UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

THE FOUNDATION FOR GOVERNMENT ACCOUNTABILITY,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 2:23-cv-207-JLB-KCD

NOTICE

Defendants respectfully notify the Plaintiff and the Court that, earlier today, Defendants published a new "Frequently Asked Questions" document, which is attached to this filing and also available on the internet. *See* CMS, FAQs About Affordable Care Act Implementation Part 61 (Sept. 27, 2023), https://perma.cc/Q5VX-LB5W. As previewed in Defendants' recent extension motion, ECF No. 41, this new document rescinds the policies of enforcement discretion that were challenged in this lawsuit. Counsel for Defendants now intends to confer promptly with counsel for Plaintiff to discuss the future of this litigation (if any).

Dated: September 27, 2023

Respectfully submitted,

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FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 61

September 27, 2023

Set out below are Frequently Asked Questions (FAQs) regarding implementation of certain provisions of the Affordable Care Act (ACA). These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the Departments). Like previously issued FAQs (available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs and http://www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

Transparency in Coverage

The Transparency in Coverage Final Rules (TiC Final Rules) require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage to make cost-sharing information available to participants, beneficiaries, and enrollees through an internet-based self-service tool and in paper form, upon request.[1] This information must be made available for plan years (in the individual market, policy years) beginning on or after January 1, 2023, with respect to the 500 items and services identified by the Departments in Table 1 of the preamble to the TiC Final Rules,[2] and with respect to all covered items and services, for plan or policy years beginning on or after January 1, 2024.[3]

The plan or issuer must make available to a participant, beneficiary, or enrollee upon request cost-sharing information for a discrete covered item or service by billing code or descriptive term, and generally must furnish it according to the participant's, beneficiary's, or enrollee's request.[4] Further, the TiC Final Rules require a plan or issuer to provide cost-sharing information for a covered item or service in connection with an in-network provider or providers, or an out-of-network allowed amount for a covered item or service provided by an out-of-network provider, according to the participant's, beneficiary's, or enrollee's request, permitting the

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[1] 26 CFR 54.9815-2715A2(b); 29 CFR 2590.715-2715A2(b); and 45 CFR 147.211(b). The Consolidated Appropriations Act, 2021 imposed a largely duplicative requirement, and added a requirement that price comparison guidance also be provided by telephone, upon request. *See also* FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 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.

[2] 85 FR 72158, 72182-90 (Nov. 12, 2020).

[3] 26 CFR 54.9815-2715A2(c)(1); 29 CFR 2590.715-2715A2(c)(1); and 45 CFR 147.211(c)(1).

[4] In responding to a participant's, beneficiary's, or enrollee's request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. 26 CFR 54.9815-2715A2(b)(2)(ii); 29 CFR 2590.715-2715A2(b)(2)(ii); and 45 CFR 147.211(b)(2)(ii).

individual to specify the information necessary for the plan or issuer to provide meaningful cost-sharing liability information.[5]

The TiC Final Rules also require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage to disclose on a public website information regarding in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs in three separate machine-readable files.[6] The machine-readable file requirements of the TiC Final Rules are applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

On August 20, 2021, the Departments released FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (FAQs Part 49) announcing the deferral of enforcement regarding certain requirements, including the requirement that plans and issuers publish machine-readable files related to prescription drugs, pending further consideration by the Departments.[7] In deferring enforcement of this requirement, the Departments noted the enactment of the prescription drug requirements under section 204 of division BB of the Consolidated Appropriations Act, 2021 (CAA), and stakeholder concern about potentially duplicative and overlapping reporting requirements for prescription drugs.

