

- h. Medicare Enrollment time frames: Effective and termination dates
- i. Medicare and VHA Dual enrollment timeframes: Effective and termination dates
- j. Date of death

### System(s) of Records

The records used in the matching program will be disclosed from the following systems of records, as authorized by routine uses published in the system of records notices (SORNs) cited below:

#### A. Systems of Records Maintained by CMS

1. Common Working File (CWF), System No. 09–70–0526, last published in full at 71 FR 64955 (Nov. 6, 2006), and partially updated at 78 FR 23938 (Apr. 23, 2013), 78 FR 32257 (May 29, 2013), and 83 FR 6591 (Feb. 14, 2018). Routine uses 2a and 10 authorize disclosures to VHA to contribute to the accuracy of CMS' proper payment of Medicare benefits, and to investigate potential fraud, waste, or abuse.

2. Medicare Beneficiary Database (MBD), System No. 09–70–0536, last published in full at 71 FR 70396 (Dec. 4, 2006), and partially updated at 78 FR 23938 (Apr. 23, 2013), 78 FR 32257 (May 29, 2013), and 83 FR 6591 (Feb. 14, 2018). Routine uses 2a and 11 authorize disclosures to VHA to contribute to the accuracy of CMS's proper payment of Medicare benefits, and to investigate potential fraud, waste, or abuse.

3. Medicare Integrated Data Repository (IDR), System No. 09–70–0571, last published in full at 71 FR 74915 (Dec. 13, 2006), and partially updated 76 FR 65196 (Oct. 20, 2011), 78 FR 23938 (Apr. 23, 2013), 78 FR 32257 (May 29, 2013), and 83 FR 6591 (Feb. 14, 2019). Routine uses 2a and 11 authorize disclosures to VHA to contribute to the accuracy of CMS's proper payment of Medicare benefits, and to investigate potential fraud, waste, or abuse.

4. National Claims History (NCH), System No. 09–70–0558, last published in full at 71 FR 67137 (Nov. 20, 2006), and partially updated at 76 FR 65196 (Oct 20, 2011), 78 FR 23938 (Apr. 23, 2013), 78 FR 32257 (May 29, 2013), and 83 FR 6591 (Feb. 14, 2018). Routine uses 2a and 10 authorize disclosure to VHA to contribute to the accuracy of CMS's proper payment of Medicare benefits, and to investigate potential fraud, waste, or abuse.

#### B. Systems of Records Maintained by VHA

1. SOR 147VA10, entitled "Enrollment and Eligibility Record-VA," last published at 86 FR 46090 (Aug. 17, 2021). Routine use 12 authorizes disclosures to federal agencies for purposes of preventing and detecting possible fraud or abuse by individuals in their operations and programs.

2. SOR 23VA10NB3, entitled "Non-VA Care (Fee) Records," last published at 80 FR 45590 (July 30, 2015). Routine use 12 authorizes disclosures to CMS for its use in identifying potential duplicate payments for healthcare services paid by VA and CMS. Routine use 30 authorizes disclosure to assist in preventing and detecting possible fraud or abuse by individuals in federal programs.

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10526]

#### 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 *June 24, 2024*.

**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:* Extension without change of a currently approved collection; *Title of Information Collection:* Cost-Sharing Reduction Reconciliation *Use:* Under established Department of Health and Human Services (HHS) regulations, although cost-sharing reduction (CSR) payments are not being advanced to qualified health plan (QHP) issuers at the present time, issuers are still permitted to submit data that compares the CSR-eligible enrollment for each issuer with their actual CSRs provided

by the issuer for covered services for each eligible enrollee in a benefit year. HHS will compare this CSR-eligible enrollment with the actual CSRs provided by the issuers that participate in the optional data submission window to verify the issuer's reporting of CSRs provided. This revised collection does not add any data elements and continues to make summary plan level reporting optional.

Based upon CMS' experience in the CSR data collection and evaluation process, CMS is not making any substantive changes to this information collection. *Form Number:* CMS-10526 (OMB Control Number: 0938-1266); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 150; *Number of Responses:* 150 *Total Annual Hours:* 2,363. (For policy questions regarding this collection, contact Deborah Noymer at 301-448-3755.)

**William N. Parham, III,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2000-D-0784]

#### International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing (Revision 1); 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 revised guidance for industry (GFI) #115 (VICH GL22) entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing (Revision 1)." 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). In order to establish the safety of veterinary drug residues in human food, a number of toxicological

evaluations are required, including the assessment of any effects on reproduction. The objective of this guidance is to ensure international harmonization of reproduction testing that is appropriate for the evaluation of effects on reproduction from long-term, low-dose exposures; these effects may be encountered from the presence of veterinary drug residues in food.

**DATES:** Submit either electronic or written comments on the draft guidance by July 22, 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-

2000-D-0784 for "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing (Revision 1)." 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 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See