OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206–AO27

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9958]

RIN 1545–BQ10

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AC07

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 149

[CMS–9905–IFC]

RIN 0938–AU66

Prescription Drug and Health Care Spending

AGENCY: Office of Personnel Management; 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: Interim final rules with request for comments.

SUMMARY: This document sets forth interim final rules implementing provisions of the Internal Revenue Code (the Code), the Employee Retirement Income Security Act (ERISA), and the Public Health Service Act (PHS Act), as enacted by the Consolidated Appropriations Act, 2021 (CAA). These provisions are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage. These interim final rules add provisions to existing rules under the Code, ERISA, and the PHS Act. These interim final rules implement provisions of the Code, ERISA, and PHS Act that increase transparency by requiring group health plans and health insurance issuers in the group and individual markets to submit certain information about prescription drugs and health care spending to the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments). The Departments are issuing these interim final rules with largely parallel provisions that apply to group health plans and health insurance issuers offering group or individual health insurance coverage. The Office of Personnel Management (OPM) is also issuing interim final rules that require Federal Employees Health Benefits (FEHB) carriers to report information about prescription drugs and health care spending in the same manner as a group health plan or health insurance issuer offering group or individual health insurance coverage.

DATES:

Effective date: These regulations are effective on December 23, 2021.

Applicability date: The regulations are generally applicable beginning December 27, 2021. The OPM-only regulations that apply to health benefits plans and carriers under the FEHB Program are applicable beginning December 27, 2021. However, as discussed in section II.C.1.b. of this preamble, the Departments will provide temporary and limited deferral of enforcement during the first year of applicability and this temporary and limited deferral of enforcement will apply, in the same manner, to FEHB plans and carriers.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, by January 24, 2022. Please see section V.E. of this preamble for information regarding submission of comments on the information collection requirements.

ADDRESSES: Written comments may be submitted to the addresses specified below.

In commenting, refer to file code CMS–9905–IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation at *https://www.regulations.gov* by entering the file code in the search window and then clicking on ''Comment.''

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9905–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9905–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Padma Babubhai Shah, Office of Personnel Management, at 202–606–4056.

Christopher Dellana, Internal Revenue Service, Department of the Treasury, at 202–317–5500.

Matthew Litton or Shannon Hysjulien, Employee Benefits Security Administration, Department of Labor, at 202–693–8335.

Christina Whitefield, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301–492–4172.

Customer Service Information: Information from OPM on health benefits plans offered under the FEHB Program can be found on the OPM website (*www.opm.gov/healthcare-insurance/healthcare/*). Individuals interested in obtaining information from DOL concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1–866–444–EBSA (3272) or visit DOL's website (*www.dol.gov/ebsa*). In addition, information from HHS on private health insurance coverage and coverage provided by non-federal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

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 Departments generally post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. The Departments will not post on *Regulations.gov* public comments that make threats to

individuals or institutions or suggest that the individual will take actions to harm the individual. The Departments continue to encourage individuals not to submit duplicative comments. The Departments will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

A. Prescription Drug and Health Care Spending Transparency Under the Consolidated Appropriations Act, 2021

On December 27, 2020, the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) (CAA) was enacted. Section 204 of Title II of Division BB of the CAA added parallel provisions at section 9825 of the Internal Revenue Code (the Code), section 725 of the Employee Retirement Income Security Act (ERISA), and section 2799A–10 of the Public Health Service Act (PHS Act), which require group health plans and health insurance issuers offering group or individual health insurance coverage to annually submit to the Departments certain information about prescription drug and health care spending. The statute provides that data shall be reported not later than 1 year after the date the CAA was enacted, and not later than June 1 of each year thereafter.

The data submission required under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act (section 204 data submissions) includes general information on the plan or coverage, such as the beginning and end dates of the plan year, the number of participants, beneficiaries, or enrollees, as applicable, and each state in which the plan or coverage is offered. Plans and issuers must also report the 50 most frequently dispensed brand prescription drugs, and the total number of paid claims for each such drug; the 50 most costly prescription drugs by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and the 50 prescription drugs with the greatest increase in plan or coverage expenditures from the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year (top 50 lists). Additionally, plans and issuers must report total spending on health care services by the plan or coverage broken down by the type of costs (including hospital costs; health care provider and clinical service costs, for primary care and specialty care separately; costs for prescription drugs; and other medical costs, including wellness services); spending on prescription drugs by the plan or coverage as well as by participants, beneficiaries, and enrollees, as applicable; and the average monthly premiums paid by participants, beneficiaries, and enrollees and paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable. Plans and issuers must report any impact on premiums by 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 amounts of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year (top 25 list). Finally, plans and issuers must report any reduction in premiums and out-of-pocket costs associated with these rebates, fees, or other remuneration. The Departments intend to provide greater technical detail regarding each data element in the section 204 data submission in the instructions for the information collection instrument. The Departments also intend to provide an internet portal where reporting entities can submit the required data.

Section 9825(b) of the Code, section 725(b) of ERISA, and section 2799A–10(b) of the PHS Act additionally require the Departments to publish on the internet a report on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under these plans or coverage, with information that is aggregated so that no drug or plan specific information is made public (section 204 public report). This section 204 public report must be published no later than 18 months after the date on which plans and issuers are required to first submit the information and biannually thereafter. The section 204 public report may not include any confidential or trade secret information submitted to the Departments, pursuant to section 9825(c) of the Code, section 725(c) of ERISA, and section 2799A–10(c) of the PHS Act. These interim final rules implement section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act. The Departments seek comment on all aspects of these interim final rules.

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 is joining 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.

On July 9, 2021, President Biden issued Executive Order 14036, ''Promoting Competition in the American Economy.'' [1] Executive Order 14036 directed the federal government to ''enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony.'' The data collection required by these interim final rules will provide valuable information about competition and market concentration in the pharmaceutical and health care industries. Policymakers can use the prescription drug and health care spending data to make informed decisions in support of the goals of Executive Order 14036, including identifying any excessive pricing of prescription drugs driven by industry concentration and monopolistic behaviors, promoting the use of lower-cost generic drugs, and addressing the impact of pharmaceutical manufacturer rebates, fees, and other remuneration on prescription drug prices and on plan, issuer, and consumer costs.

The Departments are issuing regulations implementing provisions of Title I (No Surprises Act) and Title II (Transparency) of Division BB of the CAA in several phases.

On July 13, 2021, the Departments and OPM issued interim final rules entitled, ''Requirements Related to Surprise Billing; Part I'' [2] which generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022; FEHB health benefits plans with respect to contract years beginning on or after January 1, 2022; and health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022 (July 2021 interim final rules). The July 2021 interim final rules implement sections 9816(a)–(b) and 9817(a) of the Code; sections 716(a)–(b)

[1] *https://www.federalregister.gov/documents/2021/07/14/2021-15069/promoting-competition-in-the-american-economy.*

[2] 86 FR 36872 (July 13, 2021). Public comments on this rule were due by September 7, 2021.

and 717(a) of ERISA; sections 2799A–1(a)–(b), 2799A–2(a), 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act; and 5 U.S.C. 8902(p), to protect consumers from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers of air ambulance services, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances.

Among other requirements, the July 2021 interim final rules require emergency services to be covered without any prior authorization, without regard to whether the health care provider or facility furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services, and without regard to any other term or condition of the plan or coverage other than the exclusion or coordination of benefits or a permitted affiliation or waiting period. With respect to emergency services furnished by nonparticipating providers or facilities, air ambulance services furnished by nonparticipating providers of air ambulance services, and non-emergency services furnished by nonparticipating providers at certain participating facilities, the July 2021 interim final rules generally limit cost sharing for out-of-network services to in-network levels, require such cost sharing to count toward any in-network deductibles and out-of-pocket maximums, and prohibit balance billing in certain circumstances. Balance billing refers to the practice of out-of-network providers billing patients for the difference between: (1) The provider's billed charges; and (2) the amount collected from the plan or issuer plus the amount collected from the patient in the form of cost sharing (such as a copayment, coinsurance, or amounts paid toward a deductible).

On September 16, 2021, the Departments and OPM issued proposed rules entitled, ''Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement.'' [3] These proposed rules propose to implement section 9823 of the Code; section 723 of ERISA; and sections 2723(b), 2746, 2799A–8, and 2799B–4 of the PHS Act; as well as sections 106(a) and 106(e) of the No Surprises Act. These proposed rules would implement certain provisions of the No Surprises Act that would increase transparency by requiring group health plans and health insurance issuers in the group and individual markets, and FEHB carriers, to submit certain information about air ambulance services to the Departments and OPM, as applicable, and by requiring providers of air ambulance services to submit certain information to the Secretaries of HHS and Transportation. These proposed rules also include HHS-only provisions that would increase transparency by requiring a health insurance issuer offering individual health insurance coverage or short-term, limited-duration insurance to disclose to policyholders and to report to HHS any direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage. The HHS-only proposed rules would additionally provide the process by which HHS would investigate complaints and potential violations of PHS Act provisions and, if warranted, take enforcement action, including the imposition of civil money penalties, against providers and facilities, including providers of air ambulance services. These proposed rules would amend existing regulations to clarify the process to investigate complaints and potential violations of the PHS Act and impose civil money penalties against plans and issuers. These proposed rules would also establish the process by which HHS would impose civil money penalties if a provider of air ambulance services fails to submit some or all required data to HHS.

On October 7, 2021, the Departments and OPM published interim final rules entitled, ''Requirements Related to Surprise Billing; Part II,'' [4] which generally apply to certified independent dispute resolution (IDR) entities; selected dispute resolution (SDR) entities; group health plans and health insurance issuers offering group or individual health insurance coverage and FEHB carriers; and providers, facilities, and providers of air ambulance services beginning on or after January 1, 2022, with the exception of certain provisions that apply beginning on October 7, 2021 (October 2021 interim final rules). The October 2021 interim final rules implement sections 9816(c) and 9817(b) of the Code; sections 716(c) and 717(b) of ERISA; and sections 2799A–1(c), 2799A–2(b), 2799B–6(1), 2799B–6(2)(B), and 2799B–7 of the PHS Act.

The October 2021 interim final rules implement provisions of the No Surprises Act that establish a federal IDR process that group health plans, health insurance issuers offering group or individual health insurance coverage, and FEHB carriers; and nonparticipating providers, facilities, and providers of air ambulance services may use following the end of an unsuccessful open negotiation period to determine the out-of-network rate for items or services that are emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, under certain circumstances. In addition, HHS-only provisions of the October 2021 interim final rules address good faith estimates of health care items or services for uninsured or self-pay individuals and the associated patient-provider dispute resolution process. The October 2021 interim final rules also amend final regulations issued by the Departments in 2015 related to external review in order to implement section 110 of the No Surprises Act.

Division BB of the CAA also includes: Provisions regarding transparency in plan and insurance identification cards (section 107); continuity of care (section 113); accuracy of provider network directories (section 116); and prohibition on gag clauses (section 201) that are applicable for plan years beginning on or after January 1, 2022. The Departments intend to undertake rulemaking to fully implement these provisions, with the exception of section 201 of Title II of Division BB of the CAA, prohibition on gag clauses, which is self-implementing. On August 20, 2021, the Departments issued guidance regarding implementation of each of these sections of Division BB of the CAA.[5] Until rulemaking fully implementing these provisions is finalized and effective, plans and issuers are expected to implement the requirements using a good faith, reasonable interpretation of the statute.

B. Stakeholder Consultation and Input

The Departments and OPM published a Request for Information (RFI) in the June 23, 2021 **Federal Register** (86 FR 32813). The RFI solicited comments from the public regarding implementation considerations for the data collection required by section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act and the associated impact on plans and issuers. The Departments sought input on specific data elements to be

[3] 86 FR 51730 (Sept. 16, 2021). Public comments on this rule were due by October 18, 2021.

[4] 86 FR 55980 (October 7, 2021). Public comments on this rule are due by December 6, 2021.

[5] FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021, Implementation Part 49 (Aug. 20, 2021), available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.*

collected, including the level of detail that is feasible for entities subject to the data collection requirements to report and the associated burdens and potential compliance costs. In the RFI, the Departments indicated that public comments would inform the Departments' and OPM's implementation of the statutory requirements through rulemaking and the establishment of processes to receive the required information. The Departments also sought comment from the public regarding information to include in the Departments' biannual section 204 public report. OPM sought input from the public regarding implementation considerations for the data collection as it pertains to FEHB carriers.

The Departments also held several listening sessions with employers, group health plans, issuers, and pharmacy benefit managers (PBMs) to gather public input on each aspect of the data submission requirements as well as the biannual section 204 public reports. OPM also held a listening session with FEHB carriers. The Departments consulted with stakeholders through regular contact with states, issuers, plans, trade groups, employers, and other interested parties. The Departments and OPM considered all public input received in the development of these interim final rules. The Departments and OPM also took into account the objectives of Executive Order 14036 to promote competitiveness in the health care and pharmaceutical markets and lower the price of and improve access to prescription drugs and biologics.

II. Overview of the Interim Final Rules—Departments of HHS, Labor, and the Treasury

A. Applicability

These interim final rules add 26 CFR 54.9825–2T and amend 29 CFR 2590.716–2 and 45 CFR 149.20 to include a reference to the new regulations added by these interim final rules.[6] These interim final rules include the prescription drug and health care spending data submission requirements for plans and issuers required under section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act.

These interim final rules generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage. The term ''group health plan'' includes both insured and self-funded group health plans, and includes private employment-based group health plans subject to ERISA, non-federal governmental plans (such as plans sponsored by states and local governments) subject to the PHS Act, and church plans subject to the Code. Individual health insurance coverage includes coverage offered in the individual market, through or outside of an Exchange, and includes student health insurance coverage as defined at 45 CFR 147.145. As discussed further in section III. of this preamble, OPM interim final rules require FEHB carriers to comply with these interim final rules, with respect to prescription drug and health care spending data submission requirements, subject to OPM regulation and contract provisions.

Section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act (and all provisions of the No Surprises Act that are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage) apply to grandfathered health plans. Section 1251 of the Affordable Care Act provides that grandfathered health plans are not subject to certain provisions of the Code, ERISA, or the PHS Act, as added by the Affordable Care Act, for as long as they maintain their status as grandfathered health plans. For example, grandfathered health plans are subject neither to the requirement to cover certain preventive services without cost sharing under section 2713 of the PHS Act, nor to the annual limitation on cost sharing set forth under section 2707(b) of the PHS Act. If a plan or coverage loses its grandfathered status, it is required to comply with both provisions, in addition to certain other requirements of the Affordable Care Act. However, the CAA does not include an exception for grandfathered health plans that is comparable to the exception contained in section 1251 of the Affordable Care Act. Therefore, the provisions of these interim final rules that apply to plans and issuers also apply to grandfathered health plans (as defined in 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140).

These interim final rules do not apply to health reimbursement arrangements (HRAs), or other account-based group health plans, as described in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), that make reimbursements subject to a maximum fixed dollar amount for a period, because the benefit design of these plans makes the prescription drug and health care spending data reporting concepts under section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act inapplicable. The Departments expect that account-based group health plans typically will be integrated with other coverage that will be required to report such information (such as in the case of individual coverage HRAs (ICHRAs), for which the issuer of the individual coverage will be required to report the information) or will be otherwise exempt from these requirements (such as excepted benefit HRAs). Therefore, under these interim final rules, the reporting requirements do not apply to HRAs (including ICHRAs) and other account-based group health plans. This approach is consistent with many other requirements that apply to group health plans and the existing applicability provisions in 26 CFR 54.9816–2T, 29 CFR 2590.716–2, and 45 CFR 149.20 with respect to other requirements of Division BB of the CAA.

Excepted benefits are exempt from the requirements in chapter 100 of the Code, part 7 of ERISA, and Part A and Part D of title XXVII of the PHS Act.[7] Under section 2791(b)(5) of the PHS Act, short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage and is, therefore, exempt from the new requirements established in section 2799A–10 of the PHS Act. Therefore, short-term, limited-duration insurance (as defined in 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103) and coverage that consists solely of excepted benefits (as described in section 9832(c) of the Code, section 733(c) of ERISA, and section 2791(c) of the PHS Act) are not subject to the data submission requirements set forth in these interim final rules.

The Departments seek comment as to whether there are any other plans with unique benefit designs that should be exempt from these interim final rules.

B. Definitions (26 CFR 54.9825–3T, 29 CFR 2590.725–1, 45 CFR 149.710)

The Departments adopt terms and definitions applicable to the data submission requirements set forth in these interim final rules in 26 CFR 54.9825–3T, 29 CFR 2590.725–1, and 45 CFR 149.710. In addition, the

[6] The amendment to 29 CFR 2590.716–2 also includes a technical edit to correct a cross-reference in 29 CFR 2590.716–2(a)(2).

[7] *See* section 9831 of the Code, section 732 of ERISA, and section 2722 of the PHS Act. The CAA amended the PHS Act statutory exemption for these products to include the new requirements established under new Part D of the PHS Act. *See* section 102(a)(3)(B) of the No Surprises Act, which made conforming amendments to add the phrase ''and Part D'' to section 2722(b), (c)(1), (c)(2), and (c)(3) of the PHS Act.

definitions in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30 apply to these interim final rules. In general, these interim final rules do not define terms that are commonly used in the health care and health insurance industry.

Reference Year. Section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act require plans and issuers to submit information ''with respect to the health plan or coverage in the previous plan year.'' To help ensure uniformity of data across plans and coverage and increase the usability of the data for purposes of the section 204 public report, the Departments are requiring plans and issuers to submit information based on the ''reference year,'' defined in these interim final rules as the calendar year immediately preceding the calendar year in which the section 204 data submissions are due.

Collecting data for the immediately preceding calendar year, rather than the previous plan year, better accounts for the timing of when newly introduced drugs—including new brand prescription drugs, newly available generic versions of brand prescription drugs, and biosimilars—become available and the fact that some group health plans and health insurance coverage have plan years that do not correspond to calendar years. If data are collected based on the plan year, newly introduced drugs would be reflected in the data for some plans and coverage but not others. If data are collected based on the calendar year, newly introduced drugs will be reflected in the data for every plan, regardless of the start and end date of the plan year.

Newly introduced drugs, such as biologics, are often very costly and may impact the ranking of the 50 most costly prescription drugs. Similarly, when a generic or biosimilar version of a drug becomes available, the brand version will be prescribed less frequently, which may impact the ranking of the top 50 most frequently dispensed brand prescription drugs. Therefore, if the Departments were to collect information regarding the top 50 drugs by plan or policy year as specified in plan or coverage documents, without additional specification about the measurement period, there would be inconsistency among data submissions that would make them difficult to compare to each other. Collection of all data on a calendar-year basis will enable the Departments to effectively analyze the data and understand the impact of a newly introduced drug consistently across plans and coverage, market segments, and years. In addition, using the calendar year as the reference year will enable the Departments to produce consistent data analyses across group health plans and group health insurance coverage (which may be offered on a non-calendar basis) and individual health insurance coverage (which is generally offered on a calendar-year basis) for purposes of the section 204 public report.

Second, using the calendar year as the reference year is consistent with other HHS rules and data collections related to prescription drug and health care spending. For example, similar to section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act, section 2718(a) of the PHS Act requires issuers to report Medical Loss Ratio (MLR) data ''with respect to each plan year.'' However, issuers report calendar year information to HHS for the MLR data collection instead.[8] The National Association of Insurance Commissioners (NAIC), which section 2718(c) of the PHS Act directs to make recommendations to HHS regarding definitions for the MLR data collection, recommended that the term ''plan year'' in section 2718(a) of the PHS Act be interpreted to refer to the calendar year, rather than the year specified in particular plan or policy documents.[9] The NAIC recommended this interpretation because any other definition would have precluded meaningful comparison of the reported data, reduced the reliability of the data, and increased reporting burdens. The Departments are of the view that the same rationales apply with respect to the section 204 data submissions.

In addition, the prescription drug data collection with respect to qualified health plans (QHPs), required under section 1150A of the Social Security Act related to collection of information ''for a contract year,'' also involves the submission of data on a calendar-year basis.[10] Likewise, the Medicare program, in which some Medicare Part D plans and Medicare Advantage Plans offering a prescription drug plan have non-calendar year contract years, analyzes prescription drug and prescription drug rebate data on a calendar-year basis and generally collects data in a manner that permits calendar year-based analysis.[11] Similarly, the Medicaid program, where some managed care plans have non-calendar year contract years, analyzes prescription drug and prescription drug rebate data on a calendar-year basis.[12] In addition, state data collections related to prescription drug spending and rebates, including certain state All-Payer Claims Databases, generally collect data on a calendar-year basis.[13] Collection of calendar-year data will allow the Departments to evaluate the consistency and validity of the data and compare trends across multiple data sources as well as between publicly- and privately-sponsored health coverage.

Prior to issuing these interim final rules, the Departments received comment letters from several stakeholders recommending that the Departments collect data on a calendar-year basis, including for non-calendar year plans or coverage. The Departments also solicited comment on using calendar year as the basis for the section 204 data submissions in the RFI, and the overwhelming majority of commenters that responded to this RFI question supported the calendar-year approach. Commenters stated that calendar-year data would be more meaningful when comparing trends in the group markets (where plan years may not align with the calendar year) to those in the individual market (where policy years are generally on a calendar-year basis), because all of the data would be based on the same period. Issuers additionally advised that reporting calendar-year data for purposes of the section 204 data submissions would reduce compliance burdens because issuers submit other

[8] *See* 45 CFR 158.103, which defines the MLR reporting year as a calendar year during which group or individual health insurance coverage is provided by an issuer.

[9] *https://www.naic.org/documents/committees_ex_mlr_reg_asadopted.pdf.*

[10] Pharmacy Benefit Manager Transparency for Qualified Health Plans information collection, *available at https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10725.*

[11] *See, e.g.,* 42 CFR part 423; *see also https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.*

[12] *See, e.g., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Medicaid.*

[13] *See, e.g.,* Colorado Prescription Drug Rebate Data Submission Manual (Sept. 8, 2020), *https://www.civhc.org/wp-content/uploads/2020/10/Colorado-APCD-2020-Drug-Rebate-Data-Submission-Manual_09.08.2020.pdf;* Maine Uniform Reporting System for Prescription Drug Price Data Sets, 90–590 C.M.R. ch. 570, *https://mhdo.maine.gov/_finalStatutesRules/Chapter570RxDrugPricing_2020Feb4.docx;* Massachusetts Payer Reporting of Prescription Drug Rebates Data Specification Manual (Apr. 2020), *https://www.chiamass.gov/assets/docs/p/prescription-drug-rebate/Prescription-Drug-Rebate-Data-Specification-Manual-2020.pdf;* Minnesota Commerce Department, Public Pharmacy Benefit Manager (PBM) Transparency Report (Dec. 1, 2020), *https://mn.gov/commerce-stat/pdfs/pbm-transparency-report.pdf;* Texas Pharmaceutical Benefits Reporting (Dec. 2020): Health benefit plan issuer and Pharmacy benefit manager reporting forms, *https://www.tdi.texas.gov/health/documents/hbpi.pdf* and *https://www.tdi.texas.gov/health/documents/pbm.pdf.*

related data to state and federal regulators on a calendar-year basis. The Departments share the views of these commenters.

Student Market. In these interim final rules, for purposes of section 204 data submissions, the term ''student market'' has the meaning given in 45 CFR 158.103. Under 45 CFR 149.30, the definitions in 45 CFR 144.103 apply to the provisions of 45 CFR part 149 unless otherwise specified. The definitions of many terms in 45 CFR 144.103 and 45 CFR 158.103 are identical. However, the term ''student market'' is not defined in 45 CFR 144.103, but is defined in 45 CFR 158.103 as the market for student health insurance coverage. Consistency of the definition of ''student market'' in these interim final rules with the definition in 45 CFR 158.103 will enable the Departments to validate data quality and produce consistent analyses across data submitted under section 2718(a) of the PHS Act for purposes of MLR reporting and section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act for purposes of the section 204 public report.[14] Consistency with the definition of ''student market'' in 45 CFR 158.103 will also reduce compliance burdens for plans and issuers in the fully-insured markets, because plans and issuers subject to the requirements of 45 CFR part 158 have already created group size and market determination processes and have modified systems to track data using the definitions in 45 CFR 158.103 for purposes of MLR reporting. The Departments recognize that self-funded group health plans generally are not subject to as many requirements that are based on employer size as fully-insured group health plans. Consequently, self-funded plans are likely to face more challenges in determining employer size and providing that information to third-party administrators (TPAs) that submit data on behalf of self-funded plans. Therefore, reasonable approximations for employer size determinations of self-funded group health plans will be allowed. The instructions for the information collection instrument will provide examples of approximation methods that the Departments will consider to be reasonable.

FEHB Line of Business. In these interim final rules, the term ''FEHB line of business'' refers to all health benefits plans that are offered to eligible enrollees pursuant to a contract between an FEHB Program carrier and OPM. Such plans are Federal governmental plans offered pursuant to 5 U.S.C. chapter 89.

Market Segment. In these interim final rules, the term ''market segment'' means each of the following: The individual market (excluding the student market), the student market, the fully-insured small group market, the fully-insured large group market (excluding the FEHB line of business), self-funded plans offered by small employers, self-funded plans offered by large employers, and the FEHB line of business. Mixed-funded plans, which generally self-fund some health benefits and fully insure other health benefits, should attribute information reported to a market segment based on the source of funding for the benefits included in the report. For example, self-funded pharmacy benefits might be attributed to the market for self-funded group health plans offered by large employers while the reporting for the medical component of the same plan is attributed to the fully-insured large group market, if the medical benefits are funded through an insurance contract. ''Minimum premium'' plans and similar hybrid arrangements that mimic key aspects of fully-insured arrangements or that are required to comply with state laws regarding mandated benefits must be included in the fully-insured small group and large group market segments. ''Minimum premium'' plans generally feature regular fixed-premium payments and limit the plan sponsor's monthly or annual liability for claims, similar to fully-insured coverage. Finally, because student health insurance coverage is designed, marketed, and priced for a unique and narrower population than other individual health insurance coverage, collecting student market data separately for purposes of section 204 data submissions will allow the Departments to better analyze prescription drug usage and costs in this market. In addition, issuers of coverage subject to 45 CFR part 158 already track and report data for the student market policies separately from other individual market policies.

Enrollee. In these interim final rules, in the context of provisions of section 2799A–10(a) of the PHS Act, the term ''enrollee'' means an individual who is enrolled, within the meaning of 45 CFR 144.103, in group health insurance coverage, or an individual who is covered by individual health insurance coverage, at any time during the reference year, and includes dependents.

Life-years. In these interim final rules, the term ''life-years'' means the total number of months of coverage for participants and beneficiaries, or for enrollees, as applicable, divided by 12.

Brand Prescription Drug. In these interim final rules, the term ''brand prescription drug'' means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), or under section 351 of the PHS Act (42 U.S.C. 262), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes a drug with Emergency Use Authorization issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes drugs that the U.S. Food and Drug Administration (FDA) determines to be interchangeable biosimilar products under sections 351(i)(3) and 351(k)(4) of the PHS Act (42 U.S.C. 262).

Prescription Drug or Drug. In these interim final rules, the term ''prescription drug'' or ''drug'' means a set of pharmaceutical products, including biologics, that have been assigned a National Drug Code (NDC) by FDA and are grouped by name and ingredient in the manner specified by the Departments.[15] The Departments anticipate specifying that pharmaceutical products must be grouped by name and active ingredient, separately for brand products and generic products or certain biosimilar products. Products with the same name and active ingredient will thus be considered, for the purpose of these interim final rules, to be the same prescription drug even if they have a different dosage strength, package size, mode of delivery, or, for generic products, different manufacturers.[16]

The Departments chose to group pharmaceutical products by name and ingredient because this approach will produce more meaningful top 50 and top 25 lists of prescription drugs. If products are not grouped according to name and ingredient, the same drug could occupy several spots on the top 50 or top 25 lists. For example, providers may prescribe a drug that comes in the form of pills in different strengths, such as 10 mg or 20 mg, or a drug may sometimes be dispensed as a 30-day supply and sometimes as a 90-

[14] All other relevant definitions in 45 CFR 158.103 have the same meaning or functional effect as the definitions in 45 CFR 144.103.

[15] *https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.*

[16] This definition of the term ''prescription drug'' and ''drug'' and characterization of the term ''same prescription drug'' are used only for purposes of these interim final rules and are not intended to reflect or suggest any such definition or characterization of these terms by FDA.

day supply. In addition, several different companies may manufacture the same generic drug. If each variation of the drug were considered separately, the drug could occupy several spots on a top 50 list, which would be redundant and would not clearly indicate the full scope and variety of drugs in the top 50 list. Or, conversely, the variations could disperse the frequency across so many different products that the drug would not end up making the top 50 list despite its prevalence, even if it would be included in the list if categorized by ingredient or name.

This definition is consistent with stakeholder recommendations. Although a number of commenters responding to the RFI suggested that the Departments rely on the NDC with regard to the definition of ''prescription drug,'' the majority of commenters advised the Departments to classify prescription drugs according to characteristics such as the drug's name and active ingredient and not solely by the NDC, which distinguishes products by dosage strength, form of delivery, package size, and manufacturer. Commenters generally recommended that the Departments adopt a definition of ''prescription drug'' consistent with this approach to ensure that different formulations and dosages of the same drug do not appear on the top 50 lists multiple times. Commenters also suggested that the Departments either use a common commercially available database to group prescription drugs by name, active ingredient, and therapeutic class, or provide a new uniform mapping for how prescription drugs must be grouped and classified.

Therapeutic Class. In these interim final rules, the term ''therapeutic class'' means a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, grouped in the manner specified by the Departments in guidance.[17] The Departments may specify in guidance the technical specifications for how plans and issuers must classify drugs, and may specify that plans and issuers must do so according to a commonly available public or commercial therapeutic classification system that maps prescription drugs to therapeutic classes, a therapeutic classification system provided by the Departments through guidance, or a combination thereof. The Departments will require all plans and issuers to use the same classification system. This definition is consistent with stakeholder recommendations. Commenters responding to the questions in the RFI regarding the definition of ''therapeutic class'' advised that regulated entities use a variety of commercially available therapeutic classification systems. Many commenters urged the Departments to provide a uniform mapping system for therapeutic classes. Commenters generally requested that the Departments provide clear instructions and provide adequate implementation time, including by allowing plans and issuers to phase in adoption of a new uniform classification system.

Prescription Drug Rebates, Fees, and Other Remuneration. In these interim final rules, the term ''prescription drug rebates, fees, and other remuneration'' means all remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the plan or issuer, with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees in the plan or coverage, as applicable, regardless of the source of the remuneration (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates, fees, and other remuneration also include, for example, discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. Prescription drug rebates, fees, and other remuneration include bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the plan or issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of the entity, whether or not the entity takes title to the drug.

Some commenters responding to the RFI regarding the definition of prescription drug rebates, fees, and other remuneration recommended definitions that are identical or substantially similar to the definition of prescription drug rebates and other price concessions in the MLR regulations at 45 CFR 158.103 (which generally require issuers, among other requirements, to report premiums, prescription drug and medical expenses, and administrative expenses to HHS). Some commenters recommended that the definition include significantly more detailed illustrative examples. Many commenters encouraged the Departments to collect detailed information on the various types of prescription drug rebates, fees, and other remuneration, including at the level of detail consistent with the specifications for the data collection requirements under the Exchange Establishment rule[18] and the PBM Transparency rule[19] (which generally require certain entities to submit to HHS prescription drug data with respect to QHPs). In these interim final rules, the Departments are adopting a definition of prescription drug rebates, fees, and other remuneration that overlaps with the definition in the MLR regulations at 45 CFR 158.103 to the extent consistent with section 9825(a)(9) of the Code, section 725(a)(9) of ERISA, and section 2799A–10(a)(9) of the PHS Act. As the types of prescription drug rebates, fees, and other remuneration continue to evolve, the Departments intend to provide additional examples in the instructions for the information collection instrument as may be necessary. The Departments intend to specify the level of detail at which prescription drug rebates, fees, and other remuneration must be reported in section 204 data submissions in the instructions for the information collection instrument. The Departments intend to specify a level of detail that will assist plans, issuers, and other reporting entities in correctly determining the total amount of prescription drug rebates, fees, and other remuneration, and that will be generally consistent with the categories of rebates, fees, and other remuneration specified in the data collection requirements under the Exchange Establishment rule and the PBM Transparency rule.

A number of commenters urged the Departments to include bona fide service fees in the definition of ''prescription drug rebates, fees, and other remuneration,'' stating that the statute did not provide an exception for any fees paid by manufacturers to PBMs and other service providers, and that disclosure of these fees is necessary to ensure transparency and to ensure that rebates and other fees are not improperly mischaracterized as bona fide service fees. In contrast, other commenters urged the Departments to exclude bona fide service fees from the

[17] This definition of the term ''therapeutic class'' is used only for purposes of these interim final rules and is not intended to reflect or suggest any such definition or characterization of this term by FDA.

[18] 77 FR 18308 (March 27, 2012).

[19] 86 FR 24140 (May 5, 2021).

definition of ''prescription drug rebates, fees, and other remuneration,'' stating that these fees do not affect drug costs or impact premiums, and should be excluded for consistency with the requirements under the MLR rule, the Exchange Establishment rule and the PBM Transparency rule, as well as the definitions used by the Medicare and Medicaid programs. The Departments interpret section 9825(a)(9)–(10) of the Code, section 725(a)(9)–(10) of ERISA, and section 2799A–10(a)(9)–(10) of the PHS Act to require plans and issuers to report the total amount of rebates, fees, and any other remuneration, and separately, the extent to which rebates, fees, and any other remuneration impact premiums and out-of-pocket costs. The Departments note that section 9825(a)(9) of the Code, section 725(a)(9) of ERISA, and section 2799A–10(a)(9) of the PHS Act require plans and issuers to report rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees, as applicable, in the plan or coverage, and do not provide for the exclusion of bona fide service fees or any other fees. However, the Departments recognize that bona fide service fees may not always be intended to directly affect the cost or utilization of specific prescription drugs, and generally are not passed through to plans and issuers or to participants, beneficiaries, and enrollees. Therefore, the Departments will require reporting of only the total amount of bona fide service fees, but will not require these fees to be reported separately for each therapeutic class or for each drug on the top 25 list. This approach will help reduce compliance burden by enabling plans, issuers, TPAs, and PBMs to leverage some of the reporting capabilities they have already built to meet the requirements of section 1150A of the Social Security Act, which requires QHP issuers, Medicare Advantage Organizations offering plans with Medicare Part D, and Part D plan sponsors and PBMs that manage prescription drug coverage under contracts with these entities to report certain prescription drug benefit and rebate information to HHS and to exclude bona fide service fees in such reporting.

A number of commenters urged the Departments to exclude drug manufacturer cost-sharing assistance to participants, beneficiaries, and enrollees, such as coupons and copay cards, from the definition of prescription drug rebates because these amounts are not credited to the plan or coverage or its administrators or service providers. The Departments agree with this view, and in these interim final rules, the definition of prescription drug rebates and other price concessions excludes drug manufacturer cost-sharing assistance provided to participants, beneficiaries, or enrollees, as applicable. However, to the extent these amounts impact total annual spending by health plans or issuers, or by participants, beneficiaries, and enrollees, these interim final rules include drug manufacturer cost-sharing assistance in the definition of ''total annual spending,'' as discussed in more detail later in this section of this preamble.

Dosage Unit. In these interim final rules, the term ''dosage unit'' means the smallest form in which a pharmaceutical product is administered or dispensed. Common dosage units include a pill, tablet, capsule, ampule, or measurement of grams or milliliters.[20]

Premium Amount. In these interim final rules, the term ''premium amount'' with respect to individual health insurance coverage and fully-insured group health plans has the meaning given to the term ''earned premium'' in 45 CFR 158.130, excluding the adjustments specified in 45 CFR 158.130(b)(5), which currently encompass payments and receipts related to the risk adjustment program that would not be relevant for purposes of the section 204 data submissions. Several commenters responding to the RFI requested that the Departments clarify how premiums must be reported for self-funded plans or recommended the use of premium equivalents to ensure consistent reporting between fully-insured and self-funded plans. To accurately capture the concept of premiums and the full costs of maintaining health coverage with respect to self-funded group health plans and other arrangements that do not rely exclusively or primarily on premiums, in these interim final rules, the term ''premium amount'' with respect to these plans includes premium equivalent amounts that represent the total cost of providing and maintaining coverage, such as the cost of claims, administrative costs, and stop-loss premiums.

Reporting Entity. In these interim final rules, the term ''reporting entity'' means an entity that submits some or all of the information required under these interim final rules to the Departments with respect to a plan or issuer. The term also includes entities, other than plans and issuers, that submit the information on behalf of plans and issuers, as allowed by these interim final rules. Many commenters responding to the RFI regarding potential types of reporting entities requested clarification as to which entities are responsible for section 204 data submissions. Commenters generally indicated that plans and issuers expect that issuers and TPAs will report the information on behalf of most group health plans, including self-funded group health plans. Therefore, the Departments are allowing multiple types of reporting entities to submit the required information to provide plans and issuers with flexibility and to reduce administrative burdens. Some commenters requested that the Departments require TPAs and PBMs to report the information to or on behalf of self-funded group health plans. Although the Departments understand that these entities will make the section 204 data submissions on behalf of most self-funded group health plans in the vast majority of cases, the Departments note that section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act make plans and issuers responsible for providing the required information to the Departments. Therefore, the Departments do not require TPAs and PBMs to submit the information.

In addition, many commenters urged the Departments to design a data collection system that would allow multiple reporting entities to submit different subsets of the required information with respect to the same plan or issuer. Commenters advised that a single reporting entity may not possess all of the information required to be reported under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act. For example, plans and issuers indicated that a significant amount of information on prescription drug rebates is generally maintained primarily by PBMs, while other information is only known to plan sponsors, issuers, and TPAs. Commenters also advised that a segmented data collection system would reduce compliance burden by reducing the need for the reporting entities to transfer the data among themselves before submitting it to the Departments. The Departments intend to build a data collection system that will allow multiple reporting entities to submit

[20] This definition of the term ''dosage unit '' is used only for purposes of these interim final rules and is not intended to reflect or suggest any such definition or characterization of this term by FDA.

different subsets of the required information with respect to the same plan or issuer.

Total Annual Spending. In these interim final rules, the term ''total annual spending'' means incurred claims, as that term is defined in 45 CFR 158.140, excluding the adjustments specified in 45 CFR 158.140(b)(1)(i), 45 CFR 158.140(b)(2)(iv), and 45 CFR 158.140(b)(4), and including cost sharing but net of prescription drug rebates, fees, and other remuneration. Consistent with the definition in 45 CFR 158.140, plans and issuers must calculate the components of incurred claims based on claims incurred during the reference year and paid through March 31 of the year immediately following the reference year. The adjustments specified in 45 CFR 158.140(b)(2)(iv) currently encompass claims payments recovered through fraud reduction efforts and thus do not constitute spending, while the adjustments specified in 45 CFR 158.140(b)(4) currently encompass payments and receipts related to the risk adjustment program that would not be relevant for purposes of the section 204 data submissions. The adjustments specified in 45 CFR 158.140(b)(1)(i) currently encompass prescription drug rebates and other price concessions as that term is defined in 45 CFR 158.103. However, the definition of prescription drug rebates, fees, and other remuneration adopted in these interim final rules differs in several ways from the definition of prescription drug rebates and other price concessions in 45 CFR 158.103. Similar to the definition in 45 CFR 158.140, total annual spending with respect to prescription drugs means the spending net of prescription drug rebates, fees, and other remuneration, as that term is defined in these interim final rules, in lieu of the adjustments specified in 45 CFR 158.140(b)(1)(i) for prescription drug rebates and other price concessions, as that term is defined in 45 CFR 158.103. The Departments are choosing this definition of incurred claims to be generally consistent with the financial reporting requirements in the MLR data collection under 45 CFR part 158, which will reduce compliance burdens for issuers and TPAs. Further, defining ''total annual spending'' to mean spending net of prescription drug rebates, fees, and other remuneration will enable the Departments to undertake more meaningful and accurate comparisons of the costs of different prescription drugs, by capturing the actual costs for different plans and issuers, as well as for the participants, beneficiaries, and enrollees, as applicable, of different plans and issuers.

In addition, as noted earlier in this section of this preamble regarding the definition of ''prescription drug rebates, fees, and other remuneration,'' a number of commenters that responded to the RFI urged the Departments to exclude drug manufacturer cost-sharing assistance to participants, beneficiaries, and enrollees, such as coupons and copay cards, from the definition of prescription drug rebates. Nonetheless, many commenters also urged the Departments to collect information regarding drug manufacturer cost-sharing assistance, particularly to the extent this assistance is excluded from the annual limitation on cost sharing, while a few commenters opposed collection of such information. The Departments note that section 9825(a)(7)(B) of the Code, section 725(a)(7)(B) of ERISA, and section 2799A–10(a)(7)(B) of the PHS Act direct plans and issuers to report information on prescription drug spending by the plan or coverage and by participants, beneficiaries, and enrollees, as applicable. To the extent drug manufacturer cost-sharing assistance reduces spending by the health plan or coverage or by participants, beneficiaries, and enrollees, and to the extent information regarding the amount of these reductions is available to plans, issuers, their administrators, or their service providers such as PBMs (for example, when the drug manufacturer cost-sharing assistance is excluded from the annual limitation on cost sharing) and thus can be reported to the Departments, the Departments intend to collect data on these reductions separately and incorporate such reductions into the analysis conducted for the section 204 public report.

The Departments seek comment on these definitions, including whether other terms should be defined.

C. Reporting Requirements

1. Reporting Requirements Related to Prescription Drug and Health Care Spending (26 CFR 54.9825–4T, 29 CFR 2590.725–2, and 45 CFR 149.720)

a. General Requirement

Section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act require plans and issuers to submit annually to the Departments certain information on prescription drug and health care spending, premiums, and enrollment under the plan or coverage. This general requirement is being codified at 26 CFR 54.9825–4T(a), 29 CFR 2590.725–2(a), and 45 CFR 149.720(a).

b. Timing and Form of Report

Section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act require plans and issuers to provide the first section 204 data submissions to the Departments not later than 1 year after the date of enactment of the CAA, which would be December 27, 2021, with respect to the plan or coverage in the previous plan year, and by June 1 of each year thereafter. In these interim final rules, consistent with the discussion in section II.A of this preamble regarding the definition of ''reference year,'' the Departments interpret these statutory provisions to require plans and issuers to submit calendar year 2020 information by December 27, 2021, calendar year 2021 information by June 1, 2022, calendar year 2022 information by June 1, 2023, and so forth. Therefore, these interim final rules provide that the report for the 2020 reference year must be submitted to the Secretaries of the Treasury, Labor, and HHS (Secretaries of the Departments) by December 27, 2021, and that beginning with the 2021 reference year, the report for each reference year is due by June 1 of the year following the reference year. These interim final rules also require that the report must be submitted in the form and manner prescribed jointly by the Secretaries of the Departments. These requirements are being codified at 26 CFR 54.9825–4T(b), 29 CFR 2590.725–2(b), and 45 CFR 149.720(b).

Stakeholders expressed significant concerns about the feasibility of complying with the data submission deadlines specified in the statute. Specifically, stakeholders explained that they would need between 6 months to a year to comply with the reporting requirements after: (1) These interim final rules are issued; (2) technical guidance is provided by the Departments (such as instructions for the information collection instrument); and (3) the specifications for the data collection system are published by the Departments. Stakeholders explained that they would need this time to modify contractual agreements to enable disclosure and transfer of the required data between various reporting entities; to develop internal processes and procedures; and to implement the identification, compilation, preparation, and validation of the required data. Stakeholders further noted that they are concurrently implementing measures to comply with numerous other complex requirements and near-term deadlines imposed by the other provisions in the

No Surprises Act and Title II of Division BB of the CAA, as well as the Transparency in Coverage final rule.[21]

As noted in *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49,* published by the Departments on August 20, 2021, the Departments recognize the significant operational challenges that regulated entities may face in meeting the initial deadlines for the section 204 data submissions.[22] Accordingly, the Departments are exercising discretion to defer enforcement in connection with the December 27, 2021 and the June 1, 2022 deadlines for the section 204 data submissions for the 2020 and 2021 reference years, respectively. More specifically, the Departments will not initiate enforcement action against a plan or issuer that does not report the required information by the first statutory deadline for reporting on December 27, 2021 or the second statutory deadline for reporting on June 1, 2022, and that instead submits the section 204 data submissions for the 2020 and 2021 reference years by December 27, 2022.[23] However, the Departments strongly encourage plans and issuers to start working to ensure that they are in a position to be able to report the required information with respect to the 2020 and 2021 reference years by December 27, 2022. The Departments further encourage plans and issuers that are able to submit the required information by either the December 27, 2021 or June 1, 2022 statutory deadlines to do so.

A number of commenters responding to the RFI additionally recommended that the Departments allow for a longer run-out period for prescription drug claims and rebates than allowed by the annual June 1 statutory deadline. Some commenters therefore recommended that the Departments establish regular reporting deadlines of between 4 and 18 months after the end of the reference year. The Departments recognize that longer run-out periods could lead to the submission of more accurate data, but note that section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act prescribe the annual reporting deadline of June 1. The Departments further note that the deadline for the section 204 data submissions must balance the need for accuracy with the need for timely access to the data and the statutory deadlines for the biannual section 204 public report. The Departments are confident that regulated entities will be able to produce reasonably accurate estimates of the payable and receivable prescription drug rebate, fee, and other remuneration amounts by the June 1 statutory deadlines, similar to how issuers and other reporting entities currently determine such amounts for other federal and state financial reporting purposes. However, to ensure that the Departments receive complete and accurate data and are able to evaluate the reliability of the estimates and trends, the Departments will also collect restated amounts for prescription drug rebates, fees, and other remuneration for the preceding reference year.

c. Transfer of Business

To capture meaningful and accurate information required under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act with respect to group or individual health insurance coverage provided by an issuer, these interim final rules require issuers that acquire a line or block of business from another issuer during a reference year to submit the required information and report for the acquired business, including for the part of the reference year that was prior to the acquisition. This requirement mirrors the existing requirements for issuers to report the premium, claims, and other expenditures with respect to purchased business for MLR data reporting purposes in 45 CFR 158.110(c). This requirement is being codified at 26 CFR 54.9825–4T(c), 29 CFR 2590.725–2(c), and 45 CFR 149.720(c).

The sale or transfer of blocks of policies between issuers is a common practice in the health insurance industry and could lead to inconsistencies in the reporting required under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act. For example, if part of the data for a given reference year with respect to a block of business were reported by the selling issuer, and the other part was reported by the acquiring issuer, the split reporting could result in distortions and inconsistencies in the list of the top 50 most frequently dispensed brand prescription drugs, the report on the impact of cost-sharing amounts, the report on average monthly premium amounts, and other required data elements. The Departments seek comment on whether these interim final rules should be amended through future rulemaking to require reporting of any data elements that would address the impact of mergers, splits, and similar transactions on prescription drug costs to the extent such transactions increase market concentration.

d. Reporting Entities and Special Rules To Prevent Unnecessary Duplication

As discussed in section II.B of this preamble regarding the definition of ''reporting entity,'' the Departments are allowing plans and issuers to satisfy their reporting obligations under these interim final rules by having third parties, such as issuers, TPAs, or PBMs, submit some or all of the required information on their behalf, provided a plan or issuer enters into a written agreement with the third party that is providing the information on its behalf in accordance with these interim final rules. The Departments expect that it will be rare for group health plans to report the required information on their own, but nothing in these interim final rules prohibits them from doing so.

For fully-insured group health plans, these interim final rules at 26 CFR 54.9825–4T(d)(1), 29 CFR 2590.725–2(d)(1), and 45 CFR 149.720(d)(1) provide that, to the extent coverage under a group health plan consists of group health insurance coverage, the plan may satisfy the section 204 data submission requirements if the plan requires the health insurance issuer offering the coverage to report the required information in compliance with these interim final rules, pursuant to a written agreement. Under this provision, if the issuer fails to report the required information, then the issuer, not the plan, violates the reporting requirements.

For both fully-insured and self-funded group health plans, as well as health insurance issuers offering group or individual health coverage, these interim final rules at 26 CFR 54.9825–4T(d)(2), 29 CFR 2590.725–2(d)(2), and

[21] 85 FR 72158 (Nov. 12, 2020).

[22] FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (Aug. 20, 2021), Q12, available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.*

[23] Under section 2723 of the PHS Act, states have the opportunity to be the primary enforcers of section 2799A–10 of the PHS Act with respect to health insurance issuers. However, on September 16, 2021, the Departments and OPM published a proposed rule entitled, *Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement* (86 FR 51730), in which HHS proposed to have direct enforcement authority for newly enacted provisions of the PHS Act that require health insurance issuers to submit certain information to HHS or the Departments, including section 2799A–10 of the PHS Act, unless the state notifies HHS of its intent to enforce. HHS solicited comment on this approach. Public comments on this proposed rule were due by October 18, 2021. HHS is considering public comments and intends to address the issue of enforcement of section 2799A–10 of the PHS Act enforcement in the *Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement* final rule.

45 CFR 149.720(d)(2) provide that the plan or issuer may also satisfy the section 204 data submission requirements with respect to the required information that the plan or issuer, as applicable, requires another party (such as another issuer, a PBM, a TPA, or other third party) to report in compliance with these interim final rules, pursuant to a written agreement. Under this provision, if the third-party reporting entity fails to report the required information, the plan or issuer violates the reporting requirements.

