§ 494.110 Condition: Quality assessment and performance improvement.

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility’s organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

(a) Standard: Program scope. (1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(2) The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following:

(i) Analysis of the water and dialysate quality indicates contamination; or

(ii) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.

(b) Standard: Monitoring performance improvement.

The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

(c) Standard: Prioritizing improvement activities. The dialysis facility must set
priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.

(a) Standard: Approval period. The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12-month period.

(b) Standard: Service limitation. Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must comply with paragraph (c)(1) of this section and addition to complying with the following conditions:

(i) Section 494.20 (compliance with Federal, State, and local laws and regulations).

(ii) Section 494.60 (physical environment).

(iii) Section 494.70(a) through section 494.70(c) (patient rights).

(iv) Section 494.140 (personnel qualifications).

(v) Section 494.150 (medical director).

(vi) Section 494.180 (governance).

(d) Standard: Physician contact. The facility must contact the patient’s physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient’s current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in §494.90).

(e) Standard: Documentation. All patient care provided in the special purpose facility is documented and forwarded to the patient’s usual dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide, or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory