CMS Response to Public Comments Received for CMS-10715

The Centers for Medicare and Medicaid Services (CMS) received eight comments: five from health insurance plans and issuers, one from a third-party technology developer, and two from industry advocacy organizations related to an information collection request (ICR) CMS released concerning CMS-10715, a Paperwork Reduction Act (PRA) document detailing requirements related to the Transparency in Coverage (TiC) final rules ("final rules"). This is the reconciliation of the comments. Comments addressed the following broad categories: 1) the timeline and cost of compliance with the final rule; 2) concerns relating to machine-readable file (MRF) requirements; 3) the interaction of TiC requirements and those of the Consolidated Appropriations Act of 2021 (CAA); 4) concerns regarding the internet-based self-service tool mandated by the final rule; 5) concerns regarding the anticipated quality of consumer experience; 6) comments regarding the proposed use of the GitHub platform to develop technical assistance and guidance relating to content and reporting requirements concerning data under the final rule; 7) the proposed notice to participants, beneficiaries, and enrollees required under the final rule; and 8) challenges to the legal authority to enact the final rule.

1. Timeline and Cost

Comment:

Several commenters urged that CMS align the timelines for implementing the final rules and the price comparison tool described in section 114 of the CAA by extending the implementation date for that section to January 1, 2023. Commenters noted that the CAA imposes a January 1, 2022 implementation deadline to make available an online price comparison tool, among other requirements, one year earlier than the TiC implementation deadline of January 1, 2023. Several commenters contended that extending the deadline by aligning the implementation deadlines to the later date would afford health plans critical additional time to develop substantially similar compliance capabilities involving a tremendous volume of information, and significant new data management capabilities. (BCBS, PCMA, UHG, CVS, Cigna, AHIP,).

Response:

CMS appreciates the concerns expressed by commenters to the effect that the TiC requirements are extensive, and that the transparency aspects of the CAA impose an additional, earlier deadline to achieve some comparable functionalities. Accordingly, CMS will defer enforcement of the requirement that a plan or issuer make available a price comparison tool (by internet website, in paper form, or telephone) before plan years (in the individual market, policy years) beginning on or after January 1, 2023. CMS intends to propose rulemaking regarding whether plans and issuers that comply with TiC internet-based self-service tool requirements thereby satisfy analogous requirements under the CAA. The Departments also intend to propose rulemaking requiring that the same pricing information that is available through the online tool or in paper form, as described in the TiC Final Rules, must also be provided over the telephone upon request. The existing deadlines for implementing the TiC final rules requirements will remain as published in the final rules, including to the effect that information concerning 500 designated items and services must be available through such a tool as of January 1, 2023, and

concerning all items and services as of January 1, 2024. CMS strongly encourages plans and issuers to begin building an internet-based self-service tool as soon as practicable if they do not have one, or to update and maintain an existing one. On August 20, 2021, CMS released guidance related to, among other issues, the interaction between CAA Section 114 and the TiC Final Rules.[1]

Comment:

A commenter contended that the final rules compel health plans to expend enormous resources figuring out how to accurately meet MRF data requirements concerning plan designs that are not fee-for-service arrangements. The commenter asserted that health plans frequently base payment arrangements on methodologies that are not accurately reflected by a fee-for-service reporting model. [BCBS].

Response:

CMS appreciates the comment concerning complexities of the data implicated by the final rules. Although the final rules require that price information be disclosed concerning separate items and services, CMS notes that the final rules do not prohibit additional reporting methodologies that may be more useful to consumers in specific circumstances. The final rules made clear that the data reporting system established pursuant to the final rules would accommodate pricing information to reflect bundled payment arrangements, capitated payment arrangements, and other alternatives to fee-for-service payment arrangements. CMS has established, and will maintain, a collaborative process on the GitHub platform for establishing and revising data reporting requirements to maximize the accuracy and value of price and cost information for consumers.

Comment:

Several commenters asked that CMS deem health plans and issuers in compliance with the TiC implementation requirements to also be in compliance with the CAA implementation requirements. (BCBS, PCMA, UHG).

