.213 (84 FR 7424), which would establish a set of data classes and constituent data elements to support nationwide interoperability. The USCDI standard also references content and vocabulary standards relevant to included data that are adopted under 45 CFR part 170.

On March 4, 2019, CMS also published a proposed rule, “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, 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 proposed rule).⁶³ This rule would require 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 proposed for adoption in the ONC 21st Century Cures Act proposed rule at 45 CFR 170.215. If the CMS Interoperability & Patient Access proposed rule is finalized, certain entities, such as FFE QHP issuers and companies that participate in both Medicare (by offering a Medicare Advantage plan) and the individual or group market, would be required to provide certain data through a standards-based API, while also being subject to future rulemaking under section 2715A of the PHS Act.

Sections 13111 and 13112 of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) require that federal agencies utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the PHS Act. Consistent with section 3004 of the PHS Act and sections 13111 and 13112 of the HITECH Act, and to limit additional burden, the Departments would align, to the extent possible, any standards adopted in future rulemaking under section 2715A of the PHS Act that rely on standards-based APIs with the standards adopted by HHS under section 3004 of the PHS Act. This would include the technical standards for APIs proposed in the ONC 21st Century Cures Act proposed rule for HHS adoption at 45 CFR 170.215, which are also referenced in the CMS Interoperability & Patient Access proposed

⁶³ 84 FR 7610 (March 04, 2019).

rule, though the Departments recognize that the content and vocabulary standards in the CMS Interoperability & Patient Access proposed rule relating to claims and clinical data are not applicable to pricing data.

The API standards proposed for HHS adoption in the ONC 21st Century Cures Act proposed rule are published standards. Notably, the FHIR standard is a consensus technical standard that holds great potential for supporting interoperability and enabling new entrants and competition throughout the health care industry. FHIR leverages modern computing techniques to enable users to access health care information over the internet via a standardized RESTful API. Specifically, FHIR includes both technical specifications for API transport (RESTful + JSON) and also specifications for API content known as “resources,” which are a type of software architecture that provides interoperability between the internet and computer systems. Developers can create tools that interact with FHIR APIs to provide actionable data to their stakeholders. In the short time since FHIR was first created, the health care industry has rapidly embraced the standard through substantial investments in industry pilots, specification development, and the deployment of FHIR APIs supporting a variety of business needs.

The Departments request comment on whether API technical standards, based on the FHIR standard, as aligned with the ONC 21st Century Cures Act proposed rule and the CMS Interoperability & Patient Access proposed rule, should be required in the future across group

health plans and health insurance coverage in the group and individual markets.⁶⁴ Specifically, the Departments are seeking comment on whether the Departments should propose an approach under which plans and issuers would be required to develop and implement procedures to make data available through APIs using the HL7[®] FHIR[®] IG: PSS for Patient Cost Transparency.⁶⁵ Recognizing that this IG is currently under development, the Departments could propose a staged approach to the implementation of this API requirement: (1) starting prior to when the IG is final (for example, starting January 1, 2022), payers could be required to make data available through an API; and (2) starting on or after the final IG publication date (anticipated to be October 1, 2023), plans and issuers could be required to make data available through APIs using the HL7[®] FHIR[®] IG: PSS for Patient Cost Transparency. The Departments are considering an approach under which initially plans and issuers would not be required to utilize the FHIR standard for this API, but the Departments would strongly encourage such use. While the IG for Patient Cost Transparency would not yet be finalized during this period, prior iteration(s) of the standard for trial use would be publicly available and could provide a development roadmap for payers wishing to deploy a FHIR-based API. The Departments are soliciting comment on the appropriateness of this proposed approach, the challenges it may present, and whether these suggested timeframes are appropriate.

The Departments request comment on what pricing information should be disclosed through an API, including whether all data elements required to be provided through the internet-based self-service tool and the negotiated in-network rate and allowed amount data for out-of-

⁶⁴ The Departments note that there is currently no standard HIPAA transaction applicable to data that will be made available to members of the public who are not covered entities. *See generally* 45 CFR 162.923.

⁶⁵ <https://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1514>

network providers machine-readable files should be required, whether a more limited set of data elements should be required in future rulemaking, and whether there are additional data elements that should be required.

The Departments recognize that requiring plans and issuers to disclose information related to cost-sharing liability, negotiated rates, and allowed-amounts for items and services furnished by out-of-network providers through a standards-based API would place additional burdens on issuers. The Departments seek comment on the possible scope of this burden. The Departments request comment on the potential operational impact on plans and issuers of using an API standard that aligns with the CMS Interoperability & Patient Access proposed rule to make pricing information more accessible. With adequate time for implementation, the Departments believe an API solution would not only greatly benefit patients, but may prove less burdensome for issuers and plans than requiring that the disclosures be made via machine-readable files. The Departments seek comment on plans' and issuers' readiness to disclose such data elements through an API, and the amount of time plans and issuers would need to implement such standards.

While the Departments expect that such a requirement would be justified by the increase in access to pricing information for consumers and the public, the Departments welcome comment on the utility of providing access via a standards-based API in the future, if a plan or issuer based tool and negotiated in-network rate and historical payments to out-of-network providers files are already available, as proposed elsewhere in this rule. The Departments are of the view that requiring plans and issuers to make pricing data available through a standards-based API would spur competition and reduce the burden on application developers to innovate around providing more user-friendly and effective applications for consumers. The ability to

develop an application that can effectively interconnect with multiple APIs based on a single standard rather than having to build for separate proprietary APIs (or machine-readable files) allows application developers to focus development on meeting consumer needs. These applications would then allow consumers to realize the potential associated with greater access to these data. The Departments anticipate that a future rule that would propose the use of a standards-based API consistent with the API technical standards proposed for HHS adoption in the ONC 21st Century Cures Act proposed rule, to the extent such proposals are finalized, would encourage innovation and ensure that the pricing data are standardized in ways that promote interoperability and the use of electronic technological and third-party innovation. Access to pricing data through standards-based APIs would encourage application developers to try out different application features in order to determine what features are most engaging and user friendly for consumers. The Departments are also interested in comments from application developers about potential uses for these data.⁶⁶

If the Departments move forward with a proposal in future rulemaking to require plans and issuers to make pricing information available through an API, the Departments have determined that the specific business and technical documentation necessary to interact with the proposed APIs would need to be made freely and publicly accessible. The Departments understand transparency about API technology is critical to ensuring that any interested application developer could easily obtain information needed to develop applications technically compatible with a plan's or issuer's API. Transparency would also be needed so that application developers would understand how to successfully interact with a plan's or issuer's API,

⁶⁶ See 84 FR 7628-7639.

including by satisfying any requirements the organization may establish for verification of developers' identity and their applications' authenticity, consistent with its security risk analysis and related organizational policies and procedures to ensure it maintains an appropriate level of privacy and security protection for data required to be disclosed. The Departments would likely propose to use the documentation requirements for standards-based APIs as defined in the ONC 21st Century Cures Act proposed rule and the CMS Interoperability & Patient Access proposed rule, to the extent those standards are finalized (see 84 FR 7634 through 7635). The Departments request comment on the future applicability of the documentation requirements for standards-based APIs as defined in the ONC 21st Century Cures Act proposed rule and the CMS Interoperability & Patient Access proposed rule, for the purposes of this use case specific to price transparency, and on what other documentation requirements are necessary to ensure transparency and consistency of pricing information.

The CMS Interoperability & Patient Access proposed rule proposed requirements for routine testing and monitoring of standards-based APIs (see 84 FR 7635). The Departments seek comment on whether there are reasons why different testing and monitoring requirements should apply to plans and issuers in the group and individual markets, for use specifically regarding price transparency and, if so, what requirements should apply. The Departments are also interested in comments regarding whether requiring the same testing and monitoring requirements would produce efficiencies for entities subject to both the CMS Interoperability & Patient Access proposed rule and section 2715A of the PHS Act.

The Departments recognize that while a specific standard for the standards-based API would need to be codified in regulation, the need for continually evolving standards development has historically outpaced the Departments' ability to amend regulatory text. In order to address

how standards development can outpace agencies' rulemaking schedule, the Departments are considering proposing the approach for permitting stakeholders to utilize updated standards required for the API, as proposed in the CMS Interoperability & Patient Access proposed rule, to the extent it is finalized as proposed (see 84 FR 7630-7631), which references the Standards Version Advancement Process discussed in the ONC 21st Century Cures Act proposed rule (84 FR 7497-7498). However, the Departments are interested in comments regarding the impact on plans and issuers of updating APIs, and the frequency with which such updates should occur for this test case. The Departments also welcome comments on the circumstances in which voluntary use of updated versions of adopted standards set forth in future rulemaking should be allowed, and if the Departments should maintain alignment with the approach described in the CMS Interoperability and Patient Access proposed rule.⁶⁷

The Departments are also interested in comments regarding potential privacy and security risks associated with a requirement that plans and issuers make pricing information available through a standards-based API. In the hands of a HIPAA-covered entity, such as a health care provider or health plan, or its business associate, individually identifiable pricing information about one's health care is PHI as defined at 45 CFR 160.103. As explained in the ONC 21st Century Cures Act proposed rule⁶⁸ direct-to-consumer health information technology products and services are a growing sector of the health IT market, but are often not regulated by the HIPAA Rules. Rather, the privacy and security practices of consumer-facing health IT products

⁶⁷ The Departments direct readers to the ONC 21st Century Cures Act proposed rule for further discussion on the voluntary advancement to updated versions of standards adopted for HHS use: <https://www.federalregister.gov/d/2019-02224/p-1003>.

⁶⁸ 84 FR 7424 (March 4, 2019).

and services are typically regulated by the Federal Trade Commission Act (FTC Act). However, the FTC Act applies to acts and practices that are unfair and deceptive (15 U.S.C. 45(a)(1)), and does not prescribe privacy requirements to be adopted or followed that can be leveraged for the purpose of recognizing reasonable and necessary privacy-protective practices in these proposed rules.⁶⁹

Although nothing would prevent an enrollee from requesting information through the API that is unrelated to the individual's actual health status or needs, the Departments anticipate that individuals typically would be seeking information related to their own potential health conditions and needs. For example, an individual is more likely to request cost-sharing information with in-network obstetricians if she is pregnant than if she is not. Revealing what information has been requested by individual enrollees could, thus, reveal sensitive information about their health status. Ensuring the privacy and security of these data if they are transmitted through the API would be of critical importance. To the extent that information that could be requested via the API would be considered PHI, covered entities and business associates would be able to disclose that information only to the extent permitted or required by the HIPAA Rules, and other federal and state laws. The Departments request comment on privacy and security standards that would be sufficient to protect the sensitive health data the Departments could propose in future rulemaking to be transmitted via an API, or whether additional privacy and security standards should be required.

⁶⁹ See HHS, Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA, available at: https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf.

If an enrollee directs a covered entity to send his PHI to a third-party application chosen by the individual, and that third-party application developer is neither a covered entity nor business associate under HIPAA Rules, (such as an application developer retained by the covered entity to transmit the PHI to the individual), the PHI to be transmitted through the API would not be protected under HIPAA Rules after being transmitted through the standards-based API and received by the third party, and covered entities would not be responsible for the security of that PHI once it has been received by the third-party application.⁷⁰ The Departments recognize that this could present a risk to sensitive information about enrollees' health status if the third party subsequently misuses the data or has a security breach. Nevertheless, the Departments are of the view that consumers should have access to this information to empower them to make informed health care decisions. To this end, the Departments believe consumers should be able to share such data with third-party applications of their choosing, but that they should understand that they are accepting the potential privacy and security risks that come from using a third-party application that is not required to comply with the HIPAA Rules.

The Departments are committed to maximizing enrollees' access to and control over their health information, including information designed to enable them to be more adept consumers of health care. The use of third-party applications to access pricing information is likely to

⁷⁰ HHS Office for Civil Rights, *FAQ on Access, Health Apps and APIs*, <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access-right-health-apps-apis/index.html> ("Once health information is received from a covered entity, at the individual's direction, by an app that is neither a covered entity nor a business associate under HIPAA, the information is no longer subject to the protections of the HIPAA Rules. If the individual's app – chosen by an individual to receive the individual's requested ePHI – was not provided by or on behalf of the covered entity (and, thus, does not create, receive, transmit, or maintain ePHI on its behalf), the covered entity would not be liable under the HIPAA Rules for any subsequent use or disclosure of the requested ePHI received by the app."). See also, 45 CFR 164.524(a)(1), (c)(2)(ii), and (c)(3)(ii).

introduce privacy risks of which consumers may be unaware, particularly if they do not understand that third-party application developers that are not providing an application on behalf of a covered entity are not business associates, and are not bound by the HIPAA Rules. The Departments seek comment regarding what information plans, issuers and third-party application developers should make available to individuals to better help them understand essential information about the privacy and security of their information, and what to do if they believe they have been misled or deceived about an application's terms of use or privacy policy. The Departments also seek comment regarding the manner and timing under which such information should be provided.

The Departments are considering requirements that would specify that consistent with the HIPAA Privacy Rule, plans and issuers generally may not deny access to a third party when an enrollee requests that the information be made accessible as proposed in this rule. As noted in guidance from HHS Office for Civil Rights, disagreement with the individual about the worthiness of the third party as a recipient of PHI, or even concerns about what the third party might do with the PHI, are not grounds for denying an access request.⁷¹ However, a HIPAA covered entity is not expected to tolerate unacceptable levels of risk to the PHI in its systems, as determined by its own risk analysis.⁷² Accordingly, it may be appropriate for a plan or issuer to deny or terminate specific applications' connection to its API under certain circumstances in

⁷¹ See <https://www.hhs.gov/hipaa/for-professionals/faq/2037/are-there-any-limits-or-exceptions-to-the-individuals-right/index.html>. See also, 45 CFR 164.524(a)(2), (3) and (4).

⁷² See 45 CFR 164.524(c)(2) and (3), and 164.308(a)(1), OCR HIPAA Guidance/FAQ-2036: <https://www.hhs.gov/hipaa/for-professionals/faq/2036/can-an-individual-through-the-hipaa-right/index.html>, and OCR HIPAA Guidance/FAQ-2037: <https://www.hhs.gov/hipaa/for-professionals/faq/2037/are-there-any-limits-or-exceptions-to-the-individuals-right/index.html>.

which the application poses an unacceptable risk to the PHI on its systems or otherwise violates the terms of use of the API technology. In the CMS Interoperability & Patient Access proposed rule, CMS proposed that applicable entities could, in accordance with the HIPAA Security Rule, deny access to the API if the entity reasonably determines, based on objective, verifiable criteria that are applied fairly and consistently, that allowing that application to connect or remain connected to the API would present an unacceptable level of risk to the security of PHI on the entity's systems. The Departments are considering proposing a similar standard in future rulemaking for this specific use case. The Departments seek comment on this, as well as whether there are other specific circumstances under which plans and issuers should be permitted to decline to establish or permitted to terminate a third-party application's connection to the entity's API while remaining in compliance with a requirement to offer patients access through standards-based APIs for purposes of this specific use case.

In addition, and to address the concerns related to the risk to PHI within a system, the Departments further note that there are extant best practices and technical specifications for security related to authorization and access to data through APIs, which can be applied to health care use cases. In the ONC 21st Century Cures Act proposed rule, the ONC proposed technical standards for an API including complementary security and app registration protocols – OAuth 2.0 and OpenID Connect Core. Specifically, ONC proposed to adopt the “OpenID Connect Core 1.0 incorporating errata set 1” standard in 45 CFR 170.215(b), which complements the SMART Application Launch Framework Implementation Guide Release 1.0.0 [87] (SMART Guide). The OpenID standard is typically paired with OAuth 2.0 implementations and focuses on user authentication. ONC proposed to adopt the SMART Guide in 45 CFR 170.215(a)(5) as an additional implementation specification associated with the FHIR standard. This guide is

referenced by the US FHIR Core IG and is generally being implemented by the health IT community as a security layer with which FHIR deployment is being combined (from both a FHIR server and FHIR application perspective). The use of these technical standards creates the ability for plans and issuers to use industry best practices to control authorization and access to the API and establish appropriate technical requirements for the security of third-party application access.

