de: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3366-PN]

Medicare and Medicaid Programs: National Dialysis Accreditation Commission (NDAC) for Approval of its End Stage Renal Disease (ESRD) Facility Accreditation Program

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

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from the National Dialysis Accreditation Commission (NDAC) 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: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: In commenting, refer to file code CMS-3366-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-3366-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-3366-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:

Tara Lemons, (410) 786-3030, Monda Shaver, (410) 786-3410, or

Marie Vasbinder, (410) 786-8665.

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 Web site as soon as possible after they have been

received: http://www.regulations.gov. Follow the search instructions on that Web site 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 (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 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 State survey agency 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 prohibited dialysis facilities from participating in Medicare via a CMS-approved accreditation program; however, section 50403 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 National Dialysis Accreditation Commission's (NDAC) request for CMS-approval of its ESRD facility accreditation program. This notice also solicits public comment on whether NDAC's requirements meet or exceed the Medicare conditions for coverage (CfCs) for ESRD facilities.

This is the first application from a national accreditation body seeking approval of an accreditation program for ESRD facilities.

B. Evaluation of Deeming Authority Request

NDAC 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 June 8, 2018. Under section 1865(a)(2) of the Act and our regulations at §488.5, our review and evaluation of NDAC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of NDAC's standards for ESRD facilities as compared with Medicare's CfCs for ESRD facilities.

- NDAC'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 NDAC's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ NDAC's processes and procedures for monitoring an ESRD facility found out of compliance with NDAC's program requirements. These monitoring procedures are used only when NDAC 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).

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

++ NDAC'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 NDAC's staff and other resources, and its financial viability.

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

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

++ NDAC'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. 3501 et seq.).

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: July 27, 2018.

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Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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