Transparency in Coverage
[CMS 9915-P]

Proposed Rule Summary

On November 15, 2019, 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") placed on public display a proposed rule that would require group health plans and health insurance issuers in the individual and group markets to disclose, upon request, cost-sharing amounts, in-network provider negotiated rates, and out-of-network allowed amounts to a participant, beneficiary or enrollee (hereinafter referred to as an "enrollee"). In addition, plans and issuers would be required to publicly disclose in-network provider negotiated rates and out-of-network allowed amounts. The disclosures are intended to improve the ability of individuals to effectively shop for health care services.

The Department of Health and Human Services (HHS) also proposes a change to medical loss ratio rules to allow insurers to receive credit for sharing savings with enrollees who choose lower-cost, higher-value providers. The proposed rule incorporates two requests for information, one related to disclosing information through a standards-based application programming interface (API) and a second seeking feedback on quality measurement in the private health insurance market. The proposed rule is expected to be published in the *Federal Register* (FR) on November 27th. **The comment period closes at 5 pm on January 14, 2020.**

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I. Background

On June 24, 2019, Executive Order (EO) 13877, entitled "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 issue an advance notice of proposed rulemaking

(ANPRM) to solicit comments on proposals to require greater transparency for patients about their expected out-of-pocket costs in advance of receiving health care.

The Departments have chosen to issue this notice of proposed rulemaking instead of an ANPRM to expedite the process of obtaining specific and useful comments.

The Departments describe the authority under which they propose these disclosure requirements and outline the reasons to pursue the policies. The statutory authority cited for the transparency proposals are sections 1311(e)(3) of the Affordable Care Act (ACA) and section 2715A of the Public Health Service Act (PHSA). Section 1311(e)(3) relates to transparency standards for health plans seeking certification as qualified health plans sold through health insurance Exchanges. Section 2715A of the PHSA requires group health plans and health insurance issuers not offered through Exchanges to meet the standards established in section 1311(e)(3) as required by the Secretary of HHS and to make such information 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 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 16 states with all-claims databases, 8 make price and quality information available to the public.

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.

II. Provisions of the Proposed Rule

The Departments propose 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 would be 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 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). Paragraph (a) of the proposed rules sets forth the scope and relevant definitions. With respect to the scope of the rules,

- In 26 CFR 54.9815-2715A and 29 CFR 2590.715-2715A, the proposed requirements would be applied to *group health plans and health insurance issuers offering group health insurance coverage*.
- In 45 CFR §147.210, the proposed requirements would be applied to group health plans and health insurance issuers offering coverage in the *individual and group markets* for insurance.

The following terms would be defined in proposed paragraph (a) in each of the three sets of rules:

i. *Accumulated amounts* would be 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 would include family members' amounts if the enrollee is enrolled in other than self-only coverage. Accumulated amounts would exclude 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 limitation on 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 would 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 enrollee has used).

ii. *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.

iii. *Billing code* would be 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).

iv. *Bundled payment* would mean 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* would mean the amount an enrollee is responsible for paying for a covered item or service under the terms of the group health plan or insurance. It would include 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.

vi. *Cost-sharing information* would be 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.

vii. *Covered items or services* would mean 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* would mean a provider that is a member of the network under an enrollee's group health plan or health insurance coverage.

ix. *Items or services* would mean all encounters, procedures, medical tests, supplies, drugs, durable medical equipment, and fees (including facility fees), for which a provider charges a patient.

x. *Machine-readable file* would 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.

xi. *Negotiated rate* would 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.

xii. *Out-of-network allowed amount* would mean the maximum amount a group health plan or health insurance issuer would pay for a covered item or service furnished by an out-of-network provider.

xiii. *Out-of-network provider* would mean a provider that does not have a contract under an enrollee's group health plan or health insurance coverage to provide items or services.

xiv. *Out-of-pocket limit* would mean 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.

xv. *Participant* would have the same meaning as applies under section 3(7) of ERISA which includes any employee or former employee, who is or may become eligible to receive a benefit under an employee benefit plan.

xvi. *Plain language* would mean written and presented in a manner that may be understood by the average enrollee.

xvii. *Prerequisite* would refer to certain requirements relating to medical management techniques that must be satisfied before a group health plan or health insurance issuer will cover the item or service, e.g. concurrent review, prior authorization, and step-therapy or fail-first protocols. It does not include medical necessity determinations.

B. Transparency Requirements: Information to be Disclosed to Enrollees

Paragraph (b). Paragraph (b) in each of the proposed regulations would (1) require group health plans and health insurance issuers in the individual[1] and group markets to disclose upon request, through a self-service tool made available on an internet website, cost-sharing information for a covered item or service from a particular provider or providers, and (2) require such information to be made available in paper form, as well.

The Departments note that their proposal is 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 would 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 proposed rules would not require any cost-sharing liability estimate to include costs for unanticipated items or services that a person could incur.

In anticipating concerns related to the required information being proprietary, the Departments note that because insurers and plans are required to supply this information after a beneficiary receives the services, requiring the same information in advance of receiving the services should not elevate the risk of releasing proprietary information.

The Departments also state that the information must be in plain language and would not need to include any outstanding claims that have not yet been processed.

Content of Disclosures. The required content elements of the disclosure would be:

- *Estimated cost-sharing liability for a covered item or service.* Cost sharing liability and a covered items or services are defined in paragraph (a) and described above. The

[1] Issuers of individual insurance are not incorporated in proposed amendments to ERISA because ERISA only regulates employment-based benefits. They are, however, incorporated in the proposed amendments to the IRC and the PHSA.

Departments request comment on whether other types of information would be necessary to provide an estimate of an individual's cost-sharing liability.

- *Accumulated Amounts* as defined in paragraph (a) and described above. Such disclosure would also include information on any cumulative treatment limitations related to those amounts. The meaning of accumulated amounts is described above.

- *Negotiated rate* expressed as a dollar amount. The Departments acknowledge that sometimes negotiated rates are based on formulas, but the disclosures under this rule would need to be expressed as a dollar amount to be useful for enrollees. In the preamble, the Departments state that in the event that the enrollee's cost sharing liability for an item or service is zero, then the plan or issuer would not need to disclose the negotiated rate.

  The Departments raise complications related to the disclosure of negotiated rates for prescription drugs. Often plans and issuers base cost-sharing for prescription drugs on undiscounted prices (prices that exclude rebates and other discounts, for example) which can be very different from negotiated prices. **The Departments request comment on whether a different rate, such as the undiscounted price, should be required for prescription drugs; whether and how to account for rebates, discounts, and dispensing fees to ensure meaningful cost-sharing information for prescription drugs; whether there are certain scenarios where drug pricing information should not be included in an individual's estimated cost-sharing liability (for example where drugs are paid for as part of a bundled rate); and whether the relationship between plans or issuers and pharmacy benefit managers (PBM) allows disclosure of rate information for drugs**.

- *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 the cost sharing and the out-of-network allowed amounts would need to be provided. The out-of-network allowed amount would not include any balance billing that the enrollee may be responsible for.

- *Items and services content list.* When an enrollee requests cost-sharing information for an item that is part of a bundled payment, the issuer would need to provide a list of those covered items and services in the bundled payment arrangement for which cost-sharing information is being disclosed.

- *Notice of prerequisites to coverage.* 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 would be required to include a notice to that effect. The Departments point out that general medical necessity requirements would not be considered a prerequisite to coverage and **request comment on whether there are additional medical management techniques that should be explicitly included as prerequisites for this purpose.**

- *Disclosure notice.* The disclosure notice must inform enrollees 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.

  The Departments have developed model language for this disclosure. They seek comment on the proposed model language, which can be found at www.cms.hhs.gov/PaperworkReductionActof1995. They also clarify that this proposed disclosure notice would be distinct from other disclosures required of qualified health plan issuers including under 45 CFR 156.220(a)(7) (regarding transparency of information on out-of-network cost sharing) and 45 CFR 156.230(e) (requiring notice about the possibility of additional costs if an out-of-network provider is used). **The Departments request comment on additional disclosures that may be needed, for example that cost sharing information may not include any as-yet unprocessed claims, or information about non-covered items or services.**

Methods of Disclosure. Cost-sharing information required under these proposed rules would be required to be provided in two ways: through a self-service tool available on an internet website, and in paper form.

