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Health Plan Price Transparency Requirements Final Rule Summary

On November 12, 2020, the Internal Revenue Service of the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (hereinafter referred to as "the Departments") will publish in the *Federal Register (FR*) (85 *FR* 72158) final rules requiring group health plans and health insurance issuers in the individual and group markets: 1) to disclose, upon request, cost-sharing liability including in-network provider negotiated rates, and out-of-network allowed amounts to a participant, beneficiary or enrollee (hereinafter referred to as an "enrollee") through an internet self-service tool and in paper form; 2) to publicly disclose in-network provider negotiated rates, historical out-of-network allowed amounts, and drug pricing information in machine readable data files; and 3) to permit insurers to claim credit towards their medical loss ratios (MLR) for "shared savings" when an enrollee selects a lower-cost, higher-value provider.

With respect to cost-sharing information for enrollees, disclosures of cost-sharing information for 500 items and services must be made available for plans years starting on or after January 1, 2023. For plan years beginning on or after January 1, 2024, cost-sharing information for all items and services must be made available. Public disclosure of rates will be required starting with plan years that begin on or after January 1, 2022. The amendment to MLR calculations applies beginning with the 2020 MLR reporting year.

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I. Background

On June 24, 2019, Executive Order (EO) 13877, "Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First" was issued. Section 3(b) of that EO requires the Departments to pursue policies to provide greater transparency for patients about their expected out-of-pocket costs in advance of receiving health care.

The Departments describe the authority for the finalized disclosure requirements and outline the reasons to pursue the policies. The statutory authority cited for the transparency requirements is

in sections 1311(e)(3) of the Affordable Care Act (ACA) and 2715A of the Public Health Service Act (PHSA). Section 1311(e)(3) requires health plans seeking certification as qualified health plans sold through health insurance Exchanges to meet transparency standards. Section 2715A of the PHSA requires group health plans and health insurance issuers not offered through Exchanges to also meet the standards established in section 1311(e)(3) as required by the Secretary of HHS and to make required disclosures public, providing broad authority to pursue transparency standards.

The Departments review the benefits of increasing the information that consumers can use to make informed decisions, to evaluate heath care options, to increase competition, and to reduce surprises about out-of-pocket costs. In the past, consumers have not typically known the cost of different health care services. But as consumers become responsible for a greater share of costs, through higher deductibles and more coinsurance, more and better pricing information could contribute to greater competition and lower prices. The Departments cite data on increasing deductibles and review a number of research reports that have investigated the impact of price transparency leading to lower and more uniform prices.

State and private efforts to increase transparency and health insurance issuers' use of price transparency tools are also described. The Departments note that as of 2012 there were 62 consumer oriented, state-based health care price comparison websites. Of the at least 18 states with all-claims databases, 8 make price and quality information available to the public. The Departments hold that these final rules will fill gaps left by state and private transparency efforts.

Administration initiatives undertaken in the past are described. HHS sought comments on increasing cost-sharing information in its 2020 Notice of Benefit and Payment Parameters (2020 Payment Notice) and hosted listening sessions in 2018 on the subject of increasing price transparency. HHS received support for increasing price transparency and received suggestions, recommendations, and warnings about complexity and expense. In addition, HHS has issued several rules increasing and building on price transparency requirements under section 1001 of the ACA (which added section 2718(e) to the Public Health Service Act). That provision requires hospitals to make public a list of hospital standard charges for certain items and services. Most recently, HHS issued 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 (CMS-1717-F2)* final rule to further improve access to meaningful hospital charge information.

The Departments note, however, that pricing information is needed from both providers and health insurers to be most useful to consumers. Further, despite some states acting to require insurers to disclose price information, since states do not have regulatory authority over certain employment-based health plans, federal rules are necessary.

A. Responses to Comments Regarding Legal Authority

The Departments received over 25,000 comments from a range of stakeholders. The finalized rules include certain modifications in response to comments as described further below. In

addition, the Departments lay out their arguments in response to comments that they do not have the legal authority to issue the rules. In brief:

- *Statutory authority under section 1311(e)(3).* Some commenters contend that the Departments do not have the statutory authority to require plans and issuers to make their rates negotiated with providers publicly available. The Departments disagree and believe that the rule fits squarely within the scope of the disclosure provision. In particular, the provision explicitly permits the Secretary to require plans to submit "other information as determined appropriate." This final broad category is the last item in a list that includes other information and data for regulators and the public to evaluate plans and coverage. The Departments state that the public disclosures of negotiated rates have a purpose consistent with the remainder of the itemized list and are directly tied to transparency for consumers. Other related arguments are addressed as well, including that machine-readable information is not plain language that is understandable by the typical consumer, so cannot be authorized for public disclosure under section 1311(e)(3), and that the section permits only aggregated data.
- *Constitutional concerns.* The Departments disagree that the rule compels commercial speech in violation of the First Amendment to the Constitution or is an unlawful taking of trade secrets in violation of the Fifth Amendment. They assert that the speech compelled by the rules is factual and noncontroversial information about the terms under which consumers' services are available. They argue that the disclosure of that information reflects a substantial government interest, and the requirements for that disclosure are not unduly burdensome on the commercial speech rights of plans or issuers. The Departments do not believe the requirement constitutes an unlawful taking of trade secrets because rate information is routinely provided to participants of plans.
- *Protections for proprietary, confidential business information.* Some commenters felt that negotiated rates are expressly protected from disclosure by a number of federal and state laws that protect confidential, proprietary business information and trade secrets. The Departments respond that because the information is routinely disclosed to third parties and to participants, it cannot be considered trade secrets. With respect to the concern that the disclosures would lead to anticompetitive behavior by plans, issuers, and providers, the Departments believe the opposite will be true and provides a summary of research that finds that increased price transparency produces increased competition.
- *Administrative Procedures Act (APA) and arbitrary and capricious action.* The Departments respond to charges that because they did not provide a solid rationale for the disclosures nor quantify reliably the costs or benefits of the rules, they violated the APA. They are of the view that the rules are consistent with the APA – they are consistent with section 1311(e) of the ACA, are designed to enhance market competition which will ensure that health care costs are rational and reasonable, and the required disclosures are carefully targeted to the goals of price transparency.
- *State laws and contractual concerns.* Responding to the concern that some states have laws that would prohibit such disclosure, the Departments point out that federal law preempts state law in this area. Others raise the concern that such disclosures would violate contractual arrangements between issuers and providers. The Departments acknowledge that contractual impediments will need to be changed in light of federal law in this area.

