(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*.

Issued on May 22, 2025.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2025–09892 Filed 5–30–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

RIN 1545–BR51

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AC30

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9882–NC]

RIN 0938–AV64

Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: This document is a request for information (RFI) regarding the prescription drug machine-readable file disclosure requirements in the Transparency in Coverage final rules. The Departments of Labor, Health and Human Services (HHS), and the Treasury (the Departments) are issuing this RFI to gather input regarding implementation of the prescription drug machine-readable file disclosure requirements under the Transparency in Coverage final rules, including what modifications to the disclosure requirements or additional technical implementation guidance might be necessary to better ensure the accurate and timely completion of the prescription drug file.

DATES: To be assured consideration, comments must be received at one of the addresses provided below by July 2, 2025.

ADDRESSES: Written comments may be submitted to the address specified below. Any comment that is submitted will be shared among the Departments. Please do not submit duplicates.

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

In commenting, please refer to file code 1210–AC30. The Departments cannot accept comments by facsimile (FAX) transmission. Comments must be submitted in one of the following two ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. By mail. You may mail written comments to the following address ONLY: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N–5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, *Attention:* 1210–AC30.

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

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

FOR FURTHER INFORMATION CONTACT:

Alexander Krupnick, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Elizabeth Schumacher, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335.

Kendra May, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (301) 448–3996.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor (DOL) concerning private sector employment-based health coverage laws may submit a question at askEBSA.dol.gov, call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the DOL's website (*www.dol.gov/agencies/ebsa*). In addition, information from HHS on private health insurance coverage and nonfederal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*), and information on healthcare reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Departments are soliciting information from the public to inform future rulemaking or guidance on prescription drug price transparency. As discussed below, in 2020 the Departments issued the Transparency in Coverage final rules (TiC final rules) [1] requiring group health plans and health insurance issuers offering group or individual health insurance coverage to make available to the public, among other things, certain information relating to prescription drug expenditures.

The Departments previously deferred enforcement of the provisions of the TiC final rules relating to prescription drug expenditures in published guidance, as discussed below.[2] However, transparency in healthcare pricing is a priority, and the Departments intend to implement disclosure requirements related to prescription drug expenditures and effectuate the goals of greater price transparency including transparency related to prescription drug pricing. In addition, President Trump issued an Executive Order to prioritize improving existing price transparency requirements and ensuring that patients have the information they

[1] 85 FR 72158 (Nov. 12, 2020).

[2] *See* FAQs About Affordable Care Act Implementation Part 61 (FAQs Part 61) (Sept. 27, 2023), available at *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-61.pdf* and *https://www.cms.gov/files/document/faqs-about-affordable-care-act-implementation-part-61.pdf;* FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (FAQs Part 49), Q1 (Aug. 20, 2021), available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/affordable-care-act-faqs-49-2021.pdf* and *https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-49.pdf.*

need to make well-informed decisions about their healthcare.[3] Accordingly, the Departments now seek the public's feedback on ways to effectively implement or amend the disclosure requirements related to prescription drug expenditures in the TiC final rules.

A. Statutory Background, Executive Order 13877, and the TiC Final Rules

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, PPACA) reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service (PHS) Act relating to health coverage requirements for group health plans and health insurance issuers in the group and individual markets.[4]

Section 2715A of the PHS Act, incorporated into section 715 of the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815 to the Internal Revenue Code (Code), provides that group health plans and health insurance issuers offering group or individual health insurance coverage must comply with section 1311(e)(3) of the PPACA,[5] which addresses transparency in health coverage and imposes certain reporting and disclosure requirements on health plans that are seeking certification as qualified health plans (QHPs) that may be offered on an Exchange (as defined by section 1311(b)(1) of the PPACA). A plan or coverage that is not offered through an Exchange and that is subject to section 2715A of the PHS Act is required to submit the information required to the Secretary of HHS and the relevant state's insurance commissioner, and to make that information available to the public. Together these statutory provisions require the majority of private health plans to disseminate comprehensive information to provide transparency in coverage.[6]

On June 24, 2019, President Trump issued Executive Order 13877, ''Improving Price and Quality Transparency in American Healthcare to Put Patients First.'' [7] Executive Order 13877 sought to improve transparency in healthcare and empower patients to make fully informed decisions about their healthcare. As Executive Order 13877 noted, ''patients often lack both access to useful price and quality information and the incentives to find low-cost, high-quality care.'' This ''generally leave[s] patients and taxpayers worse off than would a more transparent system.'' [8] To fulfill their responsibility under Executive Order 13877, the Departments proposed [9] and subsequently finalized the TiC final rules.[10] The TiC final rules published by the Departments on November 12, 2020, implemented section 1311(e)(3) of the PPACA. As described above, section 1311(e)(3) of the PPACA and section 2715A of the PHS Act address transparency in health coverage and require group health plans and health insurance issuers offering group or individual health insurance coverage to make certain information available to the public.

The TiC final rules require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to disclose cost-sharing information for all covered items and services to participants, beneficiaries, and enrollees through an internet-based self-service tool or, if requested by the individual, on paper. These provisions of the TiC final rules require plans and issuers to disclose cost-sharing information upon request to a participant, beneficiary, or enrollee and implement paragraph (C) of section 1311(e)(3) of PPACA.

The TiC final rules also require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to disclose on a public website three separate machine-readable files containing certain information regarding healthcare pricing under the plan or coverage. The machine-readable file disclosure requirements are intended to make healthcare pricing information accessible and useful to consumers and other stakeholders (including employers, and other purchasers of health care),[11] support efforts to lower healthcare costs by driving competition,[12] and to supplement state transparency efforts.[13] These provisions of the TiC final rules requiring plans and issuers to disclose in-network negotiated rates, out-of-network allowed amounts and the associated billed charges, and negotiated rates and historical net prices for prescription drugs implement paragraph (A) of section 1311(e)(3) of the PPACA. The provisions requiring the disclosure of out-of-network allowed amounts specifically implement the requirement in section 1311(e)(3)(A)(vii) to provide information on ''payments with respect to any out-of-network coverage.'' In addition to payment information on out-of-network charges, the Secretary of HHS determined that payment information on in-network rates and prescription drugs is also appropriate information to require plans and issuers to disclose to provide transparency in coverage under section 1311(e)(3)(A)(ix). The machine-readable file disclosure requirements of the TiC final rules are applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

B. Prescription Drug Machine-Readable File Disclosure Requirement of the TiC Final Rules

As relevant here, pursuant to the TiC final rules, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance

[3] *See* Executive Order 14221, ''Making America Healthy Again by Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information,'' 90 FR 11005 (Feb. 28, 2025). Executive Order 14221 was issued on February 25, 2025, and was published in the **Federal Register** on February 28, 2025.

[4] The PPACA also added section 715 to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815 to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act, PHS Act sections 2701 through 2728, making them applicable to group health plans and health insurance issuers providing coverage in connection with group health plans.

[5] Paragraph (A) of section 1311(e)(3) of the PPACA requires a plan seeking certification as a QHP to make the following information available to the public and submit it to state insurance regulators, the Secretary of HHS, and the Exchange (1) Claims payment policies and practices; (2) periodic financial disclosures; (3) data on enrollment; (4) data on disenrollment; (5) data on the number of claims that are denied; (6) data on rating practices; (7) information on cost-sharing and payments with respect to any out-of-network coverage, and (8)information on enrollee and participant rights under Title I of the PPACA. Paragraph (A) also requires a plan seeking certification as a QHP to submit any ''[o]ther information as determined appropriate by the Secretary.'' Paragraph (C) of section 1311(e)(3) of the PPACA requires plans, as a requirement of certification as a QHP, to permit individuals to learn the amount of cost sharing (including deductibles, copayments, and coinsurance) under the individual's coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by an in-network provider in a timely manner upon the request of the individual. Paragraph (C) specifies that, at a minimum, such information must be made available to the individual through an internet website and through other means for individuals without access to the internet.

[6] While PHS Act section 2715A generally applies to group health plans and health insurance issuers, certain plans and health insurance coverage are not subject to these transparency provisions, such as grandfathered health plans as defined under PPACA section 1251.

[7] 84 FR 30849 (June 27, 2019). Executive Order 13877 was issued on June 24, 2019, and was published in the **Federal Register** on June 27, 2019.