Self-Service Internet Tool. Group health plans and health insurance issuers would be required to provide the required information 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 would allow the enrollee to search for cost-sharing information for an item or service and include the ability 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. Other factors could include, for example, a facility name for cost-sharing amounts that differ among facilities or prescription drug dosages for cost-sharing amounts that vary by dosage.

If 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, the tool would need to permit enrollees to search by a billing code or description term, and by any other factors that would impact those rates such as by facility or location. The Departments anticipate that plans and issuers may not have complete information on providers' charges for providers who are outside of their network but note that if the plan or issuer provides coverage for out-of-network services, then it will generally have an agreed upon out-of-network allowed amount.

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). **Comments are sought on whether the tool should have additional functionality such as providing**

information by provider subspecialty or by quality rating of the provider. In addition, they request feedback on whether their use of the term "internet website" encompasses other modes of accessing the information, such as through a mobile device or whether the requirement should explicitly provide for accessing the tool through mobile devices. They are also interested in the relative resources for building an internet website versus an internet-based mobile application.

Paper Method. The Departments propose that, at the request of an enrollee, the above information must also be made available to an enrollee in paper form. 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 would be required to be mailed no later than two business days after the individual's request is received.

The Departments request feedback on whether additional methods of providing the information (such as via phone or email) should be required. In addition, they seek information on the feasibility of providing meaningful cost-sharing information if enrollees were to request it based on a treatment or procedure that might encompass multiple individual items or services; for example, for a knee-replacement where there may be multiple types of treatments, procedures, and providers involved.

Preventing Unnecessary Duplication. A group health plan providing coverage through group health insurance would be able to satisfy these 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 the plan.

Privacy, Security, and Accessibility. The Departments note that disclosures proposed under this rule may be subject to HIPAA privacy and confidentiality requirements as well as to related state laws. They establish that nothing in these proposed rules 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" would continue to apply.

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

Paragraph (c). In paragraph (c), health plans and issuers would be required 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. This information would need to be updated on a monthly basis.

The Departments cite the authority under which they propose these public disclosures and outline the reasons to pursue the policies. The statutory authority for the proposals is described as being in sections 1311(e)(3) of the ACA and section 2715A of the PHSA. Section 1311(e)(3) relates to transparency standards for health plans seeking certification as qualified health plans from health insurance Exchanges. Section 2715A of the PHSA requires group health plans and

health insurance issuers not offered through Exchanges to meet the standards established in section 1311(e)(3) that are required by the Secretary and to make such information public.

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

- Individuals without insurance coverage would 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 would be increased, disparities in health care prices would be reduced and potentially, overall health care prices would be lowered.
- More transparency would incentivize the design, development, and offering of consumer tools and support services to enable better use of health care pricing information.
- Plan sponsors would 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.

Information to be disclosed. The Departments proposed minimum requirements for standardized data elements that would be published in two machine-readable files: the Negotiated Rate File and the Allowed Amount File.

- *Plan or Coverage Identifier*. Both files would include the name or identifier for each plan option or coverage using the Employer Identification Number or the Health Insurance Oversight System ID as applicable. They seek comment on whether those are the appropriate identifiers or whether others should be considered.
- *Billing Codes*. Both files would need to include the billing codes associated with each rate.[2] A plain language description of each billing code must be included.
- *Negotiated rates or out-of-network allowed amounts.* For the Negotiated Rate File, the rate for each covered item or service furnished by in-network providers would be expressed as a dollar amount and would be associated with the provider's National Provider Identifier (NPI). If the plan or issuer uses a bundled payment rate, the plan must identify the bundle of items and services by the relevant code.

  For the Allowed Amount File, the out-of-network allowed amounts disclosed would be the amount 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 would need to be expressed as a dollar amount and associated with a provider's NPI. This amount would include both the plan's paid portion and the enrollee's share of costs.

