

For almost 30 years, the Eldercare Locator has helped older adults and their families navigate this complex environment by connecting those needing assistance with State and local agencies on aging that serve older adults and their caregivers.

The Eldercare Locator serves approximately 450,000 people a year through the call center. To ensure that the needs of those who contact the Eldercare Locator are carefully matched with the appropriate resources, information specialists are trained to listen closely to callers, identify relevant local, state and/or national resources and, when needed, provide a transfer to a particular resource.

As a trusted national resource, the supplement to the Eldercare Locator will be used to expand the capacity of the service to link a larger number of people with disabilities, including older adults and their family caregivers needing services from local organizations that can assist.

With the supplemental funding, ACL will fund the maintenance of the DIAL call center to support at least of 40,000 calls from people with disabilities and their caregivers. In addition, DIAL will utilize, maintain, and update a list of trusted resources to assist callers in making appropriate local connections. Having to sift through countless websites and make multiple phone calls to gain education and access to important community resources is a significant issue for people with disabilities.

Having an established one-stop call center to provide accurate and up-to-date state and local specific information and referrals on important information regarding local community resources for people with disabilities is critically needed. Using the established DIAL and Eldercare Locator infrastructure, this supplement will be used for maintaining and providing technical assistance about DIAL to assist people with disabilities to make appropriate state and local linkages to resources. The grantee, working with appropriate national disability organizations, will maintain a call center with a dedicated line and trained information specialists to serve approximately 40,000 people with disabilities.

Dated: August 20, 2024.

Alison Barkoff,

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

[FR Doc. 2024–19070 Filed 8–23–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0134]

Withdrawal of Approval and Amending of Mammography Quality Standards Act Alternative Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of withdrawal.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the withdrawal of two Mammography Quality Standards Act (MQSA) Alternative Standards and the amending of one Alternative Standard due to the updated MQSA regulations.

DATES: The relevant Alternative Standards will be withdrawn or amended as of September 10, 2024.

FOR FURTHER INFORMATION CONTACT: Preetham Sudhaker, Division of Mammography Quality Standards (DMQS), Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–5911.

SUPPLEMENTARY INFORMATION:

I. Background

On March 10, 2023, FDA issued a final rule (88 FR 15126) to update the mammography regulations that were issued under the Mammography Quality Standards Act of 1992 and the Federal Food, Drug, and Cosmetic Act. The final rule amending §§ 900.1 through 900.25 (21 CFR 900.1 through 900.25) will become effective September 10, 2024. Based on FDA's determination that withdrawing and amending several MQSA Alternative Standards is justified by § 900.12 (as amended in that final rule), in accordance with § 900.18, FDA is withdrawing approval of and amending those alternatives.

II. Withdrawal of Approval and Amendment of Alternative Standards

As of September 10, 2024, FDA is withdrawing approval of MQSA Alternative Standards #11 “Modifications in the Assessment Categories Used in Medical Reports” (<https://www.fda.gov/radiation-emitting-products/regulations-mqsa/mqsa-alternative-standard-11-modifications-assessment-categories-used-medical-reports>) and #12 “Assessment category for ‘Post Procedure Mammograms for Marker Placement’” (<https://www.fda.gov/radiation-emitting-products/regulations->

[mqsa/mqsa-alternative-standard-12-assessment-category-post-procedure-mammograms-marker-placement](https://www.fda.gov/radiation-emitting-products/regulations-mqsa/mqsa-alternative-standard-12-assessment-category-post-procedure-mammograms-marker-placement)). FDA is also amending the Alternative Standard #8 “Separate Assessment for Findings for Each Breast” (<https://www.fda.gov/radiation-emitting-products/regulations-mqsa/mqsa-alternative-standard-8-separate-assessment-findings-each-breast>).

FDA may approve an alternative to a quality standard under § 900.12 when the Agency determines that the proposed alternative standard is at least as effective in assuring quality mammography as the standard it proposes to replace, and is too limited in applicability to justify amending the standard, or when the expected benefit to human health is so great that the time needed to amend the standard presents an unjustifiable risk to human health. See § 900.18. Under § 900.18(g), FDA shall amend or withdraw approval of an alternative standard whenever the Agency determines that such action is necessary to protect the human health or where otherwise justified by § 900.12. For the reasons discussed below, FDA has determined that withdrawing and/or amending the Alternative Standards is justified by § 900.12.