Further, the implementation of OpenID Connect paired with OAuth 2.0 allows organizations to securely deploy and manage APIs consistent with their organizational practices to comply with existing privacy and security laws and regulations. The organization publishing the API retains control over how patients authenticate when interacting with the API. For example, a patient may be required to use the same credentials they created and use to access their health information through the internet-based self-service tool as they do when authorizing an app to access their data. Since patients complete the authentication process directly with the organization, the app would not have access to their credentials. The Departments are of the view that implementing these security controls and safeguards would help to protect health information technology from nefarious actors.

IV. Request for Information: Provider Quality Measurement and Reporting in the Private Health Insurance Market

Quality, in addition to price, is essential for making value-based purchasing decisions.⁷³ Thus, the Departments are of the view that information relating to the quality of prospective health care services is critical to achieving the objective of increasing the value of health care. The Departments understand that for this reason, many existing cost estimator tools display provider quality information along with cost-sharing information.⁷⁴ Many of the cost estimator tools use existing provider-level CMS quality measures and data. For instance, in Colorado, pricing information for health care items and services is displayed along with five-star ratings from the CMS Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey results.⁷⁵ In Maine, consumers are able to compare median provider payments alongside patient experience HCAHPS survey results and other clinical quality measures, such as measures from CMS' Hospital Compare about how well the provider prevents health care associated infections.⁷⁶

Over the years, CMS has made much progress in improving health care quality measurement and making such quality information publicly available through various mechanisms, including public use files on the CMS website.⁷⁷ In addition, CMS makes quality

⁷³ Damberg, C., Sorbero, M., Lovejoy, S., Martsolf, G., Raaen, L., Mandel, D. "Measuring Success in Health Care Value-Based Purchasing Programs." 4 RAND Health, 2014; 4(3); Q. 9. 2014. Available at: <https://www.rand.org/pubs/periodicals/health-quarterly/issues/v4/n3/09.html>.

⁷⁴ <http://www.truthinhealthcare.org/consumer-resources/cost-comparison-tools/>.

⁷⁵ Center for Improving Value in Health Care. 2019 Public Facility and Quality Reporting. Available here: https://www.civhc.org/wp-content/uploads/2018/12/Prometheus-and-Imaging-Methodology_FAQs_for-Preview.pdf.

⁷⁶ <https://www.comparemaine.org/?page=methodology>

⁷⁷ <https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf.html>

of health care information publicly available at <https://data.Medicare.gov> for a number of different health care providers and suppliers, including hospitals, nursing homes, and physicians. As exemplified in both Colorado and Maine, such data are available for the public and could be used by providers and suppliers of health care and pricing tool developers and integrated into cost-estimator tools.

The Departments also understand that many group health plans and health insurance issuers use other provider-level quality metrics as part of their provider directories and cost-estimator tools and are of the view that quality metrics play a large role in helping their participants, beneficiaries, and enrollees utilize these tools. From stakeholder engagement, the Departments know that the quality information included in these tools varies from issuer to issuer. Similar to states discussed earlier, some issuers have also used HCAHPS to provide meaningful information for consumers on patients' overall satisfaction with hospitals. In addition to CMS measures and data, plans and issuers have also used quality metrics information from the National Committee for Quality Assurance's (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS); Bridges to Excellence, Center for Improvement in Healthcare (CIHQ), DNV GL - Healthcare Accreditations and Certifications, Castle Connelly Top Doctors, the Joint Commission on Accreditation of Healthcare Organizations ("the Joint Commission"), the Core Quality Measures Collaborative, and quality based recognition programs (such as from associations like the American Board of Medical Specialties). In addition, some plans and issuers have also relied on including validated consumer reviews, since consumers often select providers through word of mouth or referral from a provider or friend, relative, or neighbor. In general, the Departments understand that plans and issuers have also found it beneficial to include information on providers' accreditation, certification status, education, and professional

achievements in their provider directory tools. This may include information from sources such as Leapfrog Hospital Safety Grade, board certification information on providers, health facilities accreditation program, and the Joint Commission.

The Departments are also aware that there are state and private sector efforts to develop and report on provider quality. In Minnesota, MN Community Measurement develops measures that are used in both the public and private sectors to report on provider quality.⁷⁸ Nationally recognized accrediting entities, such as NCQA, URAC, The Joint Commission, and National Quality Forum (NQF) have also been at the forefront of providing health care quality measures for both health plan and provider-level reporting.

The Departments are of the view that these public and private sector quality initiatives can be leveraged to complement the price transparency proposals discussed elsewhere in this proposed rule. The Departments are interested in how these public and private sector quality measures might be used to compliment cost-sharing information for plans and issuers in the private health insurance market.

To enhance the Departments' efforts in promoting competition in the health care market that is based on value, the Departments are interested in stakeholder input on a number of quality reporting related issues, including the following:

1. Whether, in addition to the price transparency requirements the Departments propose in these rules, the Departments should also impose requirements for the disclosure of quality information for providers of health care items and services.

⁷⁸ <https://mncm.org/>

2. Whether health care provider quality reporting and disclosure should be standardized across plans and issuers or if plans and issuers should have the flexibility to include provider quality information that is based on metrics of their choosing, or state-mandated measures.
3. What type of existing quality of health care information would be most beneficial to beneficiaries, participants, and enrollees in the individual and group markets? How can plans and issuers best enable individuals to use health care quality information in conjunction with cost-sharing information in their decision making before or at the time a service is sought?
4. Would it be feasible to use health care quality information from existing CMS quality reporting programs, such as the Medicare Quality Payment Program (QPP)⁷⁹ or the Quality Measures Inventory (QMI)⁸⁰ for in-network providers in the individual and group markets?
5. Could quality of health care information from state-mandated quality reporting initiatives or quality reporting initiatives by nationally recognized accrediting entities, such as NCQA, URAC, The Joint Commission, and NQF, be used to help participants, beneficiaries and enrollees meaningfully assess health care provider options?
6. What gaps are there in current measures and reporting as it relates to health care services and items in the individual and group markets?
7. The Departments are also interested in understanding any limitations plans and issuers might have in reporting on in-network provider quality in the individual and group markets.

⁷⁹ <https://qpp.cms.gov/>

⁸⁰ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measures-Inventory.html#targetText=Quality%20Measures%20Inventory,quality%2C%20reporting%20and%20payment%20programs.&targetText=It%20is%20important%20to%20note.or%20CMS%20Program%2FMeasure%20Leads>

8. The Departments seek more information about how and if quality data is currently used within plans' and issuers' provider directories and cost-estimator tools. The Departments also seek information on the data sources for quality information, and whether plans and issuers are using internal claims data or publicly-available data.

The OPSS Price Transparency final rule, discussed elsewhere in this preamble, also included a request for comment on quality measurement relating to price transparency. The Departments intend to review and consider the public input related to quality in response to that rule for future rulemaking.

V. Overview of the Proposed Rule Regarding Issuer Use of Premium Revenue under the Medical Loss Ratio Program: Reporting and Rebate Requirements – The Department of Health and Human Services

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 proposes 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 medical loss ratio (MLR) calculations. HHS believes this proposal would preserve 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 coverage) 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 recently considered or adopted legislation⁸¹ 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. In addition, at least two states and a number of self-insured group health plans⁸² have incorporated such shared savings provisions into their health plans. 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

⁸¹ See, for example, 24-A Maine Rev. Stat. Ann. §4318-A (adopted June 19, 2017); Neb. Rev. Stat. §44-1401 et seq. (adopted Apr. 23, 2018); Utah Code Ann. §31A-22-647 (adopted March 19, 2018); AZ SB 1471 (2018); N.H. HB 1784-FN (2018); MA H2184 (2017).

⁸² See, for example, the State of New Hampshire employee medical benefit, the Site of Service and Vitals SmartShopper Programs, <https://das.nh.gov/riskmanagement/active/medical-benefits/cost-savings-programs.aspx#vitals-smartshopper>; Utah Public Employees Health Program Cost Comparison Tool, <https://www.pehp.org/general/how-to-use-cost-saving-tools>.

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 this preamble, there is ample evidence that increased transparency in health care costs would lead to increased competition among providers.⁸³ 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 would 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,⁸⁴ student health insurance

⁸³ 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.

⁸⁴ See 45 CFR 158.221(b)(3) for “mini-med” plans and 45 CFR 158.221(b)(4) for “expatriate” plans. Also see the Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protections and Affordable Care Act; Interim Final Rule; 75 FR 74863 at 74872 (December 1, 2010).

plans,⁸⁵ as well as for QHPs that incurred Exchange implementation costs⁸⁶ and certain non-grandfathered plans (that is, “grandmothered” plans).⁸⁷ This authority has also been exercised to recognize the special circumstances of new plans⁸⁸ and smaller plans.⁸⁹ Consistent with this approach, HHS is proposing 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 makes this proposal to ensure, should the proposal be finalized as proposed, 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 proposes that the amendment to 45 CFR 158.221 become effective beginning with the 2020 MLR reporting year (for reports filed by July 31, 2021). HHS invites comments on this proposal.

VI. Applicability

A. In General

The Departments propose to require group health plans and health insurance issuers of individual market and group market health insurance coverage, including self-insured group health plans, to disclose pricing information as discussed in these proposed rules, with certain exceptions as discussed in more detail in this section of the preamble. The Departments are of

⁸⁵ See 45 CFR 158.221(b)(5). Also see the Student Health Insurance Coverage; Final Rule, 77 FR 16453 at 16458-16459 (March 21, 2012).

⁸⁶ See 45 CFR 158.221(b)(7). Also see the Exchange and Insurance Market Standards for 2015 and Beyond; Final Rule; 79 FR 30240 at 30320 (May 27, 2014).

⁸⁷ See 45 CFR 158.221(b)(6). Also see 79 FR at 30320 (May 27, 2014).

⁸⁸ See 45 CFR 158.121. Also see 75 FR at 74872-74873 (Dec. 01, 2010) and the HHS Notice of Benefit and Payment Parameters for 2018 Final Rule; 81 FR 94058 at 94153-94154 (Dec. 22, 2016).

⁸⁹ See 45 CFR 158.230 and 158.232. Also see 75 FR at 74880 (Dec. 01, 2010).

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 on an element as basic as price. Although the Departments considered making the proposed requirements applicable to a more limited part of the private health insurance market, the Departments are of the view that consumers across the market should come to expect and receive the same access to standardized, meaningful pricing information and estimates. This broader applicability also has the greatest potential to reform health care markets.

The Departments also considered limiting applicability to individual market plans and insured group health plans; 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 these proposed requirements would not apply and where consumers have less access to pricing information. The Departments are of the view that consumers in all private market health plans should be able to enjoy the benefits of greater price transparency and that a broader approach will have the greatest impact toward the goal of controlling the cost of health care industry-wide.

The Departments anticipate that 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. For example, some providers participate in accountable care organizations (ACOs) and may be reimbursed based on a capitation payment. ACOs are groups of doctors, hospitals, and other health care providers that come together to provide coordinated care for their patients. The goal of ACOs is to ensure that patients get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds both in delivering high-quality care and

spending health care dollars more wisely, the ACO will share in the savings it achieves. Under such arrangements, the group health plan or health insurance issuer may reimburse the providers a set dollar payment per patient per unit of time to cover a specified set of services and administrative costs without regard to the actual number of services provided. The Departments also understand that there may be certain plan benefit structures where full disclosure of these data is not aligned with the goals of these proposed rules, such as a staff model health maintenance organization (HMO). The Departments seek comment on whether there are certain reimbursement or payment models that should be partially or fully exempt from these requirements, or should otherwise be treated differently. Further, the Departments seek comment on how consumers may be more informed about their cost-sharing requirements under these reimbursement or payment models.

By statute, certain plans and coverage are not subject to the transparency provisions under section 2715A of the PHS Act and, therefore, would not be subject to these proposed rules. This includes grandfathered health plans, excepted benefits, and short-term, limited-duration insurance, as discussed later in this section of the preamble.

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 status as grandfathered health plans under the applicable rules.⁹⁰ Under section 1251 of PPACA, section 2715A of the PHS Act does not apply to grandfathered health plans. These proposed rules would not apply to grandfathered health plans (as defined in 26 CFR 54.9815-1251, 29 CFR 2590.715-1251, 45 CFR 147.140).

⁹⁰ 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, if certain conditions are satisfied. 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, these proposed rules would not apply to a plan or coverage consisting solely of excepted benefits.

The Departments propose that the proposed rules would not apply to health reimbursement arrangements, or other account-based group health 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 certain dollar amounts available, with the result that cost-sharing concepts are not applicable to those arrangements.

These proposed rules also would not apply to short-term, limited-duration insurance. Under section 2791(b)(5) of the PHS Act, short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage and generally is therefore, exempt from requirements of title XXVII of the PHS Act that apply in the individual market, including section 2715A of the PHS Act.⁹¹

These proposed rules would apply to “grandmothered” plans. Grandmothered plans refer to certain non-grandfathered health insurance coverage in the individual and small group markets

⁹¹ See 26 CFR 54.9801-2, 29 CFR 2590.701-2, and 45 CFR 144.103.

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. Under current guidance, such coverage may be renewed through policy years beginning on or before October 1, 2020, provided that all such coverage comes into compliance with the specified requirements by January 1, 2021.⁹² While grandmothered plans are not treated as being out of compliance with certain specified market reforms, section 2715A of the PHS Act is not among those specified reforms. Therefore, the Departments propose these rules would apply to “grandmothered” plans. The Departments seek comment on whether grandmothered plans may face special challenges in complying with these transparency reporting provisions and whether the proposed rules should or should not apply to grandmothered plans.

Except as otherwise provided for the proposed MLR requirements, the Departments also propose that the requirements discussed in these proposed rules would become effective for plan years (or in the individual market policy years) beginning on or after 1 year after the finalization of this rule. The Departments request feedback about this proposed timing. In particular, the Departments are interested in information and request comment from group health plans, health insurance issuers, and TPAs on the timing necessary to develop cost estimation tools and machine-readable files.

B. Good Faith Special Applicability

These proposed rules include a special applicability provision to address circumstances in

⁹² CMS Insurance Standards Bulletin Series – INFORMATION – Extension of Limited Non-Enforcement Policy through 2020. March 25, 2019. Available at: <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Limited-Non-Enforcement-Policy-Extension-Through-CY2020.pdf>.

which a group health plan or health insurance issuer, acting in good faith, makes an error or omission in its disclosures under these proposed rules. Specifically, a plan or 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, provided that the plan or issuer corrects the information as soon as practicable. Additionally, to the extent such error or omission is due to good faith reliance on information from another entity, these proposed rules include a special applicability provision that holds the plan or issuer harmless, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate. Under these proposed rules, if a plan or issuer has knowledge that such information is incomplete or inaccurate, the plan or issuer must correct the information as soon as practicable in accordance with paragraph (d)(4) of these proposed rules.

Furthermore, these proposed rules also include 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, these proposed rules provide that a plan or 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. The Departments solicit comments on 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 cost-information disclosures are not exposed to liability by virtue of providing such information as required under these proposed rules.

VII. Economic Impact Analysis and Paperwork Burden

A. Summary/ Statement of Need

This regulatory action is taken, in part, in light of Executive Order 13877 directing the Departments to issue an ANPRM, soliciting comments consistent with applicable law, requiring 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. As discussed elsewhere in the preamble, the Departments have considered the issue, including consulting with stakeholders, and have determined that an NPRM would allow for greater specificity from commenters, who would be able to respond to specific proposals. In addition, 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 for health care shopping purposes. An NPRM enables the Departments to more quickly address this pressing issue. The proposed new requirements added to 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 147 are 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. By requiring group health plans and health insurance issuers to disclose to participants, beneficiaries, or enrollees (or their authorized representatives) such individual's cost-sharing information for covered items or services furnished by a particular provider, it provides them sufficient information to determine their potential out-of-pocket costs related to needed care and encourage them to consider price when making decisions about their health care.