Response:

CMS appreciates the concerns of commenters regarding potential duplicative efforts that may result from similar requirements of the TiC rule and the CAA. As stated in the aforementioned guidance, CMS will delay enforcement action against plans and issuers for section 114 of the CAA until the TiC requirements become applicable, starting January 1, 2023.

Comment:

Two commenters contended that the timeline for implementing the final rules could detract from ongoing efforts of health plans and issuers to respond to the ongoing COVID-19 public health

[1] FAQs about Affordable Care Act Implementation Part 49 (Aug. 20, 2021), Q3, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf

emergency. The commenters contended that this circumstance merits extending the time for implementation of the final rules. (PCMA, AHIP).

Response:

CMS acknowledges the challenges to health plans and issuers and providers during the ongoing public health emergency, as well as the number of provisions under the CAA plans and issuers must comply with starting January 1, 2022. As described in the aforementioned guidance,[2] CMS will defer enforcement of the requirement to make public the MRFs for in-network rates, out-of-network allowed amounts and billed charges, until July 1, 2022. CMS will also defer enforcement of the requirement in the TiC Final Rules that plans and issuers must publish MRFs related to prescription drugs while it considers, through notice-and-comment rulemaking, whether the prescription drug MRFs requirement remains appropriate.

Comment:

Two commenters maintained that CMS underestimated the burden and related cost of compliance. (BCBS, PCMA). One commenter provided a detailed analysis to the effect that the cost of implementing the final rules would be more than 26 times what CMS estimated. (BCBS). Another commenter contended that CMS omitted from its estimate of labor costs appropriate consideration of the substantial involvement of senior management, and other professional-level employees, necessary to achieve compliance. (PCMA).

One commenter contended that negotiated rates versus historical net prices for pharmacy drugs are distinct, highly complex datasets, and the requirement under the final rules that both be included in the pharmacy drug MRF prevents Pharmacy Benefit Managers (PBMs) from leveraging existing functionalities of established systems designed to serve Medicare plans. (PCMA). Several commenters asserted that the specific data requirements of the final rules impose particularly heavy burdens due to the highly varied form of the source data, and the complex methodologies used to develop it. (BCBS, Cigna). The requirement to develop separate files for self-funded plans, and to develop historical net prices for prescription drugs, were identified by several commenters as particularly unnecessary and burdensome.

Response:

CMS appreciates the commenters for detailing their cost and burden concerns related to implementation of the final rules. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) carefully evaluated the projected costs during the process of writing the final rules and are of the view that the regulatory and economic impact analyses set forth in the final rules are reasonable. CMS did adjust its cost estimate calculations based on comments received in response to the proposed rules and anticipates that costs imposed by the final rules will decline over time as plans, issuers, and vendors develop and streamline compliance capabilities.

[2] FAQs about Affordable Care Act Implementation Part 49 (Aug. 20, 2021), Q1 and Q2, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf

Comment:

A commenter sought clarification whether, in the event CMS delays implementation deadlines to align similar TiC and CAA requirements, the out-of-network file data and historical net price prescription drug data requirements will correspondingly not be published until 180 days after a plan is first required to produce data. (PCMA, UHG).

Response:

CMS appreciates the comments. As stated in the aforementioned guidance, CMS will defer enforcement of the requirement to make public the MRF for in-network rates and out-of-network allowed amounts and billed charges, until July 1, 2022. For 2022 plan years and policy years beginning subsequent to July 1, 2022, plans and issuers should thus post the machine-readable files in the month in which the plan year (in the individual market, policy year) begins, consistent with the applicability provision of the TiC Final Rules. CMS also will defer enforcement of the requirement in the TiC Final Rules that plans and issuers must publish machine-readable file related to prescription drugs while it considers, through notice-and-comment rulemaking, whether the prescription drug machine-readable file requirement remains appropriate. The requirement under the final rules concerning out-of-network allowed amount and billed charges data requires that the data include a 90-day period beginning 180 days before the data publication date, and remains unchanged.