[8] *Id.*

[9] 84 FR 65464 (Nov. 27, 2019).

[10] 85 FR 72158 (Nov. 12, 2020).

[11] 85 FR 72158, 72161 (Nov. 12, 2020).

[12] *Id.*

[13] 85 FR 72158, 72162.

coverage must disclose to the public on an internet website, on a monthly basis, the negotiated rates and historical net prices for covered prescription drugs in a separate prescription drug machine-readable file that is publicly available and accessible to any person free of charge and without conditions.[14]

Specifically, with respect to prescription drugs, plans and issuers must make available to the public a machine-readable file containing the following information:

- for each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the Employer Identification Number (EIN); [15]
- the National Drug Code (NDC), and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration, for each covered prescription drug item or service under each coverage option offered by a plan or issuer;
- the negotiated rates; and
- historical net prices.[16]

In disclosing the negotiated rates,[17] such rates must be:

- reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;
- associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and
- associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC.[18]

Likewise, historical net prices [19] must be:

- reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;
- associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and
- associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when disclosing such data would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for payment).[20] [21]

As the Departments stated in the preamble to the TiC final rules, public disclosure of the historical net prices takes into account rebates, discounts, dispensing fees, administrative fees, and other price concessions. Together with disclosure of the negotiated rate, upon which cost sharing is based, disclosure of the historical net price provides important pricing information for achieving the goals of transparency and ensuring that individuals have access to meaningful prescription drug pricing information.[22] The prescription drug machine-readable file must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.[23] Plans and issuers must update the machine-readable file monthly and clearly indicate the date that the files were most recently updated.[24] To avoid unnecessary duplication, the TiC final rules set forth a special rule for insured group health plans, providing that, to the extent coverage under a group health plan consists of group health insurance coverage, an issuer may provide the required information on behalf of the plan pursuant to a written agreement between the plan and issuer to do so. In the event the issuer agrees to provide the required information via such written agreement but fails to do so, the issuer, but not the plan, violates the transparency disclosure requirements.[25] The TiC final rules further clarify that plans and issuers may also satisfy the requirements by entering into a written agreement under which another party (such as a third-party administrator or healthcare claims clearinghouse) will provide the required information. However, the plan must monitor the other party to ensure that the entity is providing the required disclosure.[26] In the event the party with which the group health plan or health insurance issuers has entered a written agreement fails to provide the required information, the plan or issuer violates the transparency disclosure requirements.[27]

Finally, the prescription drug machine-readable file must be made available in a form and manner specified in guidance issued by the Departments.[28] Since issuance of the TiC final rules, the Departments have published this technical implementation guidance on GitHub, a forum that allows stakeholders to engage directly with the Departments regarding technical and other implementation questions and challenges.[29] As discussed below, however, the Departments have not issued final form-and-manner guidance implementing the prescription drug machine-readable file requirement.

C. Litigation and Guidance

Following issuance of the TiC final rules and enactment of the CAA, but before the respective reporting requirements went into effect, a number of legal and operational challenges caused the Departments to delay

[14] In addition to the prescription drug machine-readable file, plans and issuers must publish separate machine-readable files disclosing in-network provider negotiated rates for covered items and services, as well as historical out-of-network allowed amounts and billed charges for covered items and services. *See* 26 CFR 54.9815–2715A3(b)(1), 29 CFR 2590.715–2715A3(b)(1), and 45 CFR 147.212(b)(1).

[15] This requirement was clarified in the Departments' Paperwork Reduction Act (CMS–10715, 10/15/21) to allow reporting HIOS ID numbers at the 10-digit level, or, if the 10-digit HIOS identifier is not available, the 5-digit HIOS identifier, and reporting of only EIN data if no relevant HIOS number is available.

[16] 26 CFR 54.9815–2715A3(b)(1)(iii), 29 CFR 2590.715–2715A3(b)(1)(iii), and 45 CFR 147.212(b)(1)(iii).

[17] For a definition of negotiated rate, *see* 26 CFR 54.9815–2715A1(a)(2)(xvi), 29 CFR 2590.715–2715A1(a)(2)(xvi), and 45 CFR 147.210(a)(2)(xvi).

