

## END STAGE RENAL DISEASE

Exemptions from Certificate of Need (CON) which require submission of information to the Health Care Authority (Authority).

End Stage Renal Disease Services (ESRD), which meet the following criteria, will not be required to address the standards.

West Virginia Code § 16-2D-11(b)(21) states: The construction, development, acquisition or other establishment of kidney disease treatment centers, including freestanding hemodialysis units but only to a medically underserved population;<sup>1</sup>

These standards apply to the provision of outpatient dialysis treatment for patients with chronic end-stage renal disease, but do not apply to inpatient dialysis treatment for acute renal failure or to inpatient dialysis for conditions other than end-stage renal disease. However, free-standing providers of dialysis services may provide dialysis services to inpatients of acute care facilities if requested by the acute care facility. These standards also do not apply to treatments other than dialysis, such as transplants, for end stage renal disease. Organ transplantation as a treatment for end-stage renal disease shall be governed by the standards applicable elsewhere in this State Health Plan to organ transplantation generally.

These standards are designed to support and maintain a high quality system of InCenter Dialysis and Home-Based Dialysis services for West Virginians with end-stage renal disease. These standards seek to promote and encourage end-stage renal disease providers to deliver high quality services, improve access to dialysis services in rural areas of the state, locate facilities in areas of the state that are currently underserved, provide greater access to Home-Based Dialysis services and to strengthen the overall dialysis service network in West Virginia.

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<sup>1</sup> See the definition of “medically underserved population” under W. Va. Code § 16-2D-2 (25) and W. Va. C.S.R. § 65-29-2.1.b.

## I. DEFINITIONS

For purposes of these standards the following terms shall mean:

- A. Driving Miles – The number of miles from the address of the proposed ESRD Treatment Facility to the address of the closest existing ESRD Treatment Facility. Driving miles is the number of miles from address to address.
- B. End-Stage Renal Disease (ESRD) - That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.
- C. End-Stage Renal Disease Treatment Facility (ESRD Treatment Facility) – A unit which is approved to furnish dialysis services directly to ESRD patients.
- D. In-Center Renal Dialysis (In-Center Dialysis) – Hemodialysis provided in an incenter facility setting, including self-care at the facility, where the individual travels to and from the center approximately three times per week to receive a dialysis treatment session lasting approximately 3 to 5 hours.
- E. Home-Based Renal Dialysis (Home-Based Dialysis) – Dialysis services provided in the home, including home hemodialysis or peritoneal dialysis services.

## II. HOME-BASED DIALYSIS SERVICES

An applicant for new ESRD Treatment Facilities shall include home training capability for those patients desiring to do home dialysis (peritoneal or home hemodialysis).

A certified and CON approved ESRD provider, currently offering In-Center Renal Dialysis in West Virginia, may offer Home-Based Dialysis training and services at any location in the state without CON approval. The offering of Home-Based Dialysis training and services by an existing certified and CON approved ESRD provider shall be exempt from CON review; provided, the provider is required to notify the Authority thirty days prior to the initiation of the Home-Based training and services. Furthermore, the provider is required to meet all federal and state requirements for certification, including but not limited to, Medicare, Medicaid and the Department of Health and Human Resources, Office of Health Facilities Licensure and Certification (OHFLAC).

### **III. NEED METHODOLOGY**

The offering of new ESRD services and the expansion or addition of In-Center Dialysis stations shall be governed by the following need methodologies.

Many patients, especially in the rural counties of West Virginia, are forced to travel significant distances to obtain routine In-Center Renal Dialysis services. The West Virginia Health Care Authority (Authority) recognizes that the larger dialysis patient populations are residing in, or near, the larger population centers of West Virginia. These populations largely have convenient access to dialysis care and services. The Authority seeks to encourage development of ESRD Treatment Facilities in those areas of the State where such services are not readily available to the dialysis patient population.

All Certificate of Need (CON) applicants shall demonstrate, with specificity, that there is an unmet need for the proposed service(s), that the proposed service(s) will not have a negative impact on the community by significantly limiting the availability and viability of other services or providers, and that the proposed service(s) are the most cost effective alternative.

The applicant shall delineate the service area by documenting the expected areas around the facility from which the center is expected to draw patients. The applicant may submit testimony or documentation on the expected service area, based upon national data statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services.

#### **A. New In-Center Dialysis Facilities**

An applicant proposing to develop a new ESRD Treatment Facility must meet the following requirements:

1. A service area is determined to have unmet need for new dialysis stations by utilizing the ratio of one station per 3,000 residents residing within the service area.
2. In a service area with a population greater than 50,000 residents, the applicant must project a minimum of ten dialysis stations in order to demonstrate unmet need.
3. There is no minimum number of stations for an applicant seeking to develop a new ESRD Treatment Facility in those service areas with populations less than 50,000 residents. However, the facility may not be located closer than ten driving miles from the closest existing ESRD Treatment Facility.

4. In calculating need, the applicant must subtract existing dialysis stations in the service area and those approved in the last twelve months in the service area from the calculation at a rate of 3,000 residents per station.
5. Need projections shall utilize the most current Population Projections for West Virginia Counties as developed by the Bureau of Business and Economic Research, College of Business and Economics, West Virginia University or the most current United States Census Bureau population projections at the time of the submission of the CON application.
6. The Centers for Medicare and Medicaid Services (CMS) require all new facilities to include a separation room unless a waiver is granted. The separation room station shall not be included when calculating utilization under the appropriate minimum threshold level.

#### **B. Expansion or Addition of In-Center Dialysis Stations**

An applicant proposing to expand or add additional In-Center Renal Dialysis stations must meet the minimum utilization requirements for the service area. Additionally, the applicant must show that the services will achieve federal certification or designation, as required for purposes of reimbursement and that reimbursement is likely to be provided under the federal program.

1. An applicant proposing to increase the number of dialysis stations including stations for respite dialysis, in an existing ESRD Treatment Facility shall document the need for the additional stations based on the applicant's utilization at that facility. The applicant must demonstrate a utilization of 2.8 patients per station per week (i.e., 70% utilization).
2. An applicant may add a maximum of four (4) stations per request. An applicant may not request additional stations until the facility has reached 70% utilization.

#### **IV. QUALITY**

An applicant for ESRD services shall document that it will be in compliance with all applicable federal and state requirements and standards, including Medicare and Medicaid requirements. This includes the availability of qualified professional and management staff. Further, an applicant shall document that the services will meet existing guidelines, recognized by the pertinent medical specialty, for dialysis treatment.

## **V. CONTINUUM OF CARE**

All ESRD services regulated by these standards shall have written practices and procedures designed to ensure that appropriate monitoring of patients will occur, and that follow-up care is available in the event any medically foreseeable complications arise which are beyond the capacity of the facility to treat.

## **VI. COST**

No Certificate of Need shall be granted for new, replacement, or renovated ESRD services, unless the applicant demonstrates that the project is financially feasible within the first three years of operation. Further, no such services shall be deemed consistent with the State Health Plan unless the projected costs are consistent with allowable costs provided for in the applicable federal reimbursement statutes and regulations. Costs shall be deemed to be reasonable if they are permitted under governing federal statutes and regulations on reimbursement. All projects which exceed the CON expenditure threshold shall be subject to review.

## **VII. ACCESSIBILITY**

An applicant for ESRD services must demonstrate how transportation will be provided for patients in the area who lack access to adequate transportation.