DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety, & Oversight Group

Admin Info: 18-15-ESRD
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DATE: **August 10, 2018**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Initial Surveys of End Stage Renal Disease (ESRD) Facilities

**** Revised to update Form CMS-855A timeline submission for initial Medicare certification****

Memorandum Summary

- **Initial surveys for ESRD Facilities:** Beginning August 8, 2018, initial Medicare certification surveys of ESRD facilities must be initiated within 90 days after the Medicare Administrative Contractor (MAC) determines the prospective provider's form CMS-855 to be complete and the prospective provider's enrollment status indicates approval is awaiting results of a pending survey.
- **Workload Adjustments:** The Centers for Medicare & Medicaid Services (CMS) is making several revisions to its current survey and certification policies to assist State Survey Agencies (SAs) to accommodate anticipated increases in workload associated with this new requirement including: 1) revising the process for review and approval of requests for relocations, expansion of services, and addition of stations requests from existing ESRD facilities; and 2) revising the methodology for the ESRD Tier 2 Outcomes List in the Mission and Priority Document (MPD).

Background

The 2018 Bipartisan Budget Act established new time requirements for initial Medicare surveys of ESRD facilities. This new requirement, which became effective on August 8, 2018, mandates that initial surveys of ESRD facilities be initiated not later than 90 days after the prospective supplier's form CMS-855 has been determined to be complete by the MAC and the status of the enrollment application indicates approval is pending the results of a survey (date approval recommended sent to the SA and CMS Regional Office (RO).

The statute also establishes an independent accreditation option for dialysis facilities to become Medicare-certified suppliers through a CMS-approved accrediting organization (AO). The National Dialysis Accreditation Commission (NDAC) was recently approved as having deeming authority as a CMS approved accreditating organization as of January 4, 2019.

Discussion

As of August 8, 2018, initial surveys for ESRD facilities will become a Tier 1 priority in the MPD. This new, statutory requirement applies to all ESRD applications submitted prior to August 8, 2018 as well as any future applications. Prospective ESRD suppliers *may submit the*

CMS-855 *within 30 days of being* fully operational *which includes completion of* all *facility* construction, patients on service (at least one patient per modality requested) *and certificates of need when applicable*, so that compliance with all ESRD Conditions for Coverage (CFCs) may be determined at the time of the initial survey. In the event that a survey team arrives to perform the initial survey and finds that either the facility is not fully operational or has not admitted patients as required, the survey should be terminated and intitial certification denied. The SA should notify the RO which will forward a CMS-2007 to the applicable MAC denying initial certification based upon the fact that the prospective supplier was not ready for survey. SAs should not "hold" the application until the prospective supplier is able to demonstrate that it is fully operational. The prospective supplier will need to submit a new enrollment application, including the submission of a new CMS-855, if it desires to continue seeking initial certification.

Additonally, the SA should request that the prospective supplier submit the following documents at the time of its request for survey:

- Form CMS-3427;
- A copy of the Certificate of Need (in States where required); and,
- Evidence of compliance with State licensure requirements (if applicable).

These documents will enable the SA to schedule the initial survey more expeditiously. However, the SA should not refuse to schedule the initial survey based solely on the fact that the supplier did not submit these documents in advance. The documents must be provided in complete form at the beginning of the survey in order for the survey to proceed.

To assist SAs in accommodating the time constraint imposed by the Statute, CMS is revising State Operations Manual (SOM) Chapter 2 to re-focus SA resources in several areas. These revisions include:

- CMS will no longer require that an onsite survey be routinely conducted when an existing ESRD facility requests an expansion of services for:
    - In-center nocturnal hemodialysis; This service, which will be provided during extended hours, is considered to be a part of the already approved in-center hemodialysis modality and must operate under the same regulatory expectations. (The provider must provide documentation clarifying how the water sytem will be maintained (e.g. disinfection and rinsing) with the extended hours; and
    - In-center peritoneal dialysis (PD) if the program is already approved for Home PD Training and Support; This service is considered to be part of the already approved modality and must operate under the same regulatory expectations.
- When a certified ESRD facility requests addition of in-center stations the SA will have the option to conduct a desk review to approve these requests. If no onsite visit will be conducted, the facility must submit design drawings that indicate the location within the facility of the existing and the proposed stations to include square footage information. The SA will review the information submitted to identify any concerns regarding inadequate space or infection control concerns. The plans submitted must confirm that space is adequate to provide for patient privacy and to accommodate emergency procedures.
- When an ESRD relocates to a new address the SA will have the option to conduct a desk review to approve these requests. A desk review may be done when documentation

submitted by the ESRD facility confirms that the facility and its operations remain essentially the same. If no onsite visit will be done, the facility must submit design drawings of the new space including the location of all dialysis stations. The SA will review the information submitted to identify any concerns regarding inadequate space or infection control or any other concerns. The plans must confirm that space is adequate to provide for patient privacy and to accommodate emergency procedures. For facilities with an approved in-center hemodialysis program, prior to the relocation of patients, the facility must provide test documentation to the SA confirming acceptable results of product water quality testing, including chemical analysis and reports of acceptable results from testing for bacteria and endotoxins at the new location. Also, facilities must submit the Life Safety Code Attestation Form to confirm their exemption from a Life Safety Code (LSC) survey. If facilities do not meet the requirements for the LSC exemption, the SA must conduct a LSC survey prior to approving the new location.

- If quality of care or safety concerns are identified during the desk review of the above requests, the State Agency (SA) should plan to conduct an on-site survey to futher evaluate the requested services prior to approval.

Also, beginning in FY 2019, CMS will implement a revised methodology to create the Outcomes List which identifies the Tier 2 targeted ESRD surveys that are to be performed by the SAs each year. The revised methodology uses a more refined algorithm focusing on the top five (5) percent of ESRD facilities comparing their clinical outcomes to the national average. Four critical indicators, which have the potential to significantly impact patient health and safety are used in the algorithm to identify programs for the Tier 2 List. The indicators include: mortality; all-cause hospitalizations; infections; and catheter use greater than 90 days.

With the implementation of the revised Outcome List, SAs will be required to survey all the ESRD facilities which appear on the list for their respective State. However, the use of the new methodology is expected to reduce ESRD Tier 2 workload nationally by an estimated 350 surveys in FY 2019. While this workload reduction will vary by State, the majority of States will see a reduction in their ESRD Tier 2 workload – with only a few States seeing a slight increase from previous years.

Contact: Questions regarding this matter should be directed to the ESRD team at ESRDQuestions@cms.hhs.gov.

Effective Date: *Immediately*. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Karen Tritz
Acting Director

cc: Survey and Certification Regional Office Management