B. Overall Impact

The Departments have examined the impacts of this rule 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. A 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 this rule is likely to have economic impacts of \$100 million or more in at least 1 year, and, therefore, meets the definition of "significant rule" under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

These proposed rules aim to enable participants, beneficiaries, or enrollees to obtain information about their potential cost-sharing liability for covered items and services that they might receive from a particular health care provider or providers by requiring plans and issuers to disclose cost-sharing information as described at [26 CFR 54.9815-2715A, 29 CFR 2590.715-2715A and 45 CFR 147.210]. As discussed previously in these proposed rules, there has been a shift in the health care market from copayments to coinsurance, coupled with increases in plans with high deductibles which generally require sizeable out-of-pocket expenditures prior to receiving coverage under the terms of the plan or policy; therefore, participants, beneficiaries, or enrollees are now beginning to shoulder a greater portion of their health care costs. With access to accurate and actionable pricing information, participants, beneficiaries, and enrollees would be able to consider the costs of an item or service when making decisions related to their health care. The Departments are of the view that disclosure of pricing information is crucial for participants, beneficiaries, and enrollees to engage in informed health care decision-making.

In addition, these proposals would require plans and issuers to make public negotiated rates of in-network providers and historical allowed amounts paid to out-of-network providers for all covered items and services. The Departments are of the view that these requirements would ensure that all consumers have the pricing information they need in a readily accessible format, which could inform their choices and have an impact on the disparities in health care costs. Public availability of information on in-network provider negotiated rates and allowed amounts for out-of-network services would allow consumers who wish to shop between plans to better understand what the cost of their care from a particular provider would be under each plan or policy. Furthermore, the Departments are of the view that the availability of price information to the public would empower the 28.5 million uninsured consumers⁹³ to make more informed health care decisions. Public availability of this information would also allow third-party developers to provide consumers more accurate information on provider, plan and issuer value and ensure that such information is available to consumers where and when it is needed (for example, via integration into electronic health records, price transparency tools, and consumer mobile applications).

1. Impact Estimates of the Transparency in Coverage Provisions and Accounting Table

This NPRM sets forth proposed 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. This NPRM also includes

⁹³ This is based on 2017 uninsured data from Keith, K. "Two New Federal Surveys Show Stable Uninsured Rate." Health Affairs Blog. September 13, 2018. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180913.896261/full/>.

proposals to require plans and issuers to disclose in-network provider-negotiated rates and historical allowed amounts for out-of-network items and services provided by out-of-network providers through machine-readable files posted on a public internet website. In accordance with OMB Circular A-4, Table 1 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 these proposed rules. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs and transfers resulting from the provisions of these proposed rules for plans, issuers, beneficiaries, participants, and enrollees.

TABLE 1: Accounting Table

Benefits					
Non-Quantified:					
<ul style="list-style-type: none"> • 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 health care services. • Potential increase in timely payments by consumers of medical bills as a result of knowing their expected 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 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 negotiated rates for providers 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 negotiated rate file 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 negotiated rates could facilitate the review of anti-trust violations. 					
Costs:	Low Estimate	High Estimate	Year Dollar	Discount Rate	Period Covered
	\$231.8 million	\$298.4 million	2019	7 percent	2020-2024
Annualized Monetized (\$/year)	\$224.5 million	\$286.5 million	2019	3 percent	2020-2024
Quantitative:					
<ul style="list-style-type: none"> • Cost to plans and issuers to plan, develop, and build the proposed internet self-service tool and to provide negotiated in-network rates and out-of-network allowed amounts in machine-readable files, maintain appropriate security standards and update the machine-readable files per the proposed rules. • Increase operating costs to plans and issuers as a result of training staff to use the internet 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 this proposal. 					
Non-Quantified:					
<ul style="list-style-type: none"> • Potential cost incurred by plans and issuers that wish to develop a mobile accessible version of their internet-based self-service tool. Potential increase in cyber security costs by plans and issuers to prevent data breaches and potential loss of personally identifiable information. 					

- Potential increase in out-of-pocket costs for consumers if providers increase prices or 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 proposed 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 internet self-service tool.
- Potential exposure of consumers to identity theft as a result of breaches and theft of personally identifiable information.
- Potential consumer confusion related to low health care literacy and the potential complexity of internet self-service tools
- Potential cost to plans and issuers to a conduct quality control review of the information in the negotiated rate and out-of-network allowed amounts machine-readable files.

Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Federal Annualized Monetized (\$/year)	\$9.3 million	2019	7 percent	2020-2024
	\$9.5 million	2019	3 percent	2020-2024
Other Annualized Monetized (\$/year)	\$150.6 million	2019	7 percent	2020-2024
	\$153.7 million	2019	3 percent	2020-2024

Quantitative:

- Transfers from the federal government to consumers in the form of increased premium tax credits by approximately \$12 million per year beginning in 2021 as a result of estimated premium increases by issuers in the individual market to comply with these proposed rules.
- Transfer from consumers to issuers in the form of reduced MLR rebate payments in the individual and group markets by approximately \$67 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 \$128 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 consumers to providers if there is an increase in health care costs if providers and services increase their negotiated rates to match those of competitors.
- Potential transfer from issuers to consumers if premiums go down 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.

Table 1 provided the anticipated benefits and costs (quantitative and non-quantified) to plans and issuers to disclose cost-sharing information as described at 26 CFR 54.9815-2715A, 29 CFR 2590.715-2715A, and 45 CFR 147.210 and make public negotiated rates of in-network providers and out-of-network allowed amounts paid for covered items and services. The following information describes benefits and costs – qualitative and non-quantified – to plans and issuers separately for these two requirements.

2. Proposed Requirements for Disclosing Cost-Sharing Information to Participant, Beneficiaries, or Enrollees under 26 CFR 54.9815-2715A(b), 29 CFR 2590.715-2715A(b), and 45 CFR 147.210(b)

Costs

In paragraph (b) of the proposed rules, the Departments are proposing to require group health plans and health insurance issuers to disclose certain relevant information in accordance with a prescribed method and format requirements, upon the request of a participant, beneficiary or enrollee (or an authorized representative on behalf of such individual). Under this requirement, the Departments are proposing seven content elements, which are described in paragraph (b)(1) of the proposed rules and discussed earlier in this preamble. The quantitative cost associated with meeting these requirements are detailed in the corresponding information collection requirement (ICR) that is discussed later in this preamble.

In addition to the costs described 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 this proposal would lower health care costs, the Departments recognize that price transparency may have the opposite effect because in some markets where pricing is very

transparent, pricing can narrow and average costs can increase.⁹⁴ Additionally, states may incur additional costs to review and enforce the requirements proposed in this rule.

As described in the corresponding ICR section, the Departments assume most self-insured group health plans would work with a TPA to meet the requirements of these proposed rules. The Departments estimated cost assumes in the high-range estimate that all health insurance issuers and TPAs (on behalf of self-insured group health plans) would need to develop and build their internet-based self-service tools from scratch. However, the Departments also provide a low-range estimate assuming that most plans, issuers, and TPAs would modify an existing web-based tool. The Departments recognize that some plans, issuers, and TPAs may also voluntarily elect to develop a mobile application, which would 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 leverage any resulting economies of scale.

Moreover, health care data breach statistics clearly show there has been an upward trend in data breaches over the past 9 years, with 2018 having more reported data breaches than any other year since records first started being published. Between 2009 and 2018, there have been 2,546 health care data breaches resulting in the theft and exposure of 189,945,874 health care records, equating to more than 59 percent of the United States population. Health care data breaches are now being reported at a rate of more than one per day.⁹⁵ Based on this information,

⁹⁴ 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>.

⁹⁵ See Report on Healthcare Data Breach Statistics, available at: <https://www.hipaajournal.com/healthcare-data-breach-statistics/>.

the Departments recognize the requirements of these proposed rules provide additional opportunities for health care data breaches. Plans and issuers may incur additional expenses to ensure a consumer's PHI and personally identifiable information (PII) is 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.

Benefits

Informed Consumer. A consumer armed with pricing information could potentially have greater control over their own health care spending, which could foster competition among providers resulting in less disparity in health care prices or a reduction in health care prices. Consumers who use this tool would be able to access their cost sharing 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, the negotiated rates with in-network providers for covered items and services, and the out-of-network allowed amounts for covered items and services. Additionally, consumers might gain some peace of mind in knowing where they stand financially with regard to their current health care needs and have the ability to plan ahead for any items and services they could 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 or items or services would have on the cost of a particular service or treatment.

Consumers may become more cost conscious. The Departments are of the view that consumers may begin to focus on costs of services because under this proposal, plans and issuers would be required to disclose cost-sharing information that puts consumers' cost-sharing liability

in the context necessary for truly cost-conscious decision-making. Consumers may know they have a coinsurance of 20 percent for an item or service, but many are unaware of what dollar amount of which they will be responsible for paying 20 percent. Knowing that dollar amount could motivate consumers to seek lower-cost providers and services. As discussed earlier in the preamble, there has been recent evidence in New Hampshire and Kentucky that supports the Departments' assumption 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 lowering overall health care costs. The Departments acknowledge that this may only hold true if cost sharing varies between providers. Cost sharing in HMOs and Exclusive Provider Organizations (EPOs) generally is through fixed copayment amounts regardless of the provider who furnishes a covered item or service and, therefore, the proposed rules would 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 proposed rules would be more likely to pay their 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 getting care.⁹⁶ In addition, a non-profit hospital network, found that the more information they shared with patients, the better prepared those patients are for meeting their responsibilities. They further note that they find it valuable to explain to patients what their benefits are, provide

⁹⁶ Kutscher, B. "Report: Consumers demand price transparency, but at what cost?" Modern Healthcare. June 2015. <https://www.modernhealthcare.com/article/20150623/NEWS/150629957/consumers-demand-price-transparency-but-at-what-cost>.

an estimate of what the patient might owe for a service, and discuss any pre-payment requirements so that the patient understands what to expect during the billing process and what their options are. The hospital network reports that providing price estimates to patients has resulted in increased point of service cash collections from \$3 million in 2010 to \$6 million in 2011.⁹⁷

Increased Competition Among Providers. The Departments are of the view that the requirements of these proposed rules would lead to competition among providers as consumers would be aware of and compare the out-of-pocket cost of a covered item or service prior to receiving that item or service, which might force higher-cost providers to lower their prices in order to compete for the price sensitive consumer.

3. Proposed Requirements for Public Disclosure of In-network Negotiated Rates and Historical Payments of Out-of-network Allowed Amounts Through Machine-readable Files under 26 CFR 54.9815-2715A(c), 29 CFR 2590.715-2715A(c), and 45 CFR 147.210(c)

Costs

In paragraph (c) of these proposed rules, the Departments are proposing to require that group health plans and health insurance issuers make available to the public on an internet website two digital files in a machine-readable format. The first file (the Negotiated Rate File) would include information regarding rates negotiated with in-network providers. The second file (the Allowed Amount File) would publish data showing allowed amounts for covered items and services furnished by out-of-network providers over a 90-day period. Plans and issuers would be

⁹⁷ HFMA Executive Roundtable: Reimagining Patient Access. December 2015. Available at: <https://api.hfma.org/Content.aspx?id=43731>.

required to make the required information available in accordance with certain method and format requirements described at paragraph (c)(2) of the proposed rules and update the files monthly. The quantitative cost associated with meeting the proposed requirements are detailed in the associated ICR section.

Non-Quantified Costs for Public Disclosure of In-network Negotiated Rates: In addition to the costs described in the associated ICR, the Departments recognize there may be other costs associated with the requirement to make in-network negotiated rates available publicly 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 this proposal would lower health care prices, there are instances in very transparent markets, where pricing can narrow and average costs can increase.⁹⁸ The Departments also recognize that plans and issuers may experience additional costs (for example, quality control reviews) to ensure they comply with the requirements of these proposed 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 low price⁹⁹ or result in a higher price equilibrium. While health insurance issuers with the highest negotiated rates may see a decrease in their negotiated rates, as their providers respond to consumer and smaller health insurance issuers' concerns of paying more for the same item and

⁹⁸ 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>.

⁹⁹ Koslov, T., Jex, E. "Price transparency or TMI?" Available at: <https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi>.

service, issuers with the lowest negotiated rates may see their lower cost providers adjust their rates upward to become equal across the board. 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.¹⁰⁰

A potential additional non-quantified cost could be the cost to remove “gag clauses” from contracts between health insurance issuers and providers. Contracts between issuers and providers often include a gag clause, which prevents issuers from disclosing negotiated rates. The Departments recognize that issuers and providers may incur a one-time expense for their attorneys to review and update their provider contracts to remove any relevant gag clause.

Another potential cost is the 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 health care providers that have contracted with a group health plan or health insurance 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 health plan’s quality standards and agreed to accept a negotiated rate for their services in exchange for the patient volume they will receive by being part of the plan’s network.¹⁰¹ Some

¹⁰⁰ Austin, D., Gravelle, J. “Report: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector.” CRS Report for Congress. June 2007. Available at: <https://fas.org/sgp/crs/secretary/RL34101.pdf>.

¹⁰¹ See Davis, E. “Health Insurance Provider Network Overview” Verywell Health, August 2019. Available at: <https://www.verywellhealth.com/health-insurance-provider-network-1738750>

plans and issuers offer a narrow network. Narrow networks operate with a smaller provider network, meaning a consumer will have few choices when it comes to in-network health care providers but often lower monthly premiums and out-of-pocket costs.¹⁰² The Departments recognize that making negotiated 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 issuers and plans when that discount will be made public. The requirements of this proposal could also result in a reduction in revenue for those smaller health insurance 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 a smaller issuer's potential inability to pay providers with higher rates, smaller issuers may further narrow their networks to include only providers with lower rates, possibly making it more difficult for smaller issuers to fully comply with network adequacy standards described at 45 CFR 156.230 or applicable state network adequacy requirements.

Non-Quantified Cost for Public Disclosure of out-of-network allowed amounts: In addition to the costs described in the associated ICR and the previous analysis related to the public disclosure of negotiated rates, the Departments recognize that there may be other costs associated with the requirement to make historical payments of out-of-network allowed amounts publicly available that are difficult to quantify, given the current lack of information and data. For example, as a result of balance billing by providers, plans and issuers may be forced to

¹⁰² Anderman, T “What to Know About Narrow Network Health Insurance Plans”, Consumer Reports, November 2018. Available at: <https://www.consumerreports.org/health-insurance/what-to-know-about-narrow-network-health-insurance-plans/>

increase their allowed amounts (such as the usual and customary and reasonable amount) to meet the demands of the price sensitive consumer.

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.

Benefits

The Departments are of the view that requiring plans and issuers to make available information regarding negotiated in-network provider rates and 90-days of historical allowed amount data for out-of-network allowed amounts for covered items and services to the public would 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 proposals because under these proposed rules a plan or issuer would know the negotiated rates of their competitors. This may allow plans and issuers that are paying higher rates for the same items or services to negotiate with certain providers to lower their rates, thereby lowering provider reimbursement rates. The Departments acknowledge, however, as noted in the costs section earlier in this preamble, that knowledge of other providers' negotiated rates could also drive up rates if a provider discovers it is currently being paid less than other providers by a plan or issuer and, thereby, negotiates higher rates.

In addition, these proposed 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 the annual 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, 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, not merely slowdowns in the rate of price growth. For example, in the first 2 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.¹⁰³

Regulatory Authorities: In many states, health insurance issuers must obtain prior approval for rate changes from the state's Department of Insurance. Regulatory authorities such as state Departments of Insurance might benefit from this proposal because knowledge of provider negotiated rates and historical 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.

