objectives for treatment of tuberculosis (TB), prevention of multi-drug resistance, and surveillance programs, CDC is requesting approval from the Office of Management and Budget to continue information collection from participants in the Model Performance Evaluation Program for Mycobacterium tuberculosis Susceptibility Testing. This revision request includes (a) modification of the Participant Biosafety Compliance Letter of Agreement to contain language to ensure that participants understand and comply with biosafety guidelines using quality management system practices; (b) modification of Instructions to Participants Letter to include detailed instructions for online data entry of DST results; (c) modification of MPEP Mycobacterium tuberculosis Results Worksheet to include fields for entering methods used for conventional and molecular DST; (d)addition of a MPEP Mycobacterium tuberculosis Minimum Inhibitory Concentration (MIC) Results form for laboratories performing this procedure to enter results manually and submit by email to *TBMPEP@cdc.gov;* and (e) reduction in request for burden hours from 156 hours to 129 hours due to fewer laboratories participating in the program compared to the previous submission request.

While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, prisoners, homeless populations, and individuals infected with HIV in major metropolitan areas. To reach the goal of eliminating TB, the Model Performance Evaluation Program for Mycobacterium tuberculosis Drug Susceptibility Testing is used to monitor and evaluate performance and practices among national laboratories performing M. tuberculosis susceptibility testing. Participation in this program is one way laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results.

Revision of this information collection provides CDC with an evaluation program to assess the ability of the laboratories to test for drug resistant M. tuberculosis strains, laboratories also have a self-assessment tool to aid in optimizing their skills in susceptibility testing. The information obtained from the laboratories on susceptibility practices and procedures is used to establish variables related to good performance, assessing training needs, and aid with the development of practice standards.

Participants in this program include domestic clinical and public health laboratories. Data collection from laboratory participants occurs twice per year. The data collected in this program will include the susceptibility test results of primary and secondary drugs, drug concentrations, and test methods performed by laboratories on a set of performance evaluation (PE) samples. The PE samples are sent to participants twice a year. Participants also report demographic data such as laboratory type and the number of tests performed annually.

There is no cost to respondents to participate other than their time. Total burden hours is 129.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Domestic Laboratories	Participant Biosafety Compliance Letter of Agreement.	80	1	5/60
	MPEP Mycobacterium tuberculosis Results Worksheet.	80	2	30/60
	Online Survey Instrument	80	2	15/60
	Minimum Inhibitory Concentration (MIC) Results Form.	4	2	15/60

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–27853 Filed 12–21–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4188–PN]

Medicare Program; Request for Renewal of Deeming Authority of the Utilization Review Accreditation Commission (URAC) for Health Maintenance Organizations and Preferred Provider Organizations

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

ACTION: Proposed notice.

SUMMARY: This proposed notice announces that CMS is considering granting approval of the Utilization Review Accreditation Commission's (URAC) renewal application for Medicare Advantage ''deeming authority'' of Health Maintenance Organizations and Preferred Provider Organizations. This new 6-year term of approval would begin on the date of publication of the final notice. This notice also announces a 30-day period for the public to submit comments on CMS' renewal of the application.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. January 25, 2019.

ADDRESSES: In commenting, refer to file code CMS–4188–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4188–PN, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4188–PN,

Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Greg McDonald, (410) 786–8941; or Nick Proy, (410) 786–8407.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services through a Medicare Advantage (MA) organization that contracts with CMS. The regulations specifying the Medicare requirements that must be met for a Medicare Advantage Organization (MAO) to enter into a contract with CMS are located at 42 CFR part 422. These regulations implement Part C of Title XVIII of the Social Security Act (the Act), which specifies the services that an MAO must provide and the requirements that the organization must meet to be an MA contractor. Other relevant sections of the Act are Parts A and B of Title XVIII and Part A of Title XI pertaining to the provision of services by Medicare certified providers and suppliers. Generally, for an entity to be an MA organization, the organization must be licensed by the state as a risk bearing organization, as set forth in 42 CFR part 422.

As a method of assuring compliance with certain Medicare requirements, an MA organization may choose to become accredited by a CMS approved accrediting organization (AO). By virtue of its accreditation by a CMS-approved AO, the MA organization may be ''deemed'' compliant in one or more requirements set forth in section 1852(e)(4)(B) of the Act. For CMS to recognize an AO's accreditation program as establishing an MA plan's compliance with our requirements, the AO must prove to CMS that their standards are at least as stringent as Medicare requirements for MA organizations. MA organizations that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs) and are accredited by an approved accrediting organization may receive, at their request, ''deemed'' status for CMS requirements for the deemable areas. At this time, recognition of accreditation does not include the Part D areas of review set out at 42 CFR 423.165(b). AOs that apply for MA deeming authority are generally recognized by the health care industry as entities that accredit HMOs and PPOs. As we specify at § 422.157(b)(2)(ii) the term for which an AO may be approved by CMS may not exceed 6 years. For continuing approval, the AO must apply to CMS to renew their ''deeming authority'' for a subsequent approval period.

