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 on the collection(s) of information must be received by the OMB desk officer by *July 28, 2025.*

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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 website 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 Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Review Choice Demonstration for Inpatient Rehabilitation Facility (IRF) Services; *Use:* Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1(a)(1)(J)) authorizes the Secretary to ''develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act).'' Pursuant to this authority, the CMS will continue the implementation of a Medicare demonstration project, which CMS believes will help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among IRFs providing services to Medicare beneficiaries.

This demonstration will assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud. The demonstration will ensure that payments for IRF services are appropriate through either pre-claim or postpayment review, thereby working towards the prevention and identification of potential fraud, waste, and abuse, as well as protecting the Medicare Trust Funds from improper payments while reducing Medicare appeals. CMS plans to continue the demonstration in Alabama and Pennsylvania, then expand to Texas, and California. After the initial four states, CMS will expand the demonstration to include the IRFs in any state that bill to Medicare Administrative Contractor (MAC) jurisdictions JJ, JL, JH, and JE. *Form Number:* CMS–10765 (OMB Control Number: 0938–1420); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profits); *Number of Respondents:* 526; *Number of Responses:* 179,910; *Total Annual Hours:* 89,955. For questions regarding this collection contact Jaclyn Gray (410) 786–3744.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Marketplace Quality Standards; *Use:* The Patient Protection and Affordable Care Act establishes requirements to support the delivery of quality health care coverage for health insurance issuers offering QHPs in Exchanges. Section 1311(c)(3) of the Patient Protection and Affordable Care Act directs the Secretary to develop a system to rate QHPs on the basis of quality and price and requires Exchanges to display this quality rating information on their respective websites. Section 1311(c)(4) of the Patient Protection and Affordable Care Act requires the Secretary to develop an enrollee satisfaction survey system to assess enrollee experience with each QHP (with more than 500 enrollees in the previous year) offered through an Exchange. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards beginning January 1, 2015.

This collection of information is necessary to provide adequate and timely health care quality information for consumers, regulators, and Exchanges in the initial years of Exchange implementation. It is also necessary to collect information to appropriately monitor and provide a process for a survey vendor to appeal HHS' decision to not approve a QHP Enrollee Survey vendor application. *Form Number:* CMS–10114 (OMB control number: 0938–1249); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 380; *Total Annual Responses:* 380; *Total Annual Hours:* 138,112. (For policy questions regarding this collection contact Preeti Hans at 301–492–5144.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–11900 Filed 6–26–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10328 and CMS–10148]

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 (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 August 26, 2025.

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 website 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–10328 Medicare Self-Referral Disclosure Protocol

CMS–10148 HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form

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 Collections

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Self-Referral Disclosure Protocol; *Use:* Section 6409 of the ACA requires the Secretary to establish a voluntary self-disclosure process that allows providers of services and suppliers to self-disclose actual or potential violations of section 1877 of the Act. The SRDP is a voluntary self-disclosure process that allows providers of services and suppliers to disclose actual or potential violations of section 1877 of the Act. For purposes of the SRDP, a person submitting a disclosure to the SRDP will be referred to as a ''disclosing party.'' CMS analyzes the disclosed conduct to determine compliance with section 1877 of the Act and the application of the exceptions to the physician self-referral prohibition.

Specifically, under the proposal a physician practice disclosing group practice noncompliance will submit an SRDP form consisting of the following components: (1) the SRDP Disclosure Form, (2) a single Group Practice Information Form covering all the physicians in the practice who made prohibited referrals to the practice, and (3) a Financial Analysis Worksheet. All other entities will continue to submit disclosures using the SRDP Disclosure Form, separate Physician Information Forms for each physician covered in the self-disclosure, and a Financial Analysis Worksheet. *Form Number:* CMS–10328 (OMB control number: 0938–1106); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 4,950. (For policy questions regarding this collection contact Caitlin Bailey at 410–786–9768.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form; *Use:* The Secretary of Health and Human Services (HHS), hereafter known as ''The Secretary,'' codified 45 CFR parts 160 and 164 Administrative Simplification provisions that apply to the enforcement of the Health Insurance Portability and Accountability Act of 1996 Public Law 104–191 (HIPAA). The provisions address rules relating to the investigation of non-compliance of the HIPAA Administrative Simplification code sets, unique identifiers, operating rules, and transactions. 45 CFR 160.306, Complaints to the Secretary, provides for investigations of covered entities by the Secretary. Further, it outlines the procedures and requirements for filing a complaint against a covered entity.

Anyone can file a complaint if he or she suspects a potential violation. Persons believing that a covered entity is not utilizing the adopted Administrative Simplification provisions of HIPAA are voluntarily requested to file a complaint with CMS via the Administrative Simplification Enforcement and Testing Tool (ASETT) online system, by mail, or by sending an email to the HIPAA mailbox at *hipaacomplaint@cms.hhs.gov.* Information provided on the standard form will be used during the investigation process to validate non-compliance of HIPAA Administrative Simplification provisions.

This standard form collects identifying and contact information of the complainant, as well as the identifying and contact information of the filed against entity (FAE). This information enables CMS to respond to the complainant and gather more information if necessary, and to contact the FAE to discuss the complaint and CMS' findings. *Form Number:* CMS–10148 (OMB control number: 0938–0948); *Frequency:* Occasionally; *Affected Public:* Private sector, Business or Not-for-profit institutions, State, Local, or Tribal Governments, Federal Government, Not-for-profits institutions; *Number of Respondents:* 400; *Total Annual Responses:* 400; *Total Annual Hours:* 400. (For policy questions regarding this collection contact Kevin Stewart at 410–786–6149).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Drug Price

Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS–10849, OMB 0938–1452); *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (''the Act''). The Act establishes the Negotiation Program to negotiate maximum fair prices (''MFPs''), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D. For the third cycle of the Negotiation Program, the Secretary of Health and Human Services (the ''Secretary'') will select up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D for negotiation. In accordance with section 1194(f)(4) of the Act, CMS will also renegotiate MFPs for drugs selected for renegotiation, if any, for initial price applicability year 2028.

Negotiation Data Elements: The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. To the extent that more than one entity meets the statutory definition of manufacturer (specified in section 1193(a)(1) of the Act) for a selected drug for purposes of initial price applicability year 2028, CMS will designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the selected drug to be ''the manufacturer'' of the selected drug (hereinafter the ''Primary Manufacturer''). The Primary Manufacturer's data submissions include the non-Federal average manufacturer price and related data for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A) of the Act, and information that the Secretary requires, pertaining to the negotiation factors outlined in section 1194(e)(1) of the Act, for the purpose of formulating offers and counteroffers pursuant to section 1193(a)(4)(B) of the Act. Some of these data are held by the Primary Manufacturer and are not currently available to CMS. Data described in sections 1194(e)(1) and 1193(a)(4) of the Act must be submitted by the Primary Manufacturer.

Section 1194(e)(2) of the Act requires CMS to consider certain data on selected drugs and their alternative treatments. Because the statute does not specify where these data come from, CMS will allow for optional submission from Primary Manufacturers and the public for drugs selected for negotiation or renegotiation. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in section 1194(e)(2) of the Act. Manufacturers may optionally submit this information as part of their Negotiation Data Elements Information Collection Request Form. The public may also optionally submit evidence about the selected drugs and their alternative treatments.

Drug Price Negotiation and Renegotiation Process: Any MFPs that are negotiated or renegotiated for these selected drugs will apply beginning in initial price applicability year 2028. For initial price applicability year 2028, the negotiation and renegotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement or February 28, 2026.

Section 1194(b)(2)(C) of the Act provides that if the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer may submit an optional written counteroffer no later than 30 days after the date of receipt of CMS' written initial offer. If the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS' written initial offer during the drug price negotiation or renegotiation process for initial price applicability year 2028, the Primary Manufacturer must submit the Counteroffer Form. *Form Number:* CMS–10849 (OMB control number: 0938–1452); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 405; *Number of Responses:* 405; *Total Annual Hours:* 51,940. (For questions regarding this collection, contact Elisabeth Daniel at 667–290–8793.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–11980 Filed 6–26–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3467–N]

Secretarial Comments on the CBE's (Battelle Memorial Institute) 2024 Activities: Report to Congress and the Secretary of the Department of Health and Human Services

AGENCY: Office of the Secretary of Health and Human Services, HHS.

ACTION: Notice.

SUMMARY: This notice acknowledges the Secretary of the Department of Health and Human Services' (the Secretary's) receipt and review of Battelle Memorial Institute's, the consensus-based entity (CBE) under a contract with the Secretary, 2024 Annual Activities Report to Congress, as mandated by section 1890(b)(5) of the Social Security Act (the Act). The Secretary has reviewed CBE's 2024 Annual Report and is publishing the report in the **Federal Register** together with the Secretary's comments on the report not later than 6 months after receiving the report in accordance with section 1890(b)(5)(B) of the Act. This notice fulfills the statutory requirements. Although the Act requires the Secretary to review and publish the report, this statutory obligation does not constitute endorsement by the Secretary of the CBE's annual report and its specific recommendations.

FOR FURTHER INFORMATION CONTACT: Charlayne Van, (410) 786–8659.

SUPPLEMENTARY INFORMATION:

I. Background

The United States Department of Health and Human Services (HHS) has long recognized that a high functioning health care system that provides higher quality care requires accurate, valid, and reliable measurement of quality and efficiency. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) added section 1890 of the Social Security Act (the Act), which requires the Secretary of HHS (the Secretary) to contract with a consensus-based entity (CBE) to perform multiple duties to help improve performance measurement. Section 3014 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148) expanded the duties of the CBE to help in the identification of gaps in available measures and to improve the selection of measures used in health care