DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10401 and CMS–10853]

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 September 18, 2023.

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. *Type of Information Collection Request:* Revision of the currently approved collection; *Title of Information Collection:* Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment; *Use:* The data collection and reporting requirements will be used by HHS to run the permanent risk adjustment program, including validation of data submitted by issuers, on behalf of States that requested HHS to run it for them. Risk adjustment is one of three market stability programs established by the Patient Protection and Affordable Care Act and is intended to mitigate the impact of adverse selection in the individual and small group health insurance markets inside and outside of the Health Insurance Exchanges. HHS will also use this data to adjust the payment transfer formula for risk associated with high-cost enrollees. Issuers and providers can use the alternative reporting requirements for mental and behavioral health records described herein to comply with State privacy laws. *Form Number:* CMS–10401 (OMB control number: 0938–1155); *Frequency:* Annually; *Affected Public:* State, local, or Tribal governments; *Number of Respondents:* 650; *Total Annual Responses:* 3,250; *Total Annual Hours:* 4,154,150. (For policy questions regarding this collection contact Jacqueline Wilson at (301–492–4400.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Patient Provider Dispute Resolution Requirements Related to Surprise Billing: Part II; *Use:* The Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently.

The Act adds a new Part E of title XXVII of the Public Health Service Act establishing requirements applicable to providers, and facilities. These include provisions at new PHS Act sections 2799B–6 which requires providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service for an individual. Providers and facilities are required to inquire if an individual is enrolled in a group health plan, group or individual health insurance coverage, a Federal Employees Health Benefits (FEHB) plan, or a Federal health care program and if enrolled in a group health plan, or group or individual health insurance coverage, or a health benefits plan under chapter 89 of title 5, whether the individual is seeking to have a claim for such item or service submitted to such plan or coverage (hereafter referred to as an ''uninsured (or self-pay) individual''). In the case that an uninsured (or self-pay) individual requesting a good faith estimate for an item or service or schedules an item or service to be furnished, PHS Act section 2799B–6(2)(B) and the October 2021 interim final rules at 45 CFR 149.610 require providers and facilities to furnish the good faith estimate to the uninsured (or self-pay) individual.

HHS will request information from uninsured (or self-pay) individuals in order to initiate patient-provider dispute resolution process. This information will be used to help determine eligibility for the patient-provider dispute resolution process and is necessary for determining which provider or facility should be contacted for dispute resolution. Providers and facilities are required to submit information to SDR entities to inform the SDR entity's payment determinations. *Form Number:* CMS–10853 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Individuals and Households, Private Sector, Business or other for-profits; *Number of Respondents:* 26,659; *Total Annual Responses:* 26,659; *Total Annual Hours:* 322,189. (For policy questions regarding

this collection contact Daniel Kidane at (301–786–0000.)

Dated: August 14, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–17731 Filed 8–16–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3104]

Optimizing the Use of Postapproval Pregnancy Safety Studies; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Optimizing the Use of Postapproval Pregnancy Safety Studies'' convened by the Duke-Margolis Center for Health Policy and supported by a cooperative agreement between FDA and Duke-Margolis. This workshop will include discussions of designs of postapproval pregnancy safety studies for drug and biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) and experiences with implementing these studies. The workshop also will include discussion of considerations for further development of a framework that describes how data from different types of postapproval pregnancy safety studies might optimally be used when it has been determined that this data should be collected.

DATES: The public workshop will be held in person and virtually on September 18, 2023, from 10 a.m. to 4 p.m., Eastern Daylight Time, and on September 19, 2023, from 10 a.m. to 2:30 p.m. Either electronic or written comments on this public workshop must be submitted by November 30, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in person at the National Press Club, 529 14th St. NW, Washington, DC 20045 and virtually using the Zoom Platform. The link for the public workshop will be sent to registrants upon registration for virtual attendance.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered for the subsequent workshop report describing the proposed framework, which will be published by October 2, 2024. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on November 30, 2023. 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–2023–N–3104 for ''Optimizing the Use of Postapproval Pregnancy Safety Studies.'' 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. 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.

FOR FURTHER INFORMATION CONTACT: Commander Vicky Chan, Food and Drug Administration, CDER, 10903 New Hampshire Ave., Bldg. 22, Rm. 3404, Silver Spring, MD 20993, 301–796–1639, *Vicky.Chan@fda.hhs.gov* or Anne Taylor, CBER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911, *Anne.Taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: