DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3366–FN]

Medicare and Medicaid Programs: Approval of an Application From National Dialysis Accreditation Commission 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 decision to approve 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: The approval announced in this notice is effective January 4, 2019 through January 4, 2023.

FOR FURTHER INFORMATION CONTACT: Renee Henry, (410) 786–7828, 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 August 7, 2018, we published a proposed notice in the **Federal Register** announcing National Dialysis Accreditation Commission's (NDAC's) request for approval of its Medicare ESRD facility accreditation program (83 FR 38697). 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 NDAC'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 NDAC'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 NDAC's Medicare accreditation program standards to our current Medicare ESRD facility Conditions for Coverage (CfCs).
- A documentation review of NDAC's survey process to do the following:

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

++ Compare NDAC'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 NDAC's procedures for monitoring ESRD Facilities it has found to be out of compliance with NDAC's program requirements. (This pertains only to monitoring procedures when NDAC 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 NDAC's ability to report deficiencies to the surveyed facilities

and respond to the facility's plan of correction in a timely manner.

++ Establish NDAC'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 NDAC's staff and other resources.

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

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

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

In accordance with section 1865(a)(3)(A) of the Act, the August 7, 2018, proposed notice also solicited public comments regarding whether NDAC's requirements met or exceeded the Medicare CfCs for ESRD facilities. Six comments were submitted. Of these comments, four were in full support of approving NDAC as a new AO for ESRD Facilities. They welcomed the additional support this would provide the industry in certifying facilities. CMS thanks them for their support. One commenter voiced support of allowing accreditation of ESRD facilities, but expressed concern that continuing to allow State Survey Agencies to conduct surveys when accreditation is allowed would cause confusion for facilities. CMS thanks the commenter for their submission; however, the law allows an ESRD facility to be surveyed by a State Survey Agency or an accrediting organization. Accreditation by an AO is a voluntary choice made by the ESRD facility. In addition, this process of allowing certification either through accreditation by an AO or through a survey performed by a State Survey Agency has been well established in other programs and does not, to our knowledge, present any confusion to providers. One commenter encouraged CMS to continue to recognize the value of home-only programs. Another commenter expressed concern with NDAC's ability to provide sufficient national coverage with limited staffing available to travel and respond to certification needs and complaints. This commenter also expressed concern over Conflict of Interest related to NDAC conducting mock surveys in the past for some facilities, which may be potential clients. In its application, NDAC addressed staffing requirements adequately to support national expansion. With respect to conflict of interest concerns, we believe that NDAC addressed these concerns adequately in their application and will conduct unbiased surveys. Firewalls and policies surrounding conflicts of interest are in line with other approved AO programs.

IV. Provisions of the Final Notice

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

We compared NDAC'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. NDAC'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 NDAC'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, NDAC has revised the following standards and certification processes:

