

the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments; (2) assist States and their political subdivisions in preventing and suppressing communicable and non-communicable diseases and other preventable conditions and in promoting health and well-being; and (3) conduct and assist in research and control activities related to injury. The Board of Scientific Counselors makes recommendations regarding policies, strategies, objectives, and priorities; and reviews progress toward injury prevention goals and provides evidence in injury prevention-related research and programs. The Board also provides advice on the appropriate balance of intramural and extramural research, the structure, progress and performance of intramural programs. The Board is designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grants, cooperative agreements, and contracts applications received in response to the funding opportunity announcements as it relates to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios, and (5) review of program proposals.

**Matters to be Considered:** The Board of Scientific Counselors will discuss science matters to include research strategies needed to guide the Center's focus on reducing opioid overdose and to review the recommendations from the opioid prescribing for acute and chronic pain workgroup. Agenda items are subject to change as priorities dictate.

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.

**Sherri Berger,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2018-23976 Filed 11-1-18; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Council for the Elimination of Tuberculosis Meeting (ACET)

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting of the Advisory Council for the Elimination of Tuberculosis Meeting (ACET). This meeting is open to the public, limited only by the space available. The meeting room accommodates approximately 80 people and has 100 ports for audio phone lines. Time will be available for public comment. The public is welcome to submit written comments in advance of the meeting. Comments should be submitted in writing by email to the contact person listed below. The deadline for receipt is Monday, December 10, 2018. Persons who desire to make an oral statement, may request it at the time of the public comment period on December 12, 2018 at 11:40 a.m., EST.

**DATES:** The meeting will be held on December 11, 2018, 8:30 a.m. to 4:30 p.m., EST and December 12, 2018, 8:30 a.m. to 12:00 p.m., EST.

**ADDRESSES:** 8 Corporate Blvd., Building 8, Conference Rooms 1-A/B/C, Atlanta, Georgia, 30329 and Web conference: 1-877-927-1433 and participant passcode: 12016435 and <https://adobeconnect.cdc.gov/r5p8l2tytpq/>.

**FOR FURTHER INFORMATION CONTACT:** Margie Scott-Cseh, Committee Management Specialist, CDC, 1600 Clifton Road, NE, Mailstop: E-07, Atlanta, Georgia, 30333, telephone (404) 639-8317; [zkr7@cdc.gov](mailto:zkr7@cdc.gov).

#### SUPPLEMENTARY INFORMATION:

**Purpose:** This Council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

**Matters to be Considered:** The agenda will include discussions on (1) Division

of Tuberculosis Elimination (DTBE) funded Demonstration Project on Latent Tuberculosis Infection (LTBI) Testing and Treatment; (2) DTBE Communications Messaging and Campaigns; (3) Update on LTBI Treatment Guidelines; (4) Update on Drug Resistant Tuberculosis Guidelines; and (5) Update from ACET workgroups. Agenda items are subject to change as priorities dictate.

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.

**Sherri Berger,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2018-23974 Filed 11-1-18; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3371-PN]

#### Medicare and Medicaid Programs: Accreditation Commission for Health Care, Inc (ACHC) for Approval of its End Stage Renal Disease (ESRD) Facility Accreditation Program

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

**ACTION:** Notice with request for comment.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from the Accreditation Commission for Health Care, Inc., for recognition as a national accrediting organization for End Stage Renal Disease Facilities that wish to participate in the Medicare or Medicaid programs.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 3, 2018.

**ADDRESSES:** In commenting, refer to file code CMS-3371-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-3371-PN, P.O. Box 8010, Baltimore, MD 21244-8010.

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-3371-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Monda Shaver, (410) 786-3410, Joann Fitzell, (410) 786-4280, or Renee Henry, (410) 786-7828.

#### **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 from an end-stage renal disease (ESRD) facility provided the facility meets the requirements established by the Secretary of the Department of Health and Human Services (the Secretary). Section 1881(b) of the Social Security Act (the Act) establishes distinct requirements for facilities seeking designation as an ESRD facility under Medicare. Regulations concerning provider agreements and supplier approval are at 42 CFR part 489 and those pertaining to activities relating to the survey, certification, and enforcement procedures of suppliers which include ESRD facilities are at 42 CFR part 488. The regulations at 42 CFR part 494 subparts A through D implement section 1881(b) of the Act, which specify the conditions that an

ESRD facility must meet in order to participate in the Medicare program and the conditions for Medicare payment for ESRD facilities.