The Departments solicit comment on this approach.

2. Required Information (26 CFR 54.9825–6T, 29 CFR 2590.725–4, and 45 CFR 149.740)

a. General Information

The provisions of these interim final rules that address the general information that plans and issuers must submit for each plan or coverage at the plan or coverage level are being codified at 26 CFR 54.9825–6T(a), 29 CFR 2590.725–4(a), and 45 CFR 149.740(a).

Plans and issuers must ensure that the information they report, or the information that is reported on their behalf, includes identifying information at the plan or coverage level, such as name and Federal Employer Identification Number (FEIN) and other relevant identification numbers, for plans, issuers, plan sponsors, and any other reporting entities. Plan- and coverage-level identifying information is necessary for the Departments to verify receipt of data from all plans and issuers subject to the section 204 data submission requirements. The identifying information will also allow the Departments to ensure that reporting entities do not submit duplicate information, and that different reporting entities do not reflect the data of the same health plan or coverage in different market segments when a plan or issuer engages multiple reporting entities to report information on its behalf. For example, if a self-funded group health plan engages a TPA to report health care spending and a PBM to report prescription drug spending, the Departments will need to verify that both reporting entities reported the data and included the data for the plan in the appropriate market segment. The identifying information will further enable the Departments to cross-reference the data to other data submitted by plans and issuers to the Departments, such as the MLR data submitted by issuers to HHS and the Form 5500 Annual Returns/Reports of Employee Benefit Plan data submitted by group health plans to DOL and the Department of the Treasury.

In addition, plans and issuers must ensure that the information they report, or that is reported on their behalf, includes the following data elements, which are required by section 9825(a)(1)–(3) of the Code, section 725(a)(1)–(3) of ERISA, and section 2799A–10(a)(1)–(3) of the PHS Act, at the plan level, regardless of whether they submit the other required information at the aggregate level, as described in section II.C.3. of this preamble: (1) The beginning and end dates of the plan year that ended on or before the last day of the reference year; (2) the number of participants, beneficiaries, and enrollees, as applicable, covered on the last day of the reference year; and (3) each state in which the plan or coverage is offered. The number of participants, beneficiaries, and enrollees, as applicable, can be measured in multiple ways, such as the average number over the course of a year, or a number at a point in time, such as at the beginning or end of the year, all of which convey different and valuable information. To ensure data consistency, these interim final rules require plans and issuers to report at the plan level the number of participants, beneficiaries, and enrollees, as applicable, covered only on the last day of the reference year. This approach will provide the Departments with the most recent information regarding enrollment at the plan level. To reduce the reporting burdens, these interim rules require plans and issuers to report the life-years attributable to the participants, beneficiaries, and enrollees, as applicable, over the course of the reference year only in total, at the state and market segment aggregate level, as described in section II.C.3. of this preamble. This approach will provide enrollment metrics that are most relevant to the other data elements collected at the aggregate level and will enable the Departments to analyze trends such as average annual spending per person. Issuers subject to MLR reporting requirements under 45 CFR part 158 will be able to leverage the life-years they compile at the state and market segment level for MLR reporting purposes.

In accordance with the requirements in section 9825(b) of the Code, section 725(b) of ERISA, and section 2799A–10(b) of the PHS Act regarding the treatment of plan-specific information in the section 204 public report, the Departments will not publicly disclose this information in a manner by which any plan can be identified.

b. Health Care Spending

Section 9825(a)(7) of the Code, section 725(a)(7) of ERISA, and section 2799A–10(a)(7) of the PHS Act require plans and issuers to report the total annual spending on health care services, broken down by the types of cost, including: (1) Hospital costs; (2) health care provider and clinical service costs, for primary care and specialty care separately; (3) costs for prescription drugs; and (4) other medical costs, including wellness services. For prescription drug spending, plans and issuers must report separately the costs incurred by the plan or coverage and the costs incurred by participants, beneficiaries, and enrollees, as applicable. The provisions related to these requirements are being codified at 26 CFR 54.9825–6T(b)(4) through (5), 29 CFR 2590.725–4(b)(4) through (5), and 45 CFR 149.740(b)(4) through (5).

Stakeholders requested that the Departments provide specific instructions for which expenses must be reported in each category. Several commenters responding to the RFI made technical suggestions regarding how the Departments should specify these expense categories. These interim final rules set forth general requirements, and the Departments intend to provide detailed technical guidance in the instructions to the information collection instrument regarding reporting by health care service type that aligns with these general requirements and provides examples of the costs that should be reported in each category. To promote consistency and reduce the reporting burden, the Departments may leverage specific data elements used in the MLR Annual Reporting Form and the Unified Rate Review Template that issuers file with HHS.[24] The Departments solicit comments on the use of MLR and rate review definitions of health care spending cost elements.

Many commenters responding to the RFI urged the Departments to exclude prescription drugs covered under the hospital or medical benefit from the section 204 data submissions due to the complexity of obtaining these data, longer run-out periods associated with these drugs, and differences in the relevant pricing mechanisms and underlying cost drivers (such as different supply chains and procurement mechanisms). Commenters

[24] *See, e.g., https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/2019-MLR-Form-Instructions.pdf* and *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/URR_v5.3-instructions.pdf.*

additionally noted that these drugs may be subject to different cost-sharing requirements than drugs dispensed by retail or mail-order pharmacies, and may present consumers with fewer opportunities to choose among drugs. The Departments acknowledge these concerns, but note that section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act do not create an exemption for prescription drugs covered under a plan's or coverage's hospital or medical benefit. The Departments further note that prescription drugs covered under a hospital or medical benefit constitute a significant proportion of the total prescription drug spending in the U.S., and include some of the more costly drugs. Therefore, these interim final rules require reporting of the total annual spending on prescription drugs administered in a hospital, clinic, provider's office, or other provider setting and covered under the hospital or medical benefit of a plan or coverage (which may be a subset of, and already reported with, the total spending on hospital or other medical costs), separately from the total annual spending on drugs covered under the pharmacy benefit of a plan or coverage. Separate reporting of spending on drugs covered under the pharmacy benefit and on drugs covered under the hospital or medical benefit will assist the Departments in evaluating prescription drug trends with respect to the setting in which the drugs are administered. However, in recognition of stakeholders' concerns regarding the compliance burdens associated with reporting information on drugs covered under the hospital or medical benefit, these interim final rules do not, at this time, require plans and issuers to report data elements other than total annual spending, as required under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act, such as the top 50 and top 25 lists, for drugs covered under the hospital or medical benefit. Instead, these data elements should reflect only the drugs covered under the pharmacy benefit. Once the Departments begin to receive the section 204 data submissions and have the opportunity to evaluate the prescription drug data, the Departments will further review and analyze the merits of this approach and may modify the provisions regarding the information to be collected on drugs covered under the hospital or medical benefit in future rulemaking. Finally, the Departments recognize that for drugs covered under the hospital or medical benefit, the cost of the prescription drugs included in some bundled payment arrangements and other alternative payment arrangements may not be readily available to the plan or issuer. In these situations, the plan or issuer is required to separately report the total annual spending attributable to the prescription drugs included in the bundle or other alternative payment arrangement in good faith and to the best of its ability. The Departments seek comment on all aspects of collecting only some of the information on drugs covered under the hospital or medical benefit. The Departments also seek comment on whether reporting flexibilities for drugs included in bundled and other alternative payment arrangements may contribute to prescription drug spending increases or facilitate anti-competitive practices.

These interim final rules require plans and issuers to separately report total annual spending on health care services by the plan or coverage, and total annual spending on health care services by participants, beneficiaries, and enrollees, as applicable. Collecting total annual spending on health care services at this level of detail will ensure consistency with the other data elements required by section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act, such as total annual spending on prescription drugs and average monthly premium amounts, which are collected separately with respect to a plan or coverage and with respect to participants, beneficiaries, and enrollees, as applicable. Consistency across the data elements will enhance the usability of the data and enable the Departments to conduct meaningful data analysis. These interim final rules additionally require plans and issuers to report, for each drug in the top 50 and top 25 lists, as well as for each therapeutic class, prescription drug spending and utilization, including: (1) Total annual spending by the plan or coverage; (2) total annual spending by participants, beneficiaries, and enrollees enrolled in the plan or coverage, as applicable; (3) the number of participants, beneficiaries, and enrollees, as applicable, with a paid prescription drug claim; (4) total dosage units dispensed; and (5) the number of paid claims. The Departments intend to collect cost-sharing amounts to obtain the total annual spending by participants, beneficiaries, and enrollees, as applicable. Inclusion of identical data elements in each of the top 50 and top 25 lists and the therapeutic class list will streamline reporting and reduce compliance burdens. Collecting these amounts for each of the top 50 and top 25 lists, as well as for each therapeutic class, will enable the Departments to include in the section 204 public report an analysis regarding the overlap (or lack thereof) and the causes of any such overlap, among the lists of the most frequently dispensed drugs, the most costly drugs, the drugs with the greatest cost increases, and the drugs generating the greatest amount of rebates. This analysis may include analysis of the differences and similarities in these five spending and utilization data elements across drugs in the top 50, top 25, and the therapeutic class lists. This analysis may further include analysis of how prescription drug spending increases are distributed among plans and issuers as compared to the participants, beneficiaries, and enrollees. The total annual spending on prescription drugs and total dosage units dispensed will enable the Departments to conduct the required analysis of prescription drug pricing trends for purposes of the section 204 public report, and to compare trends across multiple data sources as well as between publicly and privately-sponsored health coverage. The number of paid claims and the unique number of individuals with paid prescription drug claims will allow the Departments to compute average per person cost sharing, and evaluate the average impact, if any, of prescription drug spending increases and rebates on participants, beneficiaries, and enrollees, as well as analyze whether spending increases are driven by increases in drug prices or utilization. The Departments seek comment on the use of identical prescription drug data elements for each of the top 50 and top 25 lists and the therapeutic class list.

c. Premium Amounts

Section 9825(a)(8) of the Code, section 725(a)(8) of ERISA, and section 2799A–10(a)(8) of the PHS Act require plans and issuers to report the average monthly premium paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable, as well as the average monthly premium paid by participants, beneficiaries, and enrollees, as applicable. The provisions related to this requirement are being codified at 26 CFR 54.9825–6T(b)(6), 29 CFR 2590.725–4(b)(6), and 45 CFR 149.740(b)(6).

Stakeholders expressed concerns about this requirement. Employers expressed concern that reporting this information would be burdensome and suggested that the Departments utilize the information regarding the tax-deductible portion of premiums shown

on the Forms W–2. Issuers and TPAs expressed concern that information regarding the employer and participant, beneficiary, and enrollee contributions to premiums is currently only known to employers, and that it would be time-consuming and burdensome for issuers and TPAs to obtain this information from employers. Issuers and TPAs also anticipated that some employers may not want to disclose this information to issuers and TPAs. Issuers and TPAs requested that the Departments allow them to report estimated average monthly premium amounts based on a sample of employers or based on publicly available survey data.

The Departments acknowledge these concerns but note that plans and issuers are required to report this information under section 9825(a)(8) of the Code, section 725(a)(8) of ERISA, and section 2799A–10(a)(8) of the PHS Act. Furthermore, the Departments are of the view that the information on the trends in the employer versus employee contributions to premium amounts is integral to analyzing the extent to which the impact of prescription drug costs on premiums affects employers versus employees. Plans, employers, participants, beneficiaries, and enrollees experience premium increases driven by increases in prescription drug spending or, conversely, premium decreases driven by prescription drug rebates, proportionately to their share of total premium amounts, as well as the changes in this proportion over time. Existing data on premium amounts paid by employers versus by participants, beneficiaries, and enrollees are not complete for each state and market segment defined in these interim final rules. Furthermore, premium information shown on the Forms W–2 includes information related to plans that are not subject to these interim final rules (such as account-based group health plans). Therefore, these interim final rules require plans and issuers to submit the actual average monthly premium amounts separately with respect to payments by employers on behalf of participants, beneficiaries, and enrollees, and payments by participants, beneficiaries, and enrollees.

For purposes of these interim final rules, to accurately capture premium amounts with respect to all types of group health plan sponsors, the average monthly premium amount paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable, includes premium amounts paid by plan sponsors that do not directly employ individuals (for example, employee organizations or employer groups and associations acting in the interest of their members and considered an ''employer'' within the meaning of section 3(5) of ERISA) but that nonetheless make payments of premiums or premium equivalents on behalf of participants, beneficiaries, and enrollees, as applicable.

These interim final rules also require plans and issuers to report total annual premium amounts and the total number of life-years. Section 9825(a)(9)–(10) of the Code, section 725(a)(9)–(10) of ERISA, and section 2799A–10(a)(9)—(10) of the PHS Act require plans and issuers to report any impact on premiums and reductions in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers. In addition, the section 204 public report required by section 9825(b) of the Code, section 725(b) of ERISA, and section 2799A–10(b) of the PHS Act must include information on the role of prescription drug costs in contributing to premium increases or decreases. Collecting total annual premium amount information will provide the Departments with important context to understand the impact of rebates, fees, and other remuneration. For example, if the impact of rebates, fees, and other remuneration resulted in a premium decrease of $100,000 for the reference year, it is important for the Departments to know whether the reduction is based on total annual premium amounts of $1,000,000 or $10,000,000. Similarly, collection of the total number of life-years will enable the Departments to estimate the combined average premium, as well as to estimate an average impact at the per person level for the participants, beneficiaries, and enrollees, as applicable, whose premiums or out-of-pocket costs may be affected by prescription drug costs and prescription drug rebates, fees, and other remuneration.

The Departments seek comment on all aspects of the data submission requirements regarding premium amounts.

d. Top 50 Drug Lists

Section 9825(a)(4)–(6) of the Code, section 725(a)(4)–(6) of ERISA, and section 2799A–10(a)(4)—(6) of the PHS Act require plans and issuers to report, respectively: (1) The 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each such drug; (2) the 50 most costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and (3) the 50 prescription drugs with the greatest increase in plan or coverage expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year. The provisions related to these requirements are being codified at 26 CFR 54.9825–6T(b)(1) through (3), 29 CFR 2590.725–4(b)(1) through (3), and 45 CFR 149.740(b)(1) through (3).

In accordance with these interim final rules, the top 50 drugs must be determined separately for each aggregation level described in 26 CFR 54.9825–5T, 29 CFR 2590.725–3, and 45 CFR 149.730, as described in section II.C.3 of this preamble. For example, if an issuer acts as the reporting entity, has health insurance business or acts as a TPA in multiple states and market segments, and aggregates the data at the state and market segment level, then the issuer must prepare the three top 50 lists for each market segment within each state. Each of these lists must be based on the combined experience of all plans or policies included in the relevant aggregation. The Departments expect that it will be rare for self-funded plans to report these lists on their own using their own claims experience to determine the top 50 drugs, but to the extent a self-funded plan does so, any TPA that administers benefits for the plan should not include that plan's experience in the TPA's aggregated report.

As noted in section II.C.2.b. of this preamble, at this time, to simplify reporting and analysis and to reduce the reporting burden, these interim final rules require the information on the top 50 lists to include only the drugs covered under the pharmacy benefit of a plan or coverage, and exclude drugs administered in a hospital, clinic, provider's office, or other provider setting and covered under the hospital or medical benefit of a plan or coverage. Stakeholders requested that drugs covered under the hospital or medical benefit be excluded from the section 204 data submissions because these drugs may have different supply chains and procurement mechanisms, be subject to different pricing mechanisms and cost-sharing requirements than drugs dispensed by retail or mail-order pharmacies, and may present consumers with fewer opportunities to choose among drugs. As a result, the dispensing frequency, total spending, and prescription drug rebates, which are used to rank the top 50 and top 25 lists, are likely to be different for drugs covered under the pharmacy benefit and

for drugs covered under the hospital or medical benefit. Consequently, combining drugs covered under the pharmacy benefit with the hospital or medical benefit could lead to distorted ranking of the top 50 lists. Commenters responding to the RFI further pointed to the operational challenges of combining the data on drugs covered under the pharmacy benefit and the hospital or medical benefit to produce the top 50 lists, given that these data come from separate sources and may be reported by different reporting entities. The Departments will continue to review the validity of this approach and whether it adequately fulfills the objectives of section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act, and the Departments may modify the reporting requirements for the top 50 lists to include drugs covered under the hospital or medical benefit, or to require separate top 50 lists for drugs covered under the pharmacy benefit and under the hospital or medical benefit, in future rulemaking. The Departments solicit comment on this approach.

Top 50 Most Frequently Dispensed Brand Prescription Drugs. Plans, issuers, and other reporting entities must determine the most frequently dispensed brand prescription drugs based on the total number of paid claims for prescriptions filled during the reference year for each drug.

For each of the top 50 most frequently dispensed brand prescription drugs, the section 204 data submission must include the data elements listed in 26 CFR 54.9825–6T(b)(5), 29 CFR 2590.725–4(b)(5), and 45 CFR 149.740(b)(5) (required prescription drug data elements), which include: (1) Total annual spending by the plan or coverage; (2) total annual spending by participants, beneficiaries, and enrollees enrolled in the plan or coverage, as applicable; (3) the number of participants, beneficiaries, and enrollees, as applicable, with a paid prescription drug claim; (4) total dosage units dispensed; and (5) the number of paid claims. The rationale for collecting the required prescription drug data elements for each of the top 50 most frequently dispensed brand prescription drugs is described in section II.C.2.b. of this preamble.

Top 50 Most Costly Drugs. Plans, issuers, and other reporting entities must determine the 50 most costly drugs based on total annual spending per drug. Total annual spending, as defined in these interim final rules and as described in section II.B. of this preamble, must be net of prescription drug rebates, fees, and other remuneration and must include cost sharing as well as, to the extent available, drug manufacturer cost-sharing assistance. For each of the top 50 most costly drugs, the section 204 data submissions must include the required prescription drug data elements. The statute requires reporting of the top 50 most costly drugs by total annual spending with respect to the plan or coverage, which the Departments interpret to mean all spending under the plan or coverage, including both amounts spent by the plan or coverage as well as cost sharing and other amounts paid by participants, beneficiaries, and enrollees. The statute additionally requires reporting of the amounts spent only by the plan or coverage for each such drug. Because cost sharing generally corresponds to the difference between total annual spending and the amounts spent by the plan or coverage, the Departments chose to capture the amounts spent by the plan or coverage through requiring reporting of the total cost sharing paid under the plan or coverage. Reporting of total cost sharing will provide the Departments with information equivalent to that specified in the statute but will be more convenient for data analysis. The rationale for collecting the required prescription drug data elements for each of the top 50 drugs with the highest total annual spending is described in section II.C.2.b. of this preamble.

Top 50 Drugs with the Greatest Increase in Expenditures. Plans, issuers, and other reporting entities must determine the top 50 drugs with the greatest increase in expenditures based on the dollar amount of the increase in total annual spending over the preceding year. The statute requires reporting of the top 50 drugs with the greatest year-over-year increase in plan expenditures, which the Departments interpret to mean all spending under the plan or coverage, including both amounts spent by the plan or coverage as well as cost sharing and other amounts paid by participants, beneficiaries, and enrollees. This interpretation is consistent with the interpretation of the reporting methodology for the top 50 most costly drugs. A number of commenters responding to the RFI recommended that the Departments define the increase in expenditures based on the absolute amount of the increase rather than the percentage increase because the former value would enable the Departments to analyze which drugs are driving the increases in total spending on prescription drugs and would provide the Departments a better sense of the magnitude of the increases in this spending. The Departments agree with this rationale.

For each of the top 50 drugs with the greatest increase in expenditures, the section 204 data submissions must include: (1) The required prescription drug data elements for the year immediately preceding the reference year; and (2) the required prescription drug data elements for the reference year. The rationale for collecting the information on the year-over-year changes in the required prescription drug data elements for each of the top 50 drugs with the greatest increases in expenditures is described in section II.C.2.b. of this preamble. Only drugs that were approved for marketing and/or issued an Emergency Use Authorization by FDA for the entire year immediately preceding the reference year and for the entire reference year should be included in this top 50 list.[25] This approach will ensure that the cost increase is based on year-over-year changes and is not distorted by the inclusion of new drugs released in the market later in a calendar year.

The Departments seek comment on all aspects of the data submission requirements regarding the top 50 drug lists.

e. Prescription Drug Rebates, Fees, and Other Remuneration

Section 9825(a)(9) of the Code, section 725(a)(9) of ERISA, and section 2799A–10(a)(9) of the PHS Act require plans and issuers to report prescription drug rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees, as applicable, in the plan or coverage. The statute requires these amounts to be reported for each therapeutic class of drugs, as well as 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.[26] The provisions related to these requirements are being codified at 26 CFR 54.9825–6T(b)(7) through (9), 29 CFR 2590.725–4(b)(7) through (9), and 45 CFR 149.740(b)(7) through (9).

[25] This includes an Emergency Use Authorization issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) for an unapproved use of an otherwise-approved drug.

[26] As discussed in section II.B. of this preamble, in this instance, the Departments are interpreting ''plan year'' to mean ''reference year.''

As discussed in section II.B. of this preamble regarding the definition of ''prescription drug rebates, fees, and other remuneration,'' the Departments intend to generally align the categories of rebates, fees, and other remuneration in the section 204 data submissions with the categories specified in the data collection requirements under the Exchange Establishment rule [27] and the PBM Transparency rule [28] to reduce compliance burdens by allowing reporting entities to leverage some of the reporting capabilities they have already built to meet the requirements of these other HHS rules. For consistency with the Exchange Establishment rule and the PBM Transparency rule, these interim final rules further require reporting of total prescription drug rebates, fees, and other remuneration with respect to amounts passed through to the plan or issuer, amounts passed through to participants, beneficiaries, or enrollees, as applicable, and amounts retained by the PBM. Similarly, consistent with the information collected under the Exchange Establishment rule and the PBM Transparency rule, these interim final rules require reporting of the difference between total amounts that the plan or issuer pays the PBM and total amounts that the PBM pays pharmacies. One commenter responding to the RFI opposed collection of the difference between total amounts that the plan or issuer pays the PBM and total amounts that the PBM pays pharmacies, as well as collection of other details regarding prescription drug rebates, fees, and other remuneration consistent with the Exchange Establishment rule and the PBM Transparency rule; however, the commenter also recommended using the same definition for prescription drug rebates, fees, and other remuneration as used in the Exchange Establishment rule and the PBM Transparency rule. In contrast, several other commenters expressed concern with the impact on the market participants and on prescription drug pricing of the difference between total amounts that the plan or issuer pays the PBM and total amounts that the PBM pays pharmacies, and recommended that the Departments collect this information. The Departments are of the view that collection of this information is integral to the Departments' ability to analyze prescription drug reimbursements, pricing trends, and the impact of prescription drug rebates, fees, and other remuneration on premiums and cost sharing for purposes of developing the section 204 public report. This information will inform the Departments' analyses because, similar to prescription drug rebates, fees, and other remuneration, the difference between total amounts that the plan or issuer pays the PBM and total amounts that the PBM pays pharmacies is a factor that contributes to the differences between the payments for prescription drugs made by plans, issuers, enrollees, participants, and beneficiaries, and the portion of those payments captured by pharmacies and drug manufacturers, and thus impacts the cost of prescription drugs to plans, issuers, enrollees, participants, and beneficiaries. However, similar to bona fide service fees, these interim final rules provide for the submission of these amounts only in total and not at the drug or therapeutic class level. This approach will help reduce compliance burden by enabling plans, issuers, TPAs, and PBMs to leverage some of the reporting capabilities they have already built to meet the requirements of section 1150A of the Social Security Act, and will ensure that the information will be collected only to the extent that the Departments currently view that as necessary for their analysis. Last, the rationale for collecting the required prescription drug data elements for each therapeutic class and for each of the top 25 drugs that yielded the highest amount of rebates is described in section II.C.2.b. of this preamble.

Section 9825(a)(9)–(10) of the Code, section 725(a)(9)–(10) of ERISA, and section 2799A–10(a)(9)—(10) of the PHS Act additionally require plans and issuers to report the impact of the prescription drug rebates, fees, and other remuneration from drug manufacturers on premiums and out-of-pocket costs. For internal consistency, these interim final rules capture the impact on out-of-pocket costs by requiring reporting of the impact of prescription drug rebates, fees, and other remuneration on cost sharing. A number of commenters responding to the RFI indicated that plans and issuers may not know or be able to quantify the impact of prescription drug rebates on premiums or cost sharing. These commenters recommended that the Departments allow plans and issuers to provide qualitative descriptions of how prescription drug rebates, fees, and other remuneration generally provide savings to participants, beneficiaries, and enrollees, instead of attempting to collect drug-level impact amounts. The Departments intend to design the information collection instrument in a manner that would enable plans and issuers to provide both quantitative and qualitative information regarding the impact of prescription drug rebates on premiums and cost sharing.

