



DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG-117575-21]

RIN 1545-BQ27

Prescription Drug and Health Care Spending

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: Elsewhere in this issue of the **Federal Register**, the IRS is issuing temporary regulations that increase transparency by requiring group health plans and health insurance issuers in the group and individual markets to report 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 (the Departments). The IRS is issuing the temporary regulations at the same time that the Office of Personnel Management (OPM), the Employee Benefits Security Administration of DOL, and the Office of Consumer Information and Insurance Oversight of HHS are issuing substantially similar interim final rules with a request for comments. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: In commenting, please refer to file code REG-117575-21. 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 to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
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 FURTHER INFORMATION CONTACT: Christopher Dellana, (202) 317-5500,
Internal Revenue Service, Department of the Treasury, for issues related to Surprise Billing.

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. All comments received are posted before the close of the comment period on the following website as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that website to view public comments.

Proposed Applicability Date: These regulations are generally proposed to apply on and after December 27, 2021. As discussed in the preamble to the temporary regulations published elsewhere in this issue of the **Federal Register**, the Departments are temporarily deferring enforcement during the first year of applicability.

Background and Regulatory Impact Analysis

The temporary regulations published elsewhere in this issue of the **Federal Register** add §§ 54.9825–1T, 54.9825–2T, 54.9825–3T, 54.9825–4T, 54.9825–5T, and 54.9825–6T to the Miscellaneous Excise Tax Regulations. The proposed and temporary regulations are being published as part of a joint rulemaking with the OPM, DOL, and HHS. The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and provides a regulatory impact analysis.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a proposal is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis (IRFA) of the proposed rule. The Treasury Department and the IRS have not determined whether the proposed regulations, when finalized, will likely have a significant economic impact on a substantial number of small entities. This determination requires further study. However, because there is a possibility of significant economic impact on a substantial number of small entities, an IRFA is provided in these proposed regulations. The Treasury Department and the IRS invite comments on both the number of entities affected and the economic impact on small entities.

Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel of Advocacy of the Small Business Administration for comment on its impact on small business.

1. Need for and Objectives of the Rule

The proposed regulations will implement a reporting requirement for prescription drug costs and other medical expenses. Specifically, group health plans and health insurance issuers will submit key data, which the Departments will use to report and better understand prescription drug pricing trends and their impact on consumers' premiums and out-of-pocket costs. The reporting requirements apply beginning with the data for the 2020 calendar year. This will allow the Departments to better understand national prescription drug costs and identify major drivers of increases in health care spending, which may aid in examining variation of health care costs across the country.

2. Affected Small Entities

The Small Business Administration estimates in its 2020 Small Business Profile that 99.9 percent of United States businesses meet its definition of a small business.¹ The applicability of these proposed regulations does not depend on the size of the business, as defined by the Small Business Administration. As described more fully in the preamble to the temporary regulations, published elsewhere in this issue of the Federal Register, and in this IRFA, these rules may affect a variety of different businesses.

Because small entities may comply with the requirements under the proposed regulations in different ways, it is difficult to estimate at this time the impact of these proposed regulations, if any, on small businesses. Small entities might, for example, enter into contracts with other entities in order to meet the requirements in the proposed regulations. Due to the lack of knowledge regarding what small entities may decide to do in order to satisfy the requirements and any costs they might incur related to contracts, the Departments seek comment on ways that

¹ US Small Bus. Admin., *2020 Small Business Profile*, <https://cdn.advocacy.sba.gov/wp-content/uploads/2020/06/04144214/2020-Small-Business-Economic-Profile-States-Territories.pdf>.

the proposed regulations will impose additional costs and burdens on small entities and how many would be likely engage in contracts to meet the requirements.

The Treasury Department and the IRS expect to receive more information on the impact on small businesses through comments on these proposed regulations.

3. Impact of the Regulations

The proposed regulations require 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 Departments. The public reports that are required by the proposed regulations could enhance national health transparency and lower prescription drug and health care costs. Consumers could potentially benefit from the required reporting if plans and issuers 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 public reports that are required by the proposed regulations will create certain compliance burdens. The recordkeeping and reporting requirements will increase for plans and issuers subject to the regulations. This includes costs associated with developing, building, and maintaining information technology systems necessary to report the required data. The maintenance costs for these information technology systems may decrease in succeeding years as plans and issuers (or third parties on their behalf) gain efficiencies and experience in updating, managing, and submitting the required data. Although the Treasury Department and the IRS do not have sufficient data to determine precisely the likely extent of the increased costs of compliance, the estimated burden of complying with the recordkeeping and reporting requirements are described in the Paperwork Reduction Act section of the preamble to the temporary regulations, published elsewhere in this issue of the Federal Register.

4. Alternatives Considered

As described in more detail in the Regulatory Impact Analysis of the preamble to the temporary regulations, published elsewhere in this issue of the Federal Register, the Treasury Department and the IRS considered alternatives to the proposed regulations. For example, in providing rules related to the aggregation of data submitted by reporting entities, the Treasury Department and the IRS considered whether to (i) allow reporting entities to submit aggregated data, or (ii) require plans, issuers, and Federal Employees Health Benefits (FEHB) carriers to submit all of the required information on a plan-by-plan basis. As described in section II.C.3 of the preamble to the temporary regulations, published elsewhere in this issue of the Federal Register, the Treasury Department and the IRS, in consultation with DOL, HHS, and OPM, determined that allowing reporting entities to submit aggregated data would be sufficient for purposes of the statutory requirement, without creating or imposing undue burdens on taxpayers.

5. Duplicative, Overlapping, or Conflicting Federal Rules

As explained in the preamble to the temporary regulations, published elsewhere in this issue of the Federal Register, the proposed regulations would not duplicate, overlap, or conflict with any relevant Federal rules. The Treasury Department and the IRS invite comment from interested members of the public about identifying and avoiding overlapping, duplicative, or conflicting requirements.

Drafting Information

The principal author of this notice of proposed rulemaking is Christopher Dellana, Office of the Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). The proposed regulations, as well as the temporary regulations, have been developed in coordination with personnel from OPM, DOL, and HHS.

List of Subjects in 26 CFR Part 54

Excise taxes, Pensions, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph. 3. The authority citation for part 54 continues to read as follows:

Authority: 26 U.S.C. 7805

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

[The text of proposed § 54.9825–1 is the same as the text of § 54.9825–1T published elsewhere in this issue of the **Federal Register**].

[The text of proposed § 54.9825–2 is the same as the text of § 54.9825–2T published elsewhere in this issue of the **Federal Register**].

[The text of proposed § 54.9825–3 is the same as the text of § 54.9825–3T published elsewhere in this issue of the **Federal Register**].

[The text of proposed § 54.9825–4 is the same as the text of § 54.9825–4T published elsewhere in this issue of the **Federal Register**].

[The text of proposed § 54.9825–5 is the same as the text of § 54.9825–5T published elsewhere in this issue of the **Federal Register**].

[The text of proposed § 54.9825–6 is the same as the text of § 54.9825–6T published elsewhere in this issue of the **Federal Register**].

Douglas W. O'Donnell

Deputy Commissioner for Services and Enforcement