

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Region VI
1301 Young Street, Room 833
Dallas, Texas 75202

March 23,1998

REGIONAL SURVEY AND CERTIFICATION LETTER NO: 98-03

To: All State Survey Agencies (Action)
All Title XIX Single State Agencies (Action)

Subject: Requirements for Renal Dialysis Centers (RDC) and Affiliation Agreements with RDCs -- ACTION

The purpose of this memorandum is to provide guidance to the End Stage Renal Disease (ESRD) survey field concerning two current requirements of the Conditions for Coverage (CfCs) for ESRD facilities. Specifically, this guidance is in response to questions concerning the requirement that an ESRD facility have an affiliation agreement with a Renal Dialysis Center (RDC), and the necessity of a hospital to provide outpatient dialysis in order to qualify (or remain qualified) as an RDC.

Question 1

The regulation at 42 CFA 405.2160, Condition: Affiliation agreement or arrangement, states that a renal dialysis facility must have an affiliation agreement or arrangement with an RDC that provides for inpatient care and other hospital services that are determined to be medically necessary by the patient's physician. If there is a hospital that is not classified as an RDC that is more conveniently located to the dialysis facility and can provide the necessary acute care to meet the needs of the facility's patients, can the facility have an agreement with this hospital?

Answer

The intent of this requirement is to ensure that a dialysis patient requiring acute care be sent to a facility that can provide it. Instead, this requirement is hindering rather than helping access to acute care for ESRD patients. We will view the requirements of section 405.2160 as being satisfied so long as there is documentation that the renal dialysis facility has procedures for sending (and has actually sent) patients requiring acute care to hospitals that can provide that care, including acute dialysis treatment.

Question 2

Linked to the above issue is the one surrounding the regulation at 42 CFR 405.2163, Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center. This regulation states that a "facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient." In addition, the regulation states that for facilities providing outpatient dialysis services, "the facility must provide all necessary institutional dialysis services and staff required in performing the dialysis." Does this mean that a hospital wishing to be classified as an RDC must perform outpatient dialysis services?

Answer

Historically, we have interpreted this regulation as requiring that a hospital wishing to qualify as an RDC perform outpatient dialysis in addition to the other services described above. We will continue to interpret the regulation in

this manner, i.e., a hospital unit seeking to become certified as an RDC will continue to be required to perform outpatient dialysis. However, we expect that the significance of becoming an RDC will diminish since we will consider the requirements of section 405.2160 met if the ESRD facility sends its patients requiring acute care to any facility that can provide that acute care, including dialysis.

Question 3

Must we take away the RDC provider number from an RDC that no longer provides outpatient dialysis?

Answer

No. For those RDCs that in the past performed outpatient dialysis, but no longer do so, we expect that the RDC provider number assigned at the time the facility was granted RDC status will be "grandfathered," i.e., the facility will keep that identification number until further notice.

In the proposed rule for the new CfCs for ESRD facilities, we are proposing to delete the requirement that an ESRD facility have a formal agreement with an RDC because we do not believe it is necessary to prescribe these arrangements in regulation. Since we do not anticipate publication of final CfCs for some time, we are instructing the ESRD survey field to follow the guidance provided in this document.

If