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advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.

(3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

(c) *Standard: Record retention and preservation*. In accordance with 45 CFR § 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.

(d) *Standard: Transfer of patient record information*. When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.

§ 494.180 Condition: Governance.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility.

(a) *Standard: Designating a chief executive officer or administrator*. The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to—

(1) Staff appointments;

(2) Fiscal operations;

(3) The relationship with the ESRD networks; and

(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in § 494.110.

(b) *Standard: Adequate number of qualified and trained staff*. The governing body or designated person responsible must ensure that—

(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; and the registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs;

(2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated;

(3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and

(4) All employees have an opportunity for continuing education and related development activities.

(c) *Standard: Medical staff appointments*. The governing body—

(1) Is responsible for all medical staff appointments and credentialing in accordance with State law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists; and

(2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in § 494.110.

(3) Communicates expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients.

(d) *Standard: Furnishing services*. The governing body is responsible for ensuring that the dialysis facility furnishes services directly on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under § 494.100).

(e) *Standard: Internal grievance process*. The facility's internal grievance process must be implemented so that the patient may file an oral or written

grievance with the facility without reprisal or denial of services. The grievance process must include:

(1) A clearly explained procedure for the submission of grievances.

(2) Timeframes for reviewing the grievance.

(3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.

(f) *Standard: Involuntary discharge and transfer policies and procedures.* The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures. The medical director ensures that no patient is discharged or transferred from the facility unless—

(1) The patient or payer no longer reimburses the facility for the ordered services;

(2) The facility ceases to operate;

(3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or

(4) The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team—

(i) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record;

(ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge;

(iii) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility;

(iv) Contacts another facility, attempts to place the patient there, and documents that effort; and

(v) Notifies the State survey agency of the involuntary transfer or discharge.

(5) In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.

(g) *Standard: Emergency coverage.* (1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.

(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must:

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

(h) *Standard: Furnishing data and information for ESRD program administration.* Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must—

(1) Be submitted at the intervals specified by the Secretary;

(2) Be submitted electronically in the format specified by the Secretary;

(3) Include, but not be limited to—

(i) Cost reports;

(ii) ESRD administrative forms;

(iii) Patient survival information; and

(iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.

(i) *Standard: Relationship with the ESRD network.* The governing body receives and acts upon recommendations

from the ESRD network. The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and pursue network goals.

(j) *Standard: Disclosure of ownership.* In accordance with §420.200 through §420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

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