

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92-463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA-OH-22-001, Panel A, Occupational Safety and Health Education and Research Centers (ERC).

*Dates:* February 21–22, 2023.

*Times:* 12:00 p.m.–5:00 p.m. EST.

*Place:* Video-Assisted Meeting.

*Agenda:* To review and evaluate grant applications.

*For Further Information Contact:* Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505; Telephone: (304) 285-5951; Email: [MGoldcamp@cdc.gov](mailto:MGoldcamp@cdc.gov).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2022-26748 Filed 12-8-22; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10141]

**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 (the 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 February 7, 2023.

**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-10141—Medicare Prescription Drug Benefit Program**

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:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Program; *Use:* Plan sponsor and State information is used by CMS to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and ensure that correct information is disclosed to potential and current enrollees. *Form Number:* CMS-10141 (OMB control number: 0938-0964); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments; *Number of Respondents:* 4,631,393; *Total Annual Responses:* 95,802,400; *Total Annual Hours:* 25,506,943. (For policy questions

regarding this collection contact Shelly Winston at 410-786-3694.)

Dated: December 6, 2022.

**William N. Parham, III,**

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

[FR Doc. 2022-26807 Filed 12-8-22; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-D-2873]

#### Voluntary Malfunction Summary Reporting Program for Manufacturers; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled “Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers.” We are publishing this notice of availability for this draft guidance document to help manufacturers better understand and use the VMSR Program. It is intended to further explain, but not change, the conditions of the VMSR Program. This draft guidance is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by February 7, 2023 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-2022-D-2873 for “Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers.” 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)).

An electronic copy of the guidance document is available for download from the internet. See the

**SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Michelle Rios, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1116, Silver Spring, MD 20993-0002, 301-796-6107 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Each year, FDA receives over 2 million medical device reports (MDRs) of suspected device-related deaths, serious injuries, and malfunctions. The MDR Program is one of the postmarket surveillance tools that FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. Malfunction reports represent most of the MDRs received by FDA on an annual basis. As part of FDA’s postmarket surveillance for