Design (PtD) concepts, and leads the PtD program.

• Division of Field Studies and Engineering (CCK): (1) Conducts the legislatively mandated health hazard evaluation and industry-wide research programs through longitudinal record-based studies and field studies to identify the occupational causes of disease in working populations and their offspring, and determines the incidence and prevalence of acute and chronic effects from work-related exposures to hazardous substances; (2) conducts exposure, epidemiologic, and engineering research for input to standards to control occupational health hazards; (3) plans and conducts worksite and laboratory engineering research to identify, evaluate, develop and implement technology to prevent workers' exposures to chemical, biological, and physical agents; (4) plans and conducts laboratory and worksite research to develop strategies to prevent occupational hearing loss and musculoskeletal disorders; (5) develops and maintains data systems, using national and state data, that track the magnitude and extent of job-related illnesses, exposures, and hazardous agents among the nation's workers; (6) provides support for first responders during national emergency response activities; and (7) provides technical assistance and consultation on matters pertaining to occupational safety and health to other Federal, state, and local agencies, and other groups or individuals.

• Field Research Branch (CCKC): (1) Conducts and supports etiologic and exposure assessment research studies in working populations; (2) communicates research results to workers, scientists, industry, and the public; (3) provides research data for the development of health hazard controls and protective standards; and (4) conducts research using workers' compensation data and systems to identify hazards and improve workplace safety and health.

• Health Informatics Branch (CCKD): (l) Develops, maintains, and uses data and record systems to track the magnitude and extent of job-related illnesses and exposures among the nation's workers using new and existing data from sources such as Federal, State, and local agencies, labor, industry, tumor registries, medical, laboratory, and other records; (2) uses novel research methods to identify and develop, or in certain instances, support the development of new sources of data for surveillance and research purposes; (3) develops new surveillance research methods; and (4) uses new technologies to communicate health and exposure information to stakeholders and the public.

• Engineering and Physical Hazards Branch (CCKE): (1) Plans and conducts research on engineering control technology to prevent worker exposures to hazards and promotes the application of effective engineering control technologies for safeguarding worker health and safety; (2) provides consultation in the application of effective control solutions and techniques for hazard prevention; (3) conducts research related to occupational hearing loss, including causative factors, noise control, hearing protection devices, and impulse noise to prevent occupational hearing loss for workers at risk in non-mining sectors; (4) conducts research related to ergonomic hazards including developing engineering controls in the laboratory and evaluating their effectiveness in the workplace to prevent workplace musculoskeletal disorders; and (5) conducts rapid prototype research to design and develop control solutions to workplace exposure problems.

IV. Delegations of Authority: All delegations and redelegations of authority made to officials and employees of affected organizational components will continue with them or their successors pending further redelegation, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101)

Alex M. Azar II,

Secretary.

[FR Doc. 2019–07035 Filed 4–9–19; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3371–FN]

Medicare and Medicaid Programs: Approval of an Application From Accreditation Commission for Health Care, Inc. for CMS Approval of Its End Stage Renal Disease (ESRD) Facility Accreditation Program

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

ACTION: Final notice.

SUMMARY: This final notice announces our approval of the Accreditation Commission for Health Care, Inc. (ACHC) for recognition as a national accrediting organization (AO) for End Stage Renal Disease (ESRD) Facilities that wish to participate in the Medicare or Medicaid programs.

DATES: The approval announced in this final notice is effective April 11, 2019 through April 11, 2023.

FOR FURTHER INFORMATION CONTACT: Tara Lemons, (410) 786–3030, Monda Shaver, (410) 786–3410 or Joann Fitzell (410) 786–4280.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in 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 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.

For an ESRD facility to enter into a provider agreement with the Medicare program, an ESRD facility must first be certified by a State survey agency as complying with the conditions or requirements set forth in section 1881(b) of the Act and our regulations at part 494 subparts A through D. Subsequently, the ESRD facility is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. However, there is an alternative to State compliance surveys. Certification by a nationally recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that, if the Secretary finds that accreditation of a provider entity by an approved national accrediting organization (AO) meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions, that is, we may ''deem'' the provider entity to be in compliance. Accreditation by an AO is voluntary and is not required for Medicare participation.

Section 1865(a)(1) of the Act had historically excluded dialysis facilities from participating in Medicare via a Centers for Medicare & Medicaid Services (CMS)-approved accreditation program; however, section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) 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.

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. Application Approval Process

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 that were not in compliance with the conditions or requirements; and their 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.

III. Provisions of the Proposed Notice

On November 2, 2018, we published a proposed notice in the **Federal Register** announcing Accreditation Commission for Health Care, Inc.'s (ACHC's) request for approval of its Medicare ESRD facility accreditation program (83 FR 55172). In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of ACHC's Medicare ESRD Facility accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- An onsite administrative review of ACHC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ESRD facilities; and, (5) survey review and decision-making process for accreditation.
- A comparison of ACHC's Medicare accreditation program standards to our current Medicare ESRD facility Conditions for Coverage (CfCs).
- A documentation review of ACHC's survey process to do the following:

++ Determine the composition of the survey team, surveyor qualifications, and ACHC's ability to provide continuing surveyor training.

++ Compare ACHC's processes to those we require of State survey agencies, including periodic re-survey and the ability to investigate and respond appropriately to complaints against accredited ESRD Facilities.

++ Evaluate ACHC's procedures for monitoring ESRD Facilities it has found to be out of compliance with ACHC's program requirements. This pertains only to monitoring procedures when ACHC identifies non-compliance. If non-compliance is identified by a State survey agency through a validation survey, the State survey agency monitors corrections as specified at § 488.9(c)(1).

++ Assess ACHC's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

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

++ Determine the adequacy of ACHC's staff and other resources.

++ Confirm ACHC's ability to provide adequate funding for performing required surveys.

++ Confirm ACHC's policies with respect to surveys being unannounced.

++ Obtain 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 we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the November 2, 2018, proposed notice also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare CfCs for ESRD facilities. No comments were received.

IV. Provisions of the Final Notice

A. Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared ACHC's ESRD facility accreditation requirements and survey process with the Medicare CfCs at part 494, and the survey and certification process requirements of parts 488 and 489. ACHC's standards and standards crosswalk were also examined to ensure that the appropriate CMS regulations would be included in citations as appropriate. Our review and evaluation of ACHC's ESRD facility application, which was conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, ACHC has revised the following standards and certification processes:

- Section 494.30(a)(3)–(4), to ensure that its interpretive guidance includes HBV-specific procedures.
- Section 494.90(a)(7)(ii)(C), to ensure that its standard includes the full CMS regulatory reference.
- Section 494.100(c)(1)(iii), to ensure that its standard includes the full CMS regulatory reference.
- Section 494.100(c)(2), to ensure that its standards address requirements to ensure patient privacy.
- Section 494.110, to ensure that its standards address the complexity of the facility's organization.
- Section 494.120(c)(1)(iii), to correct the CMS reference noted in its standard.
- Section 494.170(c), to accurately reflect the federal requirements for retaining records when state statutes are less restrictive, and to ensure that its standard includes the full CMS regulatory reference.
- ACHC revised its policies, procedures and surveyor worksheets to ensure that survey documentation is consistently and accurately completed; contains sufficient detail; and provides quantifiable information when appropriate.
- ACHC revised its policies and procedures to clearly delineate the criteria for determining the size and composition of its survey teams.
- ACHC revised its policies and procedures to ensure all deemed surveys remain unannounced.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that ACHC's

ESRD facility accreditation program requirements meet or exceed our requirements, and its survey processes are also comparable. Therefore, we approve ACHC as a national accreditation organization for ESRD facilities that request participation in the Medicare program, effective April 11, 2019 through April 11, 2023.

V. 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.*).

Dated: April 5, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–07135 Filed 4–9–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10003]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by June 10, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10003 Notice of Denial of Medical Coverage (or Payment) (NDMCP)

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medical Coverage (or Payment) (NDMCP); *Use:* Section 1852(g)(1)(B) of the Social Security Act (the Act) requires Medicare health plans to provide enrollees with a written notice in understandable language of the reasons for the denial and a description of the applicable appeals processes. Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans (HCPPs), are required to issue the Notice of Denial of Medical Coverage (or Payment) (NDMCP) when a request for either a medical service or payment is denied, in whole or in part. Additionally, the notices inform Medicare enrollees of their right to file an appeal, outlining the steps and timeframes for filing. All Medicare health plans are required to use these standardized notices. *Form Number:* CMS–10003 (OMB control number: 0938–0829); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 694; *Total Annual Responses:* 9,373,200; *Total Annual Hours:* 1,561,575. (For policy questions regarding this collection contact Staci Paige at 410–786–1943.)

Dated: April 4, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–07022 Filed 4–9–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as