On April 19, 2022, the Departments issued FAQs About Affordable Care Act Implementation Part 53 (FAQs Part 53), which announced "…an enforcement safe harbor for satisfying the reporting requirements for plans and issuers" that were unable to comply with those requirements for specified reasons.[8] In particular, this enforcement safe harbor was intended to apply to circumstances where compliance was not possible due to "alternative reimbursement arrangements that do not permit the plans and issuers to derive with accuracy specific dollar amounts contracted for covered items and services in advance of the provision of that item or service," or when the plan or issuer "otherwise cannot disclose specific dollar amounts according to the schema as provided in the Departments' technical implementation guidance through GitHub."[9]

Q1: In light of the interim final rules issued in November 2021 implementing the prescription drug reporting requirements of the CAA and the collection of the required

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[5] 26 CFR 54.9815-2715A2(b)(1); 29 CFR 2590.715-2715A2(b)(1); and 45 CFR 147.211(b)(1).
[6] 85 FR 72158 (Nov. 12, 2020).
[7] See FAQs Part 49 (Aug. 20, 2021), Q1, 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. The Departments later reiterated that intent in further guidance published on August 19, 2022, but in doing so did not make any changes to their enforcement posture. See FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55 (Aug. 19, 2022), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-55.pdf and https://www.cms.gov/files/document/faqs-part-55.pdf.
[8] See FAQs Part 53 (April 19, 2022), available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-53.pdf and https://www.cms.gov/files/document/faqs-part-53.pdf.
[9] *Id.*

information from plans and issuers, do the Departments still intend to consider through separate notice and comment rulemaking whether the prescription drug machine-readable file requirements remain appropriate?

Not at this time. The Departments have implemented the reporting requirements in section 204 of division BB of the CAA, and have collected the required information from plans and issuers for the 2020, 2021 and 2022 reference years.[10] Based on the Departments' implementing regulations and subsequent data collections, it is now clear that there is no meaningful conflict between the reporting requirements in section 204 of division BB of the CAA and the TiC Final Rules, because the CAA requires disclosure of *different* and *additional* information than required in the TiC Final Rules. Therefore, the Departments have determined that a general or categorical exercise of enforcement discretion is no longer warranted. Rather, the Departments are of the view that a case-by-case enforcement approach is more appropriate.

Accordingly, the Departments are now rescinding 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 requirement pending further consideration in a future rulemaking by the Departments. The Departments do not intend to engage in any such rulemaking in the near term. Instead, the Departments will address enforcement decisions under the relevant requirements of the TiC Final Rules on a case-by-case basis, as the facts and circumstances warrant.

The Departments note that FAQs Part 49 made clear that the enforcement relief was intended to be temporary and that it did not change the requirements imposed by the TiC Final Rules. The Departments intend 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.

Q2: Will the Departments continue to maintain an "enforcement safe harbor" as described in FAQs Part 53?

Not at this time. In issuing FAQs Part 53, the Departments did not intend to provide a categorical exception to enforcement of the requirements of the TiC Final Rules. Instead, the Departments intended to make clear that an exercise of enforcement discretion might be warranted in circumstances where it was extremely difficult or impossible for a plan or issuer to determine and report an applicable rate for specific items or services provided under "percentage-of-billed-charges" contracts if an exact dollar amount cannot be determined for an item or service prospectively.

The Departments are rescinding the statement of enforcement discretion provided in FAQs Part 53.[11] The Departments now clarify that whether a plan or issuer is able to comply with the

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[10] Pursuant to 5 U.S.C. 8910, the Office of Personnel Management (OPM) has joined the Departments to require the submission of information from Federal Employees Health Benefits (FEHB) 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.

[11] *Supra* note 8.

requirement to disclose certain rates as dollar amounts is a fact-specific determination; therefore, the Departments intend to exercise enforcement discretion with respect to this requirement on a case-by-case basis, without any categorical "safe harbor." The Departments note that in exercising their enforcement discretion, the Departments are unlikely to pursue enforcement action if a plan or issuer can demonstrate that compliance with the relevant provisions of the TiC Final Rules would have been extremely difficult or impossible, including, but not limited to, for the reasons stated in FAQs Part 53. Plans and issuers that are unable to determine dollar amounts for the in-network rate element should continue to follow the existing technical guidance on GitHub for percentage-of-billed-charges arrangements located here: https://github.com/CMSgov/price-transparency-guide/tree/master/schemas/in-network-rates#negotiated-price-object.