[18] 26 CFR 54.9815–2715A3(b)(1)(iii)(C), 29 CFR 2590.715–2715A3(b)(1)(iii)(C), and 45 CFR 147.212(b)(1)(iii)(C).

[19] For a definition of historical net price, *see* 26 CFR 54.9815–2715A1(a)(2)(xi), 29 CFR 2590.715–2715A1(a)(2)(xi), and 45 CFR 147.210(a)(2)(xi).

[20] 26 CFR 54.9815–2715A3(b)(1)(iii)(D), 29 CFR 2590.715–2715A3(b)(1)(iii)(D), and 45 CFR 147.212(b)(1)(iii)(D).

[21] The TiC final rules also clarify that nothing in 26 CFR 54.9815–2715A3(b)(1)(iii)(D), 29 CFR 2590.715–2715A3(b)(1)(iii)(D), and 45 CFR 147.212(b)(1)(iii)(D) requires the disclosure of information that would violate any applicable health information privacy law.

[22] 85 FR 72158, 72238 (Nov. 12, 2020).

[23] 26 CFR 54.9815–2715A3(b)(2), 29 CFR 2590.715–2715A3(b)(2), and 45 CFR 147.212(b)(2).

[24] 26 CFR 54.9815–2715A3(b)(3), 29 CFR 2590.715–2715A3(b)(3), and 45 CFR 147.212(b)(3).

[25] 26 CFR 54.9815–2715A3(b)(4)(i), 29 CFR 2590.715–2715A3(b)(4)(i), and 45 CFR 147.212(b)(4)(i).

[26] 85 FR 72208.

[27] 26 CFR 54.9815–2715A3(b)(4)(ii), 29 CFR 2590.715–2715A3(b)(4)(ii), and 45 CFR 147.212(b)(4)(ii).

[28] 26 CFR 54.9815–2715A3(b)(2), 29 CFR 2590.715–2715A3(b)(2), and 45 CFR 147.212(b)(2).

[29] *See, https://github.com/CMSgov/price-transparency-guide.*

enforcement of the TiC final rules and the CAA's respective prescription drug reporting requirements.[30]

First, on August 10, 2021, the Chamber of Commerce of the United States and the Tyler (Texas) Area filed suit in the U.S. District Court for the Eastern District of Texas challenging the Departments' issuance of the TiC final rules.[31] The Chamber of Commerce alleged, among other things, that the requirement to disclose the prescription drug machine-readable file exceeded the Departments' statutory authority, was not a logical outgrowth of the proposed rule, and was otherwise arbitrary and capricious. Second, on August 12, 2021, the Pharmaceutical Care Management Association (PCMA) filed suit in the U.S. District Court for the District of Columbia, also challenging the issuance of the TiC final rules.[32] Its complaint made similar allegations.

In addition to these two lawsuits, the Departments received inquiries from stakeholders seeking guidance on how to comply with the new prescription drug reporting requirements under the CAA. Stakeholders noted the difficulty in operationalizing their reporting systems by the CAA's statutory deadline of December 27, 2021, and the TiC final rules' deadline of January 1, 2022, as well as their ''concern about potentially duplicative and overlapping reporting requirements for prescription drugs'' in the CAA and TiC final rules.[33]

In response to the lawsuits and stakeholder concerns, the Departments issued FAQs Part 49 on August 20, 2021.[34] These FAQs, in part, addressed the prescription drug reporting requirements of the TiC final rules and the CAA. With respect to the TiC final rules, the Departments announced that they would defer enforcement of the prescription drug machine-readable file requirement ''pending further rulemaking'' and consideration of ''whether the prescription drug machine-readable file requirement remains appropriate'' given the reporting requirements of the CAA.[35]

Further, the Departments acknowledged in the FAQs ''the significant operational challenges that plans and issuers may encounter in complying with'' the CAA's reporting requirements.[36] The Departments ''anticipate[d] that plans and issuers may also need additional time to modify contractual agreements to enable disclosure and transfer of the required data between various entities; to develop internal processes and procedures; and to identify, compile, prepare, and validate the required data.'' [37] In recognition of these challenges, the Departments announced their intent to ''defer enforcement'' of the CAA's first deadline for reporting on December 27, 2021, and the second deadline for reporting on June 1, 2022, pending the issuance of regulations or further guidance.[38]

