

more tables designed to collect specific information as detailed in Table 1.

TABLE 1—QUESTIONNAIRE DATA COLLECTION FORM DESIGN

Tab name	Description of data
Introduction .....	Introduction and instructions for completing and submitting the questionnaire.
Terms .....	Definitions or explanations of technical terms.
Facility Details .....	Information about facility registrations, ownership, general characteristics, facility-level data.
Room Area .....	Characteristics, inventory of components, and control of individual room areas where EtO is used or emitted.
EtO & EG Storage ..	Questions regarding EtO storage in drums and containers, and ethylene glycol (EG) tanks.
Sterilizer Chambers	Operation, monitoring, and control characteristics of sterilizer chambers, including chamber exhaust vents.
Aeration .....	Details of aeration equipment.
APCD Summary .....	Information about all air pollution control devices operated by the facility.
APCD Details .....	Details regarding air pollution control devices such as scrubbers, catalytic oxidizers, thermal oxidizers, and others.
EtO Monitoring .....	Information about workspace monitoring, personal monitoring, room monitoring conducted by facility.
Miscellaneous .....	Questions regarding facility's wastewater treatment and other items of EtO commercial sterilization operation.
Additional Info .....	Extra space to provide any additional information requested within the questionnaire.
Documents .....	Designated fields for reporter to attach documents requested throughout the questionnaire (e.g., facility diagram; process flow diagrams; air permit; permit application documents; startup, shutdown, malfunction plan; EtO calculations and supporting information; performance tests; engineering tests; parametric monitoring; standard operating procedures; EtO monitoring results; documentation of studies done on quantifying EtO residuals in your products; and other process and instrumentation diagrams).
Certification .....	Reporter's information and certification for completing and submitting the questionnaire.

As described in the instructions and the questionnaire, facilities may claim certain data as CBI in their response. There is a cell in each worksheet to indicate whether the worksheet contains CBI and if so, each cell containing data being claimed as CBI should be shaded red. It should be noted that CAA section 114(c) exempts emissions data from claims of confidentiality, and emissions data provided may be made available to the public. Emissions data should not be marked confidential. A definition of what the EPA considers emissions data is provided in 40 CFR 2.301(a)(2)(i). Facilities claiming CBI must submit both a non-confidential and confidential version of their response. All non-confidential responses to the ICR would be submitted to the EPA via email or on a thumb drive, CD-ROM, or DVD through the U.S. mail. All confidential responses to the ICR would be submitted on a thumb drive, CD-ROM, or DVD to the EPA through the U.S. mail. Non-confidential information collected from this ICR will be made available to the public. Any information designated as confidential by an ICR respondent that the EPA subsequently determines to constitute CBI or a trade secret under the EPA's CBI regulations at 40 CFR part 2, subpart B, will be protected pursuant to those regulations and, for trade secrets, under 18 U.S.C. 1905. If no claim of confidentiality accompanies the information when it is received by the EPA, it may be made available to the public by the EPA without further notice pursuant to the EPA regulations at 40 CFR 2.203.

*Form numbers:* None.

*Respondents/affected entities:* Facilities subject to 40 CFR part 63, subpart O.

*Respondent's obligation to respond:* Responses to the ICR are mandatory under the authority of section 114 of the CAA.

*Estimated number of respondents:* 66 (total).

*Frequency of response:* Once.

*Total estimated burden:* The estimated cumulative respondent burden is 6,201 hours. The estimated cumulative Agency burden to administer this ICR is 1,727 hours. Burden is defined at 5 CFR 1320.03(b).

*Total estimated cost:* The estimated cumulative costs to respondents is \$569,967, including \$995 operation and maintenance costs for media and postage for submitting questionnaires containing CBI. The estimated cumulative Agency costs is \$100,049 including \$1,440 operation and maintenance costs for data storage.

Dated: June 5, 2020.