The Departments seek comment on all aspects of the data submission requirements regarding prescription drug rebates, fees, and other remuneration.

3. Aggregate Reporting (26 CFR 54.9825–5T, 29 CFR 2590.725–3, and 45 CFR 149.730)

a. General Requirement

Section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act require plans and issuers to submit the information in section 204 data submissions to the Departments ''with respect to the health plan or coverage.'' Some of the information described in these statutory provisions pertains specifically to each group health plan, such as the beginning and end dates of the plan year, the number of participants, beneficiaries, and enrollees, as applicable, and each state where the plan or coverage is offered. However, the Departments are of the view that section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act do not strictly prescribe that every data element outlined in these provisions must be reported separately by each unique group health plan. After careful consideration of whether aggregate or plan-level information would be more appropriate to facilitate development of the section 204 public report as well as feedback received from stakeholders, the Departments have determined that plans and issuers (or other entities reporting on their behalf) may submit the majority of the information required under these interim final rules on an aggregate basis. The only plan-level information collected will be the following: (1) Identifying information for plans and issuers and other reporting entities; (2) the beginning and end dates of the plan year that ended on or before the last day of the reference year; (3) the number of participants, beneficiaries, or enrollees, as applicable, covered on the last day of the reference year; and (4) each state in which a plan or coverage is offered.

There are several reasons for collecting the majority of the information in the section 204 data submissions on an aggregate basis.

First, collecting aggregate data is necessary for the Departments to be able to draw conclusions about market trends for purposes of developing a meaningful and accurate section 204 public report. The Departments would

[27] 77 FR 18308 (Mar. 27, 2012).

[28] 86 FR 24140 (May 5, 2021).

not be able to accurately combine plan-specific top 50 lists to determine aggregate prescription drug trends within market segments, within states, and across the country. The Departments would not be able to accurately combine plan-specific top 50 lists because the statute only requires plans and issuers to report information for the top 50 drugs and not for all drugs. As a result, the Departments would not have access to the utilization and spending information for drugs that may not make the top 50 lists of every group health plan, but which may have higher combined utilization or spending across all group health plans than the drugs appearing on the plan-specific top 50 lists. Consequently, collection of plan-specific data could impair the Departments' ability to comply with the statutory requirement to produce the section 204 public report on prescription drug reimbursement and pricing trends. As a simplified example of the problems with collecting plan-specific data, suppose that the statute requires reporting of only the top 3 most frequently dispensed brand prescription drugs, rather than the top 50 drugs. Also, suppose that there is only one issuer offering two plans in a specific state and market segment. For Plan One, the four brand prescription drugs with the highest number of paid claims are Drug A with 100 claims, Drug B with 80 claims, Drug C with 75 claims, and Drug Z with 70 claims. For Plan Two, the four brand prescription drugs with the highest number of paid claims are Drug D with 110 claims, Drug E with 105 claims, Drug F with 90 claims, and Drug Z with 85 claims. If the Departments collected the top 3 brand prescription drugs at the plan level, Drug Z would be missing from the issuer's submission because it is not in the top 3 list for either plan. However, if the issuer aggregated the data at the state and market segment level before submitting it, Drug Z would have 155 paid claims and the Departments would correctly identify it as the most frequently dispensed drug in this state and market segment.

The inability to correctly identify trends in prescription drug reimbursements, pricing, and impact on premiums from the plan-specific data would inhibit the Departments' ability to comply with the requirements in section 9825(b) of the Code, section 725(b) of ERISA, and 2799A–10(b) of the PHS Act to develop and issue a public report on these trends. Collecting aggregate data will significantly reduce the possibility of such scenarios.

In addition, the data underlying the top 50 lists need to be of sufficient size for the Departments to be able to draw conclusions about market trends for purposes of developing a meaningful and accurate section 204 public report. The majority of group health plans have a relatively small number of participants, beneficiaries, or enrollees. If the Departments were to collect the top 50 lists separately for each group health plan, most of these lists would be based on small sample sizes and consequently could provide a distorted view of the market. This is because plan-specific lists would tend to be driven by the utilization of specific participants, beneficiaries, or enrollees of a given plan, which may not be representative of the market and may obscure broader trends. For example, a top 50 list for a plan with five participants and beneficiaries may contain only two steroid drugs, both purchased by a single participant to treat a skin condition. These drugs would appear as the first and second drugs on this plan-specific list. The top 50 list for another small employer plan may contain only three drugs—two drugs used to treat a rare autoimmune disease of one participant, and another drug used to manage post-surgery pain of another participant—which would likewise appear as the first, second, and third drugs on that plan-specific list. However, neither of these plan-specific lists is likely to be representative of the broader market; and, as described in the preceding paragraph, the Departments would not be able to combine the data from plan-specific top 50 lists in the manner needed to arrive at accurate totals for any given drug across states, market segments, or the country.

Another reason to collect aggregate data is to protect personally identifiable information and protected health information. Many comments received in response to the RFI stated that collection of plan-level data would raise significant privacy concerns because, as illustrated in the example above, it would not be difficult to discern which drugs and which claims were attributable to specific participants, beneficiaries, or enrollees in plan-level data. These comments argued that aggregate reporting would reduce the likelihood of collecting and transmitting personally identifiable information and protected health information, and thus the risk of inadvertent or inappropriate disclosure. The Departments share this concern and agree that aggregate reporting will better ensure that personally identifiable information and protected health information are protected from disclosure. Specifically, allowing aggregation of data will provide a larger population sample of participants, beneficiaries, or enrollees from which the data are drawn so that it is difficult to determine if a prescription drug or therapeutic class can be associated with a specific individual. In addition, HHS, which will collect the information on behalf of the Departments and OPM, intends to collect and maintain the information using information technology (IT) systems that are designed to meet all of the security standards protocols established under federal law or by HHS that are relevant to such information.[29] The Departments and OPM will further analyze the collected information to evaluate whether additional steps may be taken to ensure consumer privacy.

An additional reason to collect aggregate data is that prescription drug rebates, fees, and other remuneration generally are not negotiated separately for each plan; rather, they tend to be driven by sales volume and other considerations at the PBM level. Therefore, it is the Departments' understanding that plan-specific prescription drug rebate data generally is rarely available. Consequently, plan-specific lists of prescription drug rebates for each therapeutic class and for the top 25 drugs with the highest amount of rebates largely would be based on allocation calculations, and therefore plan-specific data would create little value beyond that created by aggregated reporting. Plan-specific lists might have some value for plans, but for purposes of the Departments' analysis of the data for the section 204 public report, there is no compelling policy reason to require plans and issuers to engage in a complex and burdensome allocation exercise, particularly because lists based on allocation calculations would not provide useful information about any specific plan.

Last, the overwhelming majority of commenters on the RFI encouraged the Departments to adopt an aggregate approach to data collection. They noted that an aggregate approach would be significantly less burdensome and urged the Departments to collect data at the highest possible aggregation level. They also raised similar concerns as those described earlier in this section of this

[29] HHS' enterprise-wide information security and privacy program was launched in FY 2003, to help protect HHS against potential IT threats and vulnerabilities. The program ensures compliance with federal mandates and legislation, including the Federal Information Security Management Act and the President's Management Agenda. The HHS Cybersecurity Program plays an important role in protecting HHS's ability to provide mission-critical operations. In addition, the HHS Cybersecurity Program is the cornerstone of the HHS IT Strategic Plan.

preamble regarding small sample sizes, usability of plan-specific data, and disclosure of personally identifiable information and protected health information. In addition, stakeholders noted that some cost elements are not tracked separately for each group health plan. Some commenters did, however, identify potential benefits of plan-specific reporting of data. One commenter noted the increased transparency that would result from plans receiving plan-specific information about prescription drugs from PBMs. The commenter also stated that plan-specific reporting would be more valuable for identifying trends than overly aggregated data. Other commenters noted that certain reporting requirements under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act are plan-specific and asserted that aggregated reporting would present operational challenges if, for example, a TPA were the reporting entity for all of the required information and it serviced different types of plans but did not have access to all of the required information for each plan. One commenter had concerns about plans being held responsible for the TPA's or PBM's failure to accurately report aggregated data.

The Departments are of the view that collection of aggregate data will substantially reduce the burdens for both the reporting entities and the federal government. The Departments estimate that reporting every data element separately for each group health plan would require plans and issuers to prepare and submit a combined total of several million reports. In contrast, reporting aggregate data would result in a combined total of approximately 2,000 reports, requiring plans and issuers to spend significantly less effort and fewer resources on calculations, validation, submission, and storage of the data while still providing a sufficiently large data pool from which to identify trends and variations in prescription drug use and costs. To the extent a TPA is the reporting entity for all of the required information for numerous plans but does not have access to all of the required information for each plan, it can either obtain it from the plan or require the plan to submit that information. As noted in this preamble, plans may need to revise their services agreements with TPAs to address liability for and the accuracy of the information that the TPA or PBM reports and the ways in which the plan can review such reporting to confirm its accuracy.

The smaller number of aggregate data reports submitted to the Departments would also reduce the Departments' burden for collecting, storing, securing, and analyzing the data.

For these reasons, these interim final rules require data to be aggregated in the section 204 data submissions for the reference year at the state and market segment levels. This general requirement is being codified at 26 CFR 54.9825–5T(a), 29 CFR 2590.725–3(a), and 45 CFR 149.730(a). Within each state and market segment, the data of fully-insured plans may be aggregated according to the issuer of the coverage provided to these plans or the FEHB carrier, as applicable, that acts as a reporting entity for these plans. The data of self-funded plans may be aggregated according to the TPA that acts as a reporting entity for these plans. The Departments are of the view that overall, aggregation at the reporting entity, state, and market segment level will capture statistics based on sufficiently large pools of underlying data while also providing a sufficient level of detail for the analysis and reporting required under section 9825(b) of the Code, section 725(b) of ERISA, and section 2799A–10(b) of the PHS Act, and is therefore the optimal aggregation level to enable the Departments to draw meaningful conclusions from the data. Aggregation at the state level will allow for the analysis of geographic variations in prescription drug trends. Aggregation at the market segment level will also allow for the analysis of variations in prescription drug trends among certain distinct populations subject to distinct plan and coverage design considerations, such as employees of small and large employers. Aggregation at the reporting entity level will allow for consistency in the data with respect to cost drivers such as negotiated rates for the provider networks used by a particular issuer or TPA, or the formulary design and prescription drug rebate agreements utilized by a particular PBM. For health insurance coverage, aggregation at the reporting entity, state, and market segment levels is also largely consistent with the aggregation rules for the MLR data collection in 45 CFR 158.120, which will minimize the health care spending reporting burden for issuers.

The Departments are of the view that, at this time, the clear benefits of the aggregate data approach outweigh the potential drawbacks. However, the Departments solicit comment on the general use and the specific aspects of this data aggregation approach versus a plan-specific data collection approach. In addition, after the Departments begin to receive section 204 data submissions and have the opportunity to evaluate the efficacy and adequacy of the aggregate data approach, the Departments will further review and analyze the merits of this approach and may modify the approach in future rulemaking if necessary or appropriate.

b. Aggregation by Reporting Entity

The requirements related to aggregation by reporting entity are being codified at 26 CFR 54.9825–5T(b), 29 CFR 2590.725–3(b), and 45 CFR 149.730(b). Specifically, 26 CFR 54.9825–5T(b)(1), 29 CFR 2590.725–3(b)(1), and 45 CFR 149.730(b)(1) provide that if a reporting entity submits data on behalf of more than one group health plan in a state and market segment, the reporting entity may aggregate the data required in 26 CFR 54.9825–6T(b), 29 CFR 2590.725–4(b), and 45 CFR 149.740(b) for the group health plans for each market segment in the state.

As discussed in sections II.C.3.a. and II.B. of this preamble, the Departments intend to make available a data collection system that will allow multiple reporting entities to submit different subsets of the required information for a single plan or issuer. These interim rules at 26 CFR 54.9825–5T(b)(2)(i), 29 CFR 2590.725–3(b)(2)(i), and 45 CFR 149.730(b)(2)(i) provide that if multiple reporting entities submit the required data related to one or more plans or issuers in a state and market segment, the data submitted by each of these reporting entities may not be aggregated at a less granular level than the aggregation level used by the reporting entity that submits the data on total annual spending on health care services in 26 CFR 54.9825–6T(b)(4), 29 CFR 2590.725–4(b)(4), and 45 CFR 149.740(b)(4) on behalf of these plans or issuers. Under this approach, the data may not, for example, be aggregated at a less granular level than the aggregation level used by the issuer providing the coverage to fully-insured plans, the TPA acting as a reporting entity for self-funded plans, or the plan sponsor acting as a reporting entity for the self-funded plans it sponsors.

For example, if a TPA is the reporting entity for the total annual spending on health care data for 20 self-funded plans in a state and market segment and aggregates the data of those plans, and a PBM is the reporting entity for the top 25 list for the same 20 self-funded plans, then the PBM must aggregate the data of only these 20 self-funded plans in the state and market segment to produce the top 25 list for these 20 self-funded

plans. If the PBM also serves as the top 25 list reporting entity for 30 other self-funded plans that utilize a different TPA for the section 204 data submission, then the PBM must additionally aggregate the data of only these 30 other self-funded plans in the state and market segment and produce a separate top 25 list for these 30 self-funded plans. However, the PBM cannot aggregate the data for all 50 self-funded plans to produce and submit a single top 25 list for the state and market segment. Conversely, a single data submission by a TPA may be associated with more than one corresponding data submission by several PBMs if the self-funded group health plans for which the TPA acts as a reporting entity do not all utilize the same PBM. Based on the Departments' estimate, discussed in section V of this preamble, that 473 issuers and 205 TPAs, but only 66 PBMs, will be involved in making section 204 data submissions, the Departments estimate that it is highly likely that a single PBM would submit data that complement data submissions of many issuers and TPAs. As a result, if a PBM aggregated data across multiple issuers and TPAs, this could significantly reduce the consistency between the prescription drug and rebate data submitted by the PBM and the health care spending, premium, and enrollment data submitted by issuers and TPAs. However, based on the estimated number of issuers, TPAs, and PBMs, the Departments anticipate that it is significantly less likely that multiple PBMs would submit data that complement the data submission of a single issuer or TPA. Therefore, the Departments are of the view that the disadvantage of the modest inconsistencies that may result from the approach adopted in these interim final rules is outweighed by the benefit of reduced compliance burdens. The Departments solicit comment on this aggregation approach.

These interim final rules additionally provide that the Departments may specify in guidance alternative or additional aggregation methods for data submitted by multiple reporting entities. In choosing alternative or additional aggregation methods, the Departments will seek to reduce compliance burdens for the reporting entities while ensuring that the aggregated data facilitate the development of the biannual public report required under section 9825(b) of the Code, section 725(b) of ERISA, and section 2799A–10(b) of the PHS Act. For example, the Departments may choose to allow data submitted by affiliated issuers to be aggregated at the holding group level within a state and market segment. Aggregation at the holding group level may further reduce compliance burden, but may obscure differences between different business models, such as preferred provider organizations and health maintenance organizations. The Departments may also choose to allow data submitted by PBMs to be aggregated at a higher level than at the level of each issuer and TPA. Aggregation of prescription drug and rebate data at the PBM level may likewise reduce compliance burdens and may enable more robust trend analysis. However, as discussed previously in this section of this preamble, this approach could significantly reduce the consistency between the prescription drug and rebate data and the health care spending, premium, and enrollment data, potentially impairing some of the analyses the Departments intend to undertake for purposes of the section 204 public report. The Departments will issue any such guidance sufficiently in advance of the data submission deadline to enable plans, issuers, and other reporting entities to adjust their processes. The Departments seek comment on which alternative aggregation methods should be considered and their respective merits and drawbacks.

As noted in section II.C.3.a. of this preamble, data submitted by reporting entities that are issuers, TPAs, or other plan service providers must be aggregated at the state and market segment level. For example, if an issuer is the reporting entity, the issuer must report the data separately for each state where it offered coverage, and within each state must aggregate the data separately for the individual market (excluding student policies), the student market, the fully-insured small group market, the fully-insured large group market (excluding FEHB plans), and the FEHB line of business, as applicable. If the issuer also provides TPA services to self-funded group health plans in the same state, the issuer must additionally aggregate the data separately for all of the self-funded plans offered by small employers and all of the self-funded plans offered by large employers for which the issuer acts as a TPA and as the reporting entity in the state.

In addition, these interim final rules at 26 CFR 54.9825–5T(b)(3), 29 CFR 2590.725–3(b)(3), and 45 CFR 149.730(b)(3) provide that when a group health plan, regardless of funding type, involves health coverage obtained from two affiliated issuers, one, often a health maintenance organization, providing in-network coverage only and the second, usually a preferred provider or similar organization, providing out-of-network coverage only, then for purposes of aggregating data at the reporting entity level, the plan's out-of-network experience may be treated as if it were all related to the contract provided by the in-network issuer. This approach ensures that in this situation the experience of employees of a single employer can be aggregated under a single reporting issuer in the same section 204 data submission, which is a reasonable approach because the coverage is priced and marketed to group health plans as one single product. In addition, this provision enables issuers to leverage existing reporting processes that they use for purposes of MLR reporting under 45 CFR part 158.

The Departments solicit comment on all aspects of the data aggregation by reporting entity approach.

c. Aggregation by State

The provisions related to aggregation by state are being codified at 26 CFR 54.9825–5T(c), 29 CFR 2590.725–3(c), and 45 CFR 149.730(c).

These interim final rules at 26 CFR 54.9825–5T(c)(1), 29 CFR 2590.725–3(c)(1), and 45 CFR 149.730(c)(1) and 26 CFR 54.9825–5T(c)(2), 29 CFR 2590.725–3(c)(2), and 45 CFR 149.730(c)(2) specify, respectively, that for purposes of aggregating data at the state level, the experience of fully-insured coverage must be attributed to the state where the contract was issued, while the experience of self-funded group health plans must be attributed to the state where the plan sponsor has its principal place of business, with certain exceptions. These requirements will ensure consistent reporting across plans, issuers, and other reporting entities, and are similar to the requirements in 45 CFR 158.120 for the MLR data collection. Attribution of experience to a state in this manner, rather than, for example, to the state where the individual obtaining health care services or prescription drugs works or resides, will significantly reduce the reporting burden because the data elements required in these interim final rules generally are not tracked based on the situs of the individual. The Departments are of the view that attribution of experience to a state in this manner is unlikely to significantly affect the data trends at the state level given that the Departments expect most if not all reporting entities to aggregate the required data, which will mitigate the possibility of an outsized impact of any given plan's experience on the top 50 lists and trends in a state.

Individuals sometimes obtain, and employers sometimes provide, health coverage through associations, trusts, or multiple employer welfare arrangements (MEWAs). Coverage issued through an association, but not in connection with a group health plan, is not group health insurance coverage for purposes of the PHS Act and is instead individual market coverage. These interim final rules at 26 CFR 54.9825–5T(c)(3), 29 CFR 2590.725–3(c)(3), and 45 CFR 149.730(c)(3) provide that the experience of individual market business sold through an association must be attributed to the issue state of the certificate of coverage. For employment-based association coverage subject to ERISA, group health plans may exist at the individual employer level (a non-plan MEWA) or at the association level, if the association qualifies as an employer under ERISA section 3(5) (a plan MEWA).[30] These interim final rules at 26 CFR 54.9825–5T(c)(4), 29 CFR 2590.725–3(c)(4), and 45 CFR 149.730(c)(4) provide that the experience of health coverage provided through a group trust or a MEWA must be attributed to the state where the individual employer (if the plan is at the individual employer level) or the association (if the association qualifies as an employer under ERISA section 3(5)), respectively, has its principal place of business or the state where the association is incorporated, if the association has no principal place of business.

These provisions apply in the same manner to group health plans covering employees in multiple states. For example, the experience of a fully-insured group health plan covering employees in multiple states must be attributed to the state in which the contract for health insurance coverage is issued or delivered as stated in the contract (except for coverage provided through an association). If the plan contracted for coverage with a different issuer in each state, then the relevant experience must be attributed to each of these states. Similarly, the experience of a self-funded group health plan providing benefits to employees in multiple states must be attributed to the state in which the plan sponsor has its principal place of business (or, in the case of an association with no principal place of business, the state where the association is incorporated), as applicable.

The Departments solicit comments on all aspects of the data aggregation by state approach.

III. Overview of the Interim Final Rules—Office of Personnel Management

A. Authority for Data Collection

OPM solicited comments on the capability of FEHB carriers to complete this reporting and if there should be any considerations taken into account specific to reporting by FEHB carriers. A few comments raised concerns about OPM's authority to require this reporting or questioned whether it was appropriate to apply section 204 to FEHB carriers.

Under 5 U.S.C. 8910(a), OPM must make a continuing study of the operation and administration of the FEHB Program, including surveys and reports on FEHB plans and on the experience of these plans. Under 5 U.S.C. 8910(b), each contract between OPM and an FEHB carrier must contain provisions requiring carriers to furnish such reasonable reports as OPM deems necessary to carry out its functions under the FEHB Act. Accordingly, OPM's contract with each FEHB carrier requires the carrier to furnish reports that OPM finds necessary to properly administer the FEHB Program.[31] In addition, 5 U.S.C. 8910(c) requires government agencies to furnish OPM with such information and reports as may be necessary to enable OPM to administer the FEHB Program. On the basis of this statutory authority, OPM will require FEHB carriers to report information about pharmacy benefits and health care spending, consistent with section 204 of Title II of Division BB of the CAA and the Departments' interim final rules. In response to comments requesting clarification of carriers' reporting responsibilities, OPM has worked with the Departments to facilitate carriers' reporting by establishing that where an entity does not possess all of the information required to be reported, another reporting entity may be responsible for the data submission on the carriers' behalf. Reporting by FEHB carriers is expected to help accomplish the CAA's intended purposes of achieving national health data transparency and lowering costs both for the FEHB Program and for the health benefits industry.

B. Reporting and Display of Data

Several RFI commenters also raised concerns about duplicative reporting or requested that OPM reconcile its current reporting requirements with any reporting required under section 204 of Title II of Division BB of the CAA. While OPM does require its FEHB carriers to submit certain data directly to OPM, the specific type of reporting diverges from section 204 of Title II of Division BB of the CAA in terms of the nature of the reporting as well as its purpose.

The OPM interim final rules amend existing 5 CFR 890.114(a) to include references to the Department of the Treasury, DOL, and HHS interim final rules to clarify that, pursuant to 5 U.S.C. 8910, FEHB carriers are required to report prescription drug and health care spending as set forth in those regulations with respect to FEHB carriers in the same manner as those provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage, subject to 5 U.S.C. 8902(m)(1) and the provisions of the carrier's contract. As provided at 5 CFR 890.114(f), the OPM Director will coordinate with the Departments in matters regarding FEHB carriers' reporting on prescription drug and health care spending, and with respect to oversight of reporting by FEHB carriers. Carriers must report FEHB plan prescription drug and health care spending data to the Departments as a part of the section 204 collection of information consistent with 45 CFR 149.720. Carriers will need to include the information identified in 45 CFR 149.740 and aggregate the data consistent with 45 CFR 149.730.

Several corrections have been made to 5 CFR 890.114. First, paragraph (a) has been revised to remove inadvertently added cross-references to 26 CFR 54.9816–7T and 29 CFR 2590.716–7, which relate to the Department of the Treasury's and DOL's complaints processes. Second, paragraph (d)(1) has been revised to change the phrase ''intent to initiate'' to ''initiation of'' the Federal IDR process. Third, paragraph (d)(2) has been revised so that cross-references to 26 CFR 54.9816–8T(c)(4)(vi)(A)(*1*), 29 CFR 2590.716–8(c)(4)(vi)(A)(*1*), and 45 CFR 149.510(c)(4)(vi)(A)(*1*) now cite paragraph (vii) instead (vi), and the term ''misrepresentation'' now reads ''material misrepresentation.''

[30] Under ERISA section 3(5), an employer is ''any person acting directly as an employer, or indirectly in the interest of an employer, in relation to an employee benefit plan; and includes a group or association of employers acting for an employer in such capacity.'' For more information, see Multiple Employer Welfare Arrangements under the Employee Retirement Income Security Act (ERISA): A Guide to Federal and State Regulation, available at *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/mewa-under-erisa-a-guide-to-federal-and-state-regulation.pdf*.

[31] In addition to this statutory authority and parallel contract language, FEHB carrier contracts incorporate FEHB regulations found at 5 CFR parts 890 through 894. As part of this rulemaking, OPM amends FEHB regulations to direct carriers to comply with requirements of 45 CFR 149.710 through 149.740.