¹⁰³ Boynton, A., Robinson, J. "Appropriate Use of Reference Pricing Can Increase Value." Health Affairs Blog. June 2015. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20150707.049155/full/>.

Consumers: Access to the negotiated rates between plans and issuers and in-network providers and the amount plans and issuers paid out-of-network providers for covered items and services would allow consumers to understand the impact of their choices for health care coverage options and providers on the cost of a particular service or treatment. Introducing this information into the consumer's health care decision-making process would give the consumer a greater degree of control over their own health care costs. Furthermore, having access to publicly available out-of-network allowed amounts would provide consumers who are shopping for coverage the ability to compare the different plan or issuer payments 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 would benefit from the requirements of this proposal, the Departments recognize that utilizing the required information would not be appropriate or reasonable in an emergency situation.

Overall Health Insurance Market: This proposal may induce an uninsured person to obtain health insurance, depending on premium rates, after learning the actual dollar difference between the usual and customary rates that they pay for items and services as an uninsured consumer and the negotiated rates and out-of-network allowed amounts under the terms of a group health plan or health insurance issuer's policy. In addition, this proposal might force providers to lower their rates for certain items and services in order to compete for the price sensitive consumer or plan; although the immediate payment impact would be categorized as a transfer, any accompanying health and longevity improvements would be considered as benefits (and any accompanying increases in utilization would, thus, be considered costs). And, as discussed elsewhere in this preamble, New Hampshire's HealthCost website was found to reduce the cost of medical imaging procedures by 5 percent. The study further found that patients saved

approximately \$7.5 million dollars on X-Ray, CT, and MRI scans over the 5 year period studied (dollars are stated in 2010 dollars).¹⁰⁴

4. Medical Loss Ratio (45 CFR 158.221)

In these proposed rules, HHS proposes to amend § 158.221 to allow health insurance issuers that share with consumers savings that result from consumers shopping for lower-cost, higher-value services, to take credit for such “shared savings” payments in issuers’ MLR calculations. For this impact estimate, HHS assumed that only relatively larger issuers (with at least 28,000 enrollees) that have consistently reported investment costs in health information technology on the MLR annual reporting form (of at least \$6.77 per enrollee, which represents issuers with 70 percent of total reported commercial market health information technology investment) or issuers that operate in states that currently (three states in 2019) or may soon support “shared savings” plan designs would initially choose to offer plan designs with a “shared savings” component, that such issuers would share, on average, 50 percent of the savings with consumers (which would increase the MLR numerator under the proposed rule), and that issuers whose MLRs were previously below the applicable MLR standards would use their retained portion of the savings to lower consumers’ premiums in future years (which would reduce the MLR denominator). Based on 2014-2017 MLR and other data, HHS estimates that this proposal could reduce MLR rebate payments from issuers to consumers by approximately \$67 million per year, while facilitating savings that would result from lower medical costs of approximately \$128

¹⁰⁴ Brown, Z. “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

million per year for issuers and consumers (some of which would be retained by issuers, shared directly with consumers, or used by issuers to reduce future premium rates).

5. Summary of Estimated Transfers

The Departments assume that because 2020 premium rates are nearly finalized, that issuers will not be able to charge for the expenses incurred due to these proposed rules in the 2020 rates. Because issuers will not have had an opportunity to reflect the 2020 development costs in the 2020 premium rates, some issuers may apply margin to the assumed ongoing expenses as they develop premium rates for 2021 and after. The Departments estimate premiums for the fully-insured markets would be \$450 billion for 2021, which includes the individual, small group, and large group markets.¹⁰⁵ The Departments estimate that the ongoing expense represents approximately 0.03 percent of premiums for the fully-insured market. Assuming this level of premium increase in the individual market, premium tax credit outlays are estimated to increase by about \$12 million per year beginning in 2021. Given that 2021 premium tax credit outlays are expected to be \$43 billion, the Departments expect the estimated increase of \$12 million to have minimal impacts on anticipated enrollment. The Departments note that any impact of these proposed rules on provider prices has not been estimated, as limited evidence has generally shown not much of an effect on health care 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.

¹⁰⁵ 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.

C. Regulatory Review Costs

Affected entities will need to understand the requirements of these proposed rules, if finalized, before they can comply. Group health plans and health insurance issuers are responsible for ensuring compliance with these proposed rules. However, as assumed elsewhere, it is expected that issuers and TPAs, and only the largest self-insured plans will likely incur this burden. The issuers and TPAs will then provide plans with rule compliant services. Therefore, the burden for the regulatory review is estimated to be incurred by the 1,959 issuers and TPAs.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret these proposed rules, if finalized, 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 these proposed rules, the Departments assume that the total number of health insurance issuers and TPAs that would be required to comply with these rules would be a fair estimate of the number of entities affected.

The Departments acknowledge that this assumption may understate or overstate the costs of reviewing these proposed rules. It is possible that not all affected entities will review these rules, if finalized, in detail, and 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 health insurance issuers and TPAs would be a fair estimate of the number of reviewers of these proposed rules. The Departments welcome any comments on the approach in estimating the number of affected entities that will review and interpret these proposed rules, if finalized.

Using the wage information from the BLS for a Computer and Information Systems Manager (Code 11-3021) and a Lawyer (Code 23-1011) the Departments estimate that the cost

of reviewing this rule is \$285.66 per hour, including overhead and fringe benefits.¹⁰⁶ Assuming an average reading speed, the Departments estimate that it would take approximately 4 hours for the staff to review and interpret these proposed rules (2 hours each for a lawyer and an Information Systems Manager), if finalized; therefore, the Departments estimate that the cost of reviewing and interpreting these proposed rules, if finalized, for each health insurance issuer and TPA is approximately \$1,142.64. Thus, the Departments estimate that the overall cost for the estimated 1,959 health insurance issuers and TPAs is \$2,238,431.76 (\$1,142.64 x 1,959 total number of estimated health insurance issuers and TPAs).

D. Regulatory Alternatives Considered

In developing the policies contained in these proposed rules, the Departments considered alternatives to the presented proposals. In the following paragraphs, the Departments discuss the key regulatory alternatives that 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

These proposed rules require plans and 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 burden on these entities. However, limiting disclosures to a specified set of items and services reduces breadth and availability of useful cost estimates to determine anticipated cost-sharing liability, limiting the impact of price transparency efforts by reducing

¹⁰⁶ Wage information is available at https://www.bls.gov/oes/current/oes_nat.htm.

the incentives to lower prices and provide higher-quality care. The Departments assume that plans (or TPAs on their behalf) and issuers, whether for a limited set of covered items and services or 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 assume that any additional burden 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 minimal additional burden is outweighed by the potentially large, albeit unquantifiable, benefit to consumers of having access to the required pricing information for the full breadth of items and services covered by their plan or issuer. For these reasons, in order to achieve lower health care costs and reduce spending through increased price transparency, the Departments propose to require cost-sharing information be disclosed for all covered items and services.

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 proposed requirements would not apply and where consumers have less access to pricing information. The Departments are of the view that consumers should be able to enjoy 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 these proposed rules were limited to only individual market plans, the Departments estimate only 13,700,000 participants, beneficiaries, and enrollees would receive the intended benefits of these rules. In contrast, under these proposed rules, a total of 193,500,000 participants, beneficiaries, and enrollees would receive the intended benefits. The Departments acknowledge that limiting applicability of the requirements of these proposed rules

to the individual market would likely reduce the overall cost and hour burden estimates identified in the corresponding ICRs section, but the overall cost and burden estimates per covered life would increase. Further, there is a great deal of overlap in health insurance issuers that offer coverage in both the individual and the group markets. Issuers offering coverage in both markets would be required to comply with the requirements of these proposed rules even if the Department limited the applicability to only the individual market. Because TPAs provide administrative functionality for self-insured group health care coverage, those non-issuer TPA entities would not incur any hourly burden or associated 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 193,500,000 participants, beneficiaries, and enrollees outweigh the increased costs and burden hours that a subset of plans and issuers (and TPAs on behalf of self-insured group health plans) that are not active participants in the individual market would incur. The Departments have determined the benefits of expanding the applicability of these proposed rules would not only expand access to health care pricing information to a greater number of individuals, but that any developed economies of scale would have a much greater likelihood of achieving the goal of controlling the cost of health care industry-wide.

2. Requirement to Post Machine-readable Files of Negotiated Rates and Historical Data for Out-of-network Allowed Amount Payments Made to Out-of-network Providers to a Public Website

In proposing the requirement that group health plans and health insurance issuers post their negotiated rates and historical data for out-of-network allowed amount payments made to out-of-network providers on a publicly accessible website, the Departments considered requiring

payers to submit the internet addresses for the machine-readable files to CMS, and CMS would make the information available to the public. A central location could allow the public to access negotiated rate information and historical data for out-of-network allowed amounts in one centralized location, reducing confusion and increasing accessibility. Posting negotiated rates and historical data for out-of-network allowed amounts in a central location may also make it easier to post available quality information alongside price information. However, to provide flexibility and reduce burden, the Departments are of the view that plans and issuers should determine where to post negotiated rate and out-of-network allowed amount information rather than prescribing the location the information is to be disclosed. Further, requiring payers to submit internet addresses for their machine-readable files to CMS would result in additional burden to the extent plans and issuers already post this information in a different centralized location.

3. Frequency of Updates to Machine-Readable Files

In proposing paragraph (c) of these proposed rules, the Departments considered requiring more frequent updates (within 10 calendar days of new rate finalization) to the negotiated rates and out-of-network allowed amounts. More frequent updates would provide a number of benefits for the patients, providers, and the public at large. Specifically, such a process could ensure 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 and health insurance issuers to update the machine-readable files more frequently would result in increased burdens and costs for those affected entities. With respect to the Negotiated Rate File, the Departments estimate that requiring updates within 10 calendar days of rate finalization would result in each plan, issuer, or TPA (on behalf of a self-insured group

health plan) incurring an annual hour burden of 1,110 hours with an associated equivalent cost of \$110,290. Based on recent data the Departments estimate a total 1,959 entities – 1,754 issuers¹⁰⁷ and 205 TPAs¹⁰⁸ – will be responsible for implementing the proposals of these rules. For all 1,754 health insurance issuers and 205 TPAs, the total hour burden would be 2,174,490 hours with an associated equivalent annual cost of \$216,057,326. As discussed in the corresponding ICR, requiring a less frequent 30 calendar day update would reduce the annual hour burden for each entity to 360 hours with an associated equivalent cost of \$35,770. For all 1,754 health insurance issuers and 205 TPAs, the total hour burden is reduced to 705,240 hours with an associated equivalent annual cost of \$70,072,646. 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 (on behalf of a self-insured group health plan) incurring an annual hour burden of 481 hours with an associated equivalent cost of \$44,952. For all 1,754 health insurance issuers and 205 TPAs, the total hour burden would be 942,279 hours with an associated equivalent annual cost of \$88,061,046. As discussed in the corresponding ICR, requiring a less frequent update would reduce the annual hour burden for each plan, issuer, and TPA to 156 hours with an associated equivalent cost of \$14,579 per file. For all 1,754 health insurance issuers and 205 TPAs, the total hour burden is reduced to 305,604 hours with an associated equivalent annual cost of \$28,560,339. By proposing monthly updates to the machine-readable files, rather than updates every 10 calendar days, the Departments have chosen

¹⁰⁷ 2018 MLR Data Trends.

¹⁰⁸ Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

to strike a balance between placing an undue burden on plans and health insurance issuers and assuring the availability of accurate information.

4. Proposed File Format Requirements

In 26 CFR 54.9815-2715A(c)(2), 29 CFR 2590.715-2715A(c)(2), and 45 CFR 147.210(c)(2), these proposed rules require payers to post information in two 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 into a computer system for further processing without human intervention, while no semantic meaning is lost. These proposed rules would require each machine-readable file to use a non-proprietary, open format. The Departments considered requiring payers to post negotiated rates and plan-specific historical charges paid for out-of-network services for all items and services using a specific file format, namely JSON. However, the Departments are of the view that being overly prescriptive in the file type would impose an unnecessary burden on payers despite the advantages of JSON, namely being downloadable and readable for many health care consumers, and the potential to simplify the ability of price transparency tool developers to access the data. Therefore, the Departments have proposed that group health plans and health insurance issuers post the negotiated rate and out-of-network allowed amount information in two distinct machine-readable files using a non-proprietary, open format to be identified by the Departments in future guidance.

In addition, the Departments considered proposing that plans and issuers provide the specific out-of-network allowed amount methodology needed for consumers to determine out-of-pocket liability for services by providers not considered to be in-network by the group health plan or health insurance 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 amounts paid by plans and issuers over a 90-day period (by date of service with a 90-day lag) for items and services provided by out-of-network providers would 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 plan or issuer cannot provide an estimate of out-of-pocket costs to the consumer.

Providing data on the costs covered by a plan or issuer for specific items and services allows a consumer to anticipate what their plan or issuer would likely contribute to the costs of items or services obtained from out-of-network providers and allows the consumer to estimate his or her out-of-pocket costs by subtracting that amount from the cost of the out-of-network services. Historical out-of-network allowed amount data will provide increased price transparency for consumers, and the burdens and 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 Departments have proposed that payers provide historical 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, 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. Proposal to Require Both Disclosure of Cost-sharing Information to Participants,

Beneficiaries, and Enrollees and Publicly-posted Machine-readable Files with Negotiated Rates and Out-of-network Allowed Amounts

The Departments considered whether proposing that group health plans and health insurance issuers be required to disclose cost-sharing information through a self-service tool or in paper form to participants, beneficiaries, or enrollees (or their authorized representatives) 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 negotiated rates and historical out-of-network allowed amounts would be duplicative. The requirement to disclose cost-sharing information to participants, beneficiaries, or enrollees proposed in these rules would 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, and enrollees would also not be available to third parties who are interested in creating consumer 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 these proposed rules, and would reduce the potential for these proposed rules to drive down health care costs by increasing competition.

As discussed in more detail in the corresponding ICR sections of this preamble, the Departments estimate that the high-end average 3-year hour burden and cost to develop only the internet-based self-service tool, including the initial tool build and maintenance, customer service training, and customer assistance burdens and costs. The Departments estimate the total

hour burden per group health plan, health insurance issuer, or TPA (on behalf of a self-insured group health plan) would be approximately 956 hours, with an associated equivalent average annual cost of approximately \$168,804. For all 1,754 health insurance issuers and 205 TPAs, the Departments estimate the total average annual hour burden, over a 3-year period, to be 1,872,564 hours with an associated equivalent total average annual cost of approximately \$161,355,868.

In contrast, and as further discussed in the corresponding ICR sections earlier in this preamble, for implementation of the currently proposed internet-based self-service tool in conjunction with the out-of-network allowed amount and in-network negotiated rate machine-readable files, the Departments estimate that the average annual high-end burden and cost, over a 3-year period, for each group health plan and health insurance issuer or TPA would be approximately 2,127 hours, with an associated equivalent cost of approximately \$190,356. For all 1,754 health insurance issuers and 205 TPAs, the Departments estimate the total average high-end annual hour burden and cost, over a 3-year period, to be 4,165,900 hours with an associated equivalent total average annual cost of approximately \$372,906,502.

Additionally, as discussed in more detail in the corresponding ICR sections, the Departments estimate that that the low-end average 3-year burden and cost to develop and maintain only the internet-based self-service tool, including the initial tool build and maintenance, customer service training, and customer assistance burdens and costs. The Departments estimate the total hour burden per plan and or TPA would be approximately 392 hours, with an associated equivalent average annual cost of approximately \$33,194. For all 1,754 health insurance issuers and 205 TPAs, the Departments estimate the total average annual hour burden, over a 3-year period, to be 767,100 hours with an associated equivalent total average annual cost of approximately \$65,027,268.