Generally, to enter into a Medicare agreement, an ESRD facility must first be certified by a State survey agency (SA) as complying with the conditions or requirements set forth in part 494 subparts A through D of our Medicare regulations. Thereafter, the ESRD facility is subject to regular surveys by a SA to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Section 1865(a)(1) of the Act had historically excluded dialysis facilities from participating in Medicare via a CMS-approved accreditation program; however, section 50404 of the Bipartisan Budget Act of 2018 amended section 1865(a) of the Act to include renal dialysis facilities as provider entities allowed to participate in Medicare through a CMS-approved accreditation program. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. An AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

### **II. Provisions of the Proposed Notice**

#### *A. Approval of Deeming Organizations*

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with

the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of Accreditation Commission for Health Care, Inc.'s (ACHC's) request for CMS-approval of its ESRD facility accreditation program. This notice also solicits public comment on whether ACHC's requirements meet or exceed the Medicare conditions for coverage (CfCs) for ESRD facilities.

#### *B. Evaluation of Deeming Authority Request*

ACHC submitted all the necessary materials to enable us to make a determination concerning its request for CMS-approval of its ESRD facility accreditation program. This application was determined to be complete on September 13, 2018. Under section 1865(a)(2) of the Act and regulations at § 488.5, our review and evaluation of ACHC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of ACHC's standards for ESRD facilities as compared with Medicare's CfCs for ESRD facilities.
- ACHC's survey process to determine the following:
  - ++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
  - ++ The comparability of ACHC's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
  - ++ ACHC's processes and procedures for monitoring an ESRD facility found out of compliance with ACHC's program requirements. These monitoring procedures are used only when ACHC identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).
  - ++ ACHC's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ ACHC's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of ACHC's staff and other resources, and its financial viability.

++ ACHC's capacity to adequately fund required surveys.

++ ACHC's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ ACHC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

### 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. Chapter 35).

### IV. Response to Public 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.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: October 19, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2018-23925 Filed 11-1-18; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-9111-N]

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2018

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

**ACTION:** Notice.

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2018, relating to the Medicare and Medicaid programs and other programs administered by CMS.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

| Addenda                                                                          | Contact                | Phone Number   |
|----------------------------------------------------------------------------------|------------------------|----------------|
| I CMS Manual Instructions                                                        | Ismael Torres          | (410) 786-1864 |
| II Regulation Documents Published in the <b>Federal Register</b>                 | Terri Plumb            | (410) 786-4481 |
| III CMS Rulings                                                                  | Tiffany Lafferty       | (410)786-7548  |
| IV Medicare National Coverage Determinations                                     | Wanda Belle, MPA       | (410) 786-7491 |
| V FDA-Approved Category B IDEs                                                   | John Manlove           | (410) 786-6877 |
| VI Collections of Information                                                    | William Parham         | (410) 786-4669 |
| VII Medicare –Approved Carotid Stent Facilities                                  | Sarah Fulton, MHS      | (410) 786-2749 |
| VIII American College of Cardiology-National Cardiovascular Data Registry Sites  | Sarah Fulton, MHS      | (410) 786-2749 |
| IX Medicare's Active Coverage-Related Guidance Documents                         | JoAnna Baldwin, MS     | (410) 786-7205 |
| X One-time Notices Regarding National Coverage Provisions                        | JoAnna Baldwin, MS     | (410) 786-7205 |
| XI National Oncologic Positron Emission Tomography Registry Sites                | Stuart Caplan, RN, MAS | (410) 786-8564 |
| XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities | David Dolan            | (410) 786-3365 |
| XIII Medicare-Approved Lung Volume Reduction Surgery Facilities                  | Sarah Fulton, MHS      | (410) 786-2749 |
| XIV Medicare-Approved Bariatric Surgery Facilities                               | Sarah Fulton, MHS      | (410) 786-2749 |
| XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials           | Stuart Caplan, RN, MAS | (410) 786-8564 |
| All Other Information                                                            | Annette Brewer         | (410) 786-6580 |

### SUPPLEMENTARY INFORMATION:

#### I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional

offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public

Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.