FDA has determined that withdrawing Alternative Standard #11 is justified by § 900.12. Alternative Standard #11 provided an alternative standard to § 900.12(c)(1)(iv) and (v), which provides the categories of overall assessment of findings for use in the reports of mammography examinations. Specifically, the approved alternative allowed use of: (1) an additional assessment category (“Known Biopsy-Proven Malignancy”), (2) a reference to the possible need to obtain prior mammograms to make a final assessment for the “Incomplete” assessment category, and (3) certain clarifying language to various existing assessment categories (e.g., “Benign Finding(s)”, “Suspicious Abnormality” (emphases added)).

Amended § 900.12(c)(1)(iv) includes the additional assessment category “Known Biopsy-Proven Malignancy” and amended § 900.12(c)(1)(v) includes a new provision that addresses the potential need for prior mammograms for comparison for “Incomplete” assessments. Specifically, the amended § 900.12(c)(1)(v)(A) and (B) provides different requirements depending on whether facilities use the assessment category of “Incomplete: Need additional imaging evaluation” or “Incomplete: Need prior mammograms for comparison.” Alternative Standard #11, however, groups these two assessment categories into a single

assessment category: “Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison.” As such, it is not clear how a facility would comply with both the Alternative Standard and the other applicable requirements in the amended regulations.

Moreover, as discussed in the MQSA small entity compliance guide, FDA has generally exercised enforcement discretion regarding the final assessment category wording where the variation in wording does not change the meaning of the assessment category (e.g., “benign finding” instead of “benign” or “suspicious abnormality” instead of “suspicious”), and FDA intends to continue such a practice. Thus, FDA has determined that Alternative Standard #11 is no longer needed, no longer appropriate, and may cause confusion, and so withdrawal of Alternative Standard #11 is justified by § 900.12.

FDA also has determined that withdrawal of Alternative Standard #12 is justified by § 900.12. Alternative Standard #12 allowed use of an additional assessment category “Post Procedure Mammograms for Marker Placement.” As of the effective date of the MQSA final rule (September 10, 2024), the nearly identical assessment statement “Post-Procedure Mammogram for Marker Placement” is included in the amended § 900.12(c)(1)(iv)(G). Because amended § 900.12(c)(1)(iv)(G) incorporates Alternative Standard #12, FDA has determined that the alternative is no longer needed, no longer appropriate, and may cause confusion, and so withdrawal of Alternative Standard #12 is justified by § 900.12.

Finally, FDA is amending Alternative Standard #8, which permitted interpreting physicians to provide a separate assessment of findings for each breast in the medical report instead of a single overall assessment of findings as set forth in § 900.12(c)(1)(iv). Specifically, the alternative permitted: “A separate assessment of findings for each breast, classified in one of the following categories,” instead of “A separate final assessment of findings for each breast, classified in one of the following categories.” This language is being amended to use the term “final assessment” to match the updated language in amended § 900.12(c)(1)(v). As a result of the amended § 900.12, amending Alternative Standard #8 is justified by § 900.12.

Dated: August 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19058 Filed 8–23–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) hereby gives notice that the National Vaccine Advisory Committee (NVAC) will hold an in-person meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held September 12–13, 2024. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: <http://www.hhs.gov/nvpo/nvac/meetings/index.html> at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting in person or participate in public comment. Please register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Tower Building, Room, 1101 Wootton Parkway, Rockville, MD 20852. Email: nvac@hhs.gov. Phone: 202–795–7697.

SUPPLEMENTARY INFORMATION: Pursuant to section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program’s responsibilities.

The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During this meeting, the NVAC will hear presentations about implementation of the universal hepatitis B vaccine recommendations of adults aged 19–59 years and adults aged 60 years and older with risk factors for hepatitis B infection, new approaches for tuberculosis vaccine innovation, and research to inform future HIV vaccine development. The NVAC will also host panels on vaccine equity, provider payment, and planning for the development of the next national vaccine strategy.

Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: <http://www.hhs.gov/nvpo/nvac/index.html>.

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Members of the public may also submit written comments. Written comments should not exceed three pages in length. Individuals planning to submit comments should email their written comments or their request to provide a comment during the meeting to nvac@hhs.gov at least five business days prior to the meeting.

Dated: August 19, 2024.

Ann Aikin,

Acting Designated Federal Official, Office of the Assistant Secretary for Health.

[FR Doc. 2024–19053 Filed 8–23–24; 8:45 am]

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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