The Utilization Review Accreditation Commission (URAC) was approved as a CMS approved accreditation organization for MA deeming of HMOs on May 26, 2012, and that term lapsed on May 25, 2018 prior to our decision on its renewal application. On October 13, 2017 URAC submitted its initial application to renew its deeming authority. On that same date, URAC submitted materials requested by CMS that included information intended to address the requirements set out at § 422.158(a) through (b) that are prerequisites for receiving approval of its accreditation program from CMS. CMS subsequently requested that additional materials, including revisions, be submitted by URAC to satisfy these requirements.

II. Provisions of the Proposed Notice

The purpose of this notice is to notify the public of URAC's request to renew its Medicare Advantage deeming authority for HMOs and PPOs. URAC submitted all the necessary materials (including its standards and monitoring protocol) to enable us to make a determination concerning its request for approval as an accreditation organization for CMS. This renewal application was determined to be complete on November 8, 2018. Under section 1852(e)(4) of the Act and § 422.158 (federal review of accrediting organizations), our review and evaluation of URAC will be conducted as discussed below.

A. Components of the Review Process

The review of URAC's renewal application for approval of MA deeming authority includes, but is not limited to, the following components:

- The types of MA plans that it would review as part of its accreditation process.
- A detailed comparison of the AO's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk) in the following 5 areas: Quality Improvement, Anti-Discrimination, Confidentiality and Accuracy of Enrollee Records, Information on Advance Directives, and Provider Participation Rules.
- Detailed information about the organization's survey process, including—

++ Frequency of surveys and whether surveys are announced or unannounced.

++ Copies of survey forms, and guidelines and instructions to surveyors.

++ Descriptions of—

—The survey review process and the accreditation status decision making process;

—The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies; and

—The procedures used to enforce compliance with accreditation requirements.

- Detailed information about the individuals who perform surveys for the accreditation organization, including—

++ The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

++ The education and experience requirements surveyors must meet;

++ The content and frequency of the in-service training provided to survey personnel;

++ The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

++ The organization's policies and practice for the participation, in surveys or in the accreditation decision process, by an individual who is professionally or financially affiliated with the entity being surveyed.

- A description of the organization's data management and analysis system for the surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.
- A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.
- A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.
- A description of all types (for example, full, partial) and categories (for

example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

- A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.
- A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization.
- The name and address of each person with an ownership or control interest in the accreditation organization.
- CMS will also consider URAC's past performance in the deeming program and results of recent deeming validation reviews, or look-behind audits conducted as part of continuing federal oversight of the deeming program under § 422.157(d).

B. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a notice in the **Federal Register** announcing the result of our evaluation. Section 1852(e)(4)(C) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. At the end of the 210-day period, we must publish an approval or denial of the application in the **Federal Register**.

III. Collection of Information Requirements

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. 3501 *et seq.*).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: December 14, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–27802 Filed 12–21–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7052–N]

Medicare & Medicaid Programs, and Other Program Initiatives, and Priorities; Meeting of the Advisory Panel on Outreach and Education (APOE), January 16, 2019

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

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning CMS programs, initiatives, and priorities. This meeting is open to the public.

DATES:

Meeting Date: Wednesday, January 16, 2019 8:30 a.m. to 4:00 p.m. eastern standard time (e.s.t).

Deadline for Meeting Registration, Presentations, Special Accommodations and Comments: Wednesday, January 2, 2019, 5:00 p.m., e.s.t.

ADDRESSES: *Meeting Location:* U.S. Department of Health & Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Room 705A, Conference Room, Washington, DC 20201.

Presentations and Written Comments: Presentations and written comments should be submitted to: Lynne Johnson, Acting Designated Federal Official (DFO), Office of Communications, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1–05–06, Baltimore, MD 21244–1850 or via email at *Lynne.Johnson@cms.hhs.gov.*

Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register at the website *https://www.regonline.com/apoe2019jan16meeting* or by contacting the Acting DFO listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, by the date listed in the **DATES** section of this notice. Individuals requiring sign language interpretation or other special accommodations should contact the Acting DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Lynne Johnson, Acting Designated Federal Official, Office of Communications, CMS, 7500 Security Boulevard, Mail Stop S1–05–06, Baltimore, MD 21244–1850, 410–786–0090, email *Lynne.Johnson@cms.hhs.gov.* Additional information about the APOE is available on the internet at: *http://www.cms.gov/Regulations-and-guidance/Guidance/FACA/APOE.html.* Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background

The Advisory Panel for Outreach and Education (APOE) (the Panel) is governed by the provisions of Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of federal advisory committees. The Panel is authorized by section 1114(f) of the Social Security Act (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a).

The Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) signed the charter establishing the Citizen's Advisory Panel on Medicare Education [1] (the predecessor to the APOE) on January 21, 1999 (64 FR 7899, February 17, 1999) to advise and make recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on the effective implementation of national Medicare education programs, including with respect to the Medicare+Choice (M+C) program added by the Balanced Budget Act of 1997 (Pub. L. 105–33).

The Medicare Modernization Act of 2003 (MMA) (Pub. L. 108–173) expanded the existing health plan options and benefits available under the

[1] We note that the Citizen's Advisory Panel on Medicare Education is also referred to as the Advisory Panel on Medicare Education (65 FR 4617). The name was updated in the Second Amended Charter approved on July 24, 2000.