

Advisory Committee on Air Ambulance Quality and Patient Safety Task Notice

ACTION: Notice of a new task assignment for the Advisory Committee on Air Ambulance Quality and Patient Safety (AAQPS).

SUMMARY: The Department of Health and Human Services (HHS) in coordination with the Department of Transportation (DOT) proposes a new AAQPS task to make recommendations in response to “The No Surprises Act” (Section 106(g)), as part of the Consolidated Appropriations Act, 2021, Public Law (Pub L.), 116-260.

This notice informs the public of the new AAQPS tasking and subcommittee activities.

BACKGROUND: Congress directed HHS and DOT to establish the AAQPS to provide recommendations to the Secretary of Health and Human Services and the Secretary of Transportation on options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances. AAQPS is governed by the provisions of the Federal Advisory Committee Act (FACA), as amended, Pub. L. 92-463, 5 United States (US) Code, Ch. 10).

The Committee, in consultation with relevant experts and stakeholders, as appropriate, shall develop and make publicly available a report on any recommendations submitted to Congress. The report must be developed and made publicly available no later than 180 days after the date of the Committee's first meeting.

On December 12, 2024, DOT and HHS assigned to AAQPS, the task to make recommendations regarding options for establishing qualifications of different clinical capability levels and tiering of such levels, patient safety and quality standards, and clinical triage criteria for air ambulances. AAQPS delegated this task to the Clinical Standards Subcommittee. Center for Clinical Standards and Quality (CCSQ) will serve as the Federal government representative to support the Clinical Standards Subcommittee.

THE TASK: The Clinical Standards Subcommittee will provide advice and recommendations pertaining to the most effective way to resolve statutory, regulatory, and guidance gaps for air ambulance clinical standards and quality. The subcommittee will review any relevant materials to assist in achieving their objective.

The subcommittee is tasked with:

1. Identifying any potential statutory, regulatory, guidance, and clinical standards gaps that are applicable to air ambulance clinical standards and quality.
2. Providing recommendations addressing the following but not limited to:
 - a. Qualifications for different clinical capability levels and tiering of such levels. This may include considerations related to specialty care versus critical care, regional certification requirements and cross state regulatory

- rules, specialty certification requirements, and scope of care and crew composition.
 - b. Patient safety and quality standards. This may include, but is not limited to, considerations related to infection prevention and control, communication and coordination with receiving medical facilities, standards of clinical care in the field, outcomes of care and accountability, and readiness capabilities.
 - c. Clinical triage criteria for air ambulances. This may include considerations related to the triaging systems currently available and used, overtriaging and undertriaging, and triage standardization.
3. Develop a summary containing recommendations on the findings and results of the tasks explained above.
 - a. The preliminary recommendations summary should document both majority and dissenting positions on the findings and the rationale for each position.
 - b. Any disagreements should be documented, including the rationale for each position and the reasons for the disagreement.
 4. The AAQPS may task the Clinical Standards Subcommittee with additional tasks.
 5. The subcommittee may be reinstated to respond to the AAQPS's questions or concerns after the preliminary recommendations have been submitted.

SCHEDULE: The recommendation summary is due May 8, 2024.

SUBCOMMITTEE ACTIVITY: The subcommittee must comply with the procedures adopted by the AAQPS and as follows:

1. Conduct a review and analysis of the assigned tasks and any other related materials or documents.
2. Provide a status report at each AAQPS meeting.
3. Draft and submit recommendation report based on the review and analysis of the assigned tasks.
4. Present the recommendation report at the AAQPS meeting.

PARTICIPATION IN THE SUBCOMMITTEE: CCSQ selected members of the Clinical Standards Subcommittee with consideration for achieving balanced membership that ensures diversity of perspectives for tasking and recommendations being considered and deliberated by the Committee. The subcommittee will solicit and collect stakeholder feedback, provide advice and recommendations on the assigned task, and review and approve submission of their recommendations to the AAQPS for its consideration. The subcommittee may invite subject matter experts to participate in the proceedings and assist the subcommittee's work.

The provisions of the guidance from the Office of Management and Budget, dated August 13, 2014, “Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards, and Commissions” (79 FR 47482), continues the ban on registered lobbyists participating on agency boards and commissions if participating in their “individual capacity”. The revised guidance now allows registered lobbyists to participate on agency boards and commissions in a “representative capacity” for the “express purpose of providing a committee with the views of a nongovernmental entity, a recognizable group of persons or nongovernmental entities (an industry, sector, labor unions, or environmental groups, etc.) or state or local government”. (For further information see Lobbying Disclosure Act of 1995 (LDA) as amended, 2 U.S.C 1603, 1604, and 1605).

The subcommittee shall not work independently of the chartered Committee and shall report all recommendations and advice to the AAQPS for deliberation and discussion.

Roles and Responsibilities

Members of the subcommittee, assigned to this new tasking should actively participate by attending all meetings, and providing written comments when requested. Members should devote the resources necessary to support the subcommittee in meetings and assigned deadlines. Subcommittee members should also keep their organization and the industry segment they may represent advised of subcommittee activities and decisions to ensure the proposed technical solutions do not conflict with the position of those they represent. Once the subcommittee has begun deliberations, members will not be added or substituted without the approval of the subcommittee chair, CCSQ, and the AAQPS Designated Federal Officer.

Confidential Information

All final work products submitted to the AAQPS are public documents. Therefore, those final work products should not contain any nonpublic proprietary, privileged, business, commercial, and other sensitive information (collectively, Confidential Information) that the subcommittee members would not want to be publicly available. With respect to the subcommittee, there may be instances where members will share Commercial Information within the subcommittee for purposes of completing an assigned task. Members must not disclose to any third party or use for any purposes other than the assigned task, any and all Confidential Information disclosed to one party by the other party, without the prior written consent of the party whose Confidential information is being disclosed. All parties must treat the Confidential Information of the disclosing party as it would treat its own Confidential Information, but in no event shall it use less than a reasonable degree of care. If any Confidential Information is shared with US government officials it must be properly marked in accordance with relevant agency policy.

The AAQPS meetings are open to the public. However, subcommittee meetings are not open to the public, except to the extent individuals with an interest and expertise are selected to participate.

FOR FURTHER INFORMATION CONTACT: For further information, contact Ashley Spence, Centers for Medicare & Medicaid Services at (410) 786–2000 or by email at AAQPS@cms.hhs.gov.