Information Collections

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare Geographic Classification Review Board Procedures and Criteria; *Use:* During the first few years of IPPS, hospitals were paid strictly based on their physical geographic location concerning the wage index (Metropolitan Statistical Areas (MSAs)) and the standardized amount (rural, other urban, or large urban). However, a growing number of hospitals became concerned that their payment rates were not providing accurate compensation. The hospitals argued that they were not competing with the hospitals in their own geographic area, but instead that they were competing with hospitals in neighboring geographic areas.

At that point, Congress enacted Section 1886(d)(10) of the Act which enabled hospitals to apply to be considered part of neighboring geographic areas for payment purposes based on certain criteria. The application and decision process are administered by the MGCRB which is not a part of CMS so that CMS could not be accused of any untoward action. However, CMS needs to remain apprised of any potential payment changes. Hospitals are required to provide CMS with a copy of any applications that they made to the MGCRB. CMS also developed the guidelines for the MGCRB that were the interim final issue of the **Federal Register** and must ensure that the MGCRB properly applied the guidelines. This check and balance process also contributes to limiting the number of hospitals that ultimately need to appeal their MGCRB decisions to the CMS Administrator. *Form Number:* CMS–R–138 (OMB control number: 0938–0573); *Frequency:* Occasionally; *Affected Public:* Businesses or other for-profits and Not-for-profit institutions; *Number of Respondents:* 850; *Total Annual Responses:* 850; *Total Annual Hours:* 850. (For policy questions regarding this collection contact Noel Manlove at 410–786–5161.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Part C and Part D Medicare Prescription Payment Plan Model Documents; *Use:* Sections 1860D–2(b)(2)(E)(v)(II)–(IV) of the Act state the requirements for Part D plan sponsors in implementing the program, which include the processes for outreach to enrollees identified as likely to benefit, election, and termination. Subsection II states that any Part D enrollee may elect into the program prior to or during the plan year. Subsection III details that Part D plan sponsors and MA organizations must have a mechanism in place to inform enrollees that they are likely to benefit from electing into the program at the point of sale (POS). Subsection IV(aa) states that plans must terminate a beneficiary's participation in the program when the beneficiary fails to pay the amounts owed under this program.

CMS has developed the seven model notices to provide standardized and consistent language for potential and active program participants, regardless of which Part D plan they may be enrolled in. The seven model notices and their content serve as an example of how to convey information on the Medicare Prescription Payment Plan to Part D enrollees and program participants, as applicable. Though Part D plan sponsors are not required to use the model materials and content verbatim, use of the model materials will satisfy the communications requirements included in § 423.137. If a Part D plan sponsor chooses not to use a model material, they must meet the content requirements in § 423.137 for the alternate notices they develop. CMS notes that the ''Medicare Prescription Payment Plan Likely to Benefit Notice,'' is a standardized material that Part D plan sponsors are required to use in the form and manner provided by CMS. *Form Number:* CMS–10882 (OMB control number: 0938–1475); *Frequency:* Yearly; *Affected Public:* Individuals and Households, Private Sector, Federal Government, Businesses or other for-profits and Not-for-profit institutions; *Number of Respondents:* 234,227; *Total Annual Responses:* 39,514,987; *Total Annual Hours:* 135,080. (For policy questions regarding this collection contact Deven Gosalia at (410) 786–8264 or *deven.gosalia@cms.hhs.gov.*)

William N. Parham, III,

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

[FR Doc. 2025–08348 Filed 5–12–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10844]

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 July 14, 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 *https://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–10844 Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request

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 with of a currently approved collection; *Title of Information Collection:* Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request; *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 information collection request forms for the Small Biotech Exception, the Biosimilar Delay, and the Selection of Renegotiation-Eligible Drugs for initial price applicability year 2028 must be submitted to CMS before CMS establishes the selected drug list for initial price applicability year 2028.