  The Departments acknowledge that the out-of-network allowed amount disclosures could raise privacy concerns, particularly where there are very few claims, and so could be associated with particular individuals or where they involve protected information such

[2] Including but 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.

as for treatment of substance use disorders. To address those privacy concerns, the Departments chose the 90-day period of time to ensure that there are enough claims to report that there could not be such privacy violations but they **seek comment on whether that length of time is sufficient or whether it should be extended to 120 or 180 days or some other period of time.**

In addition, because of those privacy concerns, the Departments propose that disclosures would not need to be made (1) if there were fewer than 10 different claims for payment for a particular item or service, or (2) if the disclosure would violate any applicable health information privacy law.

Method and format for disclosures. The two machine-readable files must be made publically available without charge or conditions such as the need for a user account, password or other credentials. The Departments considered requiring that the files be made available as JSON files which would represent a single standardized, non-proprietary file format and **seeks comment on that approach**. The files would be required to comply with technical guidance that would be issued by the Departments. **The Departments also seek feedback on whether reporting in two separate files increases burden for plans or alternately whether a single file for both types of information would be too large for users to access.**

The Departments considered requiring plans and issuers to submit the internet addresses for the data to the Centers for Medicare and Medicaid Services (CMS) and CMS would make the information available to the public but thought that plan-by-plan availability would make the data more accessible to users. **The Departments request comment on this decision and are interested in whether the burden associated with reporting the file locations to CMS is outweighed by the risk that some members of the public would be unable to locate the information.**

Timing for disclosures. The proposal would require disclosures to be updated monthly but the Departments **seek comment on whether more frequent updates may be necessary as it notes that the information in Negotiated Rate Files could change frequently**. The files must clearly indicate the date of their last update.

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 third-party administrator (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 would be permitted to aggregate the reporting under this provision for more than one plan, insurance policy, or contract. Under this approach, the minimum 10 claims threshold would apply to the aggregated claims data set.

D. Transparency Requirements: Applicability

Paragraph (d). In proposed paragraph (d), the applicability of the disclosure requirements would be described. The requirements would apply for plan years starting on or after one year following the effective date of the final rule. The provisions would not apply to grandfathered plans, health reimbursement arrangements or other account-based group health plans. It would not apply to any plans or insurance that are not subject to existing transparency requirements under section 2715A of the PHSA such as excepted benefits and short-term, limited-duration insurance.

The Departments note that the disclosure requirements in paragraphs (b) and (c) may not be aligned with certain benefit structures, for example, staff model health maintenance organizations**. It seeks comment on whether there are certain reimbursement or payment models that should be partially or fully exempt from the disclosure provisions.**

Nothing in the section would 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.

The Departments request feedback on whether data clearinghouses or TPAs could be used to meet the public disclosure requirements and to reduce plan and issuer burden. In addition, they seek comment on whether plans and issuers should have the flexibility to provide the disclosures through a publicly accessible API rather than through machine-readable files or if such an approach would present significant technical issues for plans and issuers. Finally, the Departments acknowledge the possibility that the information disclosures could result in unintended consequences such as higher prices or anticompetitive behaviors. They seek feedback on these potential concerns and whether there are additional rules that could help mitigate those outcomes.

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

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).

Beginning with the 2020 MLR reporting year, HHS proposes to permit insurers to include shared savings payments that they made to enrollees in the numerator of the MLR. HHS proposes to codify this policy change in new paragraph (b)(9) of 45 CFR §158.221.

CMS proposes this change to encourage issuers to undertake investment in developing plan features that reward consumers who choose lower-cost, higher value providers.

Regulatory Impact Statement. Using 2014 – 2017 MLR data, HHS estimates that this proposal would reduce MLR rebate payments from issuers to consumers by approximately $67 million per year. The reductions in rebates to consumers would be offset by about $128 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. Request for Information: Disclosure of Pricing Information through a Standards-based API

The Departments request information regarding the possible use of standards-based API technology for disclosure of pricing information, including the patient's cost-sharing liability as well as information on negotiated in-network rates and out-of-network allowed amounts. API technology allows software programs to talk to one another; a software developer's API enables other software developers to create applications ("apps") that interact with its software without needing to know that software's internal workings.[3] API technology is often in use by consumers employing apps for travel and personal finance. Certain technical information on standards-based APIs (sometimes referred to as "open" APIs) are openly published to facilitate uniform use and data sharing in a secure, standardized way. A standards-based API can enable an application to securely access specific data in compliance with applicable privacy and security laws and regulations.