IV. Waiver of Proposed Rulemaking

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Departments to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and title XXVII of the PHS Act. Consistent with the provisions at section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act, the Secretaries of the Departments and the OPM Director have determined that it is appropriate to issue these interim final rules to enable regulated entities sufficient time to design processes and systems necessary to comply with the data submission requirements of section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act, and to enable the Departments to comply with the public reporting requirements of section 9825(b) of the Code, section 725(b) of ERISA, and section 2799A–10(b) of the PHS Act, as explained further in this section of this preamble. Although these provisions constitute the Departments' primary authority for issuing these interim final rules, the Departments also note that section 553(b) of the Administrative Procedure Act (5 U.S.C. 551, *et seq.*) (APA), provides that a general notice of proposed rulemaking is not required when an agency for good cause finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. In addition, subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act or CRA) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3), 808(2). The Secretaries of the Departments and the OPM Director have determined that these interim final rules meet the exception to the default requirement of notice and comment rulemaking under section 553(b) of the APA. Specifically, the Secretaries of the Departments and the OPM Director have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until a full public notice and comment process has been completed, as explained further in this section of this preamble. The Secretaries of the Departments and the OPM Director also find that there is good cause to waive the delay in effective date for these interim final rules.

The time period between enactment of the CAA and the date by which plans and issuers must comply with the provisions of section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act, as added by the CAA, is insufficient to permit the Departments and OPM to pursue notice and comment rulemaking. The CAA was enacted on December 27, 2020. Section 204 of Title II of Division BB of the CAA requires plans and issuers to begin submitting the required prescription drug and health care spending information to the Departments by December 27, 2021, and to submit this information by June 1 of each year thereafter. Due to the novelty and complexity of the requirements in section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act, the Departments and OPM determined it necessary to issue an RFI to inform the Departments' and OPM's implementation of the statutory requirements through rulemaking. Following an analysis of the statutory provisions, the technical and regulatory issues surrounding the concepts, definitions, and reporting related to prescription drugs, and industry practices related to prescription drug costs and data reporting processes and capabilities, among other things, the Departments and OPM published the RFI on June 23, 2021 with a 30-day comment period.[32]

In their responses to the RFI, regulated entities and other interested parties indicated that they would need significant time to come into compliance after final rules implementing the requirements in section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act are issued. In implementing these requirements, these interim final rules require plans, issuers, and FEHB carriers to establish complex internal data compilation and reporting processes, and may require plans, issuers, FEHB carriers, TPAs, PBMs, and drug manufacturers to modify various contracts and arrangements and to coordinate data compilation and sharing among themselves in order to enable submission of complete and accurate data to the Departments in accordance with the requirements in these interim final rules. All of these entities will require time to implement the changes necessary to comply with these new requirements. In response to the RFI, although several commenters stated that they would be able to submit the required data 6 months after the Departments and OPM published the final rules, the instructions for the information collection instrument, and the technical specifications for the data collection system, the overwhelming majority of commenters advised that they would need 12 months to comply. Commenters advised that they could not begin renegotiating contracts and investing in the necessary IT systems modifications prior to the final rules, the instructions for the information collection instrument, and the technical specifications for the data collection system being issued.

In recognition of stakeholders' concerns about the feasibility of meeting the first two statutory reporting deadlines of December 27, 2021 and June 1, 2022, as discussed in section II.C.1.b. of this preamble, the Departments are exercising discretion to not initiate enforcement actions against plans or issuers that submit the section 204 data submissions for the 2020 and 2021 reference years by December 27, 2022. Although this deferred enforcement may have allowed for the promulgation of regulations with notice and comment before the Departments would consider taking enforcement action, doing so nonetheless would not have provided sufficient time for the regulated entities to come into compliance with the requirements by December 27, 2022. Issuing these rules as proposed rules would have resulted in the final rules and final technical specifications becoming available to the regulated entities no earlier than June 2022, leaving them only 6 months—well short of the 12 months that most commenters advised is necessary—to complete the complex tasks required to come into compliance. In addition, deferred enforcement does not alter the statutory deadlines, and therefore the Departments must promulgate final rules that become effective no later than December 27, 2021, and must promulgate final rules timely to enable plans and issuers to rely on these rules and adhere to the law by the December 27, 2021 and June 1, 2022 statutory deadlines. The Departments strongly encourage plans and issuers that are able to submit the required information by either the December 27, 2021 or June 1, 2022 statutory deadlines to do so.

Further, although deferring enforcement for an additional period of time beyond December 27, 2022 could have provided sufficient time to issue these rules as proposed rules, the Departments are of the view that any additional delays in collecting the

[32] 86 FR 32813.

information required under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act would be inappropriate and contrary to the public interest. First, section 9825(b) of the Code, section 725(b) of ERISA, and section 2799A–10(b) of the PHS Act require the Departments to publish biannual section 204 public reports, with the first such report due no later than 18 months after the date on which the first section 204 data submission is required. Consequently, deferring enforcement further than December 27, 2022 would foreclose the Departments' ability to prepare and timely publish the first section 204 public report. Thus, the Departments are of the view that additional delays related to the section 204 data submissions would risk causing undue and cascading delays in the publication of the section 204 public reports, potentially delaying important legislative and policymaking initiatives that may be spurred by the section 204 public reports and depriving the public of the benefit of any such initiatives. Second, any additional delays related to the section 204 data submissions could require plans and issuers to submit 3, rather than 2, years of data at once (for example, if the Departments were to defer enforcement until June 1, 2023—the statutory deadline for submission of the 2022 data—then plans and issuers would have to submit the data for 2020, 2021, and 2022 by that date). This would place a significant burden on plans and issuers and would lead to lower-quality 2022 data because plans, issuers, and other reporting entities would lose the opportunity to incorporate lessons learned from preparation and submission of the 2020 and 2021 data, and the Departments would lose the ability to provide feedback or guidance to the regulated entities based on challenges or inconsistencies identified in the 2020 and 2021 data submissions.

In addition, the Departments will require time to design, build, and test a fully operational data collection system, which cannot be done prior to the definitions and requirements in these interim final rules being finalized. The reporting entities will in turn require time to familiarize themselves with the data collection system and to adapt their processes to the technical specifications prescribed for the data collection system. Therefore, issuing these rules as interim final rules, rather than as proposed rules, will allow the Departments to develop and operationalize the data collection system and will allow the reporting entities to provide feedback on the design of this system to the Departments and to incorporate the specifications of the data collection system into their processes.

It is therefore necessary, appropriate, and in the public interest that plans, issuers, FEHB carriers, TPAs, PBMs, and the Departments have certainty regarding the standards of these requirements in order to begin implementation. Accordingly, to allow plans, issuers, FEHB carriers, TPAs, PBMs, and the Departments sufficient time to implement these new requirements and any changes necessary to comply with these new requirements, these interim final rules must be published and available to the public well in advance of the December 27, 2022 enforcement date for the initial data collection. Allowing time for a full notice and comment process prior to the requirements taking effect would not provide sufficient time for the reporting entities to comply with the requirements, and would risk collection of inaccurate and low-quality data, thwarting the statute's objective of producing an actionable section 204 public report on prescription drug pricing and its impact on premiums.

Finally, although these interim final rules reflect public comments submitted in response to the RFI, the Departments and OPM intend to expeditiously and thoroughly review and analyze the public comments that will be submitted on the specific provisions of these interim final rules, as well as any additional feedback that may be provided by reporting entities and other stakeholders following publication of these interim final rules and the information collection requirements. The Departments and OPM intend to promptly issue final rules based on these public comments.

For the foregoing reasons, the Departments and OPM have determined that it is necessary, appropriate, and in the public interest to issue these interim final rules to allow regulated entities to timely comply with the statutory data submission requirements. The Departments and OPM have further determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect.

V. Regulatory Impact Analysis

A. Summary

These interim final rules implement the provisions of section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act as enacted by section 204 of Title II of Division BB of the CAA. These provisions are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage. These interim final rules implement section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act, which increase transparency by requiring plans and issuers to annually submit to the Departments information about prescription drugs and health care spending.

Section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act require plans and issuers to submit certain information to the Departments on prescription drug and health care spending, including, but not limited to, average monthly premium amounts (paid by participants, beneficiaries, and enrollees and paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable), and the number of participants, beneficiaries, and enrollees, as applicable, with respect to the plan or coverage in the previous plan year. Additionally, plans and issuers must report prescription drug rebates, fees, and any other remuneration paid by drug manufacturers and any impact on premiums and out-of-pocket costs associated with these rebates, fees, or other remuneration. Pursuant to 5 U.S.C. 8910, OPM is joining 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. The Departments and OPM highlight that nothing prevents a TPA or a PBM from reporting the required information on behalf of plans, issuers, and FEHB carriers, or the subset of the required information that is available to them.

Section 9825(b) of the Code, section 725(b) of ERISA, and section 2799A–10(b) of the PHS Act require the Departments to publish on the internet biannual reports on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under these plans or coverage, aggregated in such a way that no drug or plan specific information is made public.

The Departments and OPM have examined the effects of these interim final rules as required by Executive Order 13563 (76 FR 3821, January 21,

2011, Improving Regulation and Regulatory Review); Executive Order 12866 (58 FR 51735, October 4, 1993, Regulatory Planning and Review); the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354); section 1102(b) of the Social Security Act (42 U.S.C. 1102(b)); section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4); Executive Order 13132 (64 FR 43255, August 10, 1999, Federalism); and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Order 12866 and 13563

Executive Order 12866 directs agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

An RIA must be prepared for major rules with economically significant effects (for example, $100 million or more in any one year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). The Departments anticipate that this regulatory action is likely to have economic impacts of $100 million or more in at least 1 year, and thus meets the definition of a ''significant rule'' under Executive Order 12866. Therefore, the Departments and OPM have provided an assessment of the potential costs, benefits, and transfers associated with these interim final rules. In accordance with the provisions of Executive Order 12866, these interim final rules were reviewed by OMB.

1. Need for Regulatory Action

There is currently limited information available about how prescription drug costs influence premiums and out-of-pocket costs. There is also limited information available on the prescription drug rebates, fees, and other remuneration paid by drug manufacturers to plans and issuers (or to their administrators or service providers) and the impact of these reimbursements on premiums and out-of-pocket costs. The data submission requirements in these interim final rules will provide the Departments and OPM with a better understanding of prescription drug and health care spending in the United States. Further, these interim final rules are necessary to meet the statutory requirements of section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act.

Plans, issuers, FEHB carriers, and other reporting entities will incur costs related to the data submission requirements set forth in these interim final rules. However, in accordance with Executive Order 12866, the Departments determined that the benefits of these interim final rules justify the costs.

2. Summary of Impacts

In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' and OPM's assessment of the benefits, costs, and transfers associated with these interim final rules. The Departments and OPM are unable to quantify all benefits, costs, and transfers associated with these interim final rules but have sought, where possible, to describe these non-quantified impacts below. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the data submission requirements in these interim final rules.

TABLE 1—ACCOUNTING STATEMENT

Benefits:

Qualitative:

- Production of a dataset that satisfies the requirements in section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act and informs the development of the section 204 public reports, which will increase transparency about prescription drugs and health care spending and potentially promote more competitive health care markets.
- The ability of the Departments and OPM to identify the factors contributing to changes in plan expenditures, including prescription drug costs, hospital costs, health care provider and clinical service costs, and other medical costs, which may inform future policymaking that addresses health care costs.
- The ability of the Departments and OPM to identify the most frequently dispensed brand prescription drugs and the most costly prescription drugs covered by plans and issuers and the corresponding expenditures, which may inform future policymaking that addresses prescription drug costs.
- Improved understanding of prescription drug pricing trends by the Departments and OPM.
- Improved understanding by the public and the Departments and OPM of the impact of prescription drug rebates, fees, and other remuneration paid by drug manufacturers to plans, issuers, or FEHB carriers (or to their administrators or service providers) on premiums and out-of-pocket costs.
- Potential to inform Congress and shape future policymaking that could benefit consumers and employers.

Costs	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	$363.63	2021	7	2021–2025
	361.09	2021	3	2021–2025

Quantitative:

Costs	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
• One-time costs to issuers, FEHB carriers, TPAs, and PBMs to design, develop, and implement needed IT systems changes and submit required information, in 2022, estimated to be approximately $1,034 million. • One-time costs to issuers, FEHB carriers, TPAs, and PBMs to update and maintain their IT systems and submit required information in 2023, estimated to be approximately $290 million. • Annual recurring costs to issuers, FEHB carriers, TPAs, and PBMs to maintain their IT systems and report data in 2024, and yearly thereafter, estimated to be approximately $211 million. • One-time costs to issuers, FEHB carriers, TPAs, and PBMs to prepare standard operating procedures and provide training to staff, in 2022, estimated to be approximately $4.7 million. • One-time costs to issuers, FEHB carriers, TPAs, and PBMs to modify existing contracts, in 2022, estimated to be approximately $8 million. • Costs to the federal government to build and maintain a system to receive, store, and analyze data submitted by issuers, FEHB carriers, TPAs, and PBMs, and to prepare section 204 reports, of approximately $4.4 million in 2021, $8.5 million in 2022, $7.3 million in 2023, $7.4 million in 2024, and $7.9 million in 2025.				
Transfers:				
Non-Quantified: • Potential transfers from providers, facilities, pharmaceutical manufacturers, and PBMs to plans, issuers, and FEHB carriers if plans, issuers, and FEHB carriers are able to achieve greater negotiating power due to improved understanding of prescription drug costs.				

a. Benefits

The reporting requirements in these interim final rules will lead to the development of a dataset that satisfies the requirements in section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act. This dataset will inform the development of the biannual section 204 public reports by the Departments regarding prescription drug and health care spending.

The prescription drug and health care spending data collection and the resultant section 204 public reports will benefit plans, issuers, FEHB carriers, employers, and policymakers by advancing their understanding of prescription drug costs and the impact of prescription drug rebates, fees, and other remuneration on premiums and out-of-pocket costs. Consumers could potentially benefit from the section 204 public reports if plans, issuers, and FEHB carriers are able to negotiate lower prescription drug prices and those reductions are passed on to the consumer in the form of reduced out-of-pocket costs and lower premiums. The section 204 data submissions will allow the Departments and OPM to identify the most frequently dispensed brand prescription drugs and the costliest prescription drugs covered by plans, issuers, and FEHB carriers along with the prescription drugs that have contributed to the greatest annual increases in plan expenditures, and the prescription drugs that have generated the highest prescription drug rebates, fees, and other remuneration. These reports will provide the Departments and OPM with an improved understanding of prescription drug costs. The dataset will also allow the Departments and OPM to identify other major drivers of increases in health care spending, including hospital costs, primary and specialty health care provider and clinical service costs, and other medical costs. The data may also allow the Departments and OPM to examine variation in health care costs across the country.

Policymakers will be able to use the information provided in the section 204 public reports to set policies that may result in lower premiums, reduced out-of-pocket costs, and decreased labor costs. Policymakers will also be able to use this information to set policies that may promote transparency and more competition in health care and prescription drug markets, consistent with the goals of Executive Order 14036.

b. Costs

The Departments and OPM estimate the burden to report the information will be the time and effort necessary for plans, issuers, FEHB carriers, and other reporting entities to submit the required information in the required format to the Departments. The Departments and OPM assume that issuers, TPAs, and PBMs will submit the required information on behalf of group health plans or FEHB carriers. The Departments and OPM acknowledge that TPAs and PBMs are likely to pass on any related costs to plans, issuers, and FEHB carriers. The Departments and OPM estimate there are 473 health insurance issuers offering individual and group health insurance,[33] 205 TPAs [34] (generally submitting on behalf of self-funded group health plans), 46 FEHB carriers, and 66 PBMs [35] (submitting on behalf of plans, issuers, and FEHB carriers) that will submit the required information annually. The Departments and OPM assume that all costs will be incurred in 2022 and beyond, since reporting entities are unlikely to begin implementation in the last month of 2021. The costs related to these information collection requirements are estimated to be $1,033,758,440 in 2022, $289,786,640 in 2023, and $211,128, 360 in 2024 and onward, as discussed in detail later in section V.D. (Paperwork Reduction Act) of this preamble. These total costs have a tendency toward overestimation because the estimate does not reflect process efficiencies for FEHB carriers that are also issuers.

Issuers, FEHB carriers, TPAs, and PBMs will incur additional costs related to the data submission. To estimate these costs, the Departments and OPM used data from the Bureau of Labor Statistics (BLS) to derive average labor costs (including a 100 percent increase for fringe benefits and overhead).[36] As explained in section V.D.1. (Paperwork Reduction Act) of this preamble, the Departments and OPM used a different data set to estimate costs related to the information collection requirements.

[33] Based on data from MLR annual reports for the 2019 MLR reporting year, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[34] Estimates for Non-issuer TPAs are based on data derived from the 2016 Benefit Year reinsurance program contributions.

[35] Source: National Association of Insurance Commissioners, last updated on March 16, 2021. Available at *https://content.naic.org/cipr_topics/topic_pharmacy_benefit_managers.htm.*

[36] May 2020 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates, available at *https://www.bls.gov/oes/current/oes_nat.htm.*

TABLE 2—ADJUSTED HOURLY WAGE RATES

Occupation title	Occupational code	Mean hourly wage ($/hour)	Fringe benefits and overhead ($/hour)	Adjusted hourly wage ($/hour)
Chief Executives	11–1011	$95.12	$95.12	$190.24
General and Operations Managers	11–1021	60.45	60.45	120.90
Computer and Information Systems Managers	11–3021	77.76	77.76	155.52
Lawyers	23–1011	71.59	71.59	143.18
Paralegals and Legal Assistants	23–2011	27.22	27.22	54.44
Executive Secretaries and Executive Administrative Assistants	43–6011	31.36	31.36	62.72
Legal Secretaries and Administrative Assistants	43–6012	25.36	25.36	50.72
Business Operations Specialists	13–1198	40.53	40.53	81.06
Computer Programmers	15–1251	45.98	45.98	91.96
Secretaries and Administrative Assistants	43–6014	19.43	19.43	38.86

Issuers, FEHB carriers, TPAs, and PBMs will incur costs associated with contract modifications regarding these reporting requirements. The Departments and OPM assume that each of the 473 issuers, 46 FEHB carriers, and 205 TPAs will need to modify or enter into contracts with PBMs for the PBMs to provide information on prescription drug rebates, or other required information, that is generally maintained primarily by PBMs. The Departments and OPM estimate that a total of 724 contracts will be modified. The Departments assume that the contract modifications will involve the time of chief executives, general and operations managers, lawyers, paralegals and legal assistants, executive secretaries and executive administrative assistants, and legal secretaries and administrative assistants from both entities. The adjusted hourly wages (which incorporate a 100 percent markup for fringe benefits and overhead costs) for those involved in contract modifications are presented in Table 2.

The Departments and OPM estimate that in order to negotiate contract revisions between issuers, FEHB carriers, TPAs, and their PBMs, for each issuer, FEHB carrier, TPA, and PBM, a chief executive will need 1 hour, general and operations managers will need 2 hours, lawyers will need 20 hours, paralegals will need 20 hours, administrative assistants will need 2 hours, and legal secretaries will need 20 hours for a total of 65 hours, at a cost of approximately $5,524 for each entity negotiating a contract revision. The total burden related to each contract negotiation between issuers, FEHB carriers, TPAs, and their PBMs is estimated to be 130 hours, with an associated cost of approximately $11,049. The total burden for all 724 contract modifications is estimated to be approximately 94,120 hours, with an associated cost of approximately $7,999,157.[37] The Departments and OPM assume that this cost will be incurred in 2022. The calculations and the total burden and cost associated with these contract modifications are presented in Table 3. The Departments and OPM seek comment on these estimates.

TABLE 3—BURDEN AND COSTS TO ISSUERS, FEHB CARRIERS, TPAS, AND PBMS ASSOCIATED WITH CONTRACT MODIFICATIONS

Occupation	2022		
	Adjusted hourly wage ($/hour)	Time (hours)	Estimated labor cost
Chief Executives	$190.24	1	$190.24
General and Operations Managers	120.90	2	241.80
Lawyers	143.18	20	2,863.60
Paralegals and Legal Assistants	54.44	20	1,088.80
Executive Secretaries and Executive Administrative Assistants	62.72	2	125.44
Legal Secretaries and Administrative Assistants	50.72	20	1,014.40
Burden and Cost for Each Issuer, FEHB Carrier, TPA, and PBM		65	5,524.28
Total Burden and Cost for Each Contract Negotiation Between an Issuer, FEHB Carrier, or TPA and Their PBM		130	11,048.56
Total Burden and Cost for All Contract Negotiations		94,120	7,999,157.44

[37] The total hour burden and equivalent cost of burden were calculated as follows: Burden Hours per Contract Modification × Number of Contract Modifications = Total Burden Hours (130 × 724 = 94,120); Total Cost per Contract Modification × Number of Contract Modifications = Equivalent Total Cost ($11,049 × 724 = $7,999,157).

All reporting entities will incur costs associated with developing standard operating procedures and training staff responsible for submitting the required data. The Departments and OPM assume that each of the 473 issuers, 46 FEHB carriers, 205 TPAs, and 66 PBMs will require the time of general and operations managers, computer and information systems managers, business operation specialists, computer programmers, and secretaries and administrative assistants to develop new standard operating procedures and deliver or receive training. The adjusted hourly wages for those involved in these changes in standard operating procedures and training requirements are presented in Table 2.

The Departments and OPM estimate that for each issuer, FEHB carrier, TPA, and PBM, it will take 8 hours for general managers, 8 hours for information system managers, 40 hours for business operation specialists, 4 hours for computer programmers, and 4 hours for administrative assistants to prepare new standard operating procedures and train staff regarding the data submission requirements. The total burden for each issuer, FEHB carrier, TPA, and PBM will be 64 hours with an associated cost of approximately $5,977. The total estimated burden of changing standard operating procedures and training staff for all 790 issuers, FEHB carriers, TPAs, and PBMs is 50,560 hours, with an associated equivalent cost of $4,721,862.[38] The Departments and OPM assume that this cost will be incurred in 2022. The calculations and the total burden and cost associated with developing standard operating procedures and training staff are presented in Table 4. The Departments and OPM seek comment on these estimates.

TABLE 4—BURDEN AND COSTS TO ISSUERS, FEHB CARRIERS, TPAS, AND PBMS ASSOCIATED WITH DEVELOPING STANDARD OPERATING PROCEDURES AND TRAINING STAFF

Occupation	2022		
	Adjusted hourly wage ($/hour)	Time (hours)	Estimated labor cost
General and Operations Managers	$120.90	8	$967.20
Computer and Information Systems Managers	155.52	8	1,244.16
Project Management Specialists and Business Operations Specialists, All Other	81.06	40	3,242.40
Computer Programmers	91.96	4	367.84
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	38.86	4	155.44
Burden and Cost for Each Issuer, FEHB Carrier, TPA, and PBM		64	5,977.04
Total Burden and Cost Associated with Developing Standard Operating Procedures and Training Staff		50,560	4,721,861.60

The federal government will incur costs of approximately $4.4 million in 2021, $8.5 million in 2022, $7.3 million in 2023, $7.4 million in 2024, and $7.9 million in 2025 to build and maintain a system to receive and store the information submitted by issuers, FEHB carriers, TPAs, and PBMs, to analyze the data, and to prepare section 204 public reports.

c. Transfers

These interim final rules could potentially lead to transfers from providers, facilities, pharmaceutical manufacturers, and/or PBMs to plans, issuers, and FEHB carriers if plans, issuers, and FEHB carriers are able to achieve greater negotiating power because of improved understanding of prescription drug costs. If consumers are able to make informed plan selections or prescription drug purchases in response to improved understanding of prescription drug costs (including trends in prescription drug prices and the impact of pharmaceutical manufacturer rebates, fees, and other remuneration on premiums and out-of-pocket costs), these interim final rules could also potentially lead to transfers from pharmaceutical manufacturers, PBMs, and/or plans, issuers, and FEHB carriers to consumers in the form of lower prescription drug prices. The Departments and OPM seek comment on any potential transfers that may occur as a result of the data submission requirements in these interim final rules.

C. Regulatory Alternatives

In developing these interim final rules, the Departments considered various alternative approaches.

Aggregation. The Departments and OPM considered requiring plans, issuers, and FEHB carriers to submit all of the required information on a plan-by-plan basis, rather than allowing reporting entities to submit aggregated data. However, as explained in section II.C.3. of this preamble, this approach would impose a large administrative burden on regulated entities and would also result in less accurate and meaningful top 50 and top 25 lists, which would inhibit the Departments' ability to produce accurate and meaningful section 204 public reports as required by the statute. Collecting the top 50 lists separately for each group health plan could produce a distorted view of the market due to the small sample sizes that would underlie these top 50 lists, and due to the Departments' inability to combine data from such plan-specific top 50 lists to determine aggregate prescription drug and rebate trends nationwide and within market segments. Collecting the top 25 rebate list for each group health plan would produce an inaccurate view of rebates, fees, and other remuneration as these rebates are not provided at the individual prescription level, and often not even at the plan level; thus, TPAs and issuers would have to speculate as to actual amounts of rebates and any price concessions for each plan. In addition, this approach would be inconsistent with the approach taken in other HHS data collections. Further, collecting plan-level, drug-specific data would increase the likelihood of collecting and transmitting patient health data and personally identifiable information, and the attendant risk of inadvertent or inappropriate disclosure of this information.

