

is submitted without a pre-claim review decision on one file, the Medicare contractor will request the information from the HHA to determine if payment is appropriate. For the post payment review option, the Medicare contractor will also request the information from the HHA provider who submitted the claim for payment from the Medicare program to determine if payment was appropriate. *Form Number:* CMS-10599 (OMB control number: 0938-1311); *Frequency:* Frequently, until the HHA reaches the target affirmation or claim approval threshold and then occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profits); *Number of Respondents:* 4,700; *Number of Responses:* 3,173,016; *Total Annual Hours:* 1,600,608. (For questions regarding this collection contact Jennifer McMullen (410)786-7635.)

**William N. Parham, III,**

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

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10630 and CMS-10198]

#### Agency Information Collection Activities: Submission for OMB Review; 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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by *August 13, 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](http://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:* Revision of a currently approved information collection; *Title of Information Collection:* The PACE Organization (PO) Monitoring and Audit Process; *Use:* Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR 460.190 and 460.192 mandate that CMS,

in conjunction with the SAA, audit POs annually for the first 3 years (during the trial period), and then on an ongoing basis following the trial period. The information gathered during this audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM), as well as the SAA, to assess POs' compliance with PACE program requirements. If outliers or other data anomalies are detected, other offices within CMS will work in collaboration with MOEG for follow-up and resolution. Additionally, POs will receive the audit results and will be required to implement corrective action to correct any identified deficiencies.

Information collected from the POs for use in the audit is obtained electronically through the Health Plan Management System (HPMS). HPMS is a system that was developed and is maintained by CMS and is used to securely transmit information between CMS and POs. All POs have access to HPMS, and users create and maintain a secure user id and password that is used each time HPMS is accessed. *Form Number:* CMS-10630 (OMB control number: 0938-1327); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 40; *Total Annual Responses:* 40; *Total Annual Hours:* 31,200. (For policy questions regarding this collection contact Katrina Hoadley at 410-786-8480 or [katrina.hoadley@cms.hhs.gov](mailto:katrina.hoadley@cms.hhs.gov)).

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Creditable Coverage Disclosure to CMS On-Line Form and Instructions; *Use:* Section 1860D-13 of the Social Security Act, as established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR 423.56(e), require that entities that offer prescription drug benefits under any of the types of coverage described in 42 CFR 423.56(b) provide a disclosure of creditable coverage to CMS. There are other disclosure and notification requirements to Part D eligible individuals in § 423.56(c), (d), and (f); this PRA covers the requirement in subsection (e). Entities required to make this disclosure state whether their prescription drug coverage meets the actuarial requirements defined in § 423.56(a).

Disclosure of whether prescription drug coverage is creditable provides Medicare with important information

relating to whether prescription drug benefits offered by an entity to Medicare Part D eligible individuals is expected to pay at least as much as the standard benefits under Medicare Part D. The form is used as a reporting tool where entities offering prescription drug coverage indicate whether the coverage being provided is considered creditable or non-creditable. *Form Number:* CMS–10198 (OMB control number 0938–1013); *Frequency:* Yearly; *Affected Public:* Individuals and Households, Private Sector, State, Local, or Tribal Governments, Federal Government, Business, and Not-for Profits; *Number of Respondents:* 141,400; *Number of Responses:* 141,400; *Total Annual Hours:* 11,786. (For questions regarding this collection contact Tammie Wall at 410–786–3317.)

**William N. Parham, III**

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

[FR Doc. 2025–13055 Filed 7–11–25; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2024–E–5009]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; KISUNLA

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for KISUNLA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

**DATES:** Anyone with knowledge that any of the dates as published (see

**SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by September 12, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 12, 2026. See “Petitions” in the

**SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 12, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### 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–E–5009 for “Determination of Regulatory Review Period for Purposes of Patent Extension; KISUNLA.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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 second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

**FOR FURTHER INFORMATION CONTACT:** Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term