2. MRF

Comment:

Two commenters recommended eliminating altogether the requirement that health plans and issuers produce MRF data, on grounds that the requirement under the CAA that health plans develop the ability to provide an advanced explanation of benefits (AEOB) to consumers that provide substantially similar information adequately fulfills the same purpose. (BCBS, AHIP)

Response:

CMS appreciates the commenters for the recommendation. As stated elsewhere in these responses, CMS will defer enforcement of the requirement in the TiC Final Rules that plans and issuers must publish machine-readable file related to prescription drugs. CMS also recognizes that several provisions of the TiC and CAA requirements overlap, and the considerable time and effort required to produce the required MRF data. Accordingly, and as stated in the aforementioned guidance, CMS will defer enforcement of the requirement to make public the MRF for in-network rates and out-of-network allowed amounts and billed charges, until July 1, 2022.

Comment:

Several commenters objected to the requirement in the final rules that health plans develop a prescription drug MRF on the grounds that the requirement was not included in the proposed rules. (BCBS, PCMA, CVS, UHG, AHI). Several commenters suggested that, if CMS believes the requirement is necessary, CMS should publish a new rule and go through the public notice

and comment process to provide the public an adequate opportunity to comment prior to finalizing a new rule. Two commenters contended that much of the data that would be useful to consumers through the prescription drug MRF will already be included in the annual report mandated by section 204 of the transparency provisions of the CAA. (PCMS, AHIP).

One commenter contended that many health plans and issuers do not store current prescription drug reimbursement rates in their own claims systems, and therefore would have to rely on historical data to develop price information for the prescription drug MRF. As a result, they are unable to currently provide cost information that complies with the prescription drug MRF requirements in the final rules. (BCBS).

A commenter contended that the requirement in the final rules that the prescription drug MRF disclose historical net prices will lead to market distortion by emphasizing unit pricing rather than overall value, whereas PBMs generally seek to create value through managing the broader mix of drugs they dispense. Similarly, by emphasizing the historical net price of individual drugs, the commenter indicated that the prescription drug MRF requirements in the final rules are likely to interfere with current trends toward value-based health plan models calculated to encourage marketplace competition. The commenter contended that a greater lag in data requirements than accommodated by the final rules and allowing aggregation of data by therapeutic class or disease would greatly reduce the anticompetitive effect of the disclosure of drug pricing information, and would provide more meaningful information to certain consumers. (PCMA)

A commenter requested clarification regarding whether historical net price and negotiated rate information should be reported on a per-pharmacy basis, or at the level of a parent entity such as a retail chain. (PCMA)

A commenter asked whether, in the event historical net price concessions are not known to an issuer on the date of publication of prescription drug MRF data and a good faith reasonable estimate is published instead, as specified by the final rules, plans will be required to disclosure the allocation method or time period used to develop the estimate. (PCMA).

Two commenters contended that the requirement that a transaction fee, administrative fee, or dispensing fee be reported as separate fields in the prescription drug MRF should be eliminated, since, under the final rules, those are listed only as factors in calculating historical net price, but not as separately reportable elements. (PCMA, Cigna).

Response:

CMS appreciates the comments. As stated in the aforementioned guidance, CMS is delaying enforcement of the MRF requirement related to prescription drug information until considering whether it is appropriate to maintain the requirement in future rulemaking. CMS welcomes feedback concerning the prescription drug MRF requirement.

Comment:

Several commenters cited ongoing industry implementation efforts concerning the Hospital Price Transparency Final Rule as evidence that releasing unit pricing information is overly complex and unhelpful to consumers. Citing ongoing delays and varied, inconsistent methodologies used by regulated entities to develop data for disclosure to the public, commenters asserted that this experience demonstrates that health care services are generally paid utilizing a mix of methodologies that are incompatible with the fee-for-service model the MRF requirement imposes under the final rules. (BCBS, Cigna, PCMA).