[38] The total hour burden and equivalent cost of burden were calculated as follows: Burden Hours per Entity × Number of Entities = Total Burden Hours (64 × 790 = 50,560); Total Cost per Entity × Number of Entities = Equivalent Total Cost ($5,977 × 790 = $4,721,862).

However, as noted in section II.C.3. of this preamble, the Departments and OPM will continue to review the merits of this alternative approach and may modify the approach to aggregation in future rulemaking.

Plan Year. The Departments and OPM considered requiring plans, issuers, and FEHB carriers to submit the required data by plan or coverage year determined according to the effective dates of each plan or policy. However, this approach is inconsistent with other HHS data collections and would limit the Departments' ability to compare trends among group and individual market segments, public- and private-sponsored health coverage, and multiple data sources. Evaluation of market trends is important both for policy development and for the required section 204 public report.

Definition of Drug. The Departments and OPM considered several different classification systems to define a drug for the purposes of section 204 data submissions. The NDC is very granular, containing information on the labeler, active ingredient, form, strength, and packaging of drugs, and would provide robust information if the Departments could collect data for every code. However, section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act give the Departments authority to collect only the information on the top 50 or top 25 drugs, as applicable, by plan or coverage. Given this limited scope of the data collection, a lower level of granularity is preferable for obtaining the most representative information possible, since multiple variations of essentially the same drug [39] are unique NDCs. With access to only the top 50 NDCs, the Departments therefore would not have the data for all NDCs associated with a given prescription drug, and thus would not be able to consolidate the NDC information to identify meaningful trends in the prescription drug markets. The Departments and OPM also considered using the RxNorm Concept Unique Identifier (RxCUI), which is slightly less granular than the NDC, but RxCUI-level data collection suffers from many of the same limitations as NDC-level data collection, and commenters responding to the RFI overwhelmingly advised against collecting the data based on RxCUI because it is not widely used by reporting entities. Instead, many public reports, such as the 2020 Report to Congress on Prescription Drug Pricing prepared by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE),[40] use a name and ingredient system that identifies drugs at a higher level, rather than granular systems such as NDC or RxCUI, to compare drug information across markets and across time. Most commenters responding to the RFI also recommended the use of a classification that would ensure that the same drug in various formulations or dosages would not appear on the top 50 lists multiple times, such as a classification based on name and ingredient. Ultimately, the Departments and OPM determined that the most useful data would be collected if prescription drug information is grouped by name and ingredient.

Most Costly Drugs. The Departments and OPM considered requiring plans, issuers, and FEHB carriers to rank the 50 most costly drugs based on spending per dosage unit rather than based on total annual spending. Per-unit spending would reflect drug prices and capture in the top 50 list the cost of the drug without the influence of the number of times a drug was prescribed. In contrast, total spending may capture the top 50 list inexpensive generic drugs that are frequently prescribed and purchased. However, the statutory language suggests that in the section 204 data submission requirements, Congress sought to identify the drugs that drive the overall prescription drug expenditure in the United States, rather than the drugs with the highest unit prices. Ranking the top 50 most costly drugs by total annual spending will provide a more informative comparison to the top 25 drugs that yielded the highest amount of prescription drug rebates because both lists would be based on total, rather than per-unit, dollar amounts.

Leveraging Similar Data Collections under the PHS Act. The Departments analyzed the reporting requirements under several existing PHS Act provisions related to prescription drug and health care spending to determine whether any of the data required under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act are already available to the Departments pursuant to other reporting requirements. The data collection requirements under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act have some similarities to the requirements under section 2718(a) of the PHS Act implemented in the MLR rules,[41] as well as section 1150A of the Social Security Act, which is implemented in the Exchange Establishment rule and the PBM Transparency rule. However, there are several important distinctions.

Section 2718(a) of the PHS Act addresses clear accounting for the costs of health insurance coverage, including health care spending, and generally requires issuers to submit annual MLR reports to HHS. HHS implemented these reporting requirements in the MLR rules, codified at 45 CFR part 158. Similar to section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act, the MLR rules require issuers to report data on premiums [42] and claims, including prescription drug claims and rebates.[43] However, unlike the requirements in section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act, the MLR rules do not require that premiums be broken down by amounts paid by employers versus employees; do not break down health care spending costs, other than prescription drug costs, by type; do not break down prescription drug costs by amounts paid by the plan or issuer versus participants, beneficiaries, and enrollees; and do not require reporting of drug-level prescription drug and rebate data. Therefore, while the total amounts for certain items reported under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act and the MLR rules may match, the amounts currently reported by issuers under the MLR rules cannot be used to satisfy all of the relevant requirements of section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act. Additionally, the MLR rules do not apply to self-funded group health plans (although issuers report certain aggregate information with respect to the experience of self-funded group health plans for which issuers provide administrative services), and data attributable to FEHB plans is not separated out under the MLR rules.

Section 1150A of the Social Security Act requires a health benefit plan or a PBM that manages prescription drug coverage under a contract with a QHP issuer to provide certain prescription drug information to the Secretary of

[39] This characterization is used only for purposes of these interim final rules and is not intended to reflect or suggest any such characterization by FDA.

[40] *https://aspe.hhs.gov/system/files/aspe-files/263451/2020-drug-pricing-report-congress-final.pdf.*

[41] 75 FR 74863 (Dec. 1, 2010); *see also* 76 FR 76573 (Dec. 7, 2011), 77 FR 28790 (May 16, 2012), 78 FR 15409 (Mar. 11, 2013), 79 FR 30339 (May 27, 2014), 80 FR 10749 (Feb. 27, 2015), 85 FR 29164 (May 14, 2020), 86 FR 24140 (May 5, 2021).

[42] 45 CFR 158.130.

[43] 45 CFR 158.140.

HHS.[44] This information includes: (a) The percentage of prescriptions dispensed through retail versus mail order pharmacies; (b) the percentage of prescriptions for generic drugs; (c) the amount and type of rebates, discounts, or price concessions (excluding bona fide service fees) that the PBM negotiates that are attributable to utilization under the plan; (d) the amount of rebates, discounts, or price concessions passed through to the plan sponsor; (e) the total number of prescriptions that were dispensed; and (f) the difference between the amount that the plan pays the PBM and the amount that the PBM pays pharmacies. HHS implemented these reporting requirements as they apply to QHP issuers in the Exchange Establishment rule,[45] and implemented these reporting requirements as they apply to PBMs in the PBM Transparency rule.[46]

Section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act, the Exchange Establishment rule, and the PBM Transparency rule require issuers to report some of the same information regarding prescription drug rebates. However, section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act apply to all plans and issuers, whereas the Exchange Establishment rule and the PBM Transparency rule only apply to individual and small group market QHPs and their PBMs. Therefore, reporting under the Exchange Establishment rule and PBM Transparency rule will not fully satisfy the relevant requirements of section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act. However, as discussed in section II.C.2.e. of the preamble, to reduce reporting burden, these interim final rules align collection of certain data elements in the section 204 data submissions with the data elements collected under the Exchange Establishment rule and the PBM Transparency rule.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (PRA), the Departments and OPM are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. These interim final rules contain information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 18. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Departments and OPM solicit comment on:

- The need for the information collection and its usefulness in carrying out the proper functions of the agency;
- The accuracy of the Departments' estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The Departments and OPM are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following ICRs.

Contemporaneously with the publication of these interim final rules, HHS has submitted a request for a new ICR containing the information collection requirements for the prescription drug and health care spending requirements created by section 204 of Title II of Division BB of the CAA. HHS has requested emergency review and approval in accordance with 5 CFR 1320.13(a)(2)(i) and (iii) of the PRA. The Secretaries of the Departments and the OPM Director have determined that public harm is likely to result and the collection of information is likely to be delayed if normal clearance procedures are followed. The ICR will be available at *https://www.RegInfo.gov.*

The Departments and OPM will be requesting approval of the emergency review requests by the effective date of these interim final rules. The Departments and OPM will be seeking approval for the ICRs for 180 days, the maximum allowed for an ICR approved using an emergency review. These interim final rules also serve as the notice providing the public with a 60-day period to submit written comments on the ICRs as part of the normal clearance process under the PRA.

1. Wage Estimates

The Departments and OPM have chosen to use the Contract Awarded Labor Category (CALC) [47] database tool to derive the hourly rates for the burden and cost estimates in these interim final rules to derive estimates of costs related to the ICR. The Departments and OPM chose to use wages derived from the CALC database because, even though the BLS data set is valuable to economists, researchers, and others that would be interested in larger, more macro-trends in parts of the economy, the CALC data set is meant to help market research based on existing government contracts in determining how much a project/product will cost based on the required skill sets needed and it includes some occupation types that are not available in the BLS data set.

[44] QHPs are offered in the individual and small group markets. Section 1150A(a) of the Social Security Act also applies to Medicare Part D plans and Medicare Advantage plans offering a prescription drug plan, and PBMs that manage prescription drug coverage under contract with a prescription drug plan sponsor of a prescription drug plan or a Medicare Advantage organization offering a Medicare Advantage prescription drug plan.

[45] 77 FR 18308 (Mar. 27, 2012).

[46] 86 FR 24140 (May 5, 2021).

[47] The CALC tool (*https://calc.gsa.gov/*) was built to assist acquisition professionals with market research and price analysis for labor categories on multiple U.S. General Services Administration (GSA) & Veterans Administration (VA) contracts. Wages obtained from the CALC database are fully burdened to account for fringe benefits and overhead costs.

TABLE 5—CALC HOURLY WAGES USED IN BURDEN ESTIMATES

Occupation:	Hourly wage rate
Project Manager/Team Lead	$110
Scrum Master	110
Senior Business Analysis	134
Technical Architect/Sr. Developer	207
DevOps Engineer/Security Engineer	143
Application Developer	111

2. ICRs Regarding Reporting of Prescription Drug and Health Care Spending (45 CFR 149.720, 149.730, and 149.740)

As discussed in section II.C. of this preamble, section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A–10(a) of the PHS Act require plans and issuers to annually submit to the Departments certain information about prescription drugs and health care spending, including, but not limited to, average monthly premium amounts, and the number of participants, beneficiaries, and enrollees, as applicable, with respect to the plan or coverage in the previous plan year. In these interim final rules, OPM also directs FEHB carriers to comply with these requirements with respect to an FEHB plan in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage. The burden estimates are based on the expected time and effort for reporting entities to prepare and submit the required data. The Departments assume that for self-funded group health plans, the costs will be incurred by TPAs and that prescription drug information will be submitted by PBMs on behalf of plans and issuers. Costs incurred by TPAs and PBMs are likely to be passed on to plans, issuers, and FEHB carriers. The Departments acknowledge that some large self-funded plans may seek to make needed IT changes and report the required information to HHS without the use or assistance of a TPA or other third-party entity. In those instances, the self-funded plan will directly incur the burden and cost to meet the requirements of these interim final rules. The Departments are unable to determine how many self-funded plans may choose to develop their IT systems and report the required information to HHS and seek comment as to the number of plans that may choose to do so. The Departments assume that all costs will be incurred in 2022 and beyond.

The Departments and OPM estimate there are 473 issuers and 46 FEHB carriers offering group and individual and health insurance coverage, 205 TPAs (generally on behalf of self-funded group health plans), and 66 PBMs (on behalf of plans, issuers, and FEHB carriers) that will submit the required data annually.

In 2022, reporting entities will incur a one-time cost to make changes to their IT systems to include the development of programs, processes, and systems for reporting the data. In 2023 and beyond, each entity will incur annual costs to update and maintain reporting capabilities and to report the required data to the Departments.

For issuers and FEHB carriers, the Departments and OPM estimate that in 2022, each issuer and FEHB carrier will incur a one-time first-year cost and hour burden to design, develop, and implement needed IT systems changes to collect and submit the required data to the Departments as set forth in these interim final rules, including obtaining employer and employee premium contributions from employers providing group health coverage. The Departments and OPM estimate that for each issuer and FEHB carrier, on average, it will take Project Managers/Team Leads 2,080 hours (at $110 per hour), Scrum Masters 1,560 hours (at $110 per hour), Senior Business Analysts 1,040 hours (at $134 per hour), Technical Architects/Sr. Developers 2,080 hours (at $207 per hour), Application Developers 2,080 hours (at $111 per hour), and DevOps Engineers/Security Engineers 520 hours (at $143 per hour) to complete this task. The Departments and OPM estimate the total burden per issuer will be approximately 9,360 hours, with an equivalent cost of approximately $1,275,560. For all 519 issuers and FEHB carriers, the total first-year burden is estimated to be 4,857,840 hours with an equivalent total cost of approximately $662,015,640.[48]

[48] Calculation of totals was done as follows: Burden Hours per Respondent × Number of Respondent = Total Burden Hours (9,360 × 519 = 4,857,840). Total Cost per Respondent × Number of Respondents = Total Cost ($1,275,560 × 519 = $662,015,640).

TABLE 6—ESTIMATED TOTAL FIRST-YEAR COST AND HOUR BURDEN FOR ISSUERS AND FEHB CARRIERS TO DESIGN, DEVELOP AND IMPLEMENT NEEDED IT SYSTEM CHANGES AND SUBMIT REQUIRED DATA

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
519	519	9,360	4,857,840	$662,015,640

In addition to the one-time first-year cost and burden estimated in the previous section of this preamble, issuers and FEHB carriers will incur an additional one-time cost and burden in the second year of implementation to maintain and update their IT systems and to submit the required data to the Departments. The Departments and OPM estimate that for each issuer and FEHB carrier it will take Project Managers/Team Leads 520 hours (at $110 per hour), Scrum Masters 260 hours (at $110 per hour), Senior Business Analysts 260 hours (at $134 per hour), Technical Architects/Sr. Developers 520 hours (at $207 per hour), Application Developers 520 hours (at $111 per hour), and DevOps Engineers/Security Engineers 260 hours (at $143 per hour) to perform these tasks. The Departments and OPM estimate the total second-year burden for each issuer will be 2,340 hours, with an equivalent cost of approximately $323,180. For all 519 issuers and FEHB carriers, the total one-time second-year implementation and reporting burden is estimated to be 1,214,460 hours with an equivalent total cost of approximately $167,730,420. The cost and burden associated with the second year will be incurred in 2023.[49]

TABLE 7—ESTIMATED ONE-TIME SECOND-YEAR COST AND HOUR BURDEN FOR ISSUERS AND FEHB CARRIERS TO UPDATE AND MAINTAIN IT SYSTEMS AND SUBMIT REQUIRED DATA

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
519	519	2,340	1,214,460	$167,730,420

In addition to the one-time first-year and second-year costs and burdens estimated earlier in this section of this preamble, issuers and FEHB carriers will incur ongoing annual costs, to be incurred from 2024 onward, related to ensuring submission accuracy, providing quality assurance, conducting maintenance and making updates, enhancing or updating any needed security measures, and submitting the required data to the Departments. The Departments and OPM estimate that for each issuer and FEHB carrier it will take Project Managers/Team Leads 520 hours (at $110 per hour), Scrum Masters 260 hours (at $110 per hour), Senior Business Analyst 40 hours (at $134 per hour), Technical Architects/Sr. Developers 520 hours (at $207 per hour), Application Developers 260 hours (at $111 per hour), and DevOps Engineers/Security Engineers 260 hours (at $143 per hour) to perform these tasks. The total annual burden for each issuer and FEHB carrier will be 1,860 hours, with an equivalent cost of approximately $264,840. For all 519 issuers and FEHB carriers, the total annual maintenance and reporting burden is estimated to be 965,340 hours with an equivalent total cost of approximately $137,451,960.[50] The Departments and OPM consider this to be an upper-bound estimate and expect maintenance costs to decline in succeeding years as issuers gain efficiencies and experience in updating, managing, and submitting the required data.

TABLE 8—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR MAINTENANCE AND REPORTING FOR ALL ISSUERS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
519	519	1,860	965,340	$137,451,960

The Departments and OPM estimate the three-year average annual total burden for all 519 issuers and FEHB carriers to develop, build, and maintain needed IT systems changes to collect and aggregate the required data, and submit that data to the Departments, will be 2,345,880 hours with an average annual total cost of $322,399,340. The total annual burden for all respondents is likely overestimated because the estimate does not reflect process efficiencies for FEHB carriers that are also issuers. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately 1,055,646 burden hours with an equivalent cost of approximately $145,079,703. The Departments and OPM seek comment on these estimates.

[49] Calculation of totals was done as follows: Burden Hours per Respondent × Number of Respondent = Total Burden Hours (2,340 × 519 = 1,214,460). Total Cost per Respondent × Number of Respondents = Total Cost ($323,180 × 519 = $167,730,420).

[50] Calculation of totals was done as follows: Burden Hours per Respondent × Number of Respondent = Total Burden Hours (1,860 × 519 = 965,340). Total Cost per Respondent × Number of Respondents = Total Cost ($264,840 × 519 = $137,451,960).

TABLE 9—ANNUAL BURDEN FOR ISSUERS AND FEHB CARRIERS IN THE INDIVIDUAL AND GROUP MARKETS

	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total estimated annual burden (hours)	Total estimated labor cost ($)
2022	234	234	9,360	2,186,028	$297,907,038
2023	234	234	2,340	546,507	75,478,689
2024	234	234	1,860	434,403	61,853,382
Three-year average	234	234	4,520	1,055,646	145,079,703

For TPAs, the Departments and OPM estimate that in 2022, each TPA will incur a one-time first-year cost and burden to design, develop, and implement needed IT systems changes to collect and submit, generally on behalf of self-funded group health plans, the data required under these interim final rules, including obtaining employer and employee premium contributions from employers providing group health coverage. The Departments and OPM estimate that for each TPA, on average, it will take Project Managers/Team Leads 2,080 hours (at $110 per hour), Scrum Masters 1,560 hours (at $110 per hour), Senior Business Analysts 1,040 hours (at $134 per hour), Technical Architects/Sr. Developers 2,080 hours (at $207 per hour), Application Developers 2,080 hours (at $111 per hour), and DevOps Engineers/Security Engineers 520 hours (at $143 per hour) to complete this task. The Departments and OPM estimate the total burden per TPA will be approximately 9,360 hours, with an equivalent cost of approximately $1,275,560. For all 205 TPAs, the total one-time first-year implementation and reporting burden is estimated to be 1,918,800 hours with an equivalent total cost of approximately $261,489,800.[51]

TABLE 10—ESTIMATED TOTAL ONE-TIME FIRST-YEAR COST AND HOUR BURDEN FOR TPAS TO DESIGN, DEVELOP, AND IMPLEMENT NEEDED IT SYSTEMS CHANGES AND SUBMIT REQUIRED DATA

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
205	205	9,360	1,918,800	$261,489,800

In addition to the one-time first-year cost and burden estimated in the previous section of this preamble, TPAs will incur an additional one-time cost and burden in the second year of implementation to maintain and update their IT systems and to submit the data to the Departments. The Departments and OPM estimate that for each TPA it will take Project Managers/Team Leads 520 hours (at $110 per hour), Scrum Masters 260 hours (at $110 per hour), Senior Business Analysts 260 hours (at $134 per hour), Technical Architects/Sr. Developers 520 hours (at $207 per hour), Application Developers 520 hours (at $111 per hour), and DevOps Engineers/Security Engineers 260 hours (at $143 per hour) to perform these tasks. The total second-year burden for each TPA will be 2,340 hours, with an equivalent cost of approximately $323,180. For all 205 TPAs, the total one-time second-year implementation and reporting burden is estimated to be 479,700 hours with an equivalent total cost of approximately $66,251,900.[52] The cost and burden associated with the second year will be incurred in 2023.

TABLE 11—ESTIMATED ONE-TIME SECOND-YEAR COST AND HOUR BURDEN FOR TPAS TO UPDATE AND MAINTAIN IT SYSTEMS AND SUBMIT REQUIRED DATA

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
205	205	2,340	479,700	$66,251,900

In addition to one-time first-year and second-year costs and burdens estimated in the previous sections of this preamble, TPAs will incur ongoing annual costs, in 2024 and subsequent years, related to ensuring submission accuracy, providing quality assurance, conducting maintenance and making updates, enhancing or updating any needed security measures, and submitting the required data to the Departments. The Departments and OPM estimate that for each TPA it will take Project Managers/Team Leads 520 hours (at $110 per hour), Scrum Masters 260 hours (at $110 per hour), Senior Business Analysts 40 hours (at $134 per hour), Technical Architects/Sr. Developers 520 hours (at $207 per hour), Application Developers 260 hours (at $111 per hour), and DevOps Engineers/Security Engineers 260 hours (at $143 per hour) to perform these tasks. The total annual burden for each TPA will be 1,860 hours, with an equivalent cost of approximately $264,480. For all 205 TPAs, the total

[51] Calculation of totals was done as follows: Burden Hours per Respondent × Number of Respondent = Total Burden Hours (9,360 × 205 = 1,918,800). Total Cost per Respondent × Number of Respondents = Total Cost ($1,275,560 × 205 = $261,489,800).

[52] Calculation of totals was done as follows: Burden Hours per Respondent × Number of Respondent = Total Burden Hours (2,340 × 205 = 479,700). Total Cost per Respondent × Number of Respondents = Total Cost ($323,180 × 205 = $66,251,900).

annual ongoing maintenance and reporting burden is estimated to be 381,300 hours with an equivalent total cost of approximately $54,292,200.[53] The Departments and OPM consider this to be an upper-bound estimate and expect maintenance costs to decline in succeeding years as issuers gain efficiencies and experience in updating, managing, and submitting the required data.

TABLE 12—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR MAINTENANCE AND REPORTING FOR ALL TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
205	205	1,860	381,300	$54,292,200

The Departments and OPM estimate the 3-year average annual total burden for all 205 TPAs to develop, build, and maintain needed IT systems changes to collect and aggregate the required data, and submit that data to the Departments, will be 926,600 hours with an average annual total cost of $127,344,633. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately 416,970 burden hours with an equivalent cost of approximately $57,305,085. The Departments and OPM seek comment on these burden estimates.

TABLE 13—ANNUAL BURDEN FOR TPAS TO DEVELOP AND MAINTAIN NEEDED IT SYSTEMS CHANGES AND SUBMIT REQUIRED DATA

	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total estimated annual burden (hours)	Total estimated labor cost ($)
2022	92	92	9,360	863,460	$117,670,410
2023	92	92	2,340	215,865	19,813,355
2024	92	92	1,860	171,585	24,431,490
Three-year Average	92	92	4,520	416,970	57,305,085

For PBMs, the Departments and OPM estimate that in 2022, each PBM will incur a one-time first-year cost and burden to design, develop, and implement needed IT systems changes to collect and submit, on behalf of plans and issuers, the data required under these interim final rules. The Departments and OPM estimate that for each PBM, on average, it will take Project Managers/Team Leads 2,080 hours (at $110 per hour), Scrum Masters 2,080 hours (at $110 per hour), Senior Business Analysts 1,560 hours (at $134 per hour), Technical Architects/Sr. Developers 2,080 hours (at $207 per hour), Application Developers 4,160 hours (at $111 per hour), and DevOps Engineers/Security Engineers 780 hours (at $143 per hour) to complete this task. The Departments and OPM estimate the total burden per PBM will be approximately 12,740 hours, with an equivalent cost of approximately $1,670,500. For all 66 PBMs, the total one-time first-year implementation and reporting burden is estimated to be 840,840 hours with an equivalent total cost of approximately $110,253,000.[54]

TABLE 14—ESTIMATED TOTAL ONE-TIME FIRST-YEAR COST AND HOUR BURDEN FOR PBMS TO DESIGN, DEVELOP, AND IMPLEMENT NEEDED IT SYSTEMS CHANGES AND SUBMIT REQUIRED DATA

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
66	66	12,740	840,840	$110,253,000

In addition to the one-time first-year cost and burden estimated in the previous section of this preamble, PBMs will incur additional one-time cost and burden in the second year of implementation to maintain and update their IT systems and to submit the required data to the Departments. The Departments and OPM estimate that for each PBM it will take Project Managers/Team Leads 1,040 hours (at $110 per hour), Scrum Master 1,040 hours (at $110 per hour), Senior Business Analysts 780 hours (at $134 per hour), Technical Architects/Sr. Developers 1,040 hours (at $207 per hour), Application Developers 2,340 hours (at $111 per hour), and DevOps Engineers/Security Engineers 260 hours (at $143 per hour) to perform these tasks. The total second-year burden for each PBM will be 6,500 hours, with an equivalent cost of approximately $845,520. For all 66 PBMs, the total one-time second-year implementation and reporting burden is estimated to be 429,000 hours with an

[53] Calculation of totals was done as follows: Burden Hours per Respondent × Number of Respondent = Total Burden Hours (1,860 × 205 = 381,300). Total Cost per Respondent × Number of Respondents = Total Cost ($264,480 × 205 = $54,292,200).

