FAQ ABOUT AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART 56

December 23, 2022

Set out below is a Frequently Asked Question (FAQ) regarding implementation of certain provisions of Title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021 (CAA). This FAQ has 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/about-ebsa/our-activities/resource-center/faqs and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), this FAQ answers questions from stakeholders to help people understand the law and promote compliance.

Reporting on Prescription Drug and Health Care Spending

Internal Revenue Code section 9825, Employee Retirement Income Security Act section 725, and Public Health Service Act section 2799A-10, as added by section 204 of Title II of Division BB of the CAA, require group health plans (plans)[1] and health insurance issuers (issuers) to report to the Departments certain information related to prescription drug and other health care expenditures. This information includes, among other things, general information regarding the plan or coverage; the 50 most frequently dispensed brand prescription drugs, the 50 most costly prescription drugs by total annual spending, and the 50 prescription drugs with the greatest increase in plan expenditures over the preceding plan year; total spending by the plan or coverage broken down by the type of costs; and the average monthly premiums paid by participants, beneficiaries, and enrollees and paid by employers. Plans and issuers must also report the impact on premiums of rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, including the amount paid with respect to each therapeutic class of drugs and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year.

The Departments and the Office of Personnel Management (OPM) issued interim final rules on November 23, 2021 to implement these provisions (November 2021 interim final rules).[2] In response to concerns expressed by the stakeholders, the November 2021 interim final rules indicated that the Departments would not initiate enforcement action against a plan or issuer that

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[1] For purposes of this document, the term "plan" includes plans offered by Federal Employees Health Benefits (FEHB) carriers. Under the FEHB Act, 5 U.S.C. 8901 *et seq.,* OPM is charged with administering the FEHB Program and maintains oversight and enforcement authority with respect to FEHB plans, which are federal governmental plans. Pursuant to 5 U.S.C. 8910, OPM has joined the Departments to require the submission of prescription drug and health care spending data from FEHB plans in the same manner as plans and issuers must provide such data under section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act. OPM has confirmed to the Departments that it is extending this FAQ's relief to plans offered by FEHB carriers.

[2] 86 FR 66662 (Nov. 23, 2021).

does not report the required information by the first statutory deadline for reporting (December 27, 2021) or the second statutory deadline for reporting (June 1, 2022), and that instead submits the required information for the 2020 and 2021 reference years by December 27, 2022.

Q1: Will the Departments take enforcement action against any plan or issuer that makes a good faith effort to comply with the prescription drug and health care spending reporting requirements for 2020 and 2021 data?

The Departments recognize the significant operational challenges that plans and issuers may have encountered in complying with these reporting requirements, including arranging and coordinating submission of a plan's or issuer's data across multiple reporting entities, and accurately classifying, compiling, and validating the required data. In particular, stakeholders have expressed concern that, given the novelty and complexity of the requirements, there may be errors or other issues with the first round of data submissions, despite good faith efforts by plans and issuers.

Accordingly, for the 2020 and 2021 data submissions that are due by December 27, 2022, the Departments will not take enforcement action with respect to any plan or issuer that uses a good faith, reasonable interpretation of the regulations and the Prescription Drug Data Collection (RxDC) Reporting Instructions in making its submission. The Departments are also providing a submission grace period through January 31, 2023, and will not consider a plan or issuer to be out of compliance with these requirements provided that a good faith submission of 2020 and 2021 data is made on or before that date.

In addition, to facilitate the submission process, the Departments are providing the following clarifications and flexibilities with respect to reporting requirements (including operational requirements within the Health Insurance Oversight System (HIOS) reporting system) for the 2020 and 2021 data: [3]

1. Multiple Submissions by the Same Reporting Entity Allowed

   While the interim final rules implemented provisions to prevent unnecessary duplication,[4] and a reporting entity generally should create only one submission in HIOS,[5] the Departments clarify that when a reporting entity submits on behalf of more than one plan or issuer for a reference year, the reporting entity may create more than one submission for that reference year, instead of including the data of all clients within a single set of plan lists and data files for the year. These multiple submissions will be considered valid and not duplicate submissions.

[3] These flexibilities apply only to the submission of data for the 2020 and 2021 reference years. The Departments will monitor stakeholder efforts to comply to determine whether to extend these flexibilities for future reporting deadlines. Any extension of these flexibilities will be communicated through guidance in advance of the relevant reporting deadline.

[4] 26 CFR 54.9825-4T(d), 29 CFR 2590.725-2(d), and 45 CFR 149.720(d).

[5] *See* FAQ ID 23159, available at https://regtap.cms.gov/faq_viewe.php?i=23159.

2. Submissions by Multiple Reporting Entities Allowed

   More than one reporting entity may submit the same data file type on behalf of the same plan or issuer, instead of working together to consolidate all of the plan's or issuer's data into a single data file for each type of data.

3. Aggregation Restriction Suspended

   Under 26 CFR 54.9825-5T(b)(2), 29 CFR 2590.725-3(b)(2), and 45 CFR 149.730(b)(2), if multiple reporting entities submit the required data on behalf of one or more plans or issuers in a state and market segment, the data submitted by each of these reporting entities must be aggregated to at least the aggregation level used by the reporting entity that submits data on the total annual spending on health care services on behalf of those plans or issuers. For 2020 and 2021 data only, a reporting entity submitting the required data may, within each state and market segment, aggregate at a less granular level than that used by the reporting entity that is submitting the total annual spending data.

4. Submission of Premium and Life-Years Data by Email Available for Certain Group Health Plans[6]

   Plans and issuers were instructed to submit information using the HIOS RxDC module.[7] However, if a group health plan or its reporting entity is submitting only the plan list, premium and life-years data, and narrative response and is not submitting any other data, it may submit the file by email to RxDCsubmissions@cms.hhs.gov instead of submitting in HIOS. The emailed submission must include the plan list file, premium and life-years data (data file D1), and a narrative response. The submission may include optional supplemental documents. The name of each file should include the reference year of the submission, the plan list or data file type (e.g. P2, D1), and the name of the group health plan sponsor.

5. Reporting on Vaccines Optional

   Plans and issuers were instructed to report information on drug names and codes using the CMS drug and therapeutic class crosswalk.[8] The CMS drug name and therapeutic class crosswalk was updated on October 3, 2022, to include National Drug Codes (NDCs) for vaccines. Reporting entities may, but are not required to, incorporate these vaccine NDCs in their data files.

6. Reporting Amounts Not Applied to the Deductible or Out-of-Pocket Maximum Optional

   Reporting entities do not have to report a value for "Amounts not applied to the deductible or out-of-pocket maximum" and the "Rx Amounts not applied to the deductible or out-of-

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[6] For a description of the submission requirements, and the file types and specifications, see Prescription Drug Data Collection (RxDC) Reporting Instructions at https://regtap.cms.gov/uploads/library/RxDC-Section-204-Reporting-Instructions-06-30-2022.pdf.
[7] *Id.*
[8] *Id.*

pocket maximum." A reporting entity should not remove these columns from data files D2 and D6 but may leave blank the data fields in these columns.

The Departments expect that plans and issuers will continue to work in good faith toward full compliance with these requirements. The Departments will continue to monitor stakeholder efforts to comply to determine whether additional guidance is needed in advance of future reporting deadlines.