In contrast, and as further discussed in the corresponding ICR sections earlier in this preamble, for implementation of the currently proposed internet-based self-service tool in conjunction with the out-of-network allowed amount and in-network negotiated rate machine-readable files, the Departments estimate that the average annual low-end hour burden and cost, over a 3-year period, for group health plan and health insurance issuer or TPA would be approximately 1,562 hours, with an associated equivalent average annual cost of approximately \$141,183. For all 1,754 health insurance issuers and 205 TPAs the Departments estimate the total average annual low-end hour burden and cost, over a 3-year period, to be 3,060,436 hours with an associated equivalent total average annual cost of approximately \$276,577,902.

While the Departments recognize that requiring disclosures through both mechanisms increases the cost and hour burdens for plans and issuers required to comply with the requirements of these proposed rules, the Departments are of the view that these additional costs are outweighed by the benefits accrued 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. Furthermore, as noted earlier in this preamble, researchers and third-party developers would also be able to use the data included in the machine-readable files in a way that could accrue even more benefits to individuals, including those individuals not currently enrolled in a particular plan or coverage. For these reasons, the Departments concluded that, in addition to proposing to require plans and issuers to be required to disclose cost-sharing information to participants, beneficiaries, or enrollees through an internet-based self-service tool or in paper form, proposing to require plans and issuers to disclose information on negotiated rates and out-of-network

allowed amounts would further the goals of price transparency and accrue more benefit to all potentially affected stakeholders.

6. Proposal to Require Machine-readable Files in Lieu of an API

The Departments considered whether to propose a requirement for group health plans and health insurance issuers to make the information required in these proposed rules to be disclosed 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. The Departments believe 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 and their patients. Additionally, being able to access these data through a standards-based APIs would allow consumers to use the application of their choice to obtain personalized, actionable health care item or service price estimates, rather than being required to use one developed by their plan or issuer, 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' current view that the burden and costs associated with building and maintaining a standards-based API would result in plans, issuers, and applicable TPAs potentially incurring higher burden and costs than estimated for the internet-based self-service tool and machine-readable files proposed in these rules and discussed in the applicable ICR sections. This view is based on the Departments' preliminary estimate that for all 1,754 health insurance issuers and 205 TPAs, the total cost could

range from \$500 million to \$1.5 billion for the first year. Looking at the average burden and cost over a 3-year period for the API for all 1,754 health insurance issuers and 205 TPAs, the Departments estimate an average annual cost that would significantly exceed the estimated annual cost of publishing the proposed internet-based self-service tool and machine-readable files. The Departments recognize that the development of the API may be streamlined through other development activities related to this proposed rule or by leveraging existing APIs currently used by plans, issuers, or TPAs for their own applications, potentially resulting in significantly lower burden and costs. Although not estimated here, the Departments expect any associated maintenance costs would also decline in succeeding years as group health plans, health insurance issuers or TPAs may gain additional efficiencies or may already undertake similar procedures to maintain any currently used internal APIs. Nonetheless, weighing the burden of group health plans, health insurance issuers and TPAs providing this information using machine-readable files against the potential burden of using a standards-based API, and given the timeframe that group health plans, health insurance issuers and TPAs have to meet the requirements of these proposals, the Departments are of the view that in the short-term, requiring machine-readable files is the more sensible approach.

Even though the Departments are of the view that a machine-readable file is 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 consumers because the public would have access to the most up-to-date rate information and would allow health care consumers to use the application of their choice to obtain personalized, actionable health care service price estimates, and third-party developers could utilize the collected data to develop consumer 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 negotiated in-network rates and historical payment data for out-of-network allowed amounts.

VIII. Collection of Information Requirements.

Under the Paperwork Reduction Act of 1995, the Departments are required to provide 60-days' notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. These proposed rules contain information collection requirements (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 16.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (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 solicit public comment on each of these issues in the following sections of this document in relation to the information collection requirements in these proposed rules.

A. Wage Estimates

To derive wage estimates, the Departments generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.¹⁰⁹ Table 2 in these proposed rules presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This 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.

TABLE 2: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hour)	Fringe Benefits and Overhead (\$/hour)	Adjusted Hourly Wage (\$/hour)
General and Operations Manager	11-1021	\$59.56	\$59.56	\$119.12
Computer and Information Systems Manager	11-3021	\$73.49	\$73.49	\$146.98
Computer Programmer	15-1131	\$43.07	\$43.07	\$86.14
Computer System Analyst	15-1121	\$45.01	\$45.01	\$90.02
Web Developer	15-1134	\$36.34	\$36.34	\$72.68
Business Operations Specialist	13-1199	\$37.00	\$37.00	\$74.00
Other Office and Administrative Support Workers	43-9000	\$17.28	\$17.28	\$34.56
Lawyer	23-1011	\$69.34	\$69.34	\$138.68
Chief Executive Officer	11-1011	\$96.22	\$96.22	\$192.44
Information Security Analysts	15-1122	\$49.26	\$49.26	\$98.52
Customer Service Representatives	43-4051	\$17.53	\$17.53	\$35.06

¹⁰⁹ See 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.

1. ICR Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees (26 CFR 54.9815-2715A(b), 29 CFR 2590.715-2715A(b), and 45 CFR 147.210(b))

The Departments propose to add 26 CFR 54.9815-2715A(b), 29 CFR 2590.715-2715A(b) and 45 CFR 147.210(b), to require group health plans and health insurance issuers in the group and individual markets to disclose, upon request, to a participant, beneficiary, or enrollee (or his or her authorized representative), such individual's cost-sharing information for covered items and services furnished by a particular provider or providers, as well as allowed amounts for covered items and services from out-of-network providers. As discussed previously in this preamble, the Departments propose in paragraphs (b)(1)(i) through (vii) to require plans and issuers to make this information available through a self-service tool on an internet website and, if requested, in paper form.

The Departments propose to require plans and issuers to disclose, upon request, certain information relevant to a determination of a consumer'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 consumer-specific estimated cost-sharing liability, the consumer-specific accumulated amounts, the negotiated 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. The Departments propose to 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 would also be permitted to add other disclaimers they determine appropriate so long as such information is not in conflict with the disclosure requirements of these proposed rules. The Departments have developed model language that plans and issuers would be able to use to satisfy the requirement to provide the notice statements described earlier in this preamble.

As discussed earlier in this preamble, the Departments propose that plans and issuers would be required to make available the information described in paragraph (b)(1) of these proposed rules through an internet-based self-service tool as described in paragraph (b)(2)(i) of these proposed rules. The information would be required to be provided in plain-language through real-time responses. Plans and issuers would be required to allow participants, beneficiaries, or enrollees (or their authorized representatives) 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 would 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 tool would be required to have the capability to refine and reorder results by geographic proximity, and the amount of cost-sharing liability to the beneficiary, participant, or enrollee.

Under paragraph (b)(2)(ii) of these proposed rules, the Departments would require plans and issuers to furnish upon request, in paper form, the information required to be disclosed under paragraph (b)(1) of these proposed rules to a participant, beneficiary, or enrollee. As discussed

in this preamble, under paragraph (b)(2)(ii)(A) and (B) of these proposed rules, a paper disclosure would be required to be furnished according to the consumer's filtering and sorting preferences and mailed to the participant, beneficiary, or enrollee (or his or her authorized representative) within 2 business days of receiving the request. As noted in these proposed rules, 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 would rely on health insurance issuers to develop and maintain the internet-based self-service tool and disclosure 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 would rely on TPAs (including issuers providing administrative services only 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 hour burden and cost as estimated for health insurance issuers and TPAs, as discussed later in this preamble. In addition, paragraphs (b)(3) and (c)(4) of these proposed rules provide for a special rule to prevent unnecessary duplication of the disclosures with respect to health 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 use health insurance issuers and TPAs as the unit of analysis for the purposes of estimating required changes to IT infrastructure and administrative hourly burden and costs. The

Departments estimate approximately 1,754 issuers and 205 TPAs will be affected by this information collection.

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 tools that meet most (if not all) of these requirements or can be easily adapted to meet the requirements of these proposed 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 tool. 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 health insurance issuers and TPAs would be affected by these proposed 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 of the preamble, the Departments seek comment on the inputs and assumptions that have been made to develop these burden and cost estimates, particularly with regard to existing efficiencies that would reduce these burden and cost estimates.

The Departments estimate that health insurance issuers and TPAs would incur a one-time cost and hour burden to complete the technical build to implement the requirements of paragraph (b) of these proposed rules to establish the internet-based, self-service tool through which disclosure of cost-sharing information (including required notice statements) in connection with a covered item or service under the terms of the plan or coverage must be made. The

Departments estimate an administrative burden on health insurance issuers and TPAs to make appropriate changes to information technology (IT) systems and processes to design, develop, implement, and operate the internet-based, self-service tool and to make this information available in paper form, transmitted through the mail. The Departments estimate that the one-time cost and burden each issuer or TPA would incur to complete the one-time technical build would include 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 proposed model and disclaimer notice materials for those that choose to make alterations. The Departments assume that this one-time cost and burden would be incurred in 2020. As mentioned earlier in this preamble, the Departments acknowledge that a number of health insurance issuers and TPAs have previously developed some level of price estimator tool similar to, and containing some functionality related to, the requirements in these proposed rules. The Departments, thus, seek to estimate an hourly burden and cost range (high-end and low-end) associated with these proposed rules for those health insurance issuers and TPAs. In order to develop the high-end hourly burden and cost estimates, the Departments assume that all health insurance issuers and TPAs would need to develop and build their internet-based self-service tool project from start-up to operational functionality. The Departments estimate that for each issuer or TPA, on average, it would take business operations specialists 150 hours (at \$74 per hour), computer system analysts 1,000 hours (at \$90.02 per hour), web developers 40 hours (at \$72.68 per hour), computer programmers 1,250 hours (at \$86.14 per hour), computer and information systems managers 40 hours (at \$146.98 per hour), operations managers 25 hours (at \$119.12 per hour), a lawyer 2 hours (at \$138.68 per hour), and a chief executive officer 1 hour (at \$192.44 per hour) to complete this task. The Departments

estimate the total hour burden per issuer or TPA would be approximately 2,508 hours, with an equivalent cost of approximately \$221,029. For all 1,754 health insurance issuers and 205 TPAs, the total one-time total hour burden is estimated to be 4,913,172 hours with an equivalent total cost of approximately \$432,996,203.

TABLE 3A: Total High- End Estimated One-time Cost and Hour Burden for Internet-based Self-service Tool for Each Health Insurance Issuer or TPA

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
General and Operations Manager	25	\$119.12	\$2,978
Computer and Information Systems Manager	40	\$146.98	\$5,879
Computer Programmer	1,250	\$86.14	\$107,675
Computer System Analyst	1,000	\$90.02	\$90,020
Web Developer	40	\$72.68	\$2,907
Business Operations Specialist	150	\$74.00	\$11,100
Lawyer	2	\$138.68	\$277
Chief Executive Officer	1	\$192.44	\$192
Total per respondent	2,508		\$221,029

TABLE 3B: Total High- End Estimated One-time Cost and Hour Burden for Internet-based Self-service Tool for All Health Insurance Issuers and TPAs

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,959	1,959	2,508	4,913,172	\$432,996,203

The Departments recognize that a significant number of health insurance issuers may already have some form of price estimator tool that allows for comparison shopping and a large number of issuers may currently provide the ability for consumers to obtain their estimated out-

of-pocket costs.¹¹⁰ For those health insurance issuers and TPAs, that currently have some level of functional cost estimator tool that would meet some of the requirements of these proposed rules, the Departments recognize that these entities would incur a lower hour burden and cost. Thus, the Departments have estimated a low-end hour burden and cost to comply with these proposed rules. Assuming that 90 percent of health insurance issuers and TPAs currently provide a cost estimator tool and would only be required to make changes to their current system in order to meet the requirements in these proposed rules, the Departments estimate that 175 health insurance issuers and 21 TPAs would be required to develop an internet-based self-service tool from start-up to operational functionality. The Departments estimate that each issuer or TPA would incur a one-time cost and hour burden of approximately 2,508 hours, with an equivalent cost of approximately \$221,029 (as discussed previously in this ICR). For the 196 health insurance issuers and TPAs, the total one-time hour burden is estimated to be 491,317 hours with an equivalent total cost of approximately \$43,299,620.

Table 4A: Low-Range One-time Cost and Hour Burden for Web-based Consumer Price Tool for Health Insurance Issuers and TPAs Requiring a Complete Build from the Start-Up to operational Functionality.

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
196	196	2,508	491,317	\$43,299,620

The Departments estimate that those health insurance issuers and TPAs that would only be required to make changes to their existing systems would already have operational

¹¹⁰ See AHIP release dated August 2, 2019 - AHIP Issues Statement on Proposed Rule Requiring Disclosure of Negotiated Prices. Available at: <https://www.ahip.org/ahip-issues-statement-on-proposed-rule-requiring-disclosure-of-negotiated-prices/>. See also Higgins, A., Brainard, N., 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](https://ajmc.s3.amazonaws.com/media/pdf/AJMC_02_2016_Higgins%20(final).pdf).

capabilities that meet approximately 75 percent of the requirements in these proposed rules and would only incur a cost and hour burden related to changes needed to fully meet the requirements of these proposed rules. Based on this assumption, the Departments estimate that 1,579 health insurance issuers and 184 TPAs would incur a one-time hour burden of 627 hours and an associated cost of \$55,257 to fully satisfy the requirements of these proposed rules. For all 1,763 health insurance issuers and TPAs, the total one-time hour burden would be 1,105,464 hours with an equivalent total cost of approximately \$97,424,146.

Table 4B: Low-End One-time Cost and Hour Burden for Web-based Consumer Price Tool for Health Insurance 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	11,763	627	1,105,464	\$97,424,146

Table 4C: Total Low-End One-time Cost and Hour Burden for Web-based Consumer Price Tool for Health Insurance Issuers and TPAs.

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,959	1,959	815	1,596,781	\$140,723,766

In addition to the range of one-time costs and hour burdens estimated in Tables 4B and 4C, health insurance issuers and TPAs would incur ongoing 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, on average, it would take business operations specialists 15 hours (at \$74.00 per hour), computer systems analysts 50 hours (at \$90.02 per hour), web developers 10 hours (at \$72.68 per hour), computer programmers 55 hours (at \$86.14 per hour), computer and information systems managers 10 hours (at \$146.98), and operations managers 5 hours (at \$119.12 per hour) each year to perform these tasks. The total annual hour burden for

each issuer or TPA would be 145 hours, with an equivalent cost of approximately \$13,141. For all 1,754 health insurance issuers and 205 TPAs, the total annual hour burden is estimated to be 284,055 hours with an equivalent total annual cost of approximately \$25,743,023. The Departments consider this to be an upper-bound estimate and expect maintenance costs to decline in succeeding years as health insurance issuers and TPAs gain efficiencies and experience in updating and managing their internet-based self-service tool.

TABLE 5A: Estimated Annual Cost and Burden for Maintenance of Internet-based Self-Service Tool for Each Health Insurance Issuer or TPA

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
General and Operations Manager	5	\$119.12	\$596
Computer and Information Systems Manager	10	\$146.98	\$1,470
Business Operations Specialist	15	\$74.00	\$1,110
Computer System Analyst	50	\$90.02	\$4,501
Web Developer	10	\$72.68	\$727
Computer Programmer	55	\$86.14	\$4,738
Total per Respondent	145		\$13,141

Table 5B: Estimated Annual Hour Burden for Maintenance of Internet-based Self-Service Tool for All Health Insurance Issuers and TPAs from 2021 Onwards

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,959	1,959	145	284,055	\$25,743,023

The Departments estimate the high-end average annual total hour burden, for all health insurance issuers and TPAs to develop, build, and maintain an internet-based consumer self-service tool, over three years would be 1,827,094 hours annually with an average annual total equivalent cost of \$161,494,083. The Departments acknowledge that the costs described earlier in this section of the preamble may vary depending on the number of lives covered, and the number of providers and items and services incorporated into the internet-based self-service tool. In recognizing that many health insurance issuers and TPAs currently have some form of cost estimator tool in operation that meet most (if not all) of the requirements in these proposed rules,

the Departments estimate the low-end average annual total hour burden, for all health insurance issuers and TPAs to develop, build, and maintain an internet-based self-service tool, over a 3-year period would be 721,630 hours annually with an average annual total equivalent cost of \$64,069,937. The Departments recognize that group health plans, issuers, and TPAs may be able to license existing online cost estimator 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 hour burden and costs estimated here.