- Section 494.30(a)(1)(i), to ensure that its interpretive guidance accurately reflects the appropriate CMS standard.
- Section 494.40(a), to ensure that appropriate maximum allowable limits for microbial and endotoxin counts are comparable to CMS requirements and to clarify that bacteria counts can be tested via outside lab or dip test.
- Section 494.60(d)(4)(ii), to correct its related standards crosswalk to accurately reflect the CMS standards references and the 2012 edition of the Life Safety Code.
- Section 494.70(a)(14), to clarify language that each facility must develop and implement an internal grievance process.
- Section 494.70(a)(16), to clarify language that each facility must inform patients that they can file a grievance.
- Section 494.70(d), to accurately reflect current CMS regulations and references.
- Section 494.90(b)(1)(i), to ensure that allowing an Advanced Practice Registered Nurse or Physician Assistant to conduct patient assessments and plans of care does not eliminate the physician from participation in the interdisciplinary team and team discussions.
- Section 494.170(b)(3), to ensure that ESRD facilities must also meet this CMS requirement for home care patients who receive supplies and equipment from a durable medical equipment supplier.
- Section 494.180(b)(1), to ensure that State-specific staffing requirements that are more stringent than CMS requirements will be cited at as the appropriate CMS standard.
- Section 494.180(c)(1), to ensure that State-specific Medical-staff requirements that are more stringent than CMS requirements will be cited at the appropriate CMS standard.
- NDAC revised its policies and procedures to ensure that its documentation demonstrates that the organization's survey reports identify, for each finding of noncompliance with accreditation standards, the appropriate comparable Medicare CfCs.
- NDAC revised its policies and procedures to ensure that all observations of non-compliance are noted on the final deficiency report and to require that an acceptable plan of correction must be submitted by the ESRD facility.
- NDAC revised its policies, procedures and surveyor worksheets to ensure that survey documentation is consistently and accurately completed.
- NDAC updated its policies and procedures to ensure that the effective date of full accreditation does not precede the receipt date of an acceptable plan of correction.
- NDAC revised its policy to include language that would specifically restrict the accreditation time period to no more than 36 months.
- NDAC revised its policies and procedures to review and assess surveyor documentation on survey reports to ensure that all findings noted on the surveyor worksheets are clearly and accurately reflected in the final survey (deficiency) report and that these findings are quantifiable where appropriate.
- NDAC revised its policies and procedures to ensure that a survey report is generated for each survey, irrespective of deficiencies found on a follow-up survey.
- NDAC revised its policies and procedures to ensure that a follow-up survey conducted for the purposes of ''clearing'' a previous observation of non-compliance at the condition level, assesses compliance with the entire condition that was previously cited.
- NDAC revised its policies and procedures to include ''denial'' of accreditation when condition-level non-compliance is found on an initial survey.
- NDAC revised its policy related to conducting follow-up surveys to clarify that the follow-up survey for condition-level non-compliance must take place within 45 calendar days from the survey end date for which the condition-level finding was originally made.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that NDAC's ESRD facility accreditation program requirements meet or exceed our requirements, and its survey processes are also comparable. Therefore, we approve NDAC as a national accreditation organization for ESRD facilities that request participation in the Medicare program, effective January 4, 2019 through January 4, 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: January 2, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–01103 Filed 2–4–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0476]

Proposed Information Collection Activity; Comment Request

Proposed Projects: Generic Clearance for Disaster Information Collection Form.

Title: Disaster Information Collection Form.

Description: This is a request by the Administration for Children and Families (ACF) for an extension without change to a generic clearance for the Disaster Information Collection Form. An approval for this extension without change to the generic clearance is being requested because each of the thirteen program offices within ACF has a slightly different need for information about program impact information collection during a disaster.

ACF oversees more than 60 programs that affect the normal day to day operations of families, children, individuals and communities in the United States. Many of these programs encourage grantees or state administrators to develop emergency preparedness plans, but do not have statutory authority to require these plans be in place. ACF facilitates the inclusion of emergency preparedness planning and training efforts for ACF programs.

Presidential Policy Directive-8 (PPD–8) provides federal guidance and planning procedures under established phases—protection, preparedness, response, recovery, and mitigation. The Disaster Information Collection Forms addressed in this clearance process provide assessment of ACF programs in disaster response, and recovery.

ACF/Office of Human Services Emergency Preparedness and Response (OHSEPR) has a requirement under PPD–8, the National Response Framework, and the National Disaster Recovery Framework to report disaster impacts to ACF-supported human services programs to the HHS Secretary's Operation Center (SOC) and interagency partners. ACF/OHSEPR works in partnership with the Assistant Secretary for Preparedness and Response (ASPR), and the Federal Emergency Management Agency (FEMA) to report assessments of disaster impacted ACF programs and the status of continuity of services and recovery.

Respondents: State Administrators, and/or ACF grantees.

Annual Burden Estimates

The estimate is based on a single disaster per year. The estimate is for one state administrator to go through all the applicable questions with the Regional and Central Office staff, if applicable.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Disaster Information Collection Form	10	15	0.08 Hours (5 Minutes) ..	12 Hours (720 Minutes).

Estimated Total Annual Burden Hours: 12 hours.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–01078 Filed 2–4–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Electronic Document Exchange (formerly titled, ''Child Support Document Exchange System'')

OMB No.: 0970–0435.

Description: The Federal Office of Child Support Enforcement's (OCSE) Federal Parent Locator Service offers the Electronic Document Exchange (EDE), formerly titled ''Child Support Document Exchange System'' (CSDES), application within the OCSE Child Support Portal. The EDE provides a centralized, secure system for authorized users in state child support