[54] Calculation of totals was done as follows: Burden Hours per Respondent × Number of Respondents = Total Burden Hours (12,740 × 66 = 840,840). Total Cost per Respondent × Number of Respondents = Total Cost ($1,670,500 × 66 = $110,253,000).

equivalent total cost of approximately $55,804,320.[55]

TABLE 15—ESTIMATED ONE-TIME SECOND-YEAR COST AND HOUR BURDEN FOR PBMS TO UPDATE AND MAINTAIN IT SYSTEMS AND SUBMIT REQUIRED DATA

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
66	66	6,500	429,000	$55,804,320

In addition to the one-time first-year and second-year costs and burdens estimated in the previous sections of this preamble, PBMs will incur ongoing annual costs related to ensuring submission accuracy, providing quality assurance, conducting maintenance and making updates, enhancing or updating any needed security measures, and submitting the required data to the Departments. The Departments and OPM estimate that for each PBM it will take Project Managers/Team Leads 520 hours (at $110 per hour), Scrum Masters 260 hours (at $110 per hour), Senior Business Analysts 40 hours (at $134 per hour), Technical Architects/Sr. Developers 520 hours (at $207 per hour), Application Developers 520 hours (at $111 per hour), and DevOps Engineers/Security Engineers 260 hours (at $143 per hour) to perform these tasks. The Departments and OPM estimate the total annual burden for each PBM will be 2,120 hours, with an equivalent cost of approximately $293,700. For all 66 PBMs, the total annual maintenance and submission burden is estimated to be 139,920 hours with an equivalent total cost of approximately $19,384,200.[56] The Departments and OPM consider this to be an upper-bound estimate and expect maintenance costs to decline in succeeding years as PBMs gain efficiencies and experience in updating, managing, and submitting the required data.

TABLE 16—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR MAINTENANCE AND REPORTING FOR ALL PBMS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
66	66	2,120	139,920	$19,384,200

The Departments and OPM estimate the three-year average annual total burden for all 66 PBMs to develop, build, and maintain needed IT systems changes to collect and aggregate the required data, and submit that data to the Departments, will be 469,920 hours with an average annual total cost of $61,813,840. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately 211,464 hours, with an equivalent cost of approximately $27,816,228. The Departments and OPM seek comment on these burden estimates.

TABLE 17—ANNUAL BURDEN FOR PBMS TO DEVELOP AND MAINTAIN NEEDED IT SYSTEMS CHANGES AND SUBMIT REQUIRED DATA

	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total estimated annual burden (hours)	Total estimated labor cost ($)
2022	30	30	12,740	378,378	$49,613,850
2023	30	30	6,500	193,050	25,111,944
2024	30	30	2,120	62,964	8,722,890
Three-year Average	30	30	7,120	211,464	27,816,228

Plans will need to provide information on the average monthly premiums paid by participants, beneficiaries, and enrollees, as applicable, and paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable, to issuers and TPAs, so that issuers and TPAs can report this information to the Departments on behalf of plans. This information is compiled by plans for other reporting purposes and should be readily available. The Departments and OPM assume that plans will be able to provide the information to issuers, FEHB carriers, and TPAs at minimal cost.

In developing the cost and burden estimates in this ICR, the Departments and OPM recognize that while there may be various reporting entities that submit the required information, IT development will require varying

[55] Calculation of totals was done as follows: Burden Hours per Respondent × Number of Respondents = Total Burden Hours (6,500 × 66 = 429,000). Total Cost per Respondent × Number of Respondents = Total Cost ($845,520 × 66 = $55,804,320).

[56] Calculation of totals was done as follows: Burden Hours per Respondent × Number of Respondent = Total Burden Hours (2,120 × 66 = 139,920). Total Cost per Respondent × Number of Respondents = Total Cost ($293,700 × 66 = $19,384,200).

degrees of effort across the reporting entities. The Departments and OPM also recognize that some reporting entities will have mature in-house engineering teams and systems that can quickly respond to the requirements in these interim final rules, while others may have contracts with external firms and may require contract negotiation to develop and build the IT systems needed to meet the requirements. There may also be process efficiencies for issuers that are also FEHB carriers. Additionally, software and system maintenance will depend on various factors such as: The maturity of software in use; the ability to access data; software development resources or ability; any dependency upon third-party developers; the size of the reporting entity; and the number of plans. Due to these unknown factors, the estimates in these ICRs are the average cost and burden each entity will assume to develop and build an IT system from scratch. The Departments and OPM seek comment on these assumptions and what barriers reporting entities may face in developing their IT systems to meet the requirements in these interim final rules. HHS is seeking an OMB control number and approval for the proposed information collection (OMB control number: 0938–NEW (Prescription Drug and Health Care Spending (CMS–10788))).

3. Summary of Annual Burden Estimates for Information Collection Requirements

TABLE 18—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting	Total cost ($)
45 CFR 149.720, 730, 740—issuer	0938–NEW	234	234	4,520	1,055,646	$137	$145,079,703
45 CFR 149.720, 730, 740—TPA	0938–NEW	92	92	4,520	416,970	137	57,305,085
45 CFR 149.720, 730, 740—PBM	0938–NEW	30	30	7,120	211,464	132	27,816,228
Total		356	356		1,684,080		230,201,016

4. Submission of PRA-Related Comments

The Departments and OPM submitted a copy of these interim final rules to OMB for review of the rules' information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit *www.cms.hhs.gov/PaperworkReductionActof1995* or call the Reports Clearance Office at 410–786–1326.

The Departments and OPM invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the ''Addresses'' section of these rules and identify the rule (CMS–9905–IFC) and the ICR's CFR citation.

ICR-related comments are due January 24, 2022.

E. Paperwork Reduction Act—Department of Labor, Department of the Treasury, and the Office of Personnel Management

As part of the continuing effort to reduce paperwork and respondent burden, the Departments and OPM conduct a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA. This process helps to ensure that the public understands the Departments' and OPM's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Departments and OPM can properly assess the impact of collection requirements on respondents.

Contemporaneously with the publication of these interim final rules, HHS as the host agency has submitted a request for a new common form ICR containing the information collection requirements for the prescription drug and health care spending requirements created by section 204 of Title II of Division BB of the CAA. Once HHS has obtained OMB approval for the information collection, DOL, the Department of the Treasury, and OPM will seek OMB approval to use the common form ICR by providing its agency-specific information to OMB.

Under the PRA, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number.

The information collections are summarized as follows:

1. ICRs Regarding Reporting of Prescription Drug and Health Care Spending (26 CFR 54.9825–1T—6T, 29 CFR 2590.725–1—4)

As discussed earlier in the HHS Paperwork Reduction Act section (V.D.2) of this preamble, issuers, FEHB carriers, TPAs, and PBMs will incur costs to submit the required information to the Departments. The Departments and OPM estimate the three-year average annual total burden, for all 519 issuers and FEHB carriers to develop, build, and maintain needed IT systems changes to collect and aggregate the required information, and submit that information to the Departments, will be 2,345,880 hours with an average annual total cost of $322,399,340. The three-year average annual total burden, for all 205 TPAs to develop, build, and maintain needed IT systems changes to collect and aggregate the required information, and submit that information to the Departments, is estimated to be 926,600 hours with an average annual total cost of $127,344,633. In addition, the three-year average annual total burden, for all 66 PBMs to develop, build, and maintain needed IT systems changes to collect and aggregate the required information, and submit that information to the Departments, will be 469,920 hours with an average annual total cost of $61,813,840. As DOL, the Department of the Treasury, OPM, and HHS share jurisdiction, HHS will account for 45 percent of the burden, DOL will account for 25 percent, the Department of the Treasury will account for 25 percent, and OPM will account for 5 percent. The burden accounted for by DOL and the Department of the Treasury each is presented in Table 19 and the burden accounted for by OPM is presented in Table 20.

TABLE 19—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS FOR DOL AND THE DEPARTMENT OF THE TREASURY

Respondent	Number of respondents	Number of responses	Total annual burden (hours)	Total labor cost of reporting
FEHB carrier	130	130	586,470	$80,599,835
TPA	51	51	231,650	31,836,158
PBM	17	17	117,480	15,453,460
Total	198	198	935,600	127,889,453

Agency: DOL–EBSA, Treasury–IRS, OPM–FEHB.

Type of Review: New information collection.

Title: Reporting of Prescription Drug and Health Care Spending.

OMB Control Number: NEW.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Forms:

Estimated Total Respondents: 198.

Estimated Total Responses: 198.

Frequency of Response: Annual.

Estimated Total Burden Hours: 935,600 (DOL—425,273, Treasury—425,273, OPM—85,055).

Estimated Total Cost Burden: $127,889,453 (DOL—$58,131,570, Treasury—$58,131,570, OPM—$11,626,314).

TABLE 20—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS FOR OPM

Respondent	Number of respondents	Number of responses	Total annual burden (hours)	Total labor cost of reporting
FEHB Carrier	26	26	117,294	$16,119,967
TPA	10	10	46,330	6,367,232
PBM	3	3	23,496	3,090,692
Total	39	39	187,120	25,577,891

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to analyze options for regulatory relief of small entities to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities. Individuals and states are not included in the definition of a small entity. These interim final rules are not preceded by a general proposed rule, and thus the requirements of the RFA do not apply.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule or any final rule for which a general proposed rule was published that includes any federal mandate that may result in expenditures in any 1 year by state, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. These interim final rules were not preceded by a general proposed rule, and thus the requirements of UMRA do not apply.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by federal agencies in formulating and implementing policies that have ''substantial direct effects'' on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government, including policies that impose direct costs on states or preempt state laws. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the interim final rules.

These interim final rules require plans, issuers, and FEHB carriers to submit prescription drug and health care spending data to the Departments, which will be used to inform a biannual public report that will be issued by the Departments regarding prescription drug reimbursements, trends, and impact on premiums. A number of states currently have laws, regulations, or guidance related to the reporting of prescription drug and health care spending data, although there is no consistency among these states in the data elements collected or the definitions used for those data elements. It is the Departments' and OPM's view that these interim final rules will not have substantial direct effects on states' ability to collect such prescription drug and health care spending data as the states may deem necessary. The rules do not impose direct costs on states or preempt state laws.

While developing these interim final rules, the Departments consulted with the states and attempted to balance the states' interests in regulating health insurance issuers with the need to ensure transparency in the prescription drug and health care market and collect data on a consistent basis in order to inform nationwide analyses. By doing

so, the Departments complied with the requirements of Executive Order 13132.

I. Congressional Review Act

These interim final rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and will be transmitted to the Congress and to the Comptroller General for review in accordance with such provisions. Under the Congressional Review Act, the Office of Information and Regulatory Affairs designated these interim final rules as a ''major rule'' as that term is defined in 5 U.S.C. 804(2), because it is likely to result in an annual impact on the economy of $100 million or more.

Statutory Authority

The Office of Personnel Management regulations are adopted pursuant to the authority contained in 5 U.S.C. 8910 and 5 U.S.C. 8913.

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002, 1135, 1182, 1185d, 1191a, 1191b, and 1191c; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2792 and 2799A–10 of the Public Health Service Act (42 U.S.C. 300gg–92 and 300gg–120).

Edward DeHarde,

Acting Associate Director, Healthcare and Insurance, Office of Personnel Management.

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Lily L. Batchelder,

Assistant Secretary of the Treasury (Tax Policy).

Signed at Washington, DC, this 12th day of November, 2021.

Ali Khawar,

Acting Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: November 12, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

List of Subjects

5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Hostages, Iraq, Kuwait, Lebanon, Military personnel, Reporting and recordkeeping requirements, Retirement.

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2510

Employee benefit plans, Pensions.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 149

Balance billing, Health care, Health insurance, Reporting and recordkeeping requirements, Surprise billing, State regulation of health insurance, Transparency in coverage.

OFFICE OF PERSONNEL MANAGEMENT

For the reasons stated in the preamble, the Office of Personnel Management amends 5 CFR part 890 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.102 also issued under sections 11202(f), 11232(e), and 11246 (b) of Pub. L. 105–33, 111 Stat. 251; Sec. 890.111 also issued under section 1622(b) of Pub. L. 104–106, 110 Stat. 521 (36 U.S.C. 5522); Sec. 890.112 also issued under section 1 of Pub. L. 110–279, 122 Stat. 2604 (2 U.S.C. 2051); Sec. 890.113 also issued under section 1110 of Pub. L. 116–92, 133 Stat. 1198 (5 U.S.C. 8702 note); Sec. 890.301 also issued under section 311 of Pub. L. 111–3, 123 Stat. 64 (26 U.S.C. 9801); Sec. 890.302(b) also issued under section 1001 of Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029 (42 U.S.C. 300gg–14); Sec. 890.803 also issued under 50 U.S.C. 3516 (formerly 50 U.S.C. 403p) and 22 U.S.C. 4069c and 4069c–1; subpart L also issued under section 599C of Pub. L. 101–513, 104 Stat. 2064 (5 U.S.C. 5561 note), as amended; and subpart M also issued under section 721 of Pub. L. 105–261 (10 U.S.C. 1108), 112 Stat. 2061.

■ 2. Amend § 890.114 by revising the section heading and paragraphs (a) and (d) and adding reserved paragraph (e) and paragraph (f) to read as follows:

§ 890.114 Surprise billing and transparency.

(a) A carrier must comply with requirements described in 26 CFR 54.9816–3T through 54.9816–6T, 54.9816–8T, 54.9817–1T, 54.9817–2T, 54.9822–1T, and 54.9825–3T through 6T; 29 CFR 2590.716–3 through 2590.716–6, 2590.716–8, 2590.717–1, 2590.717–2, 2590.722, 2590.725–1 through 2590.725–4; and 45 CFR 149.30, 149.110 through 149.140, 149.310, 149.510 and 520, and 149.710 through 149.740 in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage, subject to 5 U.S.C. 8902(m)(1), and the provisions of the carrier's contract. For purposes of application of such sections, all carriers are deemed to offer health benefits in the large group market.

* * * * *

(d)(1) In addition to notification to the Department per 26 CFR 54.9816–8T(b)(2)(iii), 29 CFR 2590.716–8(b)(2)(iii), and 45 CFR 149.510(b)(2)(iii), a carrier must notify the Director of its initiation of the Federal IDR process, or its receipt of written notice that a provider, facility, or provider of air ambulance services has initiated the Federal IDR process, upon sending or receiving such notice.

(2) The Director will coordinate with the Departments in resolving matters under 26 CFR 54.9816–8T(c)(4)(vii)(A)(*1*), 29 CFR 2590.716–8(c)(4)(vii)(A)(*1*), or 45 CFR 149.510(c)(4)(vii)(A)(*1*) where fraud or material misrepresentation are presented, and matters involving 26 CFR 54.9816–8T(c)(4)(vii)(A)(*2*), 29 CFR 2590.716–8(c)(4)(vii)(A)(*2*), and 45 CFR 149.510(c)(4)(vii)(A)(*2*). The Director will coordinate with the Departments in oversight of reports submitted by certified IDR entities with respect to carriers pursuant to 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), or 45 CFR 149.510(f).

(e) [Reserved]

(f) The Director will coordinate with the Departments in oversight of prescription drug and health care spending with respect to FEHB carriers pursuant to 45 CFR 149.710 through 149.740.

INTERNAL REVENUE SERVICE

Amendments to the Regulations

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 3.** The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 4.** Sections 54.9825–1T through 54.9825–6T are added to read as follows:

Sec.

* * * * *

* * * * *

§ 54.9825–1T Basis and scope (temporary).

(a) *Basis.* This section and §§ 54.9825–2T through 54.9825–6T implement subchapter B of chapter 100 of the Internal Revenue Code of 1986.

(b) *Scope.* This part establishes standards for group health plans with respect to surprise medical bills, transparency in health care coverage, and additional patient protections.

§ 54.9825–2T Applicability (temporary).

(a) *In general.* The requirements in §§ 54.9825–4T through 54.9825–6T apply to group health plans (including grandfathered health plans as defined in § 54.9815–1251), except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 54.9825–4T through 54.9825–6T do not apply to the following:

(1) Excepted benefits as described in § 54.9831–1(c).

(2) Short-term, limited-duration insurance as defined in § 54.9801–2.

(3) Health reimbursement arrangements or other account-based group health plans as described in § 54.9815–2711(d).

§ 54.9825–3T Definitions (temporary).

The definitions in § 54.9816–3T apply to §§ 54.9825–4T through 54.9825–6T unless otherwise specified. In addition, for purposes of §§ 54.9825–4T through 54.9825–6T, the following definitions apply:

Brand prescription drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), or under section 351 of the PHS Act (42 U.S.C. 262), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes a drug with Emergency Use Authorization issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes drugs that the U.S. Food and Drug Administration determines to be interchangeable biosimilar products under sections 351(i)(3) and 351(k)(4) of the PHS Act (42 U.S.C. 262).

Dosage unit means the smallest form in which a pharmaceutical product is administered or dispensed, such as a pill, tablet, capsule, ampule, or measurement of grams or milliliters.

Federal Employees Health Benefits (FEHB) line of business refers to all health benefit plans that are offered to eligible enrollees pursuant to a contract between the Office of Personnel Management and Federal Employees Health Benefits (FEHB) Program carriers. Such plans are Federal governmental plans offered pursuant to 5 U.S.C. chapter 89.

Life-years means the total number of months of coverage for participants and beneficiaries, as applicable, divided by 12.

Market segment means one of the following: The individual market (excluding the student market), the student market, the fully-insured small group market, the fully-insured large group market (excluding the FEHB line of business), self-funded plans offered by small employers, self-funded plans offered by large employers, and the FEHB line of business.

Premium amount means, with respect to individual health insurance coverage and fully-insured group health plans, earned premium as that term is defined in 45 CFR 158.130, excluding the adjustments specified in 45 CFR 158.130(b)(5). Premium amount means, with respect to self-funded group health plans and other arrangements that do not rely exclusively or primarily on payments of premiums as defined in 45 CFR 158.130, the premium equivalent amount representing the total cost of providing and maintaining coverage, including claims costs, administrative costs, and stop-loss premiums, as applicable.

Prescription drug (drug) means a set of pharmaceutical products that have been assigned a National Drug Code (NDC) by the Food and Drug Administration and are grouped by name and ingredient in the manner specified by the Secretary, jointly with the Secretary of Labor and the Secretary of Health and Human Services.

Prescription drug rebates, fees, and other remuneration means all remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the plan or issuer, with respect to prescription drugs prescribed to participants and beneficiaries in the plan or coverage, as applicable, regardless of the source of the remuneration (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates, fees, and other remuneration also include, for example, discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. Prescription drug rebates, fees, and other remuneration include bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the plan or issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of the entity, whether or not the entity takes title to the drug.

Reference year means the calendar year immediately preceding the calendar year in which data submissions under this section are required.

Reporting entity means an entity that submits some or all of the information required under §§ 54.9825–4T through 54.9825–6T with respect to a plan or issuer, and that may be different from the plan or issuer that is subject to the requirements of §§ 54.9825–4T through 54.9825–6T.

Student market has the meaning given in 45 CFR 158.103.

Therapeutic class means a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, grouped in the manner specified by the Secretary, jointly with the Secretary of Labor and the Secretary of Health and Human Services, in guidance. The Secretary may require plans and issuers to classify drugs according to a commonly available public or commercial therapeutic classification system, a therapeutic classification system provided by the Secretary of Health and Human Services, or a combination thereof.

Total annual spending means incurred claims, as that term is defined in 45 CFR 158.140, excluding the adjustments specified in 45 CFR 158.140(b)(1)(i), (b)(2)(iv), and (b)(4), and including cost sharing. With respect to prescription drugs, total annual spending is net of prescription drug rebates, fees, and other remuneration.

§ 54.9825–4T Reporting requirements related to prescription drug and health care spending (temporary).

(a) *General requirement.* A group health plan or a health insurance issuer offering group health insurance coverage must submit an annual report to the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor, on prescription drug and health care spending, premiums, and enrollment under the plan or coverage.

(b) *Timing and form of report.* The report for the 2020 reference year must be submitted to the Secretary by December 27, 2021. Beginning with the 2021 reference year, the report for each reference year is due by June 1 of the year following the reference year. The report must be submitted in the form and manner prescribed by the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor.

(c) *Transfer of business.* Issuers that acquire a line or block of business from another issuer during a reference year are responsible for submitting the information and report required by this section for the acquired business for that reference year, including for the part of the reference year that was prior to the acquisition.

(d) *Reporting entities and special rules to prevent unnecessary duplication*—(1) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan may satisfy the requirements of paragraph (a) of this section if the plan requires the health insurance issuer offering the coverage to report the information required by this section in compliance with this subpart pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under paragraph (a) of this section in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the reporting requirements of paragraph (a) of this section with respect to the relevant information.

(2) *Other contractual arrangements.* A group health plan or health insurance issuer offering group health insurance coverage may satisfy the requirements under paragraph (a) of this section by entering into a written agreement under which one or more other parties (such as health insurance issuers, pharmacy benefit managers, third-party administrators, or other third parties) report some or all of the information required under paragraph (a) of this section in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in accordance with paragraph (a) of this section, the plan or issuer violates the reporting requirements of paragraph (a) of this section.

(e) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 54.9825–5T Aggregate reporting (temporary).

(a) *General requirement.* A group health plan or a health insurance issuer offering group health insurance coverage must submit, or arrange to be submitted, the information required in § 54.9825–6T(b) separately for each State in which group health coverage or group health insurance coverage was provided in connection with the group health plan or by the health insurance issuer. The report must include the experience of all plans and policies in the State during the reference year covered by the report, and must include the experience separately for each market segment as defined in § 54.9825–3T.

(b) *Aggregation by reporting entity*—(1) *In general.* If a reporting entity submits data on behalf of more than one group health plan in a State and market segment, the reporting entity may aggregate the data required in § 54.9825–6T(b) for the group health plans for each market segment in the State.

(2) *Multiple reporting entities.* (i) If multiple reporting entities submit the required data related to one or more plans or issuers in a State and market segment, the data submitted by each of these reporting entities must not be aggregated at a less granular level than the aggregation level used by the reporting entity that submits the data on total annual spending on health care services, as required by § 54.9825–6T(b)(4), on behalf of these plans or issuers.

(ii) The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, may specify in guidance alternative or additional aggregation methods for data submitted by multiple reporting entities, to ensure a balance between compliance burdens and a data aggregation level that facilitates the development of the biannual public report required under section 9825(b) of the Code.

(3) *Group health insurance coverage with dual contracts.* If a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, the plan's out-of-network experience may be treated as if it were all related to the contract provided by the in-network issuer.

(c) *Aggregation by State.* (1) Experience with respect to each fully-insured policy must be included on the report for the State where the contract was issued, except as specified in paragraphs (c)(3) and (4) of this section.

(2) Experience with respect to each self-funded group health plan must be included on the report for the State where the plan sponsor has its principal place of business.

(3) For individual market business sold through an association, experience must be attributed to the issue State of the certificate of coverage.

(4) For health coverage provided to plans through a group trust or multiple employer welfare arrangement, the experience must be included in the report for the State where the employer (if the plan is sponsored at the individual employer level) or the association (if the association qualifies as an employer under ERISA section 3(5)) has its principal place of business or the state where the association is incorporated, in the case of an association with no principal place of business.

(d) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 54.9825–6T Required information (temporary).

(a) *Information for each plan or coverage.* The report required under § 54.9825–4T must include the following information for each plan or coverage, at the plan or coverage level:

(1) The identifying information for plans, issuers, plan sponsors, and any other reporting entities.

(2) The beginning and end dates of the plan year that ended on or before the last day of the reference year.

(3) The number of participants and beneficiaries, as applicable, covered on the last day of the reference year.

(4) Each State in which the plan or coverage is offered.

(b) *Information for each state and market segment.* The report required under § 54.9825–4T must include the following information with respect to plans or coverage for each State and market segment for the reference year, unless otherwise specified:

(1) The 50 brand prescription drugs most frequently dispensed by pharmacies, and for each such drug, the

data elements listed in paragraph (b)(5) of this section. The most frequently dispensed drugs must be determined according to total number of paid claims for prescriptions filled during the reference year for each drug.

(2) The 50 most costly prescription drugs and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most costly drugs must be determined according to total annual spending on each drug.

(3) The 50 prescription drugs with the greatest increase in expenditures between the year immediately preceding the reference year and the reference year, and for each such drug: The data elements listed in paragraph (b)(5) of this section for the year immediately preceding the reference year, and the data elements listed in paragraph (b)(5) of this section for the reference year. The drugs with the greatest increase in expenditures must be determined based on the increase in total annual spending from the year immediately preceding the reference year to the reference year. A drug must be approved for marketing or issued an Emergency Use Authorization by the Food and Drug Administration for the entirety of the year immediately preceding the reference year and for the entirety of the reference year to be included in the data submission as one of the drugs with the greatest increase in expenditures.

(4) Total annual spending on health care services by the plan or coverage and by participants and beneficiaries, as applicable, broken down by the type of costs, including—

(i) Hospital costs;

(ii) Health care provider and clinical service costs, for primary care and specialty care separately;

(iii) Costs for prescription drugs, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and

(iv) Other medical costs, including wellness services.

(5) Prescription drug spending and utilization, including—

(i) Total annual spending by the plan or coverage;

(ii) Total annual spending by the participants and beneficiaries, as applicable, enrolled in the plan or coverage, as applicable;

(iii) The number of participants and beneficiaries, as applicable, with a paid prescription drug claim;

(iv) Total dosage units dispensed; and

(v) The number of paid claims.

(6) Premium amounts, including—

(i) Average monthly premium amount paid by employers and other plan sponsors on behalf of participants and beneficiaries, as applicable;

(ii) Average monthly premium amount paid by participants and beneficiaries, as applicable; and

(iii) Total annual premium amount and the total number of life-years.

(7) Prescription drug rebates, fees, and other remuneration, including—

(i) Total prescription drug rebates, fees, and other remuneration, and the difference between total amounts that the plan or issuer pays the entity providing pharmacy benefit management services to the plan or issuer and total amounts that such entity pays to pharmacies.

(ii) Prescription drug rebates, fees, and other remuneration, excluding bona fide service fees, broken down by the amounts passed through to the plan or issuer, the amounts passed through to participants and beneficiaries, as applicable, and the amounts retained by the entity providing pharmacy benefit management services to the plan or issuer; and the data elements listed in paragraph (b)(5) of this section—

(A) For each therapeutic class; and

(B) For each of the 25 prescription drugs with the greatest amount of total prescription drug rebates and other price concessions for the reference year.

(8) The method used to allocate prescription drug rebates, fees, and other remuneration, if applicable.

(9) The impact of prescription drug rebates, fees, and other remuneration on premium and cost sharing amounts.

(c) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 5. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Pub. L. 116–260 134 Stat. 1182; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

Subpart D—Surprise Billing and Transparency Requirements

■ 6. Section 2590.716–1 is amended by revising paragraph (a) to read as follows:

§ 2590.716–1 Basis and scope.

(a) *Basis.* Sections 2590.716–1 through 2590.725–4 implement sections 716–725 of ERISA.

* * * * *

■ 7. Section 2590.716–2 is amended by revising paragraph (a) and paragraph (b) introductory text to read as follows:

§ 2590.716–2 Applicability.

(a) *In general.* (1) The requirements in §§ 2590.716–4 through 2590.716–7, 2590.717–1, 2590.722, and 2590.725–1 through 2590.725–4 apply to group health plans and health insurance issuers offering group health insurance coverage (including grandfathered health plans as defined in § 2590.715–1251), except as specified in paragraph (b) of this section.

(2) The requirements in §§ 2590.716–8 and 2590.717–2 apply to certified IDR entities and group health plans and health insurance issuers offering group health insurance coverage (including grandfathered health plans as defined in § 2590.715–1251) except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 2590.716–4 through 2590.716–8, 2590.717–1, 2590.717–2, 2590.722, and 2590.725–1 through 2590.725–4 do not apply to the following:

* * * * *

■ 8. Add §§ 2590.725–1, 2590.725–2, 2590.725–3, and 2590.725–4 to read as follows:

Sec.

* * * * *

* * * * *

§ 2590.725–1 Definitions.

For purposes of this section, the following definitions apply in addition to the definitions in § 2590.716–3:

Brand prescription drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or under section 351 of the Public Health Service Act (42 U.S.C. 262), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand

prescription drug'' includes a drug with Emergency Use Authorization issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes drugs that the U.S. Food and Drug Administration determines to be interchangeable biosimilar products under sections 351(i)(3) and 351(k)(4) of the PHS Act (42 U.S.C. 262).

Dosage unit means the smallest form in which a pharmaceutical product is administered or dispensed, such as a pill, tablet, capsule, ampule, or measurement of grams or milliliters.

Federal Employees Health Benefits (FEHB) line of business refers to all health benefit plans that are offered to eligible enrollees pursuant to a contract between the Office of Personnel Management and Federal Employees Health Benefits (FEHB) Program carriers. Such plans are Federal governmental plans offered pursuant to 5 U.S.C. chapter 89.

Life-years means the total number of months of coverage for participants and beneficiaries, as applicable, divided by 12.

Market segment means one of the following: The individual market (excluding the student market), the student market, the fully-insured small group market, the fully-insured large group market (excluding the FEHB line of business), self-funded plans offered by small employers, self-funded plans offered by large employers, and the FEHB line of business.

Premium amount means, with respect to fully-insured group health plans, earned premium as that term is defined in 45 CFR 158.130, excluding the adjustments specified in 45 CFR 158.130(b)(5). Premium amount means, with respect to self-funded group health plans and other arrangements that do not rely exclusively or primarily on payments of premiums as defined in 45 CFR 158.130, the premium equivalent amount representing the total cost of providing and maintaining coverage, including claims costs, administrative costs, and stop-loss premiums, as applicable.

Prescription drug (drug) means a set of pharmaceutical products that have been assigned a National Drug Code (NDC) by the Food and Drug Administration and are grouped by name and ingredient in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services.

Prescription drug rebates, fees, and other remuneration means all remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the plan or issuer, with respect to prescription drugs prescribed to participants or beneficiaries in the plan or coverage, as applicable, regardless of the source of the remuneration (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates, fees, and other remuneration also include, for example, discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. Prescription drug rebates, fees, and other remuneration include bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the plan or issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of the entity, whether or not the entity takes title to the drug.

Reference year means the calendar year immediately preceding the calendar year in which data submissions under this section are required.

Reporting entity means an entity that submits some or all of the information required under this section with respect to a plan or issuer, and that may be different from the plan or issuer that is subject to the requirements of this section.

Student market has the meaning given in 45 CFR 158.103.

Therapeutic class means a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, grouped in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, in guidance. The Secretary may require plans and issuers to classify drugs according to a commonly available public or commercial therapeutic classification system, a therapeutic classification system provided by the Secretary of Health and Human Services, or a combination thereof.

Total annual spending means incurred claims, as that term is defined in 45 CFR 158.140, excluding the adjustments specified in 45 CFR 158.140(b)(1)(i), (b)(2)(iv), and (b)(4), and including cost sharing. With respect to prescription drugs, total annual spending is net of prescription drug rebates, fees, and other remuneration.

§ 2590.725–2 Reporting requirements related to prescription drug and health care spending.

(a) *General requirement.* A group health plan or a health insurance issuer offering group health insurance coverage must submit an annual report to the Secretary, the Secretary of the Treasury, and the Secretary of Health and Human Services, on prescription drug and health care spending, premiums, and enrollment under the plan or coverage.

(b) *Timing and form of report.* The report for the 2020 reference year must be submitted to the Secretary by December 27, 2021. Beginning with the 2021 reference year, the report for each reference year is due by June 1 of the year following the reference year. The report must be submitted in the form and manner prescribed by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services.

(c) *Transfer of business.* Issuers that acquire a line or block of business from another issuer during a reference year are responsible for submitting the information and report required by this section for the acquired business for that reference year, including for the part of the reference year that was prior to the acquisition.

(d) *Reporting entities and special rules to prevent unnecessary duplication*—(1) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan may satisfy the requirements of paragraph (a) of this section if the plan requires the health insurance issuer offering the coverage to report the information required by this section in compliance with this subpart pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under paragraph (a) of this section in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the reporting requirements of paragraph (a) of this section with respect to the relevant information.

(2) *Other contractual arrangements.* A group health plan or health insurance issuer offering group health insurance coverage may satisfy the requirements under paragraph (a) of this section by entering into a written agreement under which one or more other parties (such as health insurance issuers, pharmacy benefit managers, third-party administrators, or other third parties) report some or all of the information required under paragraph (a) of this section in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in accordance with paragraph (a) of this section, the plan or issuer violates the reporting requirements of paragraph (a) of this section.

(e) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 2590.725–3 Aggregate reporting.

(a) *General requirement.* A group health plan or a health insurance issuer offering group health insurance coverage must submit, or arrange to be submitted, the information required in § 2590.725–4(b) of this section separately for each State in which group health coverage or group health insurance coverage was provided in connection with the group health plan or by the health insurance issuer. The report must include the experience of all plans and policies in the State during the reference year covered by the report, and must include the experience separately for each market segment as defined in § 2590.725–1 of this section.

(b) *Aggregation by reporting entity*—(1) *In general.* If a reporting entity submits data on behalf of more than one group health plan in a State and market segment, the reporting entity may aggregate the data required in § 2590.725–4(b) of this section for the group health plans for each market segment in the State.

(2) *Multiple reporting entities.* (i) If multiple reporting entities submit the required data related to one or more plans or issuers in a State and market segment, the data submitted by each of these reporting entities must not be aggregated at a less granular level than the aggregation level used by the reporting entity that submits the data on total annual spending on health care services, as required by § 2590.725–4(b)(4), on behalf of these plans or issuers.

(ii) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may specify in guidance alternative or additional aggregation methods for data submitted by multiple reporting entities, to ensure a balance between compliance burdens and a data aggregation level that facilitates the development of the biannual public report required under section 725(b) of ERISA.

(3) Group health insurance coverage with dual contracts. If a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, the plan's out-of-network experience may be treated as if it were all related to the contract provided by the in-network issuer.

(c) *Aggregation by State.* (1) Experience with respect to each fully-insured policy must be included on the report for the State where the contract was issued, except as specified in paragraphs (c)(3) and (4) of this section.

(2) Experience with respect to each self-funded group health plan must be included on the report for the State where the plan sponsor has its principal place of business.

(3) For individual market business sold through an association, experience must be attributed to the issue State of the certificate of coverage.

(4) For health coverage provided to plans through a group trust or multiple employer welfare arrangement, the experience must be included in the report for the State where the employer (if the plan is sponsored at the individual employer level) or the association (if the association qualifies as an employer under ERISA section 3(5)) has its principal place of business or the state where the association is incorporated, in the case of an association with no principal place of business.

(d) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 2590.725–4 Required information.

(a) *Information for each plan or coverage.* The report required under § 2590.725–2 must include the following information for each plan or coverage, at the plan or coverage level:

(1) The identifying information for plans, issuers, plan sponsors, and any other reporting entities.

(2) The beginning and end dates of the plan year that ended on or before the last day of the reference year.

(3) The number of participants and beneficiaries, as applicable, covered on the last day of the reference year.

(4) Each State in which the plan or coverage is offered.

(b) *Information for each state and market segment.* The report required under § 2590.725–2 must include the following information with respect to plans or coverage for each State and market segment for the reference year, unless otherwise specified:

(1) The 50 brand prescription drugs most frequently dispensed by pharmacies, and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most frequently dispensed drugs must be determined according to total number of paid claims for prescriptions filled during the reference year for each drug.

(2) The 50 most costly prescription drugs and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most costly drugs must be determined according to total annual spending on each drug.

(3) The 50 prescription drugs with the greatest increase in expenditures between the year immediately preceding the reference year and the reference year, and for each such drug: The data elements listed in paragraph (b)(5) of this section for the year immediately preceding the reference year, and the data elements listed in paragraph (b)(5) of this section for the reference year. The drugs with the greatest increase in expenditures must be determined based on the increase in total annual spending from the year immediately preceding the reference year to the reference year. A drug must be approved for marketing or issued an Emergency Use Authorization by the Food and Drug Administration for the entirety of the year immediately preceding the reference year and for the entirety of the reference year to be included in the data submission as one of the drugs with the greatest increase in expenditures.

(4) Total annual spending on health care services by the plan or coverage and by participants and beneficiaries, as applicable, broken down by the type of costs, including—

(i) Hospital costs;

(ii) Health care provider and clinical service costs, for primary care and specialty care separately;

(iii) Costs for prescription drugs, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and

(iv) Other medical costs, including wellness services.

(5) Prescription drug spending and utilization, including—

(i) Total annual spending by the plan or coverage;

(ii) Total annual spending by the participants and beneficiaries, as applicable, enrolled in the plan or coverage, as applicable;

(iii) The number of participants and beneficiaries, as applicable, with a paid prescription drug claim;

(iv) Total dosage units dispensed; and

(v) The number of paid claims.

(6) Premium amounts, including—

(i) Average monthly premium amount paid by employers and other plan sponsors on behalf of participants and beneficiaries, as applicable;

(ii) Average monthly premium amount paid by participants and beneficiaries, as applicable; and

(iii) Total annual premium amount and the total number of life-years.

(7) Prescription drug rebates, fees, and other remuneration, including—

(i) Total prescription drug rebates, fees, and other remuneration, and the difference between total amounts that the plan or issuer pays the entity providing pharmacy benefit management services to the plan or issuer and total amounts that such entity pays to pharmacies.

(ii) Prescription drug rebates, fees, and other remuneration, excluding bona fide service fees, broken down by the amounts passed through to the plan or issuer, the amounts passed through to participants and beneficiaries, as applicable, and the amounts retained by the entity providing pharmacy benefit management services to the plan or issuer; and the data elements listed in paragraph (b)(5) of this section—

(A) For each therapeutic class; and

(B) For each of the 25 prescription drugs with the greatest amount of total prescription drug rebates and other price concessions for the reference year.

(8) The method used to allocate prescription drug rebates, fees, and other remuneration, if applicable.

(9) The impact of prescription drug rebates, fees, and other remuneration on premium and cost sharing amounts.

(c) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 149 as set forth below:

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

■ 9. The authority citation for part 149 continues to read as follows:

Authority: 42 U.S.C. 300gg–111 through 300gg–139, as amended.

■ 10. Amend § 149.20 by revising paragraph (a)(1) and paragraph (b) introductory text to read as follows:

§ 149.20 Applicability.

(a) * * *

(1) The requirements in subparts B, D, and H of this part apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in § 147.140 of this subchapter), except as specified in paragraph (b) of this section.

* * * * *

(b) *Exceptions.* The requirements in subparts B, D, E, F, and H of this part do not apply to the following:

* * * * *

■ 11. Add subpart H to read as follows:

Subpart H—Prescription Drug and Health Care Spending

Sec.

149.710 Definitions.

149.720 Reporting Requirements Related to Prescription Drug and Health Care Spending.

149.730 Aggregate Reporting.

149.740 Required Information.

Subpart H—Prescription Drug and Health Care Spending

§ 149.710 Definitions.

For purposes of this subpart, the following definitions apply in addition to the definitions in § 149.30:

Brand prescription drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), or under section 351 of the PHS Act (42 U.S.C. 262), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes a drug with Emergency Use Authorization issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes drugs that the U.S. Food and Drug Administration determines to be interchangeable biosimilar products under sections 351(i)(3) and 351(k)(4) of the PHS Act (42 U.S.C. 262).

Dosage unit means the smallest form in which a pharmaceutical product is administered or dispensed, such as a pill, tablet, capsule, ampule, or measurement of grams or milliliters.

Enrollee means an individual who is enrolled, within the meaning of § 144.103 of this subchapter, in group health insurance coverage, or an individual who is covered by individual health insurance coverage, at any time during the reference year, and includes dependents.

Federal Employees Health Benefits (FEHB) line of business refers to all health benefit plans that are offered to eligible enrollees pursuant to a contract between the Office of Personnel Management and Federal Employees Health Benefits (FEHB) Program carriers. Such plans are Federal governmental plans offered pursuant to 5 U.S.C. chapter 89.

Life-years means the total number of months of coverage for participants and beneficiaries, or for enrollees, as applicable, divided by 12.

Market segment means one of the following: The individual market (excluding the student market), the student market, the fully-insured small group market, the fully-insured large group market (excluding the FEHB line of business), self-funded plans offered by small employers, self-funded plans offered by large employers, and the FEHB line of business.

Premium amount means, with respect to individual health insurance coverage and fully-insured group health plans, earned premium as that term is defined in § 158.130 of this subchapter, excluding the adjustments specified in § 158.130(b)(5). Premium amount means, with respect to self-funded group health plans and other arrangements that do not rely exclusively or primarily on payments of premiums as defined in § 158.130 of this subchapter, the premium equivalent amount representing the total cost of providing and maintaining coverage, including claims costs, administrative costs, and stop-loss premiums, as applicable.

Prescription drug (drug) means a set of pharmaceutical products that have been assigned a National Drug Code (NDC) by the Food and Drug Administration and are grouped by name and ingredient in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

Prescription drug rebates, fees, and other remuneration means all remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the plan or issuer, with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees in the plan or coverage, as applicable, regardless of the source of the remuneration (for example, pharmaceutical manufacturer,

wholesaler, retail pharmacy, or vendor). Prescription drug rebates, fees, and other remuneration also include, for example, discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. Prescription drug rebates, fees, and other remuneration include bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the plan or issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of the entity, whether or not the entity takes title to the drug.

Reference year means the calendar year immediately preceding the calendar year in which data submissions under this section are required.

Reporting entity means an entity that submits some or all of the information required under this subpart with respect to a plan or issuer, and that may be different from the plan or issuer that is subject to the requirements of this subpart.

Student market has the meaning given in § 158.103 of this subchapter.

Therapeutic class means a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, grouped in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, in guidance. The Secretary may require plans and issuers to classify drugs according to a commonly available public or commercial therapeutic classification system, a therapeutic classification system provided by the Secretary, or a combination thereof.

Total annual spending means incurred claims, as that term is defined in § 158.140 of this subchapter, excluding the adjustments specified in § 158.140(b)(1)(i), (b)(2)(iv), and (b)(4), and including cost sharing. With respect to prescription drugs, total annual spending is net of prescription drug rebates, fees, and other remuneration.

§ 149.720 Reporting requirements related to prescription drug and health care spending.

(a) *General requirement.* A group health plan or a health insurance issuer offering group or individual health insurance coverage must submit an annual report to the Secretary, the Secretary of the Treasury, and the Secretary of Labor, on prescription drug and health care spending, premiums, and enrollment under the plan or coverage.

(b) *Timing and form of report.* The report for the 2020 reference year must be submitted to the Secretary by December 27, 2021. Beginning with the 2021 reference year, the report for each reference year is due by June 1 of the year following the reference year. The report must be submitted in the form and manner prescribed by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(c) *Transfer of business.* Issuers that acquire a line or block of business from another issuer during a reference year are responsible for submitting the information and report required by this section for the acquired business for that reference year, including for the part of the reference year that was prior to the acquisition.

(d) *Reporting entities and special rules to prevent unnecessary duplication*—(1) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan may satisfy the requirements of paragraph (a) of this section if the plan requires the health insurance issuer offering the coverage to report the information required by this section in compliance with this subpart pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under paragraph (a) of this section in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the reporting requirements of paragraph (a) of this section with respect to the relevant information.

(2) *Other contractual arrangements.* A group health plan or health insurance issuer offering group or individual health insurance coverage may satisfy the requirements under paragraph (a) of this section by entering into a written agreement under which one or more other parties (such as health insurance issuers, pharmacy benefit managers, third-party administrators, or other third parties) report some or all of the information required under paragraph (a) of this section in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in accordance with paragraph (a) of this section, the plan or issuer violates the reporting requirements of paragraph (a) of this section.

(e) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 149.730 Aggregate reporting.

(a) *General requirement.* A group health plan or a health insurance issuer offering group or individual health insurance coverage must submit, or arrange to be submitted, the information required in § 149.740(b) separately for each State in which group health coverage or group or individual health insurance coverage was provided in connection with the group health plan or by the health insurance issuer. The report must include the experience of all plans and policies in the State during the reference year covered by the report, and must include the experience separately for each market segment as defined in § 149.710.

(b) *Aggregation by reporting entity*—(1) *In general.* If a reporting entity submits data on behalf of more than one group health plan in a State and market segment, the reporting entity may aggregate the data required in § 149.740(b) for the group health plans for each market segment in the State.

(2) *Multiple reporting entities.* (i) If multiple reporting entities submit the required data related to one or more plans or issuers in a State and market segment, the data submitted by each of these reporting entities must not be aggregated at a less granular level than the aggregation level used by the reporting entity that submits the data on total annual spending on health care services, as required by § 149.740(b)(4), on behalf of these plans or issuers.

(ii) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may specify in guidance alternative or additional aggregation methods for data submitted by multiple reporting entities, to ensure a balance between compliance burdens and a data aggregation level that facilitates the development of the biannual public report required under section 2799A–10(b) of the PHS Act.

(3) *Group health insurance coverage with dual contracts.* If a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, the plan's out-of-network experience may be treated as if it were all related to the contract provided by the in-network issuer.

(c) *Aggregation by State.* (1) Experience with respect to each fully-

insured policy must be included on the report for the State where the contract was issued, except as specified in paragraphs (c)(3) and (4) of this section.

(2) Experience with respect to each self-funded group health plan must be included on the report for the State where the plan sponsor has its principal place of business.

(3) For individual market business sold through an association, experience must be attributed to the issue State of the certificate of coverage.

(4) For health coverage provided to plans through a group trust or multiple employer welfare arrangement, the experience must be included in the report for the State where the employer (if the plan is sponsored at the individual employer level) or the association (if the association qualifies as an employer under ERISA section 3(5)) has its principal place of business or the State where the association is incorporated, in the case of an association with no principal place of business.

(d) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 149.740 Required information.

(a) *Information for each plan or coverage.* The report required under § 149.720 must include the following information for each plan or coverage, at the plan or coverage level:

(1) The identifying information for plans, issuers, plan sponsors, and any other reporting entities.

(2) The beginning and end dates of the plan year that ended on or before the last day of the reference year.

(3) The number of participants, beneficiaries, and enrollees, as applicable, covered on the last day of the reference year.

(4) Each State in which the plan or coverage is offered.

(b) *Information for each state and market segment.* The report required under § 149.720 must include the following information with respect to plans or coverage for each State and market segment for the reference year, unless otherwise specified:

(1) The 50 brand prescription drugs most frequently dispensed by pharmacies, and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most frequently dispensed drugs must be determined according to total number of paid claims for prescriptions filled during the reference year for each drug.

(2) The 50 most costly prescription drugs and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most costly drugs must be determined according to total annual spending on each drug.

(3) The 50 prescription drugs with the greatest increase in expenditures between the year immediately preceding the reference year and the reference year, and for each such drug: The data elements listed in paragraph (b)(5) of this section for the year immediately preceding the reference year, and the data elements listed in paragraph (b)(5) of this section for the reference year. The drugs with the greatest increase in expenditures must be determined based on the increase in total annual spending from the year immediately preceding the reference year to the reference year. A drug must be approved for marketing or issued an Emergency Use Authorization by the Food and Drug Administration for the entirety of the year immediately preceding the reference year and for the entirety of the reference year to be included in the data submission as one of the drugs with the greatest increase in expenditures.

(4) Total annual spending on health care services by the plan or coverage and by participants, beneficiaries, and enrollees, as applicable, broken down by the type of costs, including—

(i) Hospital costs;

(ii) Health care provider and clinical service costs, for primary care and specialty care separately;

(iii) Costs for prescription drugs, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and

(iv) Other medical costs, including wellness services.

(5) Prescription drug spending and utilization, including—

(i) Total annual spending by the plan or coverage;

(ii) Total annual spending by the participants, beneficiaries, and enrollees, as applicable, enrolled in the plan or coverage, as applicable;

(iii) The number of participants, beneficiaries, and enrollees, as applicable, with a paid prescription drug claim;

(iv) Total dosage units dispensed; and

(v) The number of paid claims.

(6) Premium amounts, including—

(i) Average monthly premium amount paid by employers and other plan sponsors on behalf of participants, beneficiaries, and enrollees, as applicable;

(ii) Average monthly premium amount paid by participants, beneficiaries, and enrollees, as applicable; and

(iii) Total annual premium amount and the total number of life-years.

(7) Prescription drug rebates, fees, and other remuneration, including—

(i) Total prescription drug rebates, fees, and other remuneration, and the difference between total amounts that the plan or issuer pays the entity providing pharmacy benefit management services to the plan or issuer and total amounts that such entity pays to pharmacies.

(ii) Prescription drug rebates, fees, and other remuneration, excluding bona fide service fees, broken down by the amounts passed through to the plan or issuer, the amounts passed through to participants, beneficiaries, and enrollees, as applicable, and the amounts retained by the entity providing pharmacy benefit management services to the plan or issuer; and the data elements listed in paragraph (b)(5) of this section—

(A) For each therapeutic class; and

(B) For each of the 25 prescription drugs with the greatest amount of total prescription drug rebates and other price concessions for the reference year.

(8) The method used to allocate prescription drug rebates, fees, and other remuneration, if applicable.

(9) The impact of prescription drug rebates, fees, and other remuneration on premium and cost sharing amounts.

(c) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

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