II. Provisions of the Final Rule

The Departments finalize with modifications described below their proposal to make nearly identical changes to existing regulations in three separate sets of rules to ensure the maximum applicability of the transparency requirements. The changes are made to Internal Revenue Service rules in 26 CFR 54.9815-2715A; to Department of Labor rules applicable to employer-sponsored benefit plans in 29 CFR 2590.715-2715A under the Employee Retirement Income Security Act of 1974 (ERISA); and to PHSA rules relating to requirements for group health plans and health insurance issuers in 45 CFR 147.210. By incorporating the rules across all three of those areas, they are applicable to health insurance insurers, to employment-based group health plans that are not traditional insurance, as well as to other types of coverage that are neither traditional insurance nor employment-based group health plans (for example church-sponsored plans) subject to the Internal Revenue Code (IRC).

A. Transparency Requirements: Scope and Definitions

Paragraph (a) of the final rules sets forth, as proposed, the scope and definitions relevant for cost-sharing liability disclosures to enrollees and for public disclosures. With respect to the scope of the rules,

- In 26 CFR 54.9815-2715A1 – A3 and 29 CFR 2590.715-2715A1 – A3, the transparency requirements are applied to *group health plans and health insurance issuers offering group health insurance coverage*.
- In 45 CFR §§147.210 – 147.212, the identical requirements are applied to group health plans and health insurance issuers offering coverage in the *individual and group markets* for insurance.

The following terms were proposed to be defined in each of the three sets of rules. Except where indicated, the definitions are finalized without substantive change.

- *Accumulated amounts* is defined as the amount of financial responsibility towards a deductible or out-of-pocket limit that an enrollee has incurred at the time a request for cost-sharing information is made. It includes family members' amounts if the enrollee is enrolled in other than self-only coverage and excludes any amounts that do not count toward a deductible or out-of-pocket limit (e.g., premium payment, out-of-pocket expense for out-of-network services, or amounts for services not covered under the plan). If plans include cumulative treatment limitations for particular items or services (e.g., a limit on the number of items, days, units, visits, or hours covered in a defined time period), it includes 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 enrollee has used).
- *Beneficiary* would have the meaning given in section 3(8) of ERISA. Under ERISA the term "beneficiary" means a person designated by a participant, or by the terms of an employee benefit plan, who is or may become entitled to benefits under the plan. *In the final rule, this definition is only finalized for Treasury regulations because a definition already exists in HHS regulations and ERISA law.*
- *Billing code* is 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 (e.g., 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 identifiers).

- *Bundled payment arrangement* means a payment model under which a provider is paid a single payment for all covered items and services provided to a patient for a specific treatment or procedure. The proposed rule had called this term "bundled payment" instead of "bundled payment arrangement."
- *Cost-sharing liability* is the amount an enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. It includes deductibles, coinsurance, and copayments, but not premiums, balance billing amounts for out-of-network providers, or the cost of items or services that are not covered under the plan or insurance.
- *Cost-sharing information* is information related to any expenditure required by or on behalf of an enrollee with respect to health care benefits that are relevant to determining the enrollee's out-of-pocket costs for a particular health care item or service.
- *Covered items or services* are 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.
- *In-network provider* is any provider of items and services that has a contract with the plan or issuer setting the terms and conditions on which an item or service is provided to an enrollee. The Departments clarify the wording of this definition and state that this includes a limited agreement or a rate agreement covering durable medical equipment in response to a request to clarify that device suppliers and manufacturers were not included. The Departments state that these rules are intended to provide the broadest level of transparency including prices for medical devices and durable medical equipment.
- *Items or services* is defined as all encounters, procedures, medical tests, supplies, drugs, durable medical equipment, and fees (including facility fees) for which a provider charges a patient.
- *Machine-readable file* is 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.
- *Negotiated rate* was proposed to mean the amount a group health plan or health insurance issuer, or a third party on behalf of a plan or issuer, has agreed to pay an in-network provider for covered items and services. In response to requests for clarification, the final rules define the negotiated rate as the amount a plan or issuer has contractually agreed to pay for a covered item or service, whether directly or indirectly through a third-party administration or PBM, to an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items or services. The finalized definition encompasses PBM prices and is broad enough to account for different plan designs for determining negotiated rates.
- *Out-of-network allowed amount* is the maximum amount a group health plan or health insurance issuer pays for a covered item or service furnished by an out-of-network provider.
- *Out-of-network provider* is a provider that does not have a contract under an enrollee's group health plan or health insurance coverage to provide items or services.
- *Out-of-pocket limit* is the maximum amount that an 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.

- *Plain language* means written and presented in a manner that may be understood by the average enrollee.
- *Prerequisite* means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. It does not include medical necessity determinations. The final rules tighten the definition so that it only refers to those four types of prerequisites, instead of the approach of proposed rule which listed those prerequisites as examples.

In the final rule, the definition for "participant" is eliminated because it is already defined in regulations issued by all three Departments. In addition, the following new definitions are added:

- *Billed charge* means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.
- *Copayment assistance* is the financial assistance a participant or beneficiary received from a prescription drug or medical supply manufacturer toward the purchase of a covered item or service.
- *Derived amount* means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers or submitting data for HHS risk adjustment.
- *Historical net price* means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees and any additional price concessions received by the plan or issuer with respect to the prescription drug. The definition includes additional specificity regarding allocations.
- *National drug code* is the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration which provides a universal product identifier for drugs in the U.S.
- *Underlying fee schedule rate* means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's or beneficiary's cost-sharing liability for the item or service when that rate is different from the negotiated rate or derived amount.

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

The Departments finalize largely as proposed, requirements for plans and issuers to disclose upon request certain information relevant for the consumer to determine their out-of-pocket costs for a particular health care item or service. They made certain modifications to the requirements after reviewing comments. Those changes are highlighted below.

In each of the three sets of regulations, group health plans and health insurance issuers in the individual[1] and group markets are required to disclose (1) through a self-service tool made

[1] Issuers of individual insurance are not incorporated in amendments to ERISA regulations because ERISA only

available on an internet website, cost-sharing information for a covered item or service from a particular provider or providers, and (2) upon request, cost-sharing information in paper form.

The Departments note that the requirements are intended to be similar to the information that generally appears on explanations of benefits (EOBs) although EOBs are provided after a service has been provided. These rules require the availability of the amounts that are anticipated that a beneficiary would be expected to pay if they obtain the treatments or services. They note that the rules do not require any cost-sharing liability estimate to include costs for unanticipated items or services that a person could incur.

The disclosures must be in plain language and need not include any outstanding claims that have not yet been processed.

Response to Comment. Commenters expressed concerns that plans and issuers often do not have access to all of the information necessary to provide beneficiaries with upfront information about their claim. Others were concerned that the elements and method of disclosure were overly prescriptive. Some requested that the Departments confirm that the intent of the rules is to permit only current enrollees to have access to the tool as opposed to potential future enrollees, which they do confirm. In addition, the Departments decline to add, as recommended by some commenters, access to the tools for authorized representatives of enrollees – noting that enrollees themselves could choose to share the information they obtain via the tool.

In response to questions posed by the Departments about whether additional information should be made available through the tools – some commenters recommended that cost information be accompanied by quality information to avoid the potential unintended consequence of encouraging the use of low-cost and potentially low-quality providers. The Departments acknowledge the value of quality information, but do not require this information at this time. They do, however, encourage plans and issuers to innovate around the baseline standards set in the rule and will consider the addition of quality information in future regulatory changes.

1. Items and Services Subject to Disclosure and Phased-In Timeline

In the final rule, the Departments clarify that the required disclosures include covered prescription drugs and durable medical equipment. Excepted benefits, such as limited-scope dental benefits offered under a separate policy that are not an integral part of a group health plan or health insurance coverage, are not subject to the disclosure requirements.

Concerns were raised that requirements to disclose the price of all items and services is overly broad. Some commenters recommended that the items and services subject to disclosure should be limited to a set number or a list of "shoppable" items and services. The Departments disagree with suggestions to limit the disclosures but acknowledge the burden and therefore finalize a phased-in implementation timeline. For plan years beginning on or after January 1, 2023, disclosures will be required for a list of 500 items or services identified by billing code (Table 1

regulates employment-based benefits. They are, however, incorporated in the amendments to the IRC and the PHSA regulations.

of the final rule). The list will be published on a publicly available website. For plan years beginning on or after January 1, 2024, disclosures for all items and services will be required.

Because plans and issuers may use different billing codes, the Departments will permit code substitutions for the 500 items and services and if needed, will issue future guidance regarding code substitutions.

2. Content of Disclosures

The final rules require the following content elements of a disclosure:

(a) Estimated cost-sharing liability for a covered item or service. Disclosures must include the cost-sharing liability for covered item and services. Those terms are defined in section A1 as described above.

The final rules do not, according to the Departments, require the disclosed prices to reflect the actual or final cost of a particular item or service. They note that unforeseen factors during the course of treatment could result in those amounts changing or unanticipated items or services could be needed resulting in cost-sharing liability that is different from amounts described in the cost-sharing liability estimate.

Response to Comment. With respect to bundled amounts, some commenters worried about confusing consumers who were unaware that copayments may be different if the item or service is billed as part of a bundle or as a separate service. In response, the final rules clarify that plans and issuers should provide one overall cost-sharing liability estimate for a bundled payment arrangement if that is the only cost sharing for which the consumer would be liable. But if the cost sharing is imposed separately for each item and service in the bundle, then plans and issuers should disclose the cost-sharing liability for those items separately. They also note that plans and issuers should take a similar approach for plan designs that incorporate other alternate payment arrangements.

The Departments reject recommendations from commenters that cost-sharing averages or ranges or some other proxy should be provided instead of or in addition to the price that the treatment could cost as other amounts would not provide personalized and specific cost-sharing information.

In answer to the concern that some plans do not have the data necessary to provide the required information and contracts with third-party administrators (TPAs) may not provide them with access to the information, the Departments state that they do not foresee barriers that would prohibit a plan or TPA from obtaining/providing this information and acknowledge that amendments to existing contracts may be necessary.

(b) Accumulated Amounts. The Departments finalize the inclusion of accumulated amounts as proposed but clarify that the estimates do not include amounts made available through separate account-based arrangements. They encourage plans and issuers to issue a disclaimer regarding such arrangements.

Response to Comment. Some commenters raised concerns about the difficulty of implementing this content element and requested it be delayed or be made optional. The Departments note that in the final rule, the timeline for implementing the disclosure requirements has been extended, so there should be ample time for plans and issuers to comply.

(c) In-Network rate expressed as a dollar amount. This element is finalized as being comprised of the negotiated rate for an in-network provider and the underlying fee schedule rate to the extent it is different from the negotiated rate.

Response to Comment. The Departments rename this element "in-network rates" instead of negotiated rate to take into account situations in which a plan design may not include negotiated rates. Under those circumstances, the final rules require plans or issuers to provide the underlying fee schedule rates for the purpose of calculating an enrollee's cost-sharing liability. If the plan or issuer does not have either negotiated rates or underlying fee schedule rates, this third content element does not apply.

In response to commenters opposed to the provision of the negotiated rate or who raised concerns that non-disclosure contracts with providers would prevent sharing those amounts, the Departments state that negotiated rates comprise the key element of overall price transparency. The Departments decline to make changes based on commenters' suggestions to provide ranges for such amounts.

The proposed rule would have required disclosure of negotiated rates only when an enrollee's cost-sharing liability was based on those amounts but feedback was requested on that provision. Upon further consideration, the Departments have determined that they agree with commenters who favor disclosure of negotiated rates even when they are not used to determine cost sharing. The final rules incorporate this change. The Departments state that they believe such disclosures will promote greater awareness and transparency.

With respect to prescription drugs, the Departments note that outside of bundled payment arrangements, cost-sharing liability is often based on an undiscounted list price which may be different from the negotiated price for the drugs. Some commenters recommended disclosure of rebates, discounts, and price concessions or disclosure when the enrollee's cost-sharing amount exceeds the price paid by the plan or issuer among many other suggestions for addressing the complexity of drug pricing and its transparency. In aiming to strike a balance between illuminating some of the factors driving drug costs and not creating confusion, the final rules require plans and issuers to disclose in the cost-sharing liability, the individual's out-of-pocket cost liability for prescription drugs and in this element, the negotiated rate for the drug. The latter disclosure will not necessitate disclosure of discounts, rebates, or price concessions.