In response, the Chamber of Commerce and PCMA dismissed their respective lawsuits without prejudice.[39] CMS also released a statement on their GitHub technical guidance repository indicating that the Departments would not issue guidance with respect to the form and manner of the TiC final rules' prescription drug machine-readable file.[40] To date, the Departments have not issued notice-and-comment rulemaking to revisit the prescription drug machine-readable file disclosure requirement and have not issued finalized form-and-manner guidance with respect to the prescription drug machine-readable file. However, on November 23, 2021, the Departments and the Office of Personnel Management (OPM) issued interim final rules implementing the separate reporting requirements added by the CAA, including the prescription drug reporting requirements.[41]

On March 23, 2023, the Foundation for Government Accountability (FGA) sued the Departments over the deferral of enforcement of the prescription drug machine-readable file disclosure requirement announced in FAQs Part 49.[42] The FGA's complaint alleged that the Departments, in deferring enforcement of the prescription drug machine-readable file disclosure requirement through guidance, had effectively amended the TiC final rules outside of notice-and-comment rulemaking, in violation of the Administrative Procedure Act. On September 27, 2023, the Departments released FAQs Part 61.[43] FAQs Part 61 rescinded Q1 of FAQs Part 49, which had expressed the Departments' general policy of deferring enforcement of the TiC final rules' prescription drug machine-readable file disclosure requirement pending further consideration in a future rulemaking.[44]

The Departments announced that they would enforce the requirement ''on a case-by-case basis, as the facts and circumstances warrant.'' [45] The Departments further indicated that they did not intend to engage in rulemaking regarding the prescription drug machine-readable file disclosure requirement in the near term but intended to ''develop technical requirements and an implementation timeline in future guidance that sufficiently account for any reliance interests that plans and issuers may have developed with regard to FAQs Part 49.'' [46] Following issuance of this guidance, FGA voluntarily dismissed its lawsuit against the Departments.[47]

D. Executive Order 14221

On February 25, 2025, President Trump issued Executive Order 14221, ''Making America Healthy Again by Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information'' (Executive Order

[30] Shortly after the Departments finalized the TiC final rules, the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) was enacted on December 27, 2020 (the CAA), which among other things, imposed new transparency requirements pertaining to reporting prescription drug expenditures. Plans and issuers must annually report to the Departments certain information about prescription drug expenditures under Code section 9825(a), ERISA section 725(a), and PHS Act section 2799A–10(a).

[31] Complaint, *Chamber of Commerce of the United States of America, et al.,* v. *U.S. Department of Health & Hum. Servs., et al.,* No. 6:21–cv–309, Dkt. 1 (E.D. Tex. Aug. 10, 2021).

[32] Complaint, *Pharmaceutical Care Management Association* v. *U.S. Department of Health & Hum. Servs., et al.,* No. 1:21–cv–02161, Dkt. 1 (D.D.C. Aug. 12, 2021).

[33] *See* FAQs Part 49, Q1, *supra* note 2.

[34] *See* FAQs Part 49.

[35] *See id.* at Q1. The Departments also deferred enforcement of the TiC final rules' other two machine-readable file requirements until July 1, 2022. *See id.* at Q1 and Q2.

[36] *Id.* at Q12.

[37] *Id.*

[38] *Id.*

[39] *See* Notice of Voluntary Dismissal, *Chamber of Commerce of the United States of America, et al.,* v. *U.S. Department of Health & Hum. Servs., et al.,* No. 6:21–cv–309, Dkt. 12 (E.D. Tex. Aug. 25, 2021); Notice of Voluntary Dismissal, *Pharmaceutical Care Management Association* v. *U.S. Department of Health & Hum. Servs., et al.,* No. 1:21–cv–2161, Dkt. 14 (D.D.C. Dec. 1, 2021).

