DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1800–NC3]

Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Draft Guidance; Comment Request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The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' draft guidance for the second cycle of the Medicare Drug Price Negotiation Program and manufacturer effectuation of the maximum fair price for 2026 and 2027 for the implementation of the Inflation Reduction Act. This and other Inflation Reduction Act-related guidance can be viewed on the dedicated Inflation Reduction Act section of the CMS website at *https://www.cms.gov/inflation-reduction-act-and-medicare/*.

DATES: Comments must be received by July 2, 2024.

ADDRESSES: Written comments should be sent to *IRARebateandNegotiation@cms.hhs.gov* with the relevant subject line, ''Medicare Drug Price Negotiation Program Draft Guidance.''

FOR FURTHER INFORMATION CONTACT: Elizabeth Daniel, *Elizabeth.daniel@cms.hhs.gov* or (667) 290–8793.

SUPPLEMENTARY INFORMATION: The Inflation Reduction Act (IRA) (*Pub. L. 117–169*) was signed into law on August 16, 2022. Sections 11001 and 11002 of the IRA established the Medicare Drug Price Negotiation Program (hereafter the ''Negotiation Program'') to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act as added by sections 11001 and 11002 of the IRA. The draft guidance describes how CMS intends to implement the Negotiation Program for Initial Price Applicability Year (IPAY) 2027 (January 1, 2027 to December 31, 2027), and specifies the requirements for manufacturer effectuation of the MFPs for 2026 and 2027.

To obtain copies of the Negotiation Program draft guidance and other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act website by copying and pasting the following web address into your web browser: *https://www.cms.gov/inflation-reduction-act-and-medicare*. If interested in receiving CMS Inflation Reduction Act updates by email, individuals may sign up for CMS Inflation Reduction Act's email updates at *https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates*.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 30, 2024.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–09750 Filed 5–3–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10054]

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 5, 2024.

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–10054 New Technology Services for Ambulatory Payment Classifications under the Outpatient Prospective Payment System

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 a currently approved collection; *Title of Information Collection:* New Technology Services for Ambulatory Payment Classifications Under Outpatient Prospective Payment System; *Use:* In the April 7, 2000 final rule with comment period first implementing the hospital outpatient prospective payment system (OPPS), we created a set of New Technology ambulatory payment classifications (APCs) to pay for certain new technology services under the OPPS. These APCs are intended to pay for new technology services that were not covered by the transitional pass-through payments provisions authorized by the Balanced Budget Refinement Act (BBRA) of 1999.

Since implementation of the hospital outpatient prospective payment system (OPPS) on August 1, 2000, transitional pass-through payments have been made to hospitals for certain drugs, biologicals, and medical devices. These are temporary additional payments required by section 1833(t)(6) of the Social Security Act (the Act), which was added by section 201(b) of the Balanced Budget Act of 1999 (BBRA). The law required the Secretary to make these additional payments to hospitals for at least 2 but no more than 3 years.

In the April 7, 2000 final rule with comment period, we specified an application process and the information that must be supplied for us to consider a request for payment under the New Technology APCs (65 FR 18478). We posted the application process on our website at *www.cms.hhs.gov.* Services were only considered eligible for assignment to a New Technology APC if we listed them in one of a number of lists published in Medicare Program Memoranda, which are posted to our website (*https://www.cms.gov/medicare/regulations-guidance/transmittals/cms-program-memoranda*). We established a quarterly application process by which interested parties could submit applications to us for particular services. We assign new services to the New Technology APCs that we determine cannot be placed appropriately in clinical APCs. Under our current policy, we retain services in a New Technology APC until we gain sufficient information about actual hospital costs incurred to furnish a new technology service. *Form Number:* CMS–10054 (OMB control number: 0938–0860); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 25; *Number of Responses:* 25; *Total Annual Hours:* 400. (For policy questions regarding this collection contact Josh Mcfeeters at 410–786–9732.)

William N. Parham, III,

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

[FR Doc. 2024–09745 Filed 5–3–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1133]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Pharmaceutical Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #290 (VICH GL61) entitled ''Pharmaceutical Development.'' This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance describes the suggested contents for the Pharmaceutical Development section, which provides an opportunity to present the knowledge gained through the application of scientific approaches and quality risk management to the development of a product and its manufacturing process.

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–1133 for ''Pharmaceutical Development.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The