The Departments confirm, in response to commenters, that plans or issuers that provide a link to prescription drug cost tools offered through PBMs or vendors will satisfy this requirement. They decline at this time, however, to incorporate any prohibitions related to a concern raised by commenters that plans or prescribers could use disclosures to steer patients to certain pharmacies. They intend to monitor for this concern.

(d) Out-of-network allowed amount. Where an enrollee requests cost-sharing information for an item or service provided by an out-of-network provider, both their cost-sharing liability and the out-of-network allowed amounts are required to be provided. The proposed rule would have required the maximum amount a group health plan or issuer would pay for a covered item or service furnished by an out-of-network provider. In the final rule, the Departments make this required element more flexible – requiring plans and issuers to disclose the out-of-network allowed amount or any other calculation that provides a more accurate estimate of the amount that a plan will pay – such as a usual, customary, and reasonable rate.

Any balance billing amounts – amounts that an enrollee must pay in excess of the plan's required cost-sharing liability – are not required as part of this disclosure.

Response to Comment. A commenter requested that health maintenance organizations (HMOs) be exempt from requirements to estimate out-of-network rates because they generally do not cover benefits out-of-network. The Departments decline to make this change noting that in certain limited circumstances, some HMOs do cover out-of-network care. In cases where the maximum allowed amount is $0, it would be beneficial for an enrollee to learn that.

(e) Items and services content list. The Departments finalize without change the fifth element of the content list – when an enrollee requests cost-sharing information for an item that is part of a bundled payment, the issuer must provide a list of those covered items and services in the bundled payment arrangement for which cost-sharing information is being disclosed.

Response to Comment. A commenter asked that the Departments clarify that disclosure for diagnostic imaging procedures should be inclusive of the combined professional and technical rates. They respond by stating that if a plan or issuer reimburses a procedure such as imaging at a global rate that includes both professional and technical charges, then that global rate is a bundled payment arrangement for which the applicable content elements must be disclosed.

(f) Notice of prerequisites to coverage. The Departments finalize a sixth content element – if an enrollee requests cost-sharing information for an item or service for which a prerequisite to coverage must be satisfied, such as concurrent review, prior authorization, or step therapy, the issuer is required to include a notice to that effect. The Departments clarify that the definition of prerequisites was intended to capture medical management techniques that require action by the covered individual. In the final definition, the list of applicable prerequisites is an exhaustive list consisting only of concurrent review, prior authorization, step-therapy and fail-first protocols.

Response to Comment. Commenters recommended that clinical coverage requirements that must be present for an item or service to be covered – such as medical conditions, documented symptoms, etc. – be added to this element. The Departments decline to include such conditions because those comprise medical necessity. Other commenters recommended adding descriptions of the prerequisites to the notice and require disclosure of all utilization controls. Other commenters recommended brief disclosure notices or a brief list of exhaustive prerequisites. As noted above, the Departments limit the list to only those four prerequisites listed in the final rule.

(g) Disclosure notice. The final rules adopt the proposed elements of a required disclosure notice and add two additional elements to the notice. As proposed, the notice must inform enrollees in plain language that:

- Out-of-network providers can balance bill and any balance billing amounts are not included in the cost-sharing disclosures;
- Actual charges may be different from those in the cost-sharing estimate depending on the services that the enrollee ultimately receives;
- The estimate of cost-sharing liability does not guarantee coverage for those items or services; and
- Any additional information or disclaimers that plans and issuers determine are necessary.

Two elements added to the disclosure notice in the final rules are:

- A statement informing the consumer whether the plan counts copayment assistance or other third-party payments towards their deductible and out of pocket maximums; and
- A statement informing the consumer that for recommended preventive services under section 2713 of the Public Health Services Act, zero cost sharing applies.

3. Methods of Disclosure

Cost-sharing information required under these final rules must be provided in two ways: through a self-service tool available on an internet website and in paper form.

(a) Self-Service Internet Tool. As proposed, group health plans and health insurance issuers are required to provide cost-sharing liability for an item or service provided by a specific in-network provider through a self-service internet tool that is free to the enrollee and provides real time information at the time of the request. The tool must also include the out-of-network allowed amount or, as added in the final rule, other metrics that the plan or issuer uses in place of out-of-network allowed amounts (as discussed in content element (d) above). The tool must allow the enrollee to search by a specific provider or by all in-network providers, by using a billing code or descriptive term, and by any other factor necessary for determining the cost-sharing amount.

The tool must permit a user to input sufficient information for determining their cost-sharing liability. For example, if cost-sharing amounts for a prescription drug depend on the quantity or dosage of a drug, a user must be able to input quantity and dosage. If cost-sharing liability amounts differ by tier, the tool would need to produce the relevant cost-sharing information for each tier.

With respect to out-of-network allowed amounts (or other rates relevant for determining out-of-network allowed amounts), the tool would need to permit enrollees to search by a billing code or descriptive term, and by any other factors that would impact those rates such as by facility or location.

The Departments state that the tool must be user friendly and to that end, points plans and issuers to federal plain language guidelines (at https://www.plainlanguage.gov/guidelines). As proposed, the tool must enable a consumer to refine and reorder search results, but only for in-network

providers. The proposed rule would have required refine and reorder functionality for all providers.

Response to Comment. Some commenters urged the Departments to evaluate the tools currently available and to give carriers and third-party administrators maximum flexibility in designing their tools. Others discouraged the Departments from requiring price estimator tools and cite studies showing that consumers don't utilize them. The Departments acknowledge the burden of updating tools and that historically there has been little use of them, but they believe that by creating minimum uniform standards, consumers will find them to be more reliable and will use them more often. They encourage plans, issuers, and providers to promote and educate consumers on the benefits of such tools.

Many commenters requested that the Departments identify a core set of functional requirements for the tools, for example allowing searches by service category or specialty, or selecting popular episodes of care using drop down menus. The Departments decline to adopt additional functional elements, however, stating that their goal is to provide for minimum standards and may consider additional necessary elements in the future.

In response to comments, the Departments clarify that the tool must support searches with multiple parameters at the same time – for example by both covered item and service and other relevant factors such as a specific provider or location or facility name, etc. A number of commenters recommended that descriptive names of conditions be included as opposed to only DRG or CPT or other codes as many consumers will not know the meaning of the codes. The Departments agree.