Response:

CMS appreciates the comments concerning the ongoing implementation of the Hospital Price Transparency Final Rule and its potential relevance to efforts to implement the final rules. As the Departments noted in the preamble to the final rules,[3] the TiC requirements are necessary precisely because the Hospital Price Transparency Final Rule concerns only services provided by hospitals and does not require any transparency with respect to other health care costs. CMS acknowledges that additional, meaningful costs will be necessary to implement the final rules. CMS remains committed to working with all stakeholders to ensure that the final rules are implemented as efficiently and effectively as possible. CMS invites public feedback in response to the CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1753-P), which includes proposed modifications to the Hospital Price Transparency Final Rule.

Comment:

A commenter recommended that CMS eliminate "plan or coverage" data elements from MRF data requirements since negotiated rates and allowed amounts do not vary based on plan design, and are instead based on provider contracts and/or health plan-specific methodologies. Reporting these data elements in relation to every separate health plan design and pharmacy benefit plan available would therefore cause extensive duplication of data and impose unnecessary additional costs. In the alternative, the commenter recommended that CMS consign this data to a separate, dedicated file that would be keyed to link back to rate data, as appropriate. The commenter also recommended that Employer Identification Number (EIN) data be linked to rate information with respect to only one EIN in cases where an employer has multiple EINs. As with plan or coverage data, the commenter maintained that EINs do not inform negotiated rates or allowed amounts, and that listing rate information for multiple EINs would similarly result in extensive duplication of data and additional costs. In the alternative, the commenter recommended that multiple EIN numbers be listed in an additional, separate file that links to rate information. (BCBS).

Response:

CMS appreciates the commenter for expressing concerns regarding the utility of "plan or coverage" and EIN data elements in the in-network MRF. CMS is currently working with plans, issuers, and vendors through the GitHub platform to explore the possibility of establishing separate files to accommodate instances in which multiple Health Insurance Oversight (HIOS) or

[3] 85 CFR 72158, 72166 (Nov 12, 2020).

EIN numbers may be implicated, along with other potential approaches to prevent the needless duplication of information by reporting entities with multiple plan or company identifiers.

Comment:

A commenter recommended removing "Name of Reporting Entity" and "Type of Reporting Entity" data elements from MRF data because the rules do not require that this information be included, and it will not help consumers understand their benefits and potential costs. The commenter asserted that the requirement would lead to numerous instances of entities being named that are not the actual plan or issuer providing coverage, such as a third-party administrator or a clearinghouse, and this would likely confuse participants, beneficiaries, and enrollees. (UHG).

Response:

CMS appreciates the commenter for recommending that CMS consider the advisability of removing the data elements "Name of Reporting Entity" and "Type of Reporting Entity" from the MRF data. CMS believes that the information is important and useful to include even if the reporting entity is not always the same as the health plan or coverage incurring claim liability in a given case. In most cases, CMS assumes that the reporting entity will be the relevant plan or coverage. Otherwise, CMS does not believe that information concerning third-party vendors and other business partners, or information regarding their role in managing claims activities, is necessarily meaningless to participants, beneficiaries, enrollees, and other stakeholders who access the data.

Comment:

A commenter recommended that the designation of "Not Available," or "Not Applicable" ("N/A") be available options for plans reporting MRF data for instances where information or a specific designation are not available. For example, a National Provider Identifier number is not provided to certain behavioral health providers, some provider contracts do not include a contract termination or expiration date, and certain providers may not be part of a specific practice or group. (UHG).

Response:

CMS appreciates the commenter for recommending that "Not Available" and "Not Applicable" ("N/A") designations be available when appropriate for purposes of reporting MRF data. CMS intends to explore the recommendation through collaboration on the GitHub platform.

Comment:

Several commenters contended that the mandate in the final rules that rate information in the MRF be associated with HIOS ID 14-digit numbers will result in an enormous proliferation of redundant information, since provider rates are not established based on distinct plan designs, but are applied across multiple plan offerings. (CVS, UHG, AHIP). Two commenters noted that 14-digit HIOS numbers are subject to frequent alteration or elimination from year to year based on commonplace changes to specific plan designs, making it impossible to report data relevant to a

particular plan for the previous year. (PCMA, AHIP). One commenter recommended that if HIOS numbers must be included in the data files, they should be reported in a separate file from other plan data and mapped to plan detail information to avoid excessive duplication. (AHIP). One commenter recommended that plans be required to report only pricing information at the 5 or 7-digit level, which captures separate health plan activities relevant to pricing and reduces the burden of needless duplication of effort and data. (PCMA). One commenter contended that HIOS and EIN data is not collected by PBMs, and it would be an additional burden on PBMs to now develop that capability. (CVS).