**Penny Lassiter,**

*Director, Sector Policies and Programs Division.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3395-N]

### Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee—July 22, 2020

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

**ACTION:** Notice.

**SUMMARY:** This notice announces a virtual public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) ("Committee") will be held on Wednesday, July 22, 2020. This meeting will focus on the home use of noninvasive positive pressure ventilation in patients with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD). We are seeking the MEDCAC's recommendations regarding the characteristics that define those patient selection and usage criteria, concomitant services, and equipment parameters necessary to best achieve positive patient health outcomes in beneficiaries with CRF consequent to COPD. This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

#### **DATES:**

*Meeting Date:* The virtual meeting will be held on Wednesday, July 22, 2020 from 8:00 a.m. until 4:30 p.m., Eastern Daylight Time (EDT).

**Deadline for Submission of Written Comments:** Written comments must be received at the email address specified in the **ADDRESSES** section of this notice by 5:00 p.m., Eastern Daylight Time (EDT), on Monday, June 22, 2020. Once submitted, all comments are final.

**Deadlines for Speaker Registration and Presentation Materials:** The deadline to register to be a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation is 5:00 p.m., EDT, on Monday, June 22, 2020. Speakers may register by phone or via email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the email address specified in the **ADDRESSES** section of this notice.

**Submission of Presentations and Comments:** Presentation materials and written comments that will be presented at the meeting must be submitted via email to [MedCACpresentations@cms.hhs.gov](mailto:MedCACpresentations@cms.hhs.gov) section of this notice by Monday June 22, 2020.

**Deadline for All Other Attendees Registration:** Individuals who want to join the meeting may register online at <https://letsmeet.webex.com/letsmeet/onstage/g.php?MTID=e6f9d4471a6f1f77e29f5c34c64ccdc4d> by 11:59 p.m. EDT, on Sunday, July 19, 2020.

**Webinar and Teleconference Meeting Information:** Teleconference dial-in instructions, and related webinar details will be posted on the meeting agenda, which will be available on the CMS website <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. Participants in the MEDCAC meeting will require the following: a computer, laptop or smartphone where the WebEx application needs to be downloaded; a strong Wi-Fi or an internet connection and access to use Chrome or Firefox web browser and a webcam if the meeting participant is scheduled to speak or make a presentation during the meeting.

**Deadline for Submitting a Request for Special Accommodations:** Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the MEDCAC Coordinator as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5:00 p.m., EDT on Friday, June 26, 2020.

**ADDRESSES:** Due to the current COVID-19 public health emergency, the Panel meeting will be held *virtually*.

**FOR FURTHER INFORMATION CONTACT:** Tara Hall, MEDCAC Coordinator, via email at [Tara.Hall@cms.hhs.gov](mailto:Tara.Hall@cms.hhs.gov) or by phone 410-786-4347.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), is advisory in nature, with all final coverage decisions resting with CMS. MEDCAC is used to supplement CMS' internal expertise. Accordingly, the advice rendered by the MEDCAC is most useful when it results from a process of full scientific inquiry and thoughtful discussion, in an open forum, with careful framing of recommendations and clear identification of the basis of those recommendations. MEDCAC members are valued for their background, education, and expertise in a wide variety of scientific, clinical, and other related fields. (For more information on MEDCAC, see the MEDCAC Charter (<http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/medcaccharter.pdf>) and the CMS Guidance Document, *Factors CMS Considers in Referring Topics to the MEDCAC* (<http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10>).

**II. Meeting Topic and Format**

This notice announces the Wednesday, July 22, 2020, virtual public meeting of the Committee. This meeting will focus on the home use of noninvasive positive pressure ventilation in patients with CRF consequent to COPD. Devices to be considered are home mechanical ventilators (HMVs), bi-level positive airway pressure (BPAP) devices and continuous positive airway pressure (CPAP) devices. We are seeking the MEDCAC's recommendations regarding the characteristics that define those patient selection and usage criteria, concomitant services, and equipment parameters necessary to best achieve positive patient health outcomes in beneficiaries with CRF consequent to COPD. The MEDCAC will specifically focus on the scientific evidence associated with the outcomes most pertinent to the affected patient population. Outcomes of interest will include decreased mortality, decreased frequency of exacerbations requiring ER or hospital admission, increased time to hospital re-admission for respiratory related disease, and improved function and quality of life.