The Departments had requested feedback on whether in addition to being available via internet, the tool should also be made available through mobile devices. In considering feedback, the Departments decline to change the rule and retain the requirement that it be available via internet website, however they encourage plans and issuers to provide access to a mobile application version as well as to an internet website.

(b) Paper Method. The Departments finalize their proposal that, at the request of an enrollee, the above information must also be made available to an enrollee in paper form without a fee. Enrollees must be permitted to specify the necessary information, parallel to the inputs to the web-based tool described above, to receive meaningful cost-sharing information. The paper disclosure must be mailed no later than two business days after the individual's request is received.

The final rules incorporate several changes in response to comments. In response to concerns that the volume of paper requests could become unwieldy especially if information on multiple providers is requested, the final rules provide that a plan or issuer can limit search results to 20 providers per request. In addition, they permit plans and issuers to provide the disclosure via phone or e-mail if requested by the enrollee. The Departments decline to require plans or issuers to set up a toll-free phone number for providing the disclosures but note that plans and issuers have the flexibility to do so if they chose.

4. Preventing Unnecessary Duplication

The Departments finalize that group health plans providing coverage through group health insurance would be able to satisfy the disclosure requirements if the issuers of the insurance policies do so on the group health plan's behalf pursuant to a written agreement. If an issuer has a written agreement with the group health plan to provide the information and the issuer fails to do so, the violation would apply to the issuer and not to the plan.

Commenters requested this rule be extended to group health plans contracting with TPAs for such disclosures. The Departments decline to specify this because the PHSA gives authority for the Departments to require this information from plans and issuers but not TPAs; therefore, it is the ultimate responsibility of the plans or issuers. As proposed, the final rules also provides that a plan or issuer will not be considered to fail to comply if it has acted in good faith and with reasonable diligence, makes an error or omission in a required disclosure and corrects the information as soon as practicable.

In response to comments, the Departments clarify in final regulations that these disclosure rules do not apply to grandfathered health plans, health reimbursement arrangements or other account-based group health plans, or to short-term limited duration insurance.

5. Ensuring Privacy, Security, and Accessibility

The Departments note that disclosures required under these rules may be subject to HIPAA privacy and confidentiality requirements as well as to related state laws. They establish that nothing in them is intended to alter such privacy and security requirements. They also indicate that the rules would not establish any new groups of persons or entities who are authorized to access and receive protected health information under these requirements. Existing laws and rules with respect to "authorized representatives" continue to apply.

C. Transparency Requirements: Public Disclosure of Negotiated Rates and Allowed Amounts

As proposed, the final rules require health plans and issuers to make information available to the public on negotiated payment rates for in-network providers and allowed amounts for covered items or services provided by out-of-network providers, as well as any other relevant information. These transparency requirements are finalized in section A3 of each of the Departments' rules (instead of in paragraph (c) as proposed). This information must be updated on a monthly basis. As described in more detail below, the final rules incorporate several changes to streamline the disclosures via contracts or clearinghouses that respond to concerns from small group plans and issuers.

According to the Departments, the benefits of such public disclosure include:

- Individuals without insurance coverage will be better informed when purchasing health care, and the ability of all consumers to assess available options for group and individual coverage would be improved.

- Competition will be increased, disparities in health care prices will be reduced, and potentially overall health care prices will be reduced.
- More transparency will incentivize the design, development, and offering of consumer tools and support services to enable better use of health care pricing information.
- Plan sponsors will benefit from greater transparency in establishing and evaluating networks of providers.
- Health care pricing trends could be better monitored and regulators would be helped in carrying out their oversight duties.

Response to Comment. The Departments state that the vast majority of commenters were supportive of the proposals or supportive of the objective of price transparency. Health insurance issuers and health care providers generally supported the objective but raised concerns about unintended consequences such as market distortion or inappropriate steering of consumers to providers based solely on price instead of other important factors including clinical expertise and quality. The Departments acknowledge that other factors are important for consumers to prioritize in choosing providers and described resources for consumers to obtain quality information. They describe other public and private efforts to provide quality information to consumers. They also note that once price information is broadly available, efforts could be made to combine the information with other important indicators such as high quality.

Some commenters were concerned that the information will be confusing or will not be meaningful to, or actionable for, consumers. The Departments disagree and cite research supporting the correlation of access to pricing information and overall consumer satisfaction. In response to those who felt that confusing or misleading information would lead to lower trust in the health care system, they note that based on the comments received, there is already very low trust in the health care system due in part to the opacity of price information.

In response to those concerned that existing gag clauses or other contract clauses would prevent them from disclosing pricing information, the Departments note that contracts can be revised and parties to such contracts are responsible for ensuring they do not violate any federal rules.

Some commenters suggested alternative roll-out approaches such as requiring price information disclosure through the Health Care Cost Institute[2] or piloting the disclosures in smaller geographic areas permitting the Departments to assess the impact on health care markets and economies. The Departments decline to make any such changes noting that the broadest implementation will be most effective and will be most likely to spur innovation in technical applications enabling the broadest use of the information.

With respect to the scope of information to be reported, some commenters recommended that the Departments require reporting of only a narrow set of shoppable services, others raised concerns that certain disclosures may violate Medicare rules relating to laboratory services. Some commenters recommended that the Departments add to the data elements to be disclosed including for such items as number of procedures, number of bed days, mean billed charges, etc. The Departments decline to make changes in response to these comments noting that they have

[2] An independent, non-profit research institute that makes health care claims data available to the public. The data are contributed by four large insurer members and include data for around 105 million lives.

chosen the data elements to target only critical pricing information and do not want to increase the level of complexity or burden of the rules.

In response to concerns about privacy of personally identifiable information, the Departments concur that privacy and security of personally identifiable health information is a top priority. To address potential privacy concerns, the Departments had proposed that disclosures would not need to be made (1) if there were fewer than 10 claims for payment for a particular item or service, or (2) if the disclosure would violate any applicable health information privacy law. They sought comment on whether a minimum threshold for reporting should be higher than 10, and in the final rules raise this minimum threshold to 20 claims. The change is intended to make it more difficult for an individual to be identified because of the small number of claims for a particular item or service are reported.

The Departments will provide additional technical guidance and note that the final rules do not prevent plans or issuers from providing additional technical material such as data dictionaries, explanatory language or other supplementary materials to health consumers and other stakeholders to understand the data.