TABLE 6: Estimated High-End Three Year Average Annual Hour Burden and Costs for All Health Insurance 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
2020	1,959	1,959	2,508	4,913,172	\$432,996,203
2021	1,959	1,959	145	284,055	\$25,743,023
2022	1,959	1,959	145	284,055	\$25,743,023
3 year Average	1,959	1,959	933	1,827,094	\$161,494,083

TABLE 7: Estimated Low-End Three Year Average Annual Hour Burden and Costs for All Health Insurance 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
2020	1,959	1,959	815	1,596,781	\$140,723,766
2021	1,959	1,959	145	284,055	\$25,743,023
2022	1,959	1,959	145	284,055	\$25,743,023
3 year Average	1,959	1,959	368	721,630	\$64,069,937

In addition to the one-time and annual maintenance costs estimated in Table 7, health insurance issuers and TPAs would also incur an annual burden and costs associated with customer service representative training, consumer assistance, and administrative and distribution costs related to the disclosures required under paragraph (b)(2)(ii) of these proposed rules. The Departments estimate that, to understand and navigate the internet-based self-service tool and be able to provide the appropriate assistance to consumers, each customer service representative would require approximately 2 hours (at \$35.06 per hour) of annual consumer assistance training at an associated cost of \$70 per hour. The Departments estimate that each issuer and TPA would train, on average, 10 customer service representatives annually, resulting in a total annual hour burden of 20 hours and associated total costs of \$701 per issuer or TPA. For all 1,754 health insurance issuers and 205 TPAs, the total annual hour burden is estimated to be 39,180 hours with an equivalent total annual cost of approximately \$1,373,651.

TABLE 8A: Estimated Annual Cost and Hour Burden per Health Insurance 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	\$35.06	\$70
Total per Respondent	2		\$70

TABLE 8B: Estimated Annual Cost and Hour Burden for All Health Insurance Issuers and TPAs from 2021 onwards 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	19,590	20	39,180	\$1,373,651

The Departments assume that the greatest proportion of beneficiaries, participants, and enrollees who would request disclosure of cost-sharing information in paper form would do so because they do not have access to the internet. However, the Departments acknowledge that

some consumers with access to the internet would also contact a plan or issuer for assistance 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 subscription¹¹¹ and that approximately 19 million Americans (6 percent of the population) lack access to fixed broadband services that meet threshold levels.¹¹² 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.¹¹³ 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.¹¹⁴ Further research indicates that younger individuals and households, including approximately 93 percent of households with householders aged 15 to 34,

¹¹¹ See 2017 U.S. Census Bureau, 2017 American Community Survey 1-Year Estimates. Available at: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_17_1YR_S2801&prodType=table.

¹¹² See Eight Broadband Progress Report. 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 do not subscribe.

¹¹³ See Anderson, M., Perrin, A., Jiang, J., Kumar, M. “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/>).

¹¹⁴ See 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).

are more likely to have smartphones compared to those aged over 65.¹¹⁵ The Departments are of the view that the population most likely to use the internet-based self-service tool would generally consist of higher-income and younger individuals, who are more likely to have internet access via broadband or smartphone technologies.

The Departments estimate there are 193.5 million¹¹⁶ beneficiaries, participants, or enrollees enrolled in group health plans or with health insurance issuers required to comply with the requirements under paragraph (b) of these proposed rules. On average, it is estimated that each issuer or TPA would annually administer the benefits for 98,775 beneficiaries, participants, or enrollees.

Assuming that 6 percent of covered individuals lack access to fixed broadband service and, taking into account that a recent study noted that only 1 to 12 percent of consumers that have been offered internet-based or mobile application-based price transparency tools use them,¹¹⁷ the Departments estimate that on average 6 percent of participants, beneficiaries, or enrollees would seek customer support (a mid-range percentage of individuals that currently use available cost estimator tools) and that an estimated 1 percent of those participants, beneficiaries, or enrollees would request any pertinent information be disclosed to them in paper form. The

¹¹⁵ See Ryan, C. “Computer and Internet Use in the United States: 2016.” American Community Survey Reports: United States Census Bureau. August 2016 Available at: <https://www.census.gov/content/dam/Census/library/publications/2018/acs/ACS-39.pdf>.

¹¹⁶ EBSA estimates that in 2016 there were 135.7 million covered individuals with private sector and 44.1 million with public sector employer sponsored coverage (see <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>). Kaiser Family Foundation reports 13.7 million enrollees in the individual market for the first quarter of 2019 (see: <https://www.kff.org/private-insurance/issue-brief/data-note-changes-in-enrollment-in-the-individual-health-insurance-market-through-early-2019/>).

¹¹⁷ See Mehrotra, A., Chernew, M., 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>.

Departments estimate that each health insurance issuer or TPA, on average, would require a customer service representative to interact with a beneficiary, participant, or enrollee approximately 59 times per year on matters related to cost-sharing information disclosures required by these proposed rules. The Departments estimate that each customer service representative would spend, on average, 15 minutes (at \$35.06 per hour) for each interaction, resulting in a cost of approximately \$9 per interaction. The Departments estimate that each issuer or TPA would incur an annual hour burden of 15 hours with an associated equivalent cost of approximately \$519 for each issuer or TPA, resulting in a total annual hour burden of 29,025 hours with an associated cost of approximately \$1,017,617 for all issuers or TPAs.

The Departments assume that all beneficiaries, participants, or enrollees that contact a customer service representative representing their plan or issuer would 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 would request the information be provided via mail. The Departments estimate that, on average, each issuer or TPA would send approximately 27 disclosures via mail annually. Based on these assumptions, the Departments estimate that the total number of annual disclosures sent by mail for all health insurance issuers and TPAs would be 53,406.

The Departments assume the average length of the printed disclosure would be approximately nine single-sided pages in length, assuming two pages of 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 health

insurance issuer or TPA would incur a material and printing costs of \$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 would incur an annual printing and mailing cost of approximately \$27, resulting in a total annual printing and mailing cost of approximately \$53,406 for all health insurance issuers and TPAs.

TABLE 9A: Estimated Annual Cost and Hour Burden per Response per Health Insurance Issuer or TPA to Accept and Fulfill Requests for a Mailed Disclosure

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Customer Service Representatives	0.25	\$35.06	\$9
Total per Respondent	0.25		\$9

TABLE 9B: Estimated Annual Cost and Hour Burden for All Health Insurance Issuers and TPAs from 2021 onwards 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	116,100	15	29,025	\$1,017,617	\$53,406	\$1,071,023

The Departments solicit comment for this collection of information request related to the overall estimated costs and hour burdens. The Departments also seek comment related to the technical and labor requirements or costs that may be required to meet the requirements of these 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 seek comment on the estimated number of health insurance 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 seek comment on any other existing efficiencies that could be leveraged to minimize the burden on group health plans, issuers, and TPAs, as well as how many or what percentage of plans, issuers, and TPAs might leverage such efficiencies. The Departments seek comment on the proposed model notice and any additional information that stakeholders feel should be included, removed, or expanded upon and its overall adaptability.

In conjunction with these proposed rules, CMS is seeking an OMB control number and approval for the proposed information collection (OMB control number: 0938-NEW (Transparency in Coverage (CMS-10715))). CMS is proposing to require the following information collections to include the following burden. DOL and Treasury will submit their burden estimates upon approval.

2. ICRs Regarding Requirements for Public Disclosure of Negotiated Rates and Historical Allowed Amount Data for Covered Items and Services from Out-of-Network Providers under 26 CFR 54.9815-2715A(c), 29 CFR 2590.715-2715A(c), and 45 CFR 147.210(c)

The Departments propose to add paragraph (c) of these proposed rules to require group health plans and health insurance issuers to make public negotiated rates with in-network providers and data outlining the different amounts a plan or issuer has paid to particular out-of-network providers for covered items or services. Plans and issuers would be required to disclose for each covered service or item, the negotiated rates for services and items furnished by particular in-network providers and out-of-network allowed amount data for each covered service or item furnished by particular out-of-network provider through two 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

previously and enumerated under paragraph (c)(1)(i) for the Negotiated Rate File and (c)(1)(ii) for the Allowed Amount File of these proposed rules. Under paragraphs (c)(2) and (3) of these proposed rules, the files must be posted on a public internet site with unrestricted access and must be updated monthly.

For the Allowed Amount File required under proposed (c)(1)(ii), the proposed rules would require plans and issuers to make available a machine-readable file showing the unique amounts a plan or issuer's coverage allowed for items or services furnished by particular out-of-network providers during the 90-day time period that begins 180 days before the publication date of the file. As discussed previously in these proposed rules, to the extent that a plan or issuer has allowed multiple amounts for an item or service to a particular provider at the same rate, the proposed rules would 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 10 or fewer claims for a covered item or service for payment to a provider during any relevant 90-day period, the plan or issuer would not be required to report those unique allowed amounts.

As discussed in the previous collection of information, the Departments assume fully-insured group health plans would rely on health insurance issuers and most self-insured group health plans would rely on issuers or TPAs to develop and update the proposed machine-readable files. The Departments recognize that there may be some self-insured plans that wish to individually comply with these proposed rules and would incur a similar hour burden and costs as described in the following paragraphs.

The Departments estimate a one-time hour burden and cost to health insurance issuers and TPAs to make appropriate changes to IT systems and processes, to develop, implement and operate the Negotiated Rate File in order to meet the proposed requirements under paragraph

(c)(1)(i). The Departments estimate that for each health insurance issuer or TPA, on average, would require business operations specialists 20 hours (at \$74 per hour), computer system analysts 500 hours (at \$90.02 per hour), computer programmers 600 hours (at \$86.14 per hour), computer and information systems managers 50 hours (at \$146.98 per hour) and operations managers 20 hours (at \$119.12 per hour) to complete this task. The total burden for each issuer or TPA would be approximately 1,190 hours on average, with an equivalent associated cost of approximately \$107,905. For all 1,754 health insurance issuers and 205 TPAs, the Departments estimate the total one-time hour burden would be 2,331,210 hours with an associated cost of approximately \$211,386,679. 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 these proposed 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 Negotiated Rate Files. The Departments request comment on these estimates and whether they substantially overestimate expected burden.

TABLE 10A: Estimated One-Time Cost and Hour Burden per Health Insurance Issuer or TPA for the Negotiated Rates for In-Network Providers Negotiated Rate File

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
General and Operations Manager	20	\$119.12	\$2,382
Computer and Information Systems Manager	50	\$146.98	\$7,349
Business Operations Specialist	20	\$74.00	\$1,480
Computer System Analyst	500	\$90.02	\$45,010
Computer Programmer	600	\$86.14	\$51,684
Total per Respondent	1,190		\$107,905

TABLE 10B: Estimated One-Time Cost and Hour Burden for All Health Insurance Issuers and TPAs for the Negotiated Rates for In-Network Negotiated Rate File

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,959	1,959	1,190	2,331,210	\$211,386,679

In addition to the one-time costs estimated Tables 10A and 10B, health insurance issuers and TPAs would incur ongoing annual burdens and costs to update the proposed Negotiated Rate File monthly as proposed under paragraph (c)(3). The Departments estimate that for each issuer or TPA, on average, it would require a general and operations manager 3 hours (at \$119.12 per hour), computer systems analysts 10 hours (at \$90.02 per hour), computer programmers 10 hours (at \$86.14 per hour), a computer and information systems manager 5 hours (at \$146.98), and a business operations specialist 2 hours (at a rate of \$74.00) to make the required updates to the Negotiated Rate File. The Departments estimate that each issuer or TPA would incur a burden of 30 hours with an associated cost of approximately \$3,002 to update the Negotiated Rate File. Assuming health insurance issuers and TPAs make changes that would require the file to be updated monthly per the requirements proposed in these rules, an issuer or TPA would need to update the Negotiated Rate File 12 times during a given year, resulting in an ongoing annual hour burden of 360 hours for each issuer or TPA with an associated equivalent cost of approximately \$36,022. The Departments estimate the total annual hour burden for all 1,959 health insurance issuers and TPAs would be 705,240 hours, with an associated equivalent cost of approximately \$70,567,725. The Departments consider this estimate to be an upper-bound estimate and expect ongoing update costs to decline in succeeding years as health insurance issuers and TPAs gain efficiencies and experience in updating and managing the machine-readable files.

The Departments seek comment on the accuracy of the burden estimates under these proposed rules, as well as any ways to further refine the burden estimates.

TABLE 11A: Estimated Annual Ongoing Cost and Burden per Health Insurance Issuer or TPA for the Negotiated Rates for In-Network Providers Negotiated Rate File

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
General and Operations Manager	3	\$119.12	\$357
Computer and Information Systems Manager	5	\$146.98	\$735
Business Operations Specialist	2	\$74.00	\$148
Computer System Analyst	10	\$90.02	\$900
Computer Programmer	10	\$86.14	\$861
Total per Respondent	30		\$3,002

TABLE 11B: Estimated Annual Ongoing Cost and Burden for All Health Insurance Issuers and TPAs from 2021 Onwards for the In-Network Providers Negotiated Rate File

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,959	23,508	360	705,240	\$70,567,725

The Departments estimate the total one-time hour burden for all health insurance issuers and TPAs of 2,331,210 hours and an associated equivalent cost of approximately \$211,386,679 to develop and build the Negotiated Rate File in a machine-readable format. In subsequent years, the Departments estimate the total annual hour burden of 705,240 hours to maintain and update the Negotiated Rate File with an annual associated equivalent cost of approximately \$70,567,725. The Departments estimate the average annual total hour burden, for all health insurance issuers and TPAs, over three years, would be 1,247,230 hours with an average annual associated equivalent total cost of \$117,507,376.

TABLE 12: Estimated Three Year Average Annual Hour Burden and Costs for All Issuers and TPAs to Develop and Maintain the In-Network Providers Negotiated Rate File

Year	Estimated Number of Health Insurance Issuers and TPAs	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
2020	1,959	1,959	1,190	2,331,210	\$211,386,679
2021	1,959	23,508	360	705,240	\$70,567,725
2022	1,959	23,508	360	705,240	\$70,567,725
3 year Average	1,959	16,325	637	1,247,230	\$117,507,376

The Departments estimate a one-time hour burden and cost to health insurance 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 proposed requirements under paragraph (c)(1)(ii) of the proposed rules related to making available a file of certain historical claims paid to out-of-network providers. The Departments estimate that each issuer or TPA, on average, would require business operations specialists 20 hours (at \$74 per hour), computer system analysts 500 hours (at \$90.02 per hour), computer programmers 600 hours (at \$86.14 per hour), computer and information systems managers 50 hours (at \$146.98 per hour), information security analysts 100 hours (at \$98.52 per hour), and operations managers 20 hours (at \$119.12 per hour) to complete this task. The total burden per issuer or TPA would be approximately 1,290 hours on average, with an equivalent associated cost of approximately \$117,757. For all 1,754 health insurance issuers and 205 TPAs, the Departments estimate the total one-time hour burden would be 2,527,110 hours with an equivalent associated cost of approximately \$230,686,747.