[40] *See https://github.com/CMSgov/price-transparency-guide.*

[41] *See* Prescription Drug and Health Care Spending, 86 FR 66662 (Nov. 23, 2021). OPM joined the Departments to require the submission of information from Federal Employees Health Benefits plans in the same manner as plans and issuers must provide such data to the Departments under Code section 9825, ERISA section 725, and PHS Act section 2799A–10.

[42] *See* Complaint, *Foundation for Government Accountability* v. *U.S. Department of Health & Hum. Servs., et al.,* No. 2:23–cv–207, Dkt. 1 (M.D. Fla. Mar. 23, 2023).

[43] FAQs About Affordable Care Act Implementation Part 61 (FAQs Part 61) (Sept. 27, 2023), available at *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-61.pdf* and *https://www.cms.gov/files/document/faqs-about-affordable-care-act-implementation-part-61.pdf.*

[44] *See id.* at Q1.

[45] *Id.*

[46] *Id.*

[47] Stipulation of Dismissal, *Foundation for Government Accountability* v. *U.S. Department of Health & Hum. Servs., et al.,* No. 2:23–cv–207, Dkt. 46 (M.D. Fla. Sept. 30, 2023).

14221).[48] Executive Order 14221 stated that ''[m]aking America healthy again will require empowering individuals with the best information possible to inform their life and healthcare choices'' and that building on the TiC final rules will make more meaningful price information available to patients to support a more competitive, innovative, affordable, and higher quality healthcare system. To that end, the Executive Order prioritizes the promotion of universal access to clear and accurate healthcare prices, including by improving existing price transparency requirements, increasing enforcement of price transparency requirements, and identifying opportunities to further empower patients with meaningful price information.

Among other things, Executive Order 14221 directs the Departments to take all necessary and appropriate action to rapidly implement and enforce healthcare price transparency regulations, including by issuing within 90 days of the date of the Executive Order guidance or proposed regulatory action updating enforcement policies designed to ensure compliance with the transparent reporting of complete, accurate, and meaningful data.

In support of Executive Order 14221 and the Departments' stated commitment to furthering meaningful disclosure of prescription drug pricing information the Departments now seek input from the public on ways to effectively implement or amend the prescription drug machine-readable file requirement, as provided below.

II. Solicitation of Comments

The Departments request comments from all interested stakeholders to gain a better understanding of the issues related to compliance with, and implementation of, the prescription drug machine-readable file disclosure requirements. The TiC final rules made substantial, initial progress towards the goals of promoting greater price transparency in healthcare and empowering individuals with the information they need to actively and effectively participate in the healthcare system, promoting competition which may bring down overall costs.

However, the Departments now seek additional input from the public to better understand how to support a market-driven healthcare system by giving consumers the information they need to make informed decisions about their healthcare, and healthcare purchases, specifically including prescription drugs. Making this information widely and easily available will ultimately foster a more competitive, innovative, affordable, and higher quality healthcare system. The Departments are particularly interested in feedback related to prescription drug disclosure requirements on the following topics: the required data elements, including potential additional or alternative data elements and other general implementation concerns.

A. Required Data Elements, Including Potential Additional or Alternative Data Elements

1. *Improvements to disclosure requirements:* Are there existing data elements described in 26 CFR 54.9815–2715A3(b)(1)(iii), 29 CFR 2590.715–2715A3(b)(1)(iii), and 45 CFR 147.212(b)(1)(iii) that would be more useful if reported in a different form or manner? Are there ways to simplify the reporting schema to streamline disclosure to relieve reporting burdens? What are the appropriate metadata elements that should be required to be associated with the public disclosure file? Are there any improvements to disclosure requirements that would be particularly useful to interested parties including consumers, employers, and other purchasers of health care?

2. *Unnecessary or irrelevant disclosures:* Are there any data elements that are currently in the public disclosure requirement with respect to prescription drugs that are not relevant or useful and could be removed in order to simplify the reporting schema while maintaining the integrity of the prescription drug pricing disclosure requirements? Should the Departments remove any data elements, and why? Are there ways to reduce the volume of redundant or duplicative data?

3. *Disclosure of dosage units:* How do plans, issuers, and PBMs store and manage pricing information for dosage units of prescription drugs? Should the Departments require a standardized format for disclosing dosage units and supply periods for prescription drugs (*e.g.,* by 7-day, 30-day, or 90-day supply, by each dosage, or some other standardized dosage unit)? Should the Departments require disclosure of the quantity of the drug on which the price is reported?

4. *Remuneration details:* What specific data elements should the Departments require to provide meaningful disclosure of pre-rebate and post-rebate pricing? Should the Departments require plans and issuers to provide specific data pertaining to bundled payment arrangements or any alternative payment models in a manner that shows actual prices?

5. *Identification of entities:* Should the Departments require plans and issuers to identify the PBM or other service provider, if any, that manages a plan's or coverage's pharmacy benefits, to facilitate better comparison of prices and data between plans and coverages? Would there be any benefit or burden associated with requiring a plan or issuer to identify pharmacies that are affiliated with the plan's or coverage's PBM and would such benefit be worth the added burden?

6. *Exclusions:* Are there any items or services that are typically processed under a plan's or coverage's pharmacy benefits that should be excluded from the prescription drug machine-readable file for any reason? For example, are there items or services typically processed under a pharmacy benefit that are not prescription drugs, that are already published in one of the other machine-readable files, or that may be omitted because they constitute confidential business data or intellectual property?

7. *Benefits structure:* Are there any prescription drugs that are typically processed under a plan's or coverage's medical benefits or under its pharmacy benefits depending on the setting in which the items or services are provided? To the extent that prescription drugs that are processed under a plan's or coverage's medical benefits are disclosed in the in-network or out-of-network machine-readable files, are there benefits to requiring that such drugs be disclosed in the prescription drug machine-readable file in addition to the other machine-readable files? For example, would such duplication reveal disparities in pricing of prescription drugs based on the setting in which they are administered or the vendor that processes the benefit?

8. *Alignment:* Are there ways the Departments should align the TiC prescription drug reporting requirements with the prescription drug data reporting requirements under the Hospital Price Transparency rule?[49]

B. General Implementation Questions

1. *Implementation timeline:* Have any plans or issuers begun building the infrastructure needed and if so, to what extent has that been completed?

2. *Operational feedback:* Are there operational, formatting, or technical considerations that would improve and quicken the Departments' ability to begin enforcement of the required

[48] 90 FR 11005 (Feb. 28, 2025). The Executive Order was issued on February 25, 2025, and was published in the **Federal Register** on February 28, 2025.

[49] 45 CFR § 180.50 (Nov. 27, 2019).

prescription drug machine-readable file while maintaining data integrity?

3. *Leveraging existing infrastructure:* Are plans and issuers able to leverage the infrastructure used to implement the in-network rates and out-of-network allowed amounts machine-readable files to comply with these requirements, and to what extent are they able to do so?

4. *File format:* What challenges and advantages would result from requiring that machine-readable prescription drug files be delivered in JSON or CSV file formats?

5. *State approaches and innovation:* Are there state laws with requirements similar to the prescription drug machine-readable file disclosure requirements that could serve as models for implementing or amending the requirements under 26 CFR 54.9815–2715A3(b)(1)(iii), 29 CFR 2590.715–2715A3(b)(1)(iii), and 45 CFR 147.212(b)(1)(iii)? If so, in what ways are these state laws directly comparable to 26 CFR 54.9815–2715A3(b)(1)(iii), 29 CFR 2590.715–2715A3(b)(1)(iii), and 45 CFR 147.212(b)(1)(iii)? Are there other innovations that states have employed with respect to prescription drug reporting that the Departments should consider implementing?

6. *File size optimization:* Are there steps that the Departments can take, either in regulations, technical implementation guidance, or otherwise, to minimize the size of the prescription drug machine-readable files while ensuring data therein remains useful and relevant?

7. *Compliance costs:* What actions could the Departments take to minimize the compliance costs of implementing and maintaining the prescription drug machine-readable file disclosure requirements of the TiC final rules?

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements under the Paperwork Reduction Act of 1995 (PRA). However, Section II of this document does contain a general solicitation of comments in the form of a request for information. In accordance with the implementing regulations of the PRA, specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the PRA.

Signed at Washington, DC.

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[FR Doc. 2025–09858 Filed 5–30–25; 8:45 am]

BILLING CODE 4510–29–P