1. Information to be Disclosed

The Departments finalize their proposal, with several modifications discussed below, to require plans and issuers to publicly disclose applicable in-network rates (including negotiated rates, derived amounts, and underlying fee schedule rates), out-of-network allowed amounts for covered items and services, including prescription drugs, through machine-readable files. The final rules also adopt the requirement that plans and issuers publicly disclose in-network historical net prices for covered prescription drugs through a machine-readable file. The final rules require the disclosures apply for plan years beginning on or after January 1, 2022.

The final rules require reporting of information through three files (instead of two as proposed). The three files are the In-network Rate File (called the Negotiated Rate file in the proposed rule), the Allowed Amount File, and the Prescription Drug File. The following content elements are finalized, also with several changes from the proposed rule as described below:

- *Plan or Coverage Identifier*. Each file must include the name or identifier for each plan option or coverage option. In the final rule, this element is clarified to call for the name, 14-digit Health Insurance Oversight System (HIOS) identifier or if not available, the 5-digis HIOS identifier, or if not available the Employer Identification Number.

- *Billing Codes*. The files must include the billing codes associated with each rate.[3] A plain language description of each billing code must be included. The final rules clarify that for prescription drugs, the NDC code must be provided.

[3] These include, but are not limited to, the CPT code, the HCPCS code, the DRG, the NDC, or other common payer identifier used by a plan or issuer, such as hospital revenue codes, as applicable.

- *Applicable Rates*. The third-content element is the in-network amount(s) for the In-network Rate File, allowed amounts and historical billed charges for the Allowed Amount File, or negotiated rates and historical net prices for the Prescription Drug File. For all files, the covered item or service must be associated with provider identifier using the National Provider Identifier (NPI). In the final rule, the Departments add that this content element should include a place of service code as well as the provider's Tax Identification Number (TIN).

(1) For the In-Network Rate File, the final rules make clarifications for plans and issuers of alternative reimbursement models. The rates that must be provided are described as the "negotiated rates, underlying fee schedule rates, or derived amounts." If the plan or issuer uses a bundled payment rate, the plan must identify the bundle of items and services by the relevant code. A notation must be added where the reimbursement arrangement is different from standard fee-for-service.

Although some commenters recommended that disclosure of rates for bundled or capitated arrangements not be required, the Departments decline to exclude those disclosures. Other commenters indicated that most plans or issuers will have alternative internal arrangements for submitting data for the HHS-operated risk adjustment program so should be able to submit at least a "derived amount." The Departments require that such amounts, to the extent they are calculated in the normal course of business, be provided if there is not an in-network rate. The preamble describes a number of examples of the disclosures required under different types of alternative reimbursement approaches including sole capitation arrangements, partial capitation models, and value-based purchasing models.

(2) For the Allowed Amount File, the out-of-network allowed amounts that must be disclosed are those amounts associated with each of the covered items or services by a particular out-of-network provider during the 90-day period that begins 180 days before the publication date of the Allowed Amount File. As with the negotiated rates, the amounts must be expressed as a dollar amount and associated with a provider's NPI, place of service code and TIN. This amount must include both the plan's paid portion and the enrollee's share of costs.

Commenters recommended, and the Departments agreed, that including reporting of billed charges will increase the ability of consumers to better understand their out-of-pocket liability. In response, billed charges are added to the required reporting in the Allowed Amount File. In addition, a definition of billed charges is added in A1 (described above) and is defined as total charges for an item or service billed to a plan or issuer by a provider.

To address potential privacy concerns, the Departments proposed that disclosures would not need to be made (1) if there were fewer than 10 claims for payment for a particular item or service, or (2) if the disclosure would violate any applicable health information privacy law. They sought comment on whether a minimum threshold for reporting should be higher than 10, and in the final rules raise this minimum threshold to 20 claims.

The Departments note that plans and issuers must report each unique combination of allowed amounts and billed charges for each out-of-network provider, their associated place of service

code, NPI and TIN. This could result in multiple entries for distinct combinations of billed charges and allowed amounts for a single provider. In addition, they clarify that if a plan or issuer has not adjudicated claims and paid allowed amounts for out-of-network services, then it is not required to disclose allowed amounts or billed charges. Further, in response to a request for clarification, they state that they do expect reporting of a scenario in which an enrollee received out-of-network care at an in-network facility. Those amounts would be captured in the Allowed Amount Files.

(3) Prescription Drug File. In the final rule, the Departments add a requirement that plans and issuers must make a third machine-readable file available to disclose pricing information for in-network prescription drugs.

Negotiated Prices. As proposed, plans and issuers must disclose negotiated prices for prescription drugs reflected as a dollar amount and associated with the last date of the contract term for each provider-specific negotiated rate.

Recognizing that such prices can fluctuate on a daily basis and there is wide variability in how negotiated rates are assigned, they permit some flexibility in the interpretation of "negotiated prices" by broadly defining them as the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a TPA or PBM. In response to commenters stating that those prices are often negotiated by PBMs and plans or issuers may not know those amounts or possess those data, the Departments reply that because PBMs negotiate such rates on behalf of plans or issuers, if they do not have access to that information, they could obtain it.

Historical Net Prices. In addition to negotiated rates, the final rules require plans and issuers to report "historical net prices" defined as the retrospective average amount a plan or issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug.

The addition of historical net prices is the result of the Departments soliciting and taking into account feedback about how to improve transparency in light of the fact that negotiated prices often do not include rebates and other discounts and often do not reflect the amounts that a consumer's cost-sharing liability is based on. After reviewing commenters' recommendations, the Departments are requiring the reporting of the historical net price of drug associated with the 90-day time period that begins 180 days before the publication of the machine-readable file.

As with out-of-network amounts, such disclosures are not required for prices for which fewer than 20 claims have been paid, and the rules do not require disclosure of any amounts that would violate any applicable health information privacy law.

Because some price concessions are paid over longer periods of time and may not be known at the time of reporting, the Departments advise plans and issuers to incorporate a reasonable

allocation and good faith estimate of those amounts. They provide several examples for allocating rebates or other price concessions that are not product-specific.

2. Method and Format for Disclosures

As proposed, the machine-readable files must be made available in a form and manner as specified in guidance; and made publically available without charge or conditions such as the need for a user account, password or other credentials. The Departments plan to make detailed technical implementation guidance available for plans and issuers to assist in developing the files through the GitHub website (a website and cloud-based service that helps developers store and manage their code). The technical implementation guidance will be available as part of the Paperwork Reduction Act package developed for the information collection requirements in the final rules. As part of that process, stakeholders will have an opportunity to submit comments for 30 days following the publication of final rules.

The Departments considered requiring that the files be made available as JSON files which would represent a single standardized, non-proprietary file format but decline to do so, preferring to maintain greater flexibility at this time.

The Departments sought feedback on the burden involved in submitting a single versus multiple files. In the final rule, they require a third file – the Prescription Drug File – but state that they do not believe this additional file will add significantly to the burdens and costs since the data would have, under the proposed rule, been included in the In-Network Rate File. They clarify that not all prescription drug pricing information required to be disclosed through the final rules is required to be included in the Prescription Drug File. Rather, the Prescription Drug File is required to include prescription drug pricing information for *in-network providers*, including pharmacies and other prescription drug dispensers, while the Allowed Amount File is required to include prescription drug pricing information for out-of-network providers, including pharmacies and other prescription drug dispensers.

Some commenters recommended against making the files publically available because their size and complexity would make them infeasible for consumers to be able to use. The Departments restate their view that the benefits to consumers will be based on the emergence of web-based tools and mobile applications developed by third-party developers, the examination and analysis of researchers, and improved oversight by regulators.

Timing for disclosures. As proposed, the final rules require disclosures to be updated monthly. The files must clearly indicate the date of their last update.

The Departments received comments suggesting that they collect the data and provide access through a centralized database rather than having individual plans and issuers post the files on their individual websites. The Departments decline to do so instead permitting flexibility for plans to determine the locations to post the data based on their determinations of where the files would be easiest for users to access. They also do not require plans to report to the Departments the location of their files but note that nothing in the final rules would prevent a federal or state regulatory body from doing so.

Special rules to prevent unnecessary duplication and allow for aggregation. With respect to *insured group plans*, consistent with the rule described above, if the group plan offers insured coverage and the issuer of that coverage agrees via written agreement to make the required disclosures, the group plan itself would not need to. If the issuer with a written agreement to make the required disclosure fails to do so, then the issuer, not the plan would be held in violation of the disclosure requirements.

A plan or issuer may satisfy the public disclosure requirements by entering into a written agreement with a third party (such as a TPA or a health care claims clearinghouse) to make the required public disclosures. However, if a plan or issuer chooses to enter into such an agreement and the third party with which it contracted fails to meet the requirements of this section, the plan or issuer would be accountable for any violation of the transparency disclosure requirements.

A plan or issuer is permitted to aggregate the reporting under this provision for more than one plan, insurance policy, or contract. Under this approach, the minimum 20 claims threshold would apply to the aggregated claims data set. In the final rule, the Departments clarify that nothing would prevent the Allowed Amount File from being hosted on a third-party website or prevent a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available.

3. Transparency Requirements: Applicability

The Departments describe the applicability of the disclosure requirements. The final rules provide that the requirements apply for plan years starting on or after January 1, 2022. They clarify that the provisions do not apply to grandfathered plans, health reimbursement arrangements or other account-based group health plans, nor to short-term limited duration plans. The preamble states that they do not apply to excepted benefits or health care sharing ministries, but they do apply to grandmothered plans.[4]

As proposed, the disclosure requirements do not alter a plan's or issuer's duty to comply with other applicable federal or state laws. The following would not be considered a failure to comply with these requirements: (1) Errors or omissions in a disclosure that are corrected as soon as practicable, (2) A temporarily inaccessible website provided that the plan or issuer makes the information available as soon as practicable, and (3) If an plan or issuer relied in good faith on information from another entity unless the plan or issuer knew or should have known that the information was incomplete or inaccurate.

A new "Severability" paragraph (d) is added to the final rules stating that any provision of this section determined to be invalid or unenforceable shall be severable; therefore, it would not affect the application of any other provision to persons not similarly situated or to dissimilar circumstances.

[4] Certain individual and small group health plans that took effect between the passage of the ACA and before Exchanges opened for business. They are permitted to remain non-compliant with certain ACA requirements.

Response to Comment. Commenters raised concerns about exempting certain plans from applicability. For example, some noted that exempting excepted benefit plans would disadvantage comprehensive plans that offer those same types of benefits (dental or vision, for example). Others pointed out that plans most likely to require very high cost sharing are excluded – STLD and health care sharing ministries – seemingly contrary to the objective of the rules. Others requested that plans with alternative payment model structures be exempted. The Departments decline to make changes in response to comments although they clarify that the rules do not apply to expatriate plans.

One commenter sought clarification of the liability of individual employers in Multiple Employer Welfare Arrangements (MEWAs) and Taft-Hartley plans (also known as a multi-employer plans). The rules are incorporated into section 715 of ERISA (via section 2715A of the PHSA). Therefore, for Taft-Hartley plans, employers who are a member of the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or are a fiduciary of the plan, are responsible for complying with the requirements. For MEWAs that are employee welfare benefit plans, the bona fide group or association that sponsors the MEWA that is responsible for operating and administering the MEWA is required to ensure compliance these rules. In cases where the MEWA itself is not a plan, each employer that provides benefits through a MEWA and, therefore, maintains its own plan, is separately responsible for compliance with the requirements of the final rules.

State regulators sought clarification on the oversight of the rules. The Departments state that because states are generally the primary enforcers of requirements of section 2715A of the PHSA, they would be the primary enforcers of these requirements on health insurance issuers.

Commenters recommended a number of additional circumstances to be added to the safe harbor provisions, for example, for circumstances where TPAs or third-party vendors have not provided the plan or issuer with the data, or to ensure that they are not held liable for any downstream breach of data privacy. The Departments decline to make changes at this time but indicate that they will take those recommendations into consideration for future rulemaking.

D. Accounting for "Shared Savings" in Medical Loss Ratio (MLR) Reporting (45 CFR 158.221)

1. Background

Under existing law (section 2718(b) of the PHSA) and regulations (45 CFR 158.221), issuers of group or individual coverage are required to provide rebates to enrollees if the issuers' medical loss ratio falls below certain specified minimum thresholds. The MLR generally represents the percentage of premium revenue that the issuer spends on clinical services and activities that improve health care quality.

The numerator of the formula includes spending on those activities while the denominator includes total revenue (taking into account certain adjustments).