Response:

CMS appreciates the commenters for their comments concerning the utility of HIOS ID numbers as elements to be reported in the MRF data. CMS understands that 14-digit HIOS numbers are subject to ongoing alteration, and that all elements identified in 14-digit format may not be relevant from year-to-year. CMS is in the process of finalizing technical implementation requirements, but currently intends to allow reporting HIOS ID numbers at the 10-digit level, if appropriate, and reporting of only EIN data if no relevant HIOS number is available. CMS anticipates that PBMs and the plans and issuers with which they contract will be able to collaborate to develop the capabilities necessary to meet all obligations concerning MRF data requirements under the final rules.

Comment:

Two commenters sought clarification as to whether MRF data is to include only payments to providers, excluding reimbursements made directly to participants, beneficiaries, and enrollees. (PCMA, UHG).

Response:

CMS appreciates these comments. Under the final rules, the *negotiated rate* and the *out-of-network allowed amount* are defined to include, respectively, the amount a health plan or coverage has contracted to pay an in-network provider for a covered item or service, and the maximum amount a plan or coverage will pay an out-of-network provider for a covered item or service. These definitions do not exclude instances where a plan or coverage reimburses a participant, beneficiary, or enrollee directly for covered items or services. Therefore, reimbursements for claims made to participants, beneficiaries, or enrollees should not be excluded from the data.

Comment:

A commenter sought clarification as to whether the term “fee-for-service” in the proposed rules means services not billed in the context of a bundled or capitation arrangement, and notes that the term has a different meaning in the context of Medicare and Medicaid. (PCMA) Another commenter recommended that fee-for-service rates always be displayed even when bundled payment information is provided, on the grounds that bundled rates are composed of underlying fee-for-service rates. (Ribbon).

Response:

CMS appreciates the comment regarding the precise meaning of the term "fee-for-service" in the final rules. In the final rules, the term "fee-for-service" is used to refer to items or services that are paid for on an individualized basis, as opposed to items or services that constitute a cost factor included under a bundling or capitation arrangement and are not separately billed or paid for. As to providing underlying fee-for-service information concurrently with bundled payment information, it is not clear that this would add value for consumers. Technical implementation issues regarding discrete information elements will be addressed in the context of the collaborative process on the GitHub platform for establishing and revising data reporting requirements to maximize accuracy and value for consumers.

Comment:

A commenter sought clarification as to whether CMS anticipates that MRF data will include prices of patient-specific compounds, or pricing information concerning physician-dispensed drugs. (PCMA).

Response:

CMS appreciates the commenter for the comment regarding patient-specific compounds. As stated previously, CMS will defer enforcement of the requirement in the TiC Final Rules that plans and issuers must publish MRF related to prescription drugs while it considers, through notice-and-comment rulemaking, whether the prescription drug MRF requirement remains appropriate.

Comment:

A commenter asked whether pharmacy-dispensed diagnostics and devices are to be included in the prescription drug MRF. (PCMA).

Response:

CMS appreciates the comment. As stated previously, CMS will defer enforcement of the requirement in the TiC Final Rules that plans and issuers must publish MRF related to prescription drugs while it considers, through notice-and-comment rulemaking, whether the prescription drug MRF remains appropriate.

Comment: A commenter asked whether retrospective quality bonuses paid to PBMs by health plans, and not tied to specific drugs, must be allocated against historical net price calculations. (PCMA).

Response:

CMS appreciates the comment. As stated in earlier responses, CMS is considering feedback concerning the prescription drug MRF requirement.