Background information about this topic, including panel materials, is

available at <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. Electronic copies of all the meeting materials will be on the CMS website no later than 2 business days before the meeting. We encourage the participation of organizations with expertise in the appraisal of the state of evidence for the use of HMV, BPAP, and CPAP equipment in the home for the affected patient population. This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 60 minutes. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than what can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 29, 2020. Your comments must focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following website prior to the meeting: <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed. Speakers presenting at the MEDCAC meeting must include a full disclosure slide as their second slide in their presentation for financial interests (for example, type of financial association—consultant, research support, advisory board, and an indication of level, such as minor association < \$10,000 or major association > \$10,000) as well as intellectual conflicts of interest (for example, involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting. If you are representing an organization, we require that you also disclose conflict of interest information for that organization. If you do not have a PowerPoint presentation, you will need to present the full disclosure information requested previously at the beginning of your statement to the Committee.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will

not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

**III. Registration Instructions**

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), and email address. You will receive a registration confirmation with instructions for your participation at the virtual public meeting.

**IV. Collection of Information**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Acting Director for the Center for Clinical Standards and Quality, at the Centers for Medicare & Medicaid Services, Jean Moody-Williams, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the **Federal Register Liaison**, to electronically sign this document for purposes of publication in the **Federal Register**.

**Authority:** 5 U.S.C. App. 2, section 10(a).

Dated: June 8, 2020.

**Evell J. Barco Holland,**

*Federal Register Liaison, Department of Health and Human Services.*

[FR Doc. 2020-12720 Filed 6-10-20; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Administration for Native Americans (ANA) Ongoing Progress Report (OPR) and Objective Work Plan (OWP)**

**AGENCY:** Administration for Native Americans, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families' (ACF) Administration for Native Americans (ANA) is requesting a revision to the information collection: Ongoing Progress Report (OPR) and the Objective Work Plan (OWP) (OMB #0970-0452). Changes are proposed to reduce the burden on the public by combining ANA's Annual Data Report (OMB #0970-0475) with the OPR.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Alternatively, copies can also be obtained by writing to the Administration for Children and

Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* Content changes are being made to the currently approved OPR. ANA will continue to use the currently approved OPR with minimal changes to the instructions for the remainder of fiscal year (FY) 2020 and will use the modified OPR beginning FY 2021. The modified OPR combines ANA's Annual Data Report (OMB #0970-0475) with the OPR. The information in the OPR is collected on a semi-annual basis to monitor the performance of grantees and better gauge grantee progress.

The OPR information collection is conducted in accordance with Sec. 811 [42 U.S.C. 2992] of the Native American Programs Act and will allow ANA to report quantifiable results across all program areas. It also provides grantees with parameters for reporting their progress and helps ANA better monitor and determine the effectiveness of their projects.

There are no changes proposed to the OWP. The OWP information collection is conducted in accordance with 42 U.S.C. of the Native American Programs Act of 1972, as amended. This collection is necessary to evaluate applications for financial assistance and determine the relative merits of the projects for which such assistance is requested, as set forth in Sec. 806 [42 U.S.C. 2991d-1](a)(1).

*Respondents:* Federally and state-recognized tribes, Native Pacific Islanders, Tribal Colleges and Universities, native non-profits, and consortia.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours*
Objective Work Plan .....	300	1	3	900	300
Ongoing Progress Report FY 2020 .....	200	2	1	400	133
Ongoing Progress Report FY 2021—Exp. Date .....	200	4	2	1600	533

\*Burden is annualized over the three year approval period.

*Estimated Total Annual Burden Hours: 966.*

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper

performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility,

and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information