other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near-duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: The docket will be opened to receive written comments June 9–20, 2025. Written comments must be received by June 20, 2025.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes, including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the June 25–27, 2025, ACIP meeting must submit a request at *https://www.cdc.gov/acip/meetings/index.html* between June 9–20, 2025, and no later than 11:59 p.m., EDT, June 20, 2025, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a random draw to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by June 23, 2025. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to three minutes, and each speaker may speak only once per meeting.

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

[FR Doc. 2025–10432 Filed 6–6–25; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3476–N]

Medicare Program; Public Meeting for Air Ambulance Quality & Patient Safety Advisory Committee Notice of Public Meeting—July 10, 2025

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a virtual public meeting of the Air Ambulance Quality and Patient Safety (AAQPS) Advisory Committee. The AAQPS Advisory Committee will review options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances.

DATES:

Virtual Meeting Dates: The AAQPS Advisory Committee will hold a virtual meeting on July 10, 2025, from 10:00 a.m. to 5:00 p.m., Eastern Time.

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received at least 2 weeks before the meeting.

Registration Link: The virtual meeting will be open to the public and held via the Zoom webinar platform. Virtual attendance information will be provided upon registration. To register for the meeting, please visit *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-air-ambulance-quality-and-patient-safety.* Attendance is open to the public subject to any technical or capacity limitations.

Deadline for Registration: All individuals who plan to attend the virtual public meeting must register to attend. Request to provide oral comments are due at least 14 calendar days prior to the meeting date. Interested parties are encouraged to register as far in advance of the meeting as possible.

A detailed agenda and materials will be available prior to the meeting on the AAQPS Advisory Committee website at *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-air-ambulance-quality-and-patient-safety.*

A transcript and a summary of the meeting will be made available on the AAQPS Advisory Committee website approximately 45 calendar days after the meeting.

ADDRESSES: All meetings are open to the public and will be held virtually. Instructions to view the meeting will be posted on the AAQPS Advisory Committee website and upon registration. If you wish to provide oral comments during the meeting you must complete a registration form on the AAQPS Advisory Committee website at *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-air-ambulance-quality-and-patient-safety,* and submit a written copy of your remarks to *AAQPS@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Ashley Spence at (410) 786–2000 or via email at *AAQPS@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the U.S. Department of Health and Human Services (HHS) and the Secretary of the U.S. Department of Transportation established the Air Ambulance and Patient Safety (AAQPS) Advisory Committee on August 22, 2023, in response to Section 106 of the No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, div. BB, tit. I, Public Law 116–260 (December 27, 2020). The AAQPS Advisory Committee is tasked with reviewing options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances. The AAQPS Advisory Committee held its first meeting on December 12, 2024.

The AAQPS Advisory Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92–463 (October 6, 1972), as amended Title 5 of the United States Code (5 U.S.C. Ch.10).

II. Summary of the Agenda

The AAQPS Advisory Committee will review options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances at the July 10, 2025, meeting. The Centers for Medicare

& Medicaid Services (CMS) will make available a more detailed agenda and meeting materials no later than 3 days before the meeting on the AAQPS Committee website at *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-air-ambulance-quality-and-patient-safety.*

III. Public Participation

The meeting is open to the public for virtual attendance on a first-come, first-served basis, as there may be capacity or technical limitations. Please see the **ADDRESSES** section to view the meeting link.

We are committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as a sign language interpreter, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than 2 weeks before the meeting.

Presenting Oral Comments

CMS will accept oral comments, which must be limited to the objectives of the Committee and limited to 3 minutes per person. Individual members of the public who wish to present oral comments must register and provide a written copy of prepared remarks for inclusion in the meeting records and for circulation to AAQPS Advisory Committee members. All prepared remarks submitted on time will be considered as part of the meeting's record.

IV. Submitting Written Comments

Members of the public may submit written comments for consideration by the Committee at any time via email to *AAQPS@cms.hhs.gov.* Additionally, members of the public will have the opportunity to submit comments during the July 10, 2025, virtual meeting through the chat feature of the Zoom webinar platform. Members of the public are encouraged to email lengthy written comments to *AAQPS@cms.hhs.gov.* Advance submissions that are within the scope of the Advisory Committee will become part of the official record of the meeting.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–10401 Filed 6–6–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1873]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 9, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0508. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device User Fee Small Business Qualification and Certification

OMB Control Number 0910–0508—Revision

This information collection helps support implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), most recently reauthorized in 2022 from October 1, 2022, until September 30, 2027. To qualify as a ''small business,'' and therefore be eligible for reduced or waived fees, respondents submit information to FDA so we can determine whether the applicant is a small business. Sections 738(d)(2)(A) and (e)(2)(A) of the FD&C Act (21 U.S.C. 379j(d)(2)(A) and (e)(2)(A)) define a ''small business'' as an entity that reported $100 million or less of gross receipts or sales in its most recent Federal income tax return, including such returns of its affiliates, partners, and parent firms. If a firm's gross receipts or sales are no more than $30 million (including all affiliates, partners, and parent firms), they will also qualify for a waiver of the fee for their first (ever) premarket application (PMA), product development protocol (PDP), biological licensing application (BLA), or premarket report.

In the **Federal Register** of February 22, 2024 (89 FR 13349), FDA announced the availability of the draft guidance for industry entitled ''Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-medical-device-user-fee-small-business-qualification-and-certification-guidance*). The guidance includes select updates to the guidance ''Medical Device User Fee Small Business Qualification and Certification'' (August 2018), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification*) which describe how FDA plans to determine if a small business is experiencing ''financial hardship'' that makes them eligible for a waiver of their registration fee. A manufacturer seeking the small business fee waiver may provide evidence of a reported $1 million or less of gross receipts or sales in its most recent Federal income tax return, as well as evidence that they have filed a petition for bankruptcy and that the bankruptcy is currently active. The proposed updates also reflect that firms based in jurisdictions without a National Taxing Authority (NTA) need not submit a