2. Inclusion of Shared Savings in Numerator

HHS finalizes without change its proposal that, beginning with the 2020 MLR reporting year, insurers may include shared savings payments that they made to enrollees in the numerator of the MLR. HHS codifies this change in new paragraph (b)(9) of 45 CFR §158.221. The Department states the rule change will encourage issuers to develop plan features that reward consumers who choose lower-cost, higher value providers. It states that it will provide additional technical guidance to clarify the reporting of "shared savings" specifically for MLR purposes.

3. Response to Comment

Most commenters supported the proposal, although some raised concerns that the proposal fails to ensure that some of the savings are actually used for health care or quality improvement activities and could actually compromise quality of care by driving consumers toward lower cost providers without consideration of the quality. HHS agrees that cost as well as quality should both be components of shared savings arrangements and notes that the regulatory language permits inclusion in the numerator of shared savings payments resulting from enrollees choosing to obtain health care from a "lower-cost, higher-value provider."

4. Regulatory Impact Statement

Using 2017 – 2019 MLR data, HHS estimates that this proposal would reduce MLR rebate payments from issuers to consumers by approximately $120 million per year. The reductions in rebates to consumers would be offset by about $154 million in annual savings accruing to issuers and consumers in medical costs. HHS does not estimate how much of those savings would accrue to consumers versus issuers.

III. Regulatory Impact Analysis (RIA)

The Departments examined the impacts of the rule as required by EO 12866 on Regulatory Planning and Review (September 30, 1993), EO 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), EO 13132 on Federalism (August 4, 1999), and EO 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

The rule is expected to result in economically significant effects of more than $100 million in any year, so it is considered to be a "significant rule" under EO 12866.

In the final rule, the Departments reevaluated the cost estimates at least in part in response to comments that the economic analysis and cost estimates were not sufficient. They summarize the impact of the rule in Table 2 which includes the non-quantified benefits and potential costs.

Commenters raised a number of concerns about the potential adverse consequences of the required disclosures including disruptions to contract negotiations, spurring anticompetitive behavior, tightening networks and inability of issuers to negotiate in-network rates. The Departments maintain, however, that the rules will improve the competitiveness of markets and lower health care costs.

The Departments provide high range estimates (assuming that all issuers and TPAs will need to develop and build an internet-based self-service tool) and a low range estimate (over 90 percent of plans, issuers or TPAs will be able to modify an existing internet-based self-service tool).

Overall, the Departments estimate that the transparency requirements would result in an increase in 2022 premiums of 2.4 percent, 1.4 percent in 2023, and 0.5 percent in 2025 for the fully-insured market. Those premium impacts are considerably greater than those estimated for the proposed rule. The premium changes are expected to result in increased premium tax credit outlays of about $1 billion in 2022 (compared to the proposed estimate of $12 million). The Departments believe the increase would have minimal impact on anticipated enrollment.

The costs of reviewing the final rules for plans, issuers, and TPAs are estimated to be $1.1 billion.

The Departments summarize the alternatives considered:

- To limit cost-sharing disclosures to a limited number of items and services or limiting plans subject to requirements to only individual market and fully-insured group plans;
- To post machine-readable files to a public website;
- To require more frequent updates of files;
- To use alternative file formats;
- Limiting disclosures to only plan participants, beneficiaries and enrollees with no public disclosures; and
- To require an API for disclosures instead of machine-readable files.

IV. Information Collection Requirements

A. Requirements for Disclosing Cost-sharing Information to Enrollees

The Departments provide the estimated hourly wages for the 11 types of employees whose skill sets would be necessary to build the internet-based self-service tool (Table 3). Those personnel assumptions are used to estimate a range of costs based on the assumptions (described above) about the need for issuers or TPAs to build tools from the ground up. They are summarized in Tables 4 through 7 and are comprised of the following components:

- First-year, one-time cost of the technical build, incurred in 2022, are estimated to be between $3.8 and $10.4 billion.
- Second-year, one-time costs associated with meeting full disclosure requirements, incurred in 2023, are estimated to be $6.6 billion.

- Recurring annual costs of ensuring cost estimation accuracy, providing quality assurance, conducting website maintenance and making updates estimated to be $2.2 billion per year.
- Recurring annual costs of maintaining the internet-based self-service tools are estimated to range from $4.2 billion to $6.6 billion.
- Recurring annual costs of providing customer service employees is estimated at $1.6 million, and the cost of the customer services interactions is estimated at $1.2 million per year.
- Recurring annual costs of responding to requests for mailed disclosures is estimated to be $1.3 million.

B. Requirements for Public Disclosure of In-network Rates, Historical Allowed Amounts, and Prescription Drug Pricing Information

The Departments described commenters' concerns that estimates included in the proposed ICRs were insufficient. They describe an independent study conducted by Bates White Economic Consulting commissioned by a commenter that estimated the costs to be 20 times costlier than the Departments' analysis. Other commenters provided estimates that were about 13 times higher than the Departments' analysis. In response to these concerns, the Departments provide updated estimates that, like those described above, are considerably higher than the estimates in the proposed rule.

The costs of the disclosures in the In-network rate file are estimated to include the following components, described in Tables 12 – 15 that taken altogether, average to a 3-year cost of $848 million. The components include:

- One-time, year one costs of developing, implementing, and operating the in-network rate file is estimated to be $2.0 billion.
- One-time, year two burden of updating the in-network file monthly of $414 million.
- Ongoing costs of monthly updating is estimated at $106 million.

The Departments do not estimate the costs of renegotiating contracts or updating legal agreements to conform to the new rules.

The Allowed Amounts file is estimated to cost on average, over three years $454 million. The three components included in that amount are described in Tables 16-19 and include:

- One-time, year one costs of developing, implementing, and operating the Allowed Amount File of $1.1 billion.
- One-time, year two burden of updating the Allowed Amounts file monthly of $190 million.
- Ongoing costs of monthly updates is estimated at $40 million.

The Prescription Drug File is estimated to cost on average, over three years $290 million. The three components included in that amount are described in Tables 20-23 and include:

- One-time, year one costs of developing, implementing, and operating the Prescription Drug File of $492 million.
- One-time, year two burden of updating the Prescription Drug File monthly of $272 million.
- Ongoing costs of monthly updates is estimated at $106 million.

All of the costs estimated with the enrollee cost-sharing liability disclosures and the public disclosures are summarized in Table 24.