TABLE 13A: Estimated One-Time Cost and Hour Burden per Health Insurance Issuer or TPA for the Out-of-Network Allowed Amount File

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
General and Operations Manager	20	\$119.12	\$2,382
Computer and Information Systems Manager	50	\$146.98	\$7,349
Business Operations Specialist	20	\$74.00	\$1,480
Computer System Analyst	500	\$90.02	\$45,010
Information Security Analysts	100	\$98.52	\$9,852
Computer Programmer	600	\$86.14	\$51,684
Total per Respondent	1,290		\$117,757

TABLE 13B: Estimated One-Time Cost and Hour Burden for All Health Insurance Issuers and TPAs for the Out-of-Network Allowed Amount File

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,959	1,959	1,290	2,527,110	\$230,686,747

In addition to the one-time costs estimated in Tables 13A and 13B, health insurance issuers and TPAs would incur ongoing annual burdens and costs to update the proposed Allowed Amount File monthly. The Departments estimate that for each issuer or TPA, on average, it would require a computer systems analysts 5 hours (at \$90.02 per hour), computer programmers 5 hours (at \$86.14 per hour), a computer and information systems manager 1 hour (at \$146.98), and an information security analyst 2 hours (at \$98.52 per hour) to make the required Allowed Amount File updates. The Departments estimate that each issuer or TPA would incur a monthly burden of 13 hours with an equivalent associated cost of approximately \$1,225 to update the Allowed Amount File. Assuming health insurance issuers and TPAs make changes that would require the file to be updated monthly per the requirements in these proposed rules an issuer or TPA would need to update Allowed Amount File 12 times during a given year, resulting in an ongoing annual burden of approximately 156 hours for each issuer or TPA with an equivalent

associated cost of approximately \$14,698. The Departments estimate the total annual hour burden for all 1,959 health insurance issuers and TPAs would be 305,604 hours with an equivalent associated cost of approximately \$28,793,069. 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 health insurance issuers and TPAs gain efficiencies and experience in updating and managing the Allowed Amount File.

TABLE 14A: Estimated Annual Ongoing Cost and Burden per Health Insurance Issuer or TPA for the Out-of-Network Allowed Amount File

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Computer and Information Systems Manager	1	\$146.98	\$147
Computer System Analyst	5	\$90.02	\$450
Computer Programmer	5	\$86.14	\$431
Information Security Analysts	2	\$98.52	\$197
Total per Respondent	13		\$1,225

TABLE 14B: Estimated Annual Ongoing Cost and Burden for All Health Insurance Issuers and TPAs from 2021 onwards for the Out-of-Network 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	\$28,793,069

The Departments estimate the total one-time hour burden for all health insurance issuers and TPAs of 2,527,110 hours and an equivalent associated cost of approximately \$230,686,747 to develop and build the Allowed Amount File to meet the requirements of these proposed rules. In subsequent years, the Departments estimate the total annual hour burden of 305,604 hours to maintain and update the Allowed Amount File with an annual equivalent associated cost of approximately \$28,793,069. The Departments estimate the average annual total hour burden, for all health insurance issuers and TPAs, over three years, would be 1,046,106 hours with an average annual total equivalent associated cost of \$96,090,961.

TABLE 15: Estimated Three Year Average Annual Hour Burden and Costs for All Health Insurance Issuers and TPAs to Develop and Maintain the Out-of-Network Allowed Amount File

Year	Estimated Number of Health Insurance Issuers and TPAs	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
2020	1,959	1,959	1,290	2,527,110	\$230,686,747
2021	1,959	23,508	156	305,604	\$28,793,069
2022	1,959	23,508	156	305,604	\$28,793,069
3 year Average	1,959	16,325	534	1,046,106	\$96,090,961

The Departments solicit comment for this collection of information related to all aspects of the estimated hour burden and costs. Specifically, the Departments seek comment 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 seek comment related to the technical and labor requirements or costs that may be required to meet the requirements proposed in this rule; specifically, any factors that could minimize the frequency of updates that health insurance issuers or TPAs would be required to make to the Allowed Amount File.

The Departments solicit comment for this collection of information related to all aspects of the estimated hour burden and costs. Specifically, the Departments seek comment 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, 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 machine-readable file. The Departments also seek

comment related to the technical and labor requirements or costs that may be required to meet the requirements proposed in this rule; specifically, any factors that could minimize the burden and costs associated with updates that health insurance issuers or TPAs would be required to make to the Allowed Amount File.

The Departments also propose that a group health plan may satisfy the proposed requirements by making available the historical amounts paid to out-of-network providers by its health insurance issuer or service provider that includes allowed amounts information on the issuer's or service provider's book of business and a plan or issuer may rely on information provided by its claims clearinghouse in aggregate. To the extent a plan or issuer is providing out-of-network historical payment information in the aggregate, the Departments further propose to apply the 10 minimum claims threshold to the aggregated claims data set, and not at the plan or issuer level.

The Departments acknowledge that as many as 95 percent of group health plans and health insurance issuers might already contract with claims clearinghouses that currently collect some or all of the information required to be disclosed under these proposed rules and might easily be able meet the requirements in these proposed rules, 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 would still incur burden, albeit reduced, related to oversight and quality assurance related to any associated clearinghouse activities. The Departments seek comment 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 health insurance issuers, TPAs, or self-insured plans may already contract with

clearinghouses that collect the information required and may be able to fulfill requirements in these proposed rules.

The Departments understand that plans and issuers may include “gag clauses” in their provider contracting agreements, which prevent disclosure of negotiated rates. The Departments seek comment on whether such agreements would need to be renegotiated to remove such clauses, and, if so, seek comment regarding any costs and burden associated with this action. In conjunction with these proposed rules, CMS is seeking an OMB control number and approval for the proposed information collection (OMB control number: 0938-NEW (Transparency in Coverage (CMS-10715)). CMS is proposing to require the following information collections to include the following burden. DOL and Treasury will submit their burden estimates upon approval.

2. ICRs Regarding Medical Loss Ratio (45 CFR 158.221)

HHS proposes to amend §158.221 to allow issuers 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 provider. HHS does not anticipate that implementing this provision would require significant changes to the MLR annual reporting form and 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.

3. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 16: 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 (\$)
§§ 54.9815-2715A(b)(2)(i); 2590.715-2715A(b)(2)(i); and 147.210(b)(2)(i)	0938-NEW*	1,959	1,959	933	1,827,094	\$161,494,083	\$0	\$161,494,083
§§ 54.9815-2715A(b)(2)(ii); 2590.715-2715A(b)(2)(ii); and 147.210(b)(2)(ii)	0938-NEW	1,306	77,400	10	19,350	\$678,411	\$35,604	\$714,015
§§ 54.9815-2715A(c); 2590.715-2715A(c); and 147.210(c)(1)(i)	0938-NEW	1,959	16,325	637	1,247,230	\$117,507,376	\$0	\$117,507,376
§§ 54.9815-2715A(c)(1)(i); 2590.715-2715A(c)(1)(i); and 147.210(c)(1)(ii)	0938-NEW	1,959	16,325	534	1,046,106	\$96,090,961	\$0	\$96,090,961
Total			112,009	2,113	4,139,780	\$375,770,831	\$35,604	\$375,806,435

* High-end three year estimated values are represented in the table and used to determine the overall estimated three-year average.

For PRA purposes the Departments are splitting the burden; where CMS will account for 50 percent of the associated costs and burdens and the Departments of Labor and Treasury will each account for 25 percent of the associated costs and burdens. The hour burden for CMS will be 2,069,890 hours with an equivalent associated cost of approximately \$187,886,416 and a cost burden of \$17,802. For the Departments of Labor and Treasury, each Department will account

for an hour burden of 1,034,945 hours with an equivalent associated cost of approximately \$93,942,708 and a cost burden of \$8,901.

B. Submission of PRA-related Comments

The Departments have submitted a copy of these proposed rules to the OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

Department of Health and Human Services

To obtain copies of the supporting statement and any related forms for the proposed collections discussed earlier in this preamble, please visit CMS's Website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410-786-1326.

The Departments invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the ADDRESSES section of these proposed rules and identify the rule (CMS-9915-P), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due [INSERT DATE 60-DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

C. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial 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.

These proposed rules propose to require that group health plans and health insurance issuers disclose to a participant, beneficiary, or enrollee (or his or her authorized representative) such individual’s cost-sharing information for covered items or services from a particular provider or providers. The Departments are of the view that these issuers generally exceed the size thresholds for “small entities” established by the SBA, thus, 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. While the Departments’ are of the view that these plans would rely on the larger health insurance issuers and TPAs to comply with these proposed rules, they would still experience increased costs due to the requirements as the costs are passed onto them. However, the Departments are not of the view that the additional costs meet the significant impact requirement. These assertions are discussed later in this section of the preamble. In addition, while the requirements of this proposal 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 health insurance 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 for these North American Industry

Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$35 million or less.¹¹⁸ 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 report¹¹⁹ 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. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 72 percent of these small companies belong to larger holding groups, and most, if not all, of these small companies 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 apply to those TPAs that would be affected by the proposed rules. The Departments do not expect any of these 90 potentially small entities to experience a change in rebates under the proposed amendments to the MLR provisions of these proposed rules in 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 proposed 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 seek comment on ways that the proposed rules

¹¹⁸ “Table of Small Business Size Standards Matched to North American Industry Classification System Codes.” U.S. 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.

¹¹⁹ “Medical Loss Ratio Data and System Resources.” CCIIO. Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

will impose additional costs and burdens on small entities and how many would be likely engage in contracts to meet the requirements.

For purposes of the RFA, the Department of Labor continues to consider a small entity to be an employee benefit plan with fewer than 100 participants.¹²⁰ Further, while some large employers may have small plans, in general small employers maintain most small plans.

Thus, the Departments are of the view that assessing the impact of these proposed 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 requests comments on the appropriateness of the size standard used in evaluating the impact of these proposed rules on small entities. Using this 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 proposed rules were 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 \$159.70 (\$371,990,734/2,329,298). Instead, if those costs are spread evenly across the estimated 193.5 million¹²¹ beneficiaries, participants, or enrollees enrolled in plans or issuers required to comply with the requirements then the average cost per covered individual would be \$1.92

¹²⁰ 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.

¹²¹ EBSA estimates that in 2016 there were 135.7 million covered individuals with private sector and 44.1 million with public sector employer sponsored coverage (available at: <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>). Kaiser Family Foundation reports 13.7 million enrollees in the individual market for the first quarter of 2019 (available at: <https://www.kff.org/private-insurance/issue-brief/data-note-changes-in-enrollment-in-the-individual-health-insurance-market-through-early-2019/>)

(\$371,990,734/193.5 million). Neither the cost per entity nor the cost per covered individual is a significant impact.

In addition, section 1102(b) of the SSA (42 U.S.C. 1302) requires us 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 603 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. These proposed rules would not affect small rural hospitals. Therefore, the Departments have determined that this would 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, these proposed rules have been submitted to the Chief Counsel for Advocacy of the SBA for comment on their impact on small business.

D. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain actions before issuing a proposed 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 2019, that threshold is approximately \$154 million.

State, local, or tribal governments may incur cost to enforce some of the requirements of these proposed rules. These proposed rules include instructions for disclosures that would affect private sector firms (for example, health insurance issuers offering 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 these proposed rules and although the Departments have not been able to quantify all costs, the Departments expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed 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 the preamble to the regulation.

In the Departments' view, these proposed rules may have federalism implications, because it would have direct effects on the states, the relationship between national governments and states, or on the distribution of power and responsibilities among various levels of government relating to the disclosure of health insurance coverage information to consumers.

Under these proposed 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, would be required to develop an internet-based online tool or non-internet disclosure method to disclose to a participant, beneficiary, or enrollee (or an authorized representative on behalf of such individual), the consumer-specific estimated cost-sharing liability for covered items or services from a particular provider. These proposed rules also include proposals to require plans and issuers to disclose provider negotiated rates and historical data on out-of-network allowed amounts through a digital file in a machine-readable format posted publicly on

an internet website. Such federal standards developed under section 2715A of the PHS Act would 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 this rule and the statutory authority under which it is promulgated.

The Departments are of the view that these proposed 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.¹²² Under these state provisions, state requirements vary broadly in terms of the level of disclosure required,¹²³ 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 on request. In contrast, other states use websites or software applications (or apps) that allow consumers to compare prices across providers. Still, only seven states have published the pricing information of health insurance issuers on consumer-facing public websites.¹²⁴ Thus, to the extent the disclosure provision these proposed rules required additional information to be disclosed, this proposed rule would require a higher level of disclosure by plans and issuers.

¹²²“Transparency and disclosure of health costs and provider payments: state actions.” National Conference of State Legislatures. March 2017. Available at:<http://www.ncsl.org/reserach/health/transparency-and-disclosure-health-costs.aspx>.

¹²³ Mehrotra, A., Chernew, M., 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>.

¹²⁴ 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>.

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. While ERISA prohibits states from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (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 states law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance 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 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 continue to apply state law requirements to health insurance 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 health insurance 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 the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis. It is expected that the Departments act in a similar fashion in enforcing PPACA, including the provisions of section 2715A of the PHS Act. While developing

this rule, the Departments attempted to balance the states' interests in regulating health insurance issuers with Congress' intent to provide an improved level of price transparency to consumers 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 this proposed rule, the Departments certify that the Department of Treasury, Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached proposed rule in a meaningful and timely manner.

F. Congressional Review Act

These proposed 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, and has been transmitted to the Congress and the Comptroller for review.

G. 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 designation of this rule, if finalized, would be informed by public comments received; however, these proposed rules, if finalized as proposed, would be an E.O. 13771 regulatory action.¹²⁵

IX. Statutory Authority

The Department of the Treasury regulations are proposed to be adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are proposed to be 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 proposed to be adopted pursuant to the authority contained in sections 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.

¹²⁵ The Departments estimate cost of approximately \$877.31 million in 2020 and annual cost of approximately \$127.55 million thereafter. Thus the annualized value of cost, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, is \$128.86 million.

Sunita Lough
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.
Signed at Washington DC, this 12th day of November, 2019

CMS-9915-P

Signed at Washington DC, this 12th day of November, 2019

Preston Rutledge
Assistant Secretary
Employee Benefits Security Administration
Department of Labor

CMS-9915-P

Dated: November 5, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: November 7, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

List of Subjects26 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.

DEPARTMENT OF THE TREASURY**Internal Revenue Service****Proposed Amendments to the Regulations**

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

Par. 1. The authority citation for part 54 continues to read as follows:

Authority: 26 U.S.C. 7805

* * * *

Section 54.9815-2715A is also issued under 26 U.S.C. 9833.

* * * *

Par. 2. Section 54.9815-2715A is added to read as follows:

§ 54.9815-2715A Transparency in coverage.

(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 health plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, 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, either with respect to a deductible or 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 or beneficiary 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 deductible and/or out-of-pocket limit, as applicable. For this purpose, accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but excludes 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).

(ii) *Beneficiary* has the meaning given the term under section 3(8) of the Employee Retirement Income Security Act of 1974 (ERISA).

(iii) *Billing code* means the code used by a group health plan or health insurance issuer or its in-network providers 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* means a payment model under which a provider is paid a single payment for all covered items and services provided to a patient for a specific treatment or procedure.

(v) *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. This term generally includes deductibles, coinsurance, and copayments, but it does not include premiums, balance billing amounts for out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(vi) *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 a participant's or beneficiary's out-of-pocket costs for a particular health care item or service.

(vii) *Covered items or services* means those items or services for which the costs are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(viii) *In-network provider* means a provider that is a member of the network of contracted providers established or recognized under a participant's or beneficiary's group health plan or health insurance coverage.

(ix) *Items or services* means all encounters, procedures, medical tests, supplies, drugs, durable medical equipment, and fees (including facility fees), for which a provider charges a patient in connection with the provision of health care.

(x) *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.

(xi) *Negotiated rate* means 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.

(xii) *Out-of-network allowed amount* means 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.

(xiii) *Out-of-network provider* means a provider 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.

(xiv) *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.

(xv) *Participant* has the meaning given the term under section 3(7) of ERISA.

(xvi) *Plain language* means written and presented in a manner calculated to be understood by the average participant or beneficiary.

(xvii) *Prerequisite* means certain requirements relating to medical management techniques for covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. Prerequisites include concurrent review, prior authorization, and step-therapy or fail-first protocols. The term prerequisite does not

include medical necessity determinations generally or other forms of medical management techniques.

