data collections include online and onsite training session evaluations.

CMS uses information from the data collection activities to determine the extent to which the goals of each training and support session were achieved and to help CMS make improvements for future training and support sessions. The collected data helps CMS address its Government Performance and Results Act (GPRA) requirements, as well as CMS and HHS goals for support for, and open dialogue with, stakeholders.

The Affordable Care Act (ACA) was enacted to assist millions of Americans in obtaining affordable health care services and to allow more employers to offer insurance coverage to their employees in a cost-effective manner. Since the implementation of ACA in 2014, individuals and small businesses have been able to purchase private health insurance through competitive marketplaces called the ''Health Insurance Marketplace'' (Marketplace). CMS issued regulations for the establishment and practices of Marketplaces in States. The cooperation and coordination of States, health insurance issuers, the Federal Government and other key stakeholders is essential to the continued success of the Marketplace.

The Consolidated Appropriations Act (CAA) of 2021 became law on December 27, 2020. It is a $1.4 trillion omnibus spending agreement that encompasses many different provisions. Two (2) acts within the law apply to the Centers for Medicare and Medicaid Services (CMS) Center for Consumer Information and Insurance Oversight (CCIIO): Title I, ''No Surprises Act'' and Title II, ''Transparency'' (NST). Beginning in 2022, new protections through the No Surprises Act are in place to shield millions of consumers from surprise medical bills.

CMS is strongly committed to providing training, outreach, and technical assistance to stakeholders participating in the Marketplace and/or programs mandated by the ACA or NST. In addition, CMS recognizes that the success of Marketplaces and associated programs relies on the cooperation and coordination of States, issuers, Assisters, self-insured health plans, third-party administrators (TPA) of self-insured health plans, agents and brokers, Providers/Facilities, and other stakeholders. Therefore, CMS expects to design and conduct various consumer satisfaction and feedback surveys, usability tests, and focus groups for these respondents to complete. *Form Number:* CMS–10598 (OMB Control Number: 0938–1331); *Frequency:* Annually; *Affected Public:* Individuals and Households, Private Sector, State, Local, and Tribal Governments, Federal Government, Business or other for-profit, and not-for-profit institutions; *Number of Respondents:* 9,588; *Number of Responses:* 9,588 *Total Annual Hours:* 2,397 hours. (For policy questions regarding this collection contact Sonia Henderson at 301–492–4320.)

2. *Type of Information Collection Request:* Extension without change of a previously approved collection; *Title of Information Collection:* Federally Qualified Health Center Cost Report Form; *Use:* The Form CMS–224–14 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and to calculate the FQHC settlement amount. These providers, paid under the FQHC prospective payment system (PPS), may receive reimbursement outside of the PPS for Medicare reimbursable bad debts, pneumococcal, influenza, and COVID–19 vaccines, and monoclonal antibody products. CMS uses the Form CMS–224–14 for rate setting; payment refinement activities, including developing a FQHC market basket; Medicare Trust Fund projections; and to support program operations. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the FQHC Medicare cost report data to calculate Medicare margins; to formulate recommendations to Congress regarding the FQHC PPS; and to conduct additional analysis of the FQHC PPS. *Form Number:* CMS–224–14 (OMB control number: 0938–1298); *Frequency:* Yearly; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 2,967; *Total Annual Responses:* 2,967; *Total Annual Hours:* 172,086. (For policy questions regarding this collection contact LuAnn Piccione at 410–786–5423.)

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

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10516]

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 October 30, 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*. 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. Title of Information Collection: Program Integrity II; *Type of Information Collection Request:* Extension without change of a currently approved collection; *Use:* On March 23, 2010, the Patient Protection and Affordable Care Act (PPACA; Pub. L. 111–148) was signed into law and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was signed into law. The two laws implement various health insurance policies. On June 19, 2013, the Department of Health and Human Services (HHS) published proposed rule CMS–9957–P: Program Integrity: Exchanges, SHOP, Premium Stabilization Programs, and Market Standards (78 FR 37302) (Program Integrity Proposed Rule) which, among other things, contained third party disclosure requirements and data collections that supported the oversight of premium stabilization programs, State Exchanges, and qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FFEs). Parts of the proposed rule were finalized as Patient Protection and Affordable Care Act; Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule (Program Integrity Final Rule II), 78 FR 25326 (October 24, 2013). This information collection request relates to a portion of the information collection requirements set forth in the final rule. Form Number: CMS–10516 (OMB control number: 0938–1277); Frequency: Annually; Affected Public: Private Sector, State, Local, or Tribal Governments; Business or other for-profits, and Not-for Profits; Number of Respondents: 457; Number of Responses: 457; Total Annual Hours: 42,771. (For questions regarding this collection, contact Andrea Honig at (301) 492–4147.)

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–0598]

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: Genotoxicity Testing (Revision 2); 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) #116 (VICH GL23) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (Revision 2).'' 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 recommends a Standard Battery of Tests that can be used for the evaluation of the genotoxicity of veterinary drug residues in food.

DATES: Submit either electronic or written comments on the draft guidance by November 29, 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–0598 for ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (Revision 2).'' 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