Earlier this year the Office of the National Coordinator (ONC) for Health Information Technology issued a proposed rule, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" (84 FR 7424-7610) which, among other things, would establish technical standards for API technology. The proposed API standards included the HL7 Fast Healthcare Interoperability Resources (FHIR) standard and complementary security and app registration protocols, OAuth 2.0 and OpenID Connect Core and the United States Core Data for Interoperability (USCDI). A separate 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," issued by CMS (84 FR 7610-7680) would require the listed payers to provide enrollees with access to select data, including claims data, through a standards-based API.

The Departments believe that providing access to pricing information through a standards-based API could benefit patients, providers, and the general public. Examples offered are the incorporation of pricing information into third-party applications used by consumers or into electronic medical records for point-of-care decision-making and referral opportunities by

[3]For more information on APIs, readers are referred to https://www.healthit.gov/api-education-module/story_html5.html.

clinicians. Consumers would have the flexibility to use a third-party application of their choice rather than being tied to their health plan's specific application or online tool.

Comments are requested on several issues regarding use of API technology:

- 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. Specifically, should the Departments 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? Under the possible approach the Departments could propose a staged implementation because the FHIR implementation guide (IG) is still in development: (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 plans and issuers would initially not be required to use the FHIR API standard but would be strongly encouraged to do so. Prior iteration(s) of the FHIR standard for trial use would be publicly available and could provide a development roadmap for payers wishing to deploy a FHIR-based API. Comments are sought on the appropriateness of this proposed approach, the challenges it may present, and whether the suggested timeframes are appropriate.
- 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-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 possible scope of the burden of 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.
- 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.
- Plans' and issuers' readiness to disclose data elements through an API, and the amount of time plans and issuers would need to implement such standards.
- 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 in this rule.
- Comments from API developers about potential uses for data. The Departments believe that requiring plans and issuers to make pricing data available through a standards-based API would spur competition, reduce the burden on application developers, and benefit consumers. Developers could 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).

- 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 Departments discuss the critical need for transparency about API technology to support application development and interaction with an API, including an API's requirements for verification of developers' identity and their applications' authenticity, consistent with its security risk analysis and related organizational policies and procedures to provide appropriate privacy and security protection for the data that would be disclosed.
- Whether there are reasons why testing and monitoring requirements other than those proposed in the CMS Interoperability & Patient Access proposed rule (84 FR 7635) should apply to APIs used for 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 Public Health Service Act (explain reference).
- The impact on plans and issuers of updating APIs, and the frequency with which such updates should occur for this test case; 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 (see 84 FR 7630-7631). The Departments note 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 their ability to amend regulatory text.

The RFI also includes a discussion of privacy and security issues relating to use of a standards-based API for price transparency and seeks comment on potential concerns. The Departments note that to the extent that information that could be requested via the API would be considered personal health information (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. However, direct-to-consumer health information technology products and services are often not regulated by the HIPAA Rules. The limitations of Federal Trade Commission regulations for this purpose are discussed.[4]

The Departments note that if an enrollee directs a covered entity to send his PHI to his or her chosen third-party application and that third-party application developer is neither a covered entity nor business associate under HIPAA Rules, the PHI to be transmitted through the API would not be protected under HIPAA Rules after being transmitted through the standards-based

[4] Readers are referred to 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.

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.[5] While recognizing the potential risk to sensitive information if the third party subsequently misuses the data or has a security breach, the Departments believe consumers should be able to share personal health information with third-party applications of their choosing, but the potential privacy and security risks should be explained.

The Departments are considering requirements that, consistent with the HIPAA Privacy Rule, plans and issuers generally could not deny access to a third party when an enrollee requests that the information be made accessible as proposed in this rule. Under 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. 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; therefore it may be appropriate for a plan or issuer to deny or terminate specific applications' connection to its API under certain circumstances in which the application poses an unacceptable risk to the PHI on its systems or otherwise violates the terms of use of the API technology. Under the CMS Interoperability & Patient Access proposed rule, 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.

