

# Compliance risks for suppliers of end-stage renal disease services

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With the new focus on quality-of-care issues as compliance risks, it is important to review Medicare's requirements for certification of an entity for participation in the Medicare program as part of any ongoing compliance risk assessment. Liability under the federal False Claims Act may be alleged if an entity provides services, and submits claims for those services, when it knows—or should know—that it does not meet the material requirements to participate in the Medicare program. A failure to look diligently at the certification requirements might be deemed to meet the “reckless disregard” standard for intent required under that statute.

End-stage renal disease (ESRD) facilities, including hospital transplantation centers, hospital dialysis centers, renal dialysis facilities (clinics), and special-purpose dialysis facilities, must meet the Conditions for Coverage in Subpart U of Part 405 of the Medicare regulations in order to be approved for Medicare participation. Although dialysis care (which is most typically provided by dialysis clinics) is covered by Part B, dialysis suppliers are treated more like Part A providers, and all ESRD facilities are subject to an initial survey, and periodic re-surveys, to assure that they meet the Conditions for Coverage. If a termination of coverage is based on conditions other than failure to participate in ESRD

Network activities, a period of reasonable assurance may be required before an entity may be reinstated [42 C.F.R. § 405.2180(c)]. A renal transplantation center or a renal dialysis center operated by a hospital may qualify for Medicare approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program (42 C.F.R. § 405.2131).

It is important to comply with all the Conditions for Coverage, but some are particularly prone to compliance risks, particularly in the setting of dialysis clinics providing chronic care. In these clinics, patients are typically seen three times a week, each time for several hours of treatment. Treatment often extends for many years, often until death or transplantation. Most dialysis patients have similar medical histories and co-morbid conditions, and treatment often is relatively routine and repetitive in nature. Physicians are usually not present during clinic treatments, although they frequently make rounds in the clinic a few times each month and often also monitor the care of these patients in their own offices. Given the nature of the treatment, a particular compliance risk is to assure that physician involvement in the treatment of each patient is adequately documented. The Conditions for Coverage include the following specific requirements for physician involvement:

- An express requirement that the governing body of ESRD and transplant facilities ensure continuing physician supervision of ESRD patients. Every patient must be under the continuing supervision of a physician, and a physician must be avail-

able in emergency situations [42 C.F.R. § 405.2136(g)]. Documentation should be available in the patient's medical chart which confirms that the medical condition of each patient has been individually assessed to devise short- and long-term care plans, including input by the physician [42 C.F.R. § 405.2137(a)(1) and (b)]; (See also the discussion with respect to medical records which appears below). The now somewhat antiquated (1998) OIG Compliance Program Guidance for Clinical Laboratories indicates that, with respect to lab orders for dialysis patients, standing orders are generally disfavored and should not extend more than 12 months without written confirmation of continuing validity [63 Fed. Reg. 45076, 45081 (Aug. 24, 1998)]. The use of protocols or extended standing orders (for lab tests and other services) applicable to all patients should be closely scrutinized by compliance staff to ensure documentation of medical necessity, particularly for items or services which are separately payable.

- Treatment at a renal dialysis facility or renal dialysis center must be under the general supervision of a physician medical director. The medical director must participate in the selection of a suitable treatment modality, ensure adequate training of the nurses and technicians in dialysis techniques, and ensure adequate monitoring of the patient and dialysis proceedings (42 C.F.R. § 405.2161). The experience required to be viewed as a qualified medical director is included in the definitional provisions at 42 C.F.R. § 405.2102 (“Physician-Director”), and specific professional credentials and experience are referenced. Among other responsibilities, the physician-director of the facility is designated in writing to be responsible for the execution of patient care policies [42 C.F.R. § 405.2136(f)(2)]. If this responsibility is delegated by the

physician-director, s/he must still provide medical guidance in such matters.

A medical director is required by the Conditions for Coverage, but ESRD suppliers must take care to ensure that any payments to contracted medical directors can be justified, as within fair market value for the services provided. Medical directors are typically referral sources for dialysis facilities. Historically, referring physicians have sometimes been involved in joint ventures with the provider of dialysis services that have included contracts for medical director services. OIG has looked critically at such arrangements under the Anti-kickback Statute and related civil money penalties. Medical director contracts and other arrangements with physicians should be drafted to meet the requirements for safe harbors as closely as possible.

Additional areas of particular risk for suppli-

ers of ESRD services include:

- The ESRD facility must provide services through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through “agreements” or “arrangements”) [42 C.F.R. § 405.2102 (defining “Furnishes directly”)]. If the ESRD facility makes use of outside resources as authorized in the Conditions for Coverage, a detailed document must be signed by an authorized individual for the facility and by the person or agency providing the service [42 C.F.R. § 405.2136(e)].
- Medical records must contain sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately [42 C.F.R. § 405.2139(a)]. This can sometimes be a compliance challenge if physician records are retained in the physician office rather

than in the clinic. Because medical records are needed to document medical necessity for a particular item or service, record-keeping deficiencies may be noted during routine audits by the Medicare contractors, and patterns or practices of inadequate recordkeeping pose significant risk that services will be reviewed more globally.

### Conclusion

The Centers for Medicare and Medicaid Services (CMS) is in the process of revising the current and long-standing Conditions for Coverage for Suppliers of ESRD Services. Both the existing and proposed Conditions, as well as the Guidance to Surveyors for ESRD Facilities (which appears at Appendix H to the State Operations Manual, CMS Publication 100-07), provide significant guidance for compliance staff who are charged with assessing and reducing the risks associated with non-compliance. ■