system and improve data collection to enable a full understanding of the workforce issue.

The intended outcomes of the initiative are as follows:

1. Increase the availability and visibility of tools and resources to attract, train and retain the direct care workforce in quality jobs where they earn livable wages and have voice in their working environment, and have access to benefits and opportunities for advancement.

2. Increase the number of states that develop and sustain collaborations across state systems and workforce agencies to implement strategies that will improve the recruitment, retention, and advancement of high quality DCW jobs.

Program Name: Strengthening the Direct Care Workforce: A Technical Assistance and Capacity Building Initiative.

Recipient: The National Council on Aging.

Period of Performance: The supplement award will be issued for the third year of the five-year project period of September 30, 2022 through September 29, 2027.

Total Award Amount: $3,087,207 in FY 2024.

Award Type: Cooperative Agreement.

Statutory Authority: Section 411(13) of the Older Americans Act, section 161 (2) of the Developmental Disabilities Assistance and Bill of Rights Act, and section 21 program of the Rehabilitation Act of 1973.

Basis for Award: The National Council on Aging is currently funded to carry out the objectives of the project entitled *Strengthening the Direct Care Workforce: A Technical Assistance and Capacity Building Initiative* for the project period of September 30, 2022 through September 29, 2027. This supplement will enable the grantee to carry their work even further, providing technical assistance to more state partnerships. The additional funding will also expand grantee's capability to produce issue briefs, case studies, and other materials to disseminate lessons learned and best practices via the Direct Care Workforce Strategies Center website. The NCOA is uniquely positioned to complete the work called for under this cooperative agreement. NCOA's partners on this project include the University of Minnesota Institute on Community Integration, National Association of Councils on Developmental Disabilities, Advancing States, PHI, Lincoln University Paula J. Carter Center on Minority Health and Aging, National Association of Medicaid Directors, National Council on Independent Living, Center for Innovation, National Alliance for Caregiving, National Association of State Directors of Developmental Disabilities Services, and Social Policy Research Associates (SPR). The grantee, and all partners, will work in close coordination with one another and ACL on those tasks and activities to which they have committed to ensure realization of project goals and objectives.

ACL believes it is in the best interest of the Federal Government to supplement the current grantee's existing project. Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. Further, it could create unintended duplication of effort and missed opportunities for greater coordination. Additionally, if this supplement is not provided, the project would be unable to expand its current technical assistance and training efforts to reach more state partnerships across aging, disability and workforce stakeholders to work together to strengthen the direct care workforce.

Dated: August 24, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–19418 Filed 8–28–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2873]

Voluntary Malfunction Summary Reporting Program for Manufacturers; 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 a final guidance entitled ''Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers.'' This final guidance document is intended to help manufacturers better understand and use the VMSR Program. This guidance describes and clarifies several aspects of the VMSR Program, including the FDA's approach to determining the eligibility of product codes for the program and the conditions for submitting medical device reports (MDRs) for device malfunctions in summary format under the program.

DATES: The announcement of the guidance is published in the **Federal Register** on August 29, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 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 James Myers, 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 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 devices, the Agency reviews the MDRs submitted by both mandatory and voluntary reporters.

FDA has determined that for many devices, it is appropriate to permit manufacturers to submit malfunction summary reports on a quarterly basis, for certain malfunctions related to devices with certain product codes, instead of individual, 30-day malfunction reports. FDA is issuing this final guidance document to help manufacturers better understand and use the VMSR Program. This guidance describes and clarifies several aspects of the VMSR Program, including FDA's approach to determining the eligibility of product codes for the program and the conditions for submitting MDRs for device malfunctions in summary format under the program. The program began in 2018 when FDA issued a notification in the **Federal Register** of an order granting an alternative under 21 CFR 803.19 that permits manufacturers of devices in eligible product codes to report certain device malfunction MDRs in summary form on a quarterly basis, subject to the conditions of the alternative (83 FR 40973). FDA's VMSR Program is intended to yield benefits for FDA, the public, and manufacturers, such as increasing transparency for the public, helping FDA to process certain malfunction reports more efficiently, allowing both FDA and the public to identify malfunction trends more readily, and reducing the burden on manufacturers.

A notice of availability of the draft guidance appeared in the **Federal Register** of December 9, 2022 (87 FR 75634). FDA considered comments received and revised the guidance as appropriate in response to the comments. Changes from the draft to the final guidance include that the final guidance provides further clarification regarding how FDA determines the eligibility of a product code for inclusion in the VMSR Program and the conditions for submitting medical device reports for device malfunctions in summary format under the program. The final guidance also provides additional examples to facilitate submission utilizing Form FDA 3500A. It also clarifies how manufacturers may opt out of the VMSR program and provides links to an updated website to find product codes that are eligible for inclusion in the voluntary VMSR program.

Published elsewhere in this edition of the **Federal Register,** FDA is issuing a notification announcing a minor, technical modification to the VMSR Program alternative granted under 21 CFR 803.19, to align with the most current version of Form FDA 3500A and with current adverse event codes. This guidance is consistent with that modification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Voluntary

Malfunction Summary Reporting (VMSR) Program for Manufacturers'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00021007 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
803	Medical Device Reporting	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
806	Medical Devices; Reports of Corrections and Removals	0910–0359
Form FDA 3500A	MedWatch: Adverse Event and Product Experience Reporting System	0910–0291

Dated: August 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19413 Filed 8–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Minority Health and Health Disparities Special Emphasis Panel, August 28, 2024, 10 a.m. to August 29, 2024, 6 p.m., National Institutes of Health, NIMHD, DEM II, Suite 800, 6707 Democracy Boulevard, Virtual Meeting, Bethesda, MD, 20892 which was published in the **Federal Register** on July 22, 2024, FR Doc. No. 2024–16018, 89 FR 59124.

This notice is being amended to change the meeting dates from August 28–29, 2024 to August 28, 2024, 10:00 a.m. to 06:00 p.m. The meeting will be held as a virtual meeting and is closed to the public.

Dated: August 23, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–19402 Filed 8–28–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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. 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: Center for Scientific Review Special Emphasis Panel; Training in Veterinary and Comparative Medicine.

Date: October 3, 2024.

Time: 10:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joonil Seog, SCD Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–9791, *joonil.seog@nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Maximizing Investigators' Research Award—F Study Section.

Date: October 7–8, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Brian Paul Chadwick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3586, *chadwickbp@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 23, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–19405 Filed 8–28–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 1009 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. 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: National Institute of Nursing Research Special Emphasis Panel; Institutional Training Grant Review.

Date: September 27, 2024.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Nursing Research, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Weiqun Li, MD, Chief, Office of Scientific Review, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, Room 729, Bethesda, MD 20892, (301) 594–5966, *wli@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)