



Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director



Michael L. Parson
Governor

Bureau of Ambulatory Care, Phone: (573) 751-1588

RE: *Initial Packet*

Dear Applicant:

Under the end stage renal disease facility program, each facility desiring to furnish dialysis services to the Medicare program is required to meet all Medicare Conditions of Coverage requirements, demonstrate its ability to meet minimal utilization rates, and comply with medical review of patient care requirements.

If you decide to apply for this program, the following must be submitted to this office, as soon as possible, for transmittal to the Regional Office:

1. Complete the End Stage Renal Disease Application/Notification and Survey and Certification Report Form CMS-3427 (attached) and mail to our office.
2. The CMS-855A form and the provider-based questionnaire should be requested from your intermediary/carrier. Please direct any questions regarding this form to the intermediary/carrier as well.
3. For a Provider-Based Program: the intermediary will be the same as the **parent provider**. For a Free-Standing Program: the intermediary is **Wisconsin Physicians Service (WPS) you may contact them at:** Provider Enrollment, PO Box 1787, Madison, WI 53701, Phone (866-734-9444). The intermediary/carrier must approve the facility and send the notification to the State of Missouri before an onsite Certification Survey can be conducted.
4. Submit a Narrative Statement describing the service(s) to be provided and the need for such service(s) to our office.
5. Further, please review and follow the instructions given on the attached sheet.

A copy of the Medicare End Stage Renal Disease Conditions Final Rule and the CMS 3437 as well as other helpful information may be found on the internet at:

<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>

These regulations introduce in the end stage renal disease facility program a survey, certification and determination process. Under this process, State health agencies will survey to determine the facility's compliance with the Conditions of Coverage. This is similar to the process for all providers and suppliers participating in Medicare. On February 9, 2009, the NFPA101 Life Safety Code became applicable to all ESRD facilities. All new ESRD facilities must meet the requirements of Chapter 20 for New Ambulatory Health Care Occupancies if adjacent to or in a high hazard area or patients do not exit at grade level. In addition, the regulations require such facilities to join into regional networks to assure

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coordinated patient referral and access to resources. Through the networks, Medical Review Boards will be established to assure review of the quality of patient care and services.

If after reading the enclosed regulatory requirements you desire to pursue certification as a supplier of ESRD services, it is important that you contact this office as soon as possible to schedule a review of your plans to develop the physical plant. If after the review you desire to proceed with your plans, it is imperative that you keep this Bureau informed of your progress. In order for our survey staff to schedule a survey of your facility, please inform this office of your proposed beginning operational date at least thirty (30) days prior to the operational date and when you have your first patient (s).

Our office will maintain the file open for 90 days, after receiving the enclosed application forms. At the end of this period, the file will be closed if there is no continued effort in pursuing the program certification.

Finally, if you plan to reuse hemodialyzers and other dialysis supplies, you will note in the regulations that you must comply with the voluntary guidelines adopted by the Association for the Advancement of Medical Instrumentation (AAMI), (RD 62:2001, RD 52:2004, RD 47:2002/A1:2003 if doing reuse), as well as the additional requirements indicated in the Code of Federal Regulations, Section 42 CFR Part 494, Subparts A, B,C,D. Therefore, prior to the initial Medicare survey being conducted, it is important that you forward to the office at least two (2) weeks prior to the scheduled operating date, information on the water system to be used including, at a minimum a diagram and description of the water distribution system and its components. Also, a copy of the chemical analysis pre and post RO and one (1) bacteriologic and endotoxin test results of the water system. **Water samples ARE NOT REQUIRED for Peritoneal Dialysis.** Please include the dialysate bacteriologic and endotoxin test results on each dialysis machine.

Please complete the enclosed forms and return to:

Missouri Department of Health
Bureau of Outpatient Healthcare
P. O. Box 570
Jefferson City, MO 65102

You will be informed of the determination made on your request as soon as review of the forms is completed at the CMS-Regional Office.

Sincerely,



Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services