unresponsive to optimal ventilation and/or pharmacologic management.

On January 8, 2013 (78 FR 1158), FDA issued a proposed order which, if made final, would make the class III ECMO devices class II subject to premarket notification (510(k)) and special controls. The regulatory history of ECMO devices has been discussed as part of the proposed rule (78 FR 1158).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to PMA) or reclassify to class II and comment on whether special controls are adequate to assure the safety and effectiveness of this device.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 28, 2013. On September 11, 2013, oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. for session I and between 2 p.m. and 2:30 p.m. for session II. On September 12, 2013, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 20, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA 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 August 22, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 7, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–19521 Filed 8–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Black Lung Clinics Program Performance Measures OMB No. 0915–0292—Extension.

Abstract: The Health Resources and Services Administration, Office of Rural Health Policy (HRSA/ORHP) conducts an annual data collection of user information for the Black Lung Clinic Program, which has been ongoing with OMB approval since 2004. The purpose of the Black Lung Clinic Program is to improve the health status of coal workers by providing services to minimize the effects of respiratory and pulmonary impairments of coal miners, including treatment required in the management of problems associated with black lung disease which improves the miners' quality of life and reduces economic costs associated with morbidity and mortality arising from pulmonary diseases. Collecting this data will provide HRSA information on how well each grantee is meeting the needs of active and retired miners in their communities.

Need and Proposed Use of the Information: Data from the annual report will provide quantitative information about the clinics, specifically: (a) The characteristics of the patients they serve (gender, age, disability level, occupation type); (b) the characteristics of services provided (medical encounters, non-medical encounters, benefits counseling, or outreach); and (c) the number of patients served. This assessment will enable HRSA to provide data required by Congress under the Government Performance and Results Act of 1993. It will also ensure that funds are effectively used to provide services that meet the target population needs. HRSA/ORHP's intent in using the current measures until the next competitive grant cycle (July 2014) is to allow grantees to make adjustments to their data collection/data reporting systems, as well as revise the general program requirements to more closely align with the statute.

Summary of Prior Comments and Agency Response

A 60-day **Federal Register** Notice was published in the **Federal Register** on

June 12, 2013, Vol. 78, No. 113; p. 35287. There were two public comments. One of the grantees recommended HRSA/ORHP eliminate the process measures and focus on outcome measures. HRSA is currently working on revising the measures for the entire program, and, as the grantee suggested, is attempting to focus the measures more on outcomes. As noted above, HRSA/ORHP's intent in using the current measures until the next competitive grant cycle (July 2014) is to allow grantees to make adjustments to their data collection/data reporting systems, as well as revise the general program requirements to more closely align with the statute. There will also be another period for the general public to comment on the new measures. Another grantee requested a copy of the measures, seeking clarification on what was being asked. Clarification was provided that none of the measures will be changed this year. The measures have been the same for the last several years.

Likely Respondents: Black Lung Clinics Program Grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Name of instrument	Black Lung Clinics Program Measures	1	15	10.0	150.00
Total	.....	1	15	10.0	150.00

Dated: August 6, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–19569 Filed 8–12–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: September 5, 2013, 10:00 a.m. to 4:00 p.m. EDT.

Place: Audio Conference Call and Adobe Connect Pro.

The ACCV will meet on Thursday, September 5 from 10:00 a.m. to 4:00 p.m. (EDT). The public can join the meeting by:

1. (Audio Portion) Calling the conference Phone Number 800–369–3104 and providing the following information:

Leaders Name: Dr. Vito Caserta

Password: ACCV

2. (Visual Portion) Connecting to the ACCV Adobe Connect Pro Meeting using the following URL: *https://hrsa.connectsolutions.com/accv/* (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL:

https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm and get a quick overview by following URL: *http://www.adobe.com/go/connectpro_overview.*

Call (301) 443–6634 or send an email to *aherzog@hrsa.gov* if you are having trouble connecting to the meeting site.

Agenda: The agenda items for the September meeting will include, but are not limited to, updates from the Division of Vaccine Injury Compensation (DVIC); Department of Justice (DOJ); National Vaccine Program Office (NVPO); Immunization Safety Office (Centers for Disease Control and Prevention); National Institute of Allergy and Infectious Diseases (National Institutes of Health); and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (*http://www.hrsa.gov/vaccinecompensation/accv.htm*) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857 or email: *aherzog@hrsa.gov.* Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by email, mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the ACCV should contact Annie Herzog, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; Telephone (301) 443–6593 or email: *aherzog@hrsa.gov.*

Dated: August 7, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–19576 Filed 8–12–13; 8:45 am]

BILLING CODE 4165–15–P