3. Interaction with CAA

Comment:

Several commenters recommended that CMS align and consolidate the consumer tool requirements of the final rules with those specified in the CAA. The commenters observe that the CAA requires that health plans make available to plan participants, beneficiaries, and enrollees a price comparison tool that will allow plan participants, beneficiaries, and enrollees to compare the amount of cost-sharing they will be responsible for paying for a particular service and recommend that the cost calculator required by the CAA be combined with the internet-based self-service tool required under the final rules to avoid duplication of effort and potential confusion to consumers as a result of creating separate, competing tools. (BCBS, UHG, Cigna, AHIP).

Response:

CMS appreciates the comments concerning the price comparison tool required by the CAA and the internet-based self-service tool required under the TiC final rules. As stated in the aforementioned guidance, since the price comparison tool required by the CAA substantially duplicates the requirements of the internet-based self-service tool required by TiC final rules, CMS intends to seek through future rulemaking public comment concerning whether compliance with such requirements under the TiC final rules satisfies consumer tool requirements under the CAA. The Departments also intend to propose rulemaking requiring that the same pricing information that is available through the online tool or in paper form, as described in the TiC Final Rules, must also be provided over the telephone upon request.

Comment:

One commenter contended that the CAA provisions concerning new pharmacy benefits disclosure requirements are more focused and useful to consumers than those in the final rules and include an explicit mandate to protect confidential and trade secret information. The commenter contended that this is evidence of Congressional intent regarding disclosure of pricing and rate information that contradicts the approach CMS has taken on disclosure of this information in the final rules. (CVS).

Response:

CMS appreciates the commenter for the comment concerning confidential and trade secret information in relation to pharmacy benefits. As stated previously, CMS will defer enforcement of the requirement in the TiC Final Rules that plans and issuers must publish MRF related to prescription drugs while it considers, through notice-and-comment rulemaking, whether the prescription drug MRF requirement remains appropriate.

4. Internet-based Self-service Tool

Comment:

Two commenters contended that the requirement under the final rules to provide cost-sharing information available for 500 services identified in the final rules by January 1, 2023, and for all services by January 1, 2024, would be of little assistance to the great majority of consumers, while imposing costly implementation burdens on health plans and issuers. (BCBS, AHIP).

Several commenters contended that the great majority of consumer inquiries regarding cost information under existing mechanisms is highly concentrated among a much narrower range of services. (BCBS, AHIP, UPMC).

Response:

CMS appreciates the commenters for their comments concerning the scope of services concerning which cost information must be provided under the final rules. The Departments acknowledged in the preamble to the final rules the significant burden associated with implementing these requirements, and accordingly instituted a tiered approach to implementation. Under the tiered approach, only 500 specified items and services must be searchable upon initial implementation by January 1, 2023, and there is an additional year to make available cost information concerning all items and services. CMS does not believe, however, that it is in the public interest to limit the data available as recommended by the commenters. The purpose of the final rules is to provide price transparency to all consumers regardless of the frequency with which cost information concerning particular items or services may be sought.

Comment:

A commenter contended that the requirement in the final rules that health plans provide information concerning covered services based on billing codes, rather than user-friendly terminology and "curated estimates" based on case-specific expectations, will cause confusion and afford little value to consumers. Mandating the use of billing codes may also suppress the development of value-based care models. (BCBS).

Response:

CMS appreciates the commenter for the comment concerning billing codes. The final rules acknowledge that the use of individual billing codes by themselves may not suffice to communicate effectively to consumers in all cases. Accordingly, the data requirements adopted by the final rules also require a plain language description for each billing code to ensure consumers receive sufficient information to meaningfully inform health care purchasing decisions. CMS anticipates working collaboratively and extensively with health plans and issuers to develop technical specifications and guidance over time that will improve the value of the data to consumers.

Comment:

A commenter asserted that providing historical net data concerning pharmacy benefits is likely to require extensive suppression of data elements for privacy purposes, which could make the information unclear to consumers. Providing aggregated data instead would better serve the public. (PCMA).

Response:

CMS appreciates the comments. CMS is considering feedback concerning the prescription drug MRF requirement.

5. Consumer Concerns

Comment:

Several commenters contended that the MRFs specified in the final rules are likely to mislead or confuse consumers because member costs are often affected by factors not captured by the MRF data schematics, such as member-specific attributes, and dynamics related to discrete combinations of billing codes. As a result, displaying negotiated rates for certain services may not capture a useful estimate of actual member costs in many circumstances (BCBS, AHIP, Cigna) Two commenters contended that the development of the out-of-network MRF specifically, using averages of claims data as specified under the final rules, does not account for the complexities of actual claims operations across different health plans, and is likely to lead to inconsistent data that is of little or no value to consumers. (BCBS, AHIP).

Response:

CMS appreciates the commenters for their comments concerning the usefulness of the data in the MRFs. CMS acknowledges the data may not provide fully accurate information to consumers in all cases, in particular initially. Over time, CMS intends to develop improvements to the content and format of data to address such shortcomings, most immediately through the collaborative process of developing technical guidance on the GitHub platform.

Comment:

A commenter contended that the prescription drug MRF requirement that plans disclose historical net prices will confuse and mislead consumers, since net prices are not charged to consumers. Member cost-sharing is instead based on negotiated rates paid to the pharmacy, which are also subject to disclosure under the final rules. (PCMA).

Response:

CMS appreciates the comment.

As previously stated, CMS is considering feedback concerning the prescription drug MRF requirement.

Comment:

A commenter recommended that the Departments establish a “glide-path” for health plans to use a Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interface (API) transfer rather than generating MRFs. The commenter contended that using a FHIR-API system aligns with current trends in the health care industry and would ensure adherence to the Health Information Portability and Accountability Act (HIPAA) privacy and security standards for any third-party applications used to access health data. (BCBS)

Response:

CMS appreciates the comment concerning the potential for using an API, both as a practical alternative to MRFs and as a means of addressing privacy and security concerns. The Departments received comments on the proposed rules concerning the proposal to require plans to use an API to provide cost-sharing data to consumers, and the Departments considered the issue. The final rules provide that CMS will continue to consider the advisability of this approach for purposes of future rulemaking. The Departments are not of the view, however, that the disclosures required under the final rules implicate significant HIPAA privacy concerns. The information that the final rules require to be disclosed through MRFs does not include personally identifiable information or personal health information. Also, in an effort to ensure that the disclosures balance price transparency with the need to protect privacy, the final rules modified the proposed rules to increase the minimum disclosure threshold from 10 to 20 unique payment amounts.

6. GitHub

Comment:

Two commenters expressed concerns regarding CMS's proposed use of the GitHub platform for providing technical guidance concerning implementation of the final rules with respect to MRF architecture and content. The commenters requested a clearer description of the intended use of the GitHub platform, and the extent to which guidance provided through GitHub will be binding on health plans and issuers, and how final CMS guidance decisions may be distinguished from deliberative discussion on the platform. (PCMA, Cigna)

Response:

CMS appreciates the comments. As explained in the preamble to the final rules,[4] GitHub will provide a collaborative platform to enable regulated entities and third-party developers to work with CMS to develop technical implementation assistance to ensure health plans and issuers can meet the reporting and disclosure requirements of the final rules in a consistent and uniform manner, despite significant potential variation in data management systems, product lines, and payment models. This technical assistance will include targeted assistance in cases of unique of system or product attributes. Furthermore, as outlined in the preamble to the final rules, the GitHub platform will include a repository of schemas for each data file that clearly set forth all current specifications for reporting each data element, including markers indicating what changes are made over time and when they are made. The content of these schemas will serve as the definitive source of current implementation requirements concerning the data files.

Comment:

One commenter expressed concern regarding the adequacy of health plan and issuer awareness of updates to implementation guidance over time. One commenter recommended that CMS post all final MRF implementation guidance on the CMS website and develop a notice system to provide adequate public notice as guidance evolves over time. (Cigna).

Response:

[4] 85 CFR 72158, 72242 (Nov 12, 2020).

CMS appreciates the comments. CMS does not plan to post information concerning technical implementation requirements for the MRFs on the CMS website. However, CMS does plan to link to the GitHub platform from the CMS website. As noted previously, the schema repository for the data files will include markers that show all changes made over time, and when they are made. CMS is considering options within the GitHub platform to provide notice to system users when such changes are made.

7. Model Notice

Comment: One commenter expressed concern that the proposed model disclosure form is complicated and appears to exceed the reading level of an average reader. The commenter also noted that the notice does not include the disclosures regarding potential out-of-pocket costs required under the CAA. The commenter urged CMS to revise the notice to make it more readable and understandable, and to include the disclosures required by the CAA. (UHG)

Response:

CMS appreciates the commenter for the comment concerning the model notice, and its apparent overlap with disclosure requirements in the CAA. In response to concerns regarding the disclosure requirements of the final rules and the requirements of the CAA, and as stated in the aforementioned guidance,[5] CMS will defer enforcement of the requirement that plans and issuers must provide an Advanced Explanation of Benefits. CMS intends to undertake notice and comment rulemaking in the future to implement this provision, including establishing appropriate data transfer standards.

Comment:

A commenter noted that the model notice includes a disclaimer that mentions that prerequisites to coverage include any prior authorization requirements that involve a determination of medical necessity by the health plan. The notice does not, however, make clear that any determinations of medical necessity also applies in the context of concurrent review. The commenter therefore recommended that the model notice be revised to clarify that concurrent review may include a determination concerning medical necessity. (UPMC).

Response:

CMS appreciates the commenter's recommendation concerning concurrent review and medical necessity. A plan or issuer may modify or add information to the model notice, provided the modification or additional information does not conflict with the information required to be provided under the final rules.

Comment:

A commenter recommended that the Model Notice created pursuant to the final rule be revised in several respects, including the description or definition of several terms and concepts, including *Allowed Amount*, *Cost Sharing*, *Accumulated Amount*, and *Prior Authorization*. (UPMC).

Response:

[5] FAQs about Affordable Care Act Implementation Part 49 (Aug. 20, 2021), Q6, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.

CMS appreciates the commenter for the recommendations concerning key terms used in the model notice. A plan or issuer may modify or add information to the model notice, provided the modification or additional information does not conflict with the information required to be provided under the final rules.

8. Legal Concerns

Comment:

Two commenters contended that CMS has no statutory authority to require under the final rules that health plans and issuers make public negotiated rates and out-of-network allowed amounts. They asserted that CMS's reliance on section 1311(e)(3) of the Affordable Care Act is in error. Specifically, they contended that CMS's reliance on section 1311(e)(3)(A)(ix), which authorizes CMS to specify "other information as determined appropriate" that must be disclosed, among a list of other required disclosures, does not provide authority for the requirements of the final rules. Under principles of statutory construction, they contended, such a "catch-all" provision may only encompass subject matter similar to that which is already enumerated. (CVS, PCMA).

Response:

CMS appreciates the commenters for their comments concerning the legal authority for the final rules. CMS disagrees with the comments. As the Departments stated in the preamble to the final rules, the disclosures required under the final rules are similar in nature to the categories of information listed along with the catch-all provision under 1311(e)(3)(A)(ix). Those categories include information regarding payment of claims, claims denials, cost-sharing, and payment for covered services received out-of- network. As a result, the final rules are neither inconsistent with the rule of statutory construction the commenters invoke nor the statutory authority relied upon in the final rules.

Comment:

One commenter contended that CMS violated the Administrative Procedure Act (APA) by imposing a requirement that health plans and issuers disclose historical net prices for prescription drugs in a separate MRF because the requirement was not included in the proposed rules, and there was no notice and opportunity for public comment. (CVS).

Response:

CMS appreciates the comment concerning whether the prescription drug MRF, as imposed by the final rules, complies with the requirements of the APA.

As previously stated, CMS is deferring enforcement of the MRF related to prescription drugs and will consider whether the requirement remains appropriate in future notice-and-comment rulemaking.