Regarding the risks to PHI within a system, the Departments further note existing 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. The ONC 21st Century Cures Act proposed rule, included proposed technical standards, the "OpenID Connect Core 1.0 incorporating errata set 1" standard, which is typically paired with OAuth 2.0 implementations and focuses on user authentication. The Departments believe that the use of these technical standards creates the ability for plans and issuers to (1) 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, and (2) securely deploy and manage APIs consistent with their organizational practices to comply with existing privacy and security laws and regulations. The Departments believe that implementing these security controls and safeguards would help to protect health information technology from nefarious actors.

Comments related to privacy and security aspects of using API technology for pricing transparency are specifically requested on the following:

- Potential privacy and security risks associated with a requirement that plans and issuers make pricing information available through a standards-based API, and what privacy and security standards that would be sufficient to protect the sensitive health data the Departments could

[5] The Departments cite HHS Office for Civil Rights, *FAQ on Access, Health Apps and APIs*, https://www.hhs.gov/hipaa/forprofessionals/privacy/guidance/access-right-health-apps-apis/index.html.

propose in future rulemaking to be transmitted via an API, or whether additional privacy and security standards should be required.

- The information that 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 potential application of the CMS Interoperability & Patient Access proposed rule provision under which applicable entities could deny access to the API if certain conditions are met, 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.

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

Information is requested from stakeholders on how public and private sector quality measures might be used to complement cost-sharing information for plans and issuers in the private health insurance market. The proposed rule reviews how existing cost estimator tools display provider quality information along with cost-sharing information. These include display of star ratings from the CMS Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey results (Colorado) and performance on CMS and other clinical quality measures (Maine) along with pricing information. The Departments also note that issuers often include quality information as part of their provider directories and cost estimator tools. This includes data on CMS quality measures and those of the National Committee for Quality Assurance (NCQA), and other private and state-based organizations.

The Departments are interested in how public and private sector quality measures might be used to compliment cost-sharing information for plans and issuers in the private health insurance market. Specifically, comments are sought on the following:

1. Whether, in addition to the price transparency requirements proposed in these rules, the Departments should also impose requirements for the disclosure of quality information for providers of health care items and services.
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) or the Quality Measures Inventory (QMI) 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. Any limitations that plans and issuers might have in reporting on in-network provider quality in the individual and group markets.
8. How and if quality data is currently used within plans' and issuers' provider directories and cost-estimator tools, the data sources for quality information, and whether plans and issuers are using internal claims data or publicly available data.

Responses to a similar request for comment included in the Medicare Hospital Outpatient Prospective Payment System proposed rule for 2020 will also be considered for future rulemaking by the Departments.

V. Regulatory Impact Analysis (RIA)

The Departments examined the impacts of this proposed rule as required by EO12866 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 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 EO13771 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.

The Departments summarize the impact of the rule in Table 1 which includes the non-quantified benefits and potential costs. The Department did not quantify the potential impact that the disclosure would have in reducing health care prices and acknowledges again that there is some potential that prices may rise instead of fall due to the disclosures in this proposed rule. They did estimate the expenses that would be associated with the proposed requirements. Overall, they estimate an increase of 0.03 percent in premiums for the fully-insured market which would result in increased premium tax credit outlays of about $12 million per year beginning in 2021. The Departments believe the increase would have minimal impact on anticipated enrollment.

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.

VI. Information Collection Requirements

The Departments estimate that all 1,754 issuers and 205 TPAs would be impacted by the information collection duties proposed. Overall, the total costs of the proposed rule are estimated to be $375.8 million per year for the first three years (calculated on a three-year average).

That amount is comprised primarily of:

- $161.5 million of annual costs on average over the first 3 years to develop, build, and maintain an internet-based consumer self service tool. Those costs would be borne by 1,959 health insurance issuers and TPAs, with an average annual cost for each of those entities of about $82,400.
- $117.5 million of annual costs on average over the first 3 years to develop, build, maintain, and update the Negotiated Rate File. Those costs would be borne by 1,959 health insurance issuers and TPAs, with an average annual cost for each of those entities of about $60,000.
- $96.1 million of annual costs on average over the first 3 years to develop and build, maintain, and update the Allowed Amount File. Those costs would be borne by 1,959 health insurance issuers and TPAs, with an average annual cost for each of those entities of about $49,000.