Small Biotech Exception: In accordance with section 1192(d)(2) of the Act, the term ''negotiation-eligible drug'' excludes, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the ''Small Biotech Exception,'' or ''SBE''). This information is required in order for CMS to accurately identify whether a given drug meets the criteria for the Small Biotech Exception in accordance with section 1192(d)(2) of the Act. To ensure that drugs payable under Part B and/or drugs covered under Part D that meet the requirements for the SBE are excluded from the term ''negotiation-eligible drug,'' a manufacturer that seeks the SBE for its drug payable under Part B and/or covered under Part D (''Submitting Manufacturer'') must submit information to CMS about the company and its products in order for the drug to be considered for the exception. If the Submitting Manufacturer seeks the SBE for a drug payable under Part B and/or covered under Part D it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021, for drugs covered under Part D and information related to the holder of the New Drug Application(s) (NDA)(s) or Biologics License Applications(s) (BLA)(s) as of December 31, 2021 for drugs payable under Part B. If the Submitting Manufacturer was acquired by another entity after December 31, 2021, the Submitting Manufacturer must provide information regarding that acquiring entity for CMS to assess whether the acquisition triggers the limitation at section 1192(d)(2)(B)(ii) of the Act.

Biosimilar Delay: In accordance with section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product (''Biosimilar Manufacturer'' of a ''Biosimilar'') may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a ''Reference Drug'') on the selected drug list for a given initial price applicability year (the ''Biosimilar Delay''). This information is required in order for CMS to accurately determine if a drug meets the criteria for the Biosimilar Delay for initial price applicability year 2028 in accordance with section 1192(f) of the Act. To ensure that the delay of selection and negotiation of biologics is only applied if there is a high likelihood that the Biosimilar will be licensed and marketed, a Biosimilar Manufacturer that seeks the Biosimilar Delay must submit information to CMS related to the Biosimilar. This information includes identifying information for the Biosimilar and the Reference Drug; the licensure status of the Biosimilar; attestations that the Biosimilar Manufacturer is not the same or treated as the same entity as the Reference Manufacturer, that the Biosimilar Manufacturer and the Reference Manufacturer (who is the manufacturer of the Reference Drug) have not entered into an agreement that requires or incentivizes the Biosimilar Manufacturer to submit the Biosimilar Delay, or directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time; and documentation specified under section 1192(f)(3) of the Act to demonstrate there is a high likelihood that the Biosimilar will be licensed and marketed within two years of the statutorily-defined selected drug publication date for initial price applicability year 2028.

Selection of Renegotiation-Eligible Drugs: Section 1194(f) of the Act establishes the requirements governing the identification of renegotiation-eligible drugs and selection of drugs for renegotiation. CMS will offer Primary Manufacturers [1] the voluntary option to submit information to CMS to inform CMS' determinations of which selected drugs qualify as a renegotiation-eligible drug and may be selected for renegotiation in accordance with section 1194(f)(3) of the Act. Specifically, section 1194(f)(2)(D) of the Act instructs CMS to identify whether a selected drug is eligible for renegotiation because a new indication has been added to the selected drug and based on a material change to any of the factors listed in section 1194(e) of the Act. *Form*

[1] 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'').

Number: CMS–10844 (OMB control number 0938–1443); *Frequency:* Once; *Affected Public:* Private Sector, Business, and Not-for Profits; *Number of Respondents:* 65; *Number of Responses:* 65; *Total Annual Hours:* 3,677.50. (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. 2025–08423 Filed 5–9–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; SBIR/STTR Review Meeting C.

Date: May 28, 2025.

Time: 4:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Karin Eyrich Garg, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20892, *karin.garg@nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 07, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–08335 Filed 5–12–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social and Environmental Determinants of Health Study Section.

Date: June 11–12, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ananya Paria, MPH, DHSC, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1007H, Bethesda, MD 20892, (301) 827–6513, *pariaa@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; HEAL Initiative: JCOIN Phase II Clinical Research Hubs and Community Engaged Research Resource Centers.

Date: June 11, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Trinh T. Tran, Ph.D., Scientific Review Officer, Scientific Review Branch, Office of Extramural Policy, National Institute on Drug Abuse, National Institutes of Health, Bethesda, MD 20892, (301) 827–5843, *trinh.tran@nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Emerging Imaging Technologies and Applications Study Section.

Date: June 12–13, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Zheng Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3385, *zheng.li3@nih.gov*.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Molecular Cancer Diagnosis and Classification Study Section.

Date: June 12–13, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Victor A. Panchenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 802B2, Bethesda, MD 20892, (301) 867–5309, *victor.panchenko@nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Structure and Regeneration Study Section.

Date: June 12–13, 2025.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yanming Bi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 451–0996, *ybi@csr.nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Kidney and Urological Systems Function and Dysfunction Study Section.

Date: June 12–13, 2025.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 435–5947, *banerjees5@mail.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroscience of Interoception and Chemosensation Study Section.

Date: June 12–13, 2025.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Myongsoo Matthew Oh, Ph.D., Scientific Review Officer, Center for