

CMS Response to Public Comments Received for CMS-10715

The Centers for Medicare and Medicaid Services (CMS) received four comments 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) and concerns relating to the prescription drug content requirements of the final rule and subsequent subregulatory guidance.

1) Timeline and Cost

Comment:

Three commenters urged that CMS further extend the implementation and enforcement date for the machine-readable file (MRF) requirements, to a new deadline of September 1, 2022. Commenters contended that the current time between schema finalization and the implementation deadline is not sufficient for plans and issuers to meet the MRF requirements, and recommended extending the deadline to afford health plans critical additional time to develop their files to the schema requirements. (AHIP, PCMA, Kaiser Permanente).

Response:

CMS appreciates the concerns expressed by commenters to the effect that the TiC requirements are extensive and require significant effort on the part of plans and issuers to meet. On August 20, 2021, CMS released guidance deferring enforcement of the requirement to make public the MRFs for in-network rates, out-of-network allowed amounts and billed charges, by six months, from January 1, 2022 to July 1, 2022.¹ While CMS acknowledges the concerns raised by commenters about the period of time between schema finalization and implementation, CMS strongly encourages plans and issuers to begin developing MRFs as soon as practicable prior to the March 1, 2022 schema finalization date if they have not already begun development, to ensure compliance by the July 1, 2022 implementation deadline. CMS will continue to communicate changes to the schema as they are finalized up to the March 1, 2022 schema freeze date.

2) Machine-Readable Files

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>

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

Comment:

One commenter recommended deferring enforcement of the requirement that health plans and issuers produce an out-of-network MRF pending future rulemaking to seek comment on whether to rescind the requirement for public disclosure of historical allowed amounts for out-of-network providers. The commenter contended that new surprise billing protections in the No Surprises Act provide more consumer-specific information on out-of-network payments, and that the information required for disclosure in the out-of-network MRF would unfairly advantage providers in the arbitration process between plans and providers and increase overall health care spending. (AHIP)

Response:

CMS appreciates the commenter for the recommendation. CMS also recognizes that several provisions of the TiC and No Surprises Act 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:

One commenter expressed concern that the MRF disclosure requirements would not result in meaningful or actionable information for consumers and would lead to consumer confusion. The commenter also expressed concern that the disclosures could have the effect of driving health care costs higher and decoupling price from value. (Kaiser Permanente)

Response

CMS recognizes that the information required to be disclosed through the MRFs would most benefit consumers once analyzed and personalized for the consumer and believes third party developers and researchers are well-positioned to digest and analyze the data to enhance consumer-shopping and price transparency tools. While the pricing effects of these requirements is not yet known, CMS believes that greater transparency is essential to empower consumers to shop for coverage based on something as fundamental as price. CMS acknowledges that quality and value are essential metrics for consumers shopping for health care services, and anticipates future efforts to integrate value into the consumer shopping experience.

Comment:

One commenter recommended additional actions to be taken by CMS to reduce MRF file size concerns. The commenter contended that large file sizes create challenges in development, storage, and access for issuers, clients, and end users, and recommended that CMS adopt additional schema changes to continue to reduce file size and minimize burden. (AHIP)

Response:

CMS appreciates the recommendations from commenters for further reduction in MRF file size. CMS has implemented several changes already to the schema aimed at reducing file size, including allowing plan and service code arrays and allowing NPI/TIN grouping for specific negotiated rates to reduce duplication. CMS will continue to evaluate other options for file size reduction and will communicate to plans and issuers any additional schema changes as they are finalized.

3) Prescription Drug MRF

Comments:

Three commenters recommended eliminating the prescription drug MRF requirement from the ICR entirely through a new round of rulemaking (AHIP, PCMA, Kaiser Permanente). One commenter also recommended that, if CMS does maintain the prescription drug MRF requirements in future rulemaking, CMS conducts a separate comment opportunity for the prescription drug MRF data elements (AHIP).

One commenter expressed concern about the ability of pharmacy benefit managers (PBMs) to mask incoming revenue associated with prescription drugs as service fees, to avoid reporting these fees to CMS. The commenter urged CMS to consider the inclusion of pharmacy direct and indirect remuneration (DIR) fees in their calculations of remuneration, to increase the transparency of the financial operations of the PBMs and the costs associated with prescription drugs (NCPA).

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.