(b) *Required disclosures to participants or beneficiaries.* At the request of a participant or beneficiary (or his or her authorized representative), a group health plan or health insurance issuer offering group or individual health insurance coverage must provide to the participant or beneficiary (or his or her authorized representative) 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 covered item or service and a particular provider or providers, to the extent relevant to the participant's or beneficiary's cost-sharing liability:

(i) An estimate of the participant's or beneficiary's cost-sharing liability for a requested covered item or service provided by a provider or providers that is calculated based on the information described in paragraphs (b)(1)(ii) through (iv) of this section;

(ii) Accumulated amounts the participant or beneficiary has incurred to date;

(iii) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service;

(iv) Out-of-network allowed amount for the requested covered item or service, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider;

(v) If a participant or beneficiary requests information for an item or service subject to a bundled payment arrangement that includes the provision of multiple covered items and services, a list of the items and services 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; and,

(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 bill charges and the sum of the amount collected from the group health plan or health insurance issuer and from the patient 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;

(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; and

(D) 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 or beneficiaries (or their authorized representatives).* 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 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 (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 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 (or his or her authorized representative). The group health plan or health insurance issuer is required to:

(A) 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), (B), and (C) of this section; and

(B) Mail the cost-sharing information no later than 2 business days after an individual's request is received.

(3) *Special rule to prevent unnecessary duplication with respect to group health coverage.* 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 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).

(c) *Requirements for public disclosure of in-network provider negotiated rates and out-of-network allowed amounts for covered items and services.* A group health plan or health

insurance issuer must make available on an internet website the information required under paragraph (c)(1) of this section in two machine-readable files in accordance with the method and format requirements described in paragraph (c)(2) of this section and updated as required under paragraph (c)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (c) that are made available to the public by a group health plan or health insurance issuer must include:

(i) Negotiated rate machine-readable file:

(A) The name and Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) identifier, as applicable, for each plan option or coverage offered by a health insurance issuer or group health plan;

(B) A billing code 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, and a plain language description for each billing code; and

(C) Negotiated rates that are:

(1) Reflected as dollar amounts, with respect to each covered item or service under the plan or coverage that is furnished by an in-network provider;

(2) Associated with the National Provider Identifier (NPI) for each in-network provider; and

(3) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each covered item or service, including rates for both individual items and services and items and services in a bundled payment arrangement.

(ii) Out-of-network allowed amount file:

(A) The name and Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) identifier, as applicable, for each plan option or coverage offered by a health insurance issuer or group health plan;

(B) A billing code 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, and a plain language description for each billing code; and

(C) Unique out-of-network allowed amounts 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 requirement would require the group health plan or health insurance issuer to report payment of out-of-network allowed amounts in connection with fewer than 10 different claims for payments). Consistent with paragraph (d)(3) of this section, nothing in this paragraph 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 under the plan or coverage that is furnished by an out-of-network provider; and

(2) Associated with the National Provider Identifier (NPI) for each out-of-network provider.

(2) *Required method and format for disclosing information to the public.* The machine-readable files that must be made available under paragraph (c) of this section must comply with technical guidance issued jointly by the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury. The first machine-readable file

must include information regarding rates negotiated for in-network providers with each of the required elements described in paragraph (c)(1)(i) of this section. The second machine-readable file must include information related to the historical data showing allowed amounts for covered items and services furnished by out-of-network providers and include the required elements described in paragraph (c)(1)(ii) of this section. 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 (c) 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 (c) 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 (c) 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 (c).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (c) 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 (c) 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 (c), the group health plan or health insurance issuer violates the transparency disclosure requirements of this paragraph (c).

(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 (c)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, a health insurance issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or health insurance issuer has contracted may aggregate out-of-network allowed amounts for more than one group health plan or insurance policy or contract.

(d) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after 1 year after [effective date of the final rule]. As provided under § 54.9815-1251, this section does not apply to grandfathered health plans.

(2) This section does not apply to health reimbursement arrangements or other account-based group health plans defined in § 54.9815-2711(d)(6).

(3) Nothing in the 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 group health plans and health insurance 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) or (c) 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.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons stated in the preamble, the Department of Labor amends 29 CFR parts 2590 as follows:

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; Secretary of Labor's Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

4. Section 2590.715-2715A is added to read as follows:

§ 2590.715-2715A Transparency in coverage.

(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 health plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, 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, either with respect to a deductible or 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 or beneficiary has incurred toward meeting his or her individual deductible and/or out-of-pocket limit, as well as the amount of financial responsibility that has been incurred toward meeting the other-than-self-only deductible and/or out-of-pocket limit, as applicable. For this purpose, accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but excludes 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).

(ii) *Billing code* means the code used by a group health plan or health insurance issuer or its in-network providers 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.

(iii) *Bundled payment* means a payment model under which a provider is paid a single payment for all covered items and services provided to a patient for a specific treatment or procedure.

(iv) *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. This term generally includes deductibles, coinsurance, and copayments, but it does not include premiums, balance billing amounts for out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(v) *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 a participant's or beneficiary's out-of-pocket costs for a particular health care item or service.

(vi) *Covered items or services* means those items or services for which the costs are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(vii) *In-network provider* means a provider that is a member of the network of contracted providers established or recognized under a participant's or beneficiary's group health plan or health insurance coverage.

(viii) *Items or services* means all encounters, procedures, medical tests, supplies, drugs, durable medical equipment, and fees (including facility fees), for which a provider charges a patient in connection with the provision of health care.

(ix) *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.

(x) *Negotiated rate* means 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.

(xi) *Out-of-network allowed amount* means 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.

(xii) *Out-of-network provider* means a provider 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.

(xiii) *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.

(xiv) *Plain language* means written and presented in a manner calculated to be understood by the average participant or beneficiary.

(xv) *Prerequisite* means certain requirements relating to medical management techniques for covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. Prerequisites include concurrent review, prior authorization, and step-therapy or fail-first protocols. The term prerequisite does not include medical necessity determinations generally or other forms of medical management techniques.

(b) *Required disclosures to participants or beneficiaries.* At the request of a participant or beneficiary (or his or her authorized representative), a group health plan or health insurance issuer offering group coverage must provide to a participant or beneficiary (or his or her authorized representative) 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 covered item or service and a particular provider or providers, to the extent relevant to the participant's or beneficiary's cost-sharing liability:

(i) An estimate of the participant's or beneficiary's cost-sharing liability for a requested covered item or service provided by a provider or providers that is calculated based on the information described in paragraphs (b)(1)(ii) through (iv) of this section;

(ii) Accumulated amounts the participant or beneficiary has incurred to date;

(iii) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service;

(iv) Out-of-network allowed amount for the requested covered item or service, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider;

(v) If a participant or beneficiary requests information for an item or service subject to a bundled payment arrangement that includes the provision of multiple covered items and services, a list of the items and services 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; and,

(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 bill charges and the sum of the amount collected from the group health plan or health insurance issuer and from the patient 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;

(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; and

(D) 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 or beneficiaries (or his or her authorized representative).* 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 for a covered item or service provided by out-of-network providers by inputting:

(1) A billing code or descriptive term, and

(2) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount (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 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. The group health plan or health insurance issuer is required to:

(A) 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), (B), and (C) of this section; and

(B) Mail the cost-sharing information no later than 2 business days after an individual's request is received.

(3) *Special rule to prevent unnecessary duplication with respect to group health coverage.* 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 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).

(c) *Requirements for public disclosure of in-network provider negotiated rates and out-of-network allowed amounts for covered items and services.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (c)(1) of this section in two machine-readable files in accordance with the method and format requirements described in paragraph (c)(2) of this section and updated as required under paragraph (c)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (c) that are made available to the public by a group health plan or health insurance issuer must include:

(i) Negotiated rate machine-readable file:

(A) The name and Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) identifier, as applicable, for each plan option or coverage offered by a health insurance issuer or group health plan;

(B) A billing code 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, and a plain language description for each billing code; and

(C) Negotiated rates that are:

(1) Reflected as dollar amounts, with respect to each covered item or service under the plan or coverage that is furnished by an in-network provider;

(2) Associated with the National Provider Identifier (NPI) for each in-network provider;
and

(3) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each covered item or service, including rates for both individual items and services and items and services in a bundled payment arrangement.

(ii) Out-of-network allowed amount file:

(A) The name and Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) identifier, as applicable, for each plan option or coverage offered by a health insurance issuer or group health plan;

(B) A billing code 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, and a plain language description for each billing code; and

(C) Unique out-of-network allowed amounts 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 requirement would require the group health plan or health insurance issuer to report payment of out-of-network allowed amounts in connection with fewer than 10 different claims for payments. Consistent with paragraph (d)(3) of this section, nothing in this paragraph 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 under the plan or coverage that is furnished by an out-of-network provider; and

(2) Associated with the National Provider Identifier (NPI) for each out-of-network provider.

(2) *Required method and format for disclosing information to the public.* The machine-readable files that must be made available under paragraph (c) of this section must comply with technical guidance issued jointly by the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury. The first machine-readable file must include information regarding rates negotiated for in-network providers with each of the required elements described in paragraph (c)(1)(i) of this section. The second machine-readable file must include information related to the historical data showing allowed amounts for covered items and services furnished by out-of-network providers and include the required elements described in paragraph (c)(1)(ii) of this section. 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 (c) 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 (c) 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 (c) 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 (c).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (c) 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 (c) 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 (c), the group health plan or health insurance issuer violates the transparency disclosure requirements of this paragraph (c).

(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 (c)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, a health insurance issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or health insurance issuer has contracted may aggregate out-of-network allowed amounts for more than one group health plan or insurance policy or contract.

(d) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after 1 year after [effective date of the final rule]. As provided under section 2590.715-1251 of this part, this section does not apply to grandfathered health plans.

(2) This section does not apply to health reimbursement arrangements or other account-based group health plans defined in section 2590.715-2711(d)(6) of this part.

(3) Nothing in the 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 group health plans and health insurance 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) or (c) 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 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. Section 147.210 is added to read as follows:

§ 147.210 Transparency in coverage.

(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 group health plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, 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, either with respect to a deductible or 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 deductible and/or out-of-

pocket limit, as applicable. For this purpose, accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but excludes 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).

(ii) *Beneficiary* has the meaning given the term under section 3(8) of the Employee Retirement Income Security Act of 1974 (ERISA).

(iii) *Billing code* means the code used by a group health plan or health insurance issuer or its in-network providers 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* means a payment model under which a provider is paid a single payment for all covered items and services provided to a patient for a specific treatment or procedure.

(v) *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. This term generally includes deductibles, coinsurance, and copayments, but it does not include premiums, balance billing amounts for out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(vi) *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 a participant's, beneficiary's, or enrollee's out-of-pocket costs for a particular health care item or service.

(vii) *Covered items or services* means those items or services for which the costs are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(viii) *Enrollee* means an individual who is covered under an individual health insurance policy as defined under section 2791(b)(5) of the PHS Act.

(ix) *In-network provider* means a provider that is a member of the network of contracted providers established or recognized under a participant's, beneficiary's, or enrollee's group health plan or health insurance coverage.

(x) *Items or services* means all encounters, procedures, medical tests, supplies, drugs, durable medical equipment, and fees (including facility fees), for which a provider charges a patient in connection with the provision of health care.

(xi) *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.

(xii) *Negotiated rate* means 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.

(xiii) *Out-of-network allowed amount* means 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.

(xiv) *Out-of-network provider* means a provider 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.

(xv) *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.

(xvi) *Participant* has the meaning given the term under section 3(7) of ERISA.

(xvii) *Plain language* means written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee.

(xviii) *Prerequisite* means certain requirements relating to medical management techniques for covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. Prerequisites include concurrent review, prior authorization, and step-therapy or fail-first protocols. The term prerequisite does not

include medical necessity determinations generally or other forms of medical management techniques.

(xix) *Qualified Health Plan (QHP)* has the meaning given the term in 42 U.S.C. §18021.

(b) *Required disclosures to participants, beneficiaries, or enrollees.* At the request of a participant, beneficiary, or enrollee (or his or her authorized representative), a group health plan or health insurance issuer offering group or individual health insurance coverage must provide to the participant, beneficiary, or enrollee (or his or her authorized representative) 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 covered item or service and a particular provider or providers, to the extent relevant to the participant's, beneficiary's, or enrollee's cost-sharing liability:

(i) An estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for a requested covered item or service provided 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;

(ii) Accumulated amounts the participant, beneficiary, or enrollee has incurred to date;

(iii) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service;

(iv) Out-of-network allowed amount for the requested covered item or service, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider;

(v) If a participant, beneficiary, or enrollee requests information for an item or service subject to a bundled payment arrangement that includes the provision of multiple covered items and services, a list of the items and services 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; and,

(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 bill charges and the sum of the amount collected from the group health plan or health insurance issuer and from the patient 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;

(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; and

(D) 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 (or their authorized representative).* 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 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 (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 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 (or his or her authorized representative). The group health plan or health insurance issuer is required to:

(A) 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), (B), and (C) of this section; and

(B) Mail the cost-sharing information no later than 2 business days after an individual's request is received.

(3) *Special rule to prevent unnecessary duplication with respect to group health coverage.* 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 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).

(c) *Requirements for public disclosure of in-network provider negotiated rates and out-of-network allowed amounts for covered items and services.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (c)(1) of this section in two machine-readable files in accordance with the method and format requirements described in paragraph (c)(2) of this section and updated as required under paragraph (c)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (c) that are made available to the public by a group health plan or health insurance issuer must include:

(i) Negotiated rate machine-readable file:

(A) The name and Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) identifier, as applicable, for each plan option or coverage offered by a health insurance issuer or group health plan;

(B) A billing code 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, and a plain language description for each billing code; and

(C) Negotiated rates that are:

(1) Reflected as dollar amounts, with respect to each covered item or service under the plan or coverage that is furnished by an in-network provider;

(2) Associated with the National Provider Identifier (NPI) for each in-network provider; and

(3) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each covered item or service, including rates for both individual items and services and items and services in a bundled payment arrangement.

(ii) Out-of-network allowed amount file:

(A) The name and Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) identifier, as applicable, for each plan option or coverage offered by a health insurance issuer or group health plan;

(B) A billing code 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, and a plain language description for each billing code; and

(C) Unique out-of-network allowed amounts 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 requirement would require the group health plan or health insurance issuer to report payment of out-of-network allowed amounts in connection with fewer than 10 different claims for payments. Consistent with paragraph (d)(3) of this section, nothing in this paragraph 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 under the plan or coverage that is furnished by an out-of-network provider; and

(2) Associated with the National Provider Identifier (NPI) for each out-of-network provider.

(2) *Required method and format for disclosing information to the public.* The machine-readable files that must be made available under paragraph (c) of this section must comply with technical guidance issued jointly by the Department of Health and Human Services,

the Department of Labor, and the Department of the Treasury. The first machine-readable file must include information regarding rates negotiated for in-network providers with each of the required elements described in paragraph (c)(1)(i) of this section. The second machine-readable file must include information related to the historical data showing allowed amounts for covered items and services furnished by out-of-network providers and include the required elements described in paragraph (c)(1)(ii) of this section. 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 (c) 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 (c) 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 (c) 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 (c).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (c) 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 (c) 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 (c), the group health plan or health insurance issuer violates the transparency disclosure requirements of this paragraph (c).

(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 (c)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, a health insurance issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or health insurance issuer has contracted may aggregate out-of-network allowed amounts for more than one group health plan or insurance policy or contract.

(d) *Applicability.* (1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after 1 year after [effective date of the final rule]. As provided under § 147.140, this section does not apply to grandfathered health plans.

(2) This section does not apply to health reimbursement arrangements or other account-based group health plans defined in § 147.126(d)(6)].

(3) Nothing in the 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 group health plans and health insurance 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) or (c) 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.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

7. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg-18), as amended.

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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