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Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10221 and CMS-10788]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA web site by copying and pasting the following web address into your web browser: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10221 Independent Diagnostic Testing Facilities (IDTFs) Site Investigation Collection

CMS-10788 Prescription Drug and Health Care Spending

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request*: Extension of currently approved collection; *Title of Information Collection:* Independent Diagnostic Testing Facilities (IDTFs) Site Investigation Collection; *Use*: The purpose of the site investigation is to ensure that the IDTF is in compliance with the provisions of 42 CFR § 410.33, as well as all other applicable Federal, State and local laws and regulations. It is also used to verify the information the IDTF furnished on its CMS- 855B enrollment application. Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due to a provider or other person. To fulfill this requirement, CMS must collect information on any IDTF supplier who submits a claim to Medicare or who applies for a Medicare billing number before allowing the IDTF to enroll. This information must, minimally, clearly identify the provider and its' place of business as required by C.F.R. § 424.500 (Requirements for Establishing and Maintaining Medicare Billing Privileges) and provide all necessary documentation to show they are qualified to perform the services for which they are billing. The site inspection form allows inspectors to verify the information using a standardized information collection methodology. *Form Number*: CMS-10221 (OMB control number: 0938-1029); *Frequency:* Occasionally; *Affected Public Sector*: Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 652; *Total Annual Responses*: 652; *Total Annual Hours:* 1,304. (For policy questions regarding this collection contact Angelika Broznowicz at 410-786-8242).

2. *Type of Information Collection Request*: Revision of currently approved collection; *Title of Information Collection:* Prescription Drug and Health Care Spending; *Use*: On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law. 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) that require group health plans and health insurance issuers offering group or individual health insurance coverage to annually report to the Department of the Treasury, the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, "the Departments") certain information about prescription drug and health care spending, premiums, and enrollment under the plan or coverage. This information will support the development of public reports that will be published by the Departments 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 the plans or coverage. The 2021 interim final rules, "Prescription Drug and Health Care Spending" (2021 interim final rules), issued by the Departments and the Office of Personnel Management (OPM) 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. OPM joined the Departments in issuing the 2021 interim final rules, requiring Federal Employees Health Benefits (FEHB) carriers to report information about prescription drug and health care spending, premiums, and plan enrollment in the same manner as a group health plan or health insurance issuer offering group or individual health insurance coverage. *Form Number*: CMS-10788 (OMB control number: 0938-1407); *Frequency:* Annually; *Affected Public Sector*: Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 356; *Total Annual Responses*: 356; *Total Annual Hours:* 764,442. (For policy questions regarding this collection contact Christina Whitefield at 202-536-8676.)

Dated: March 21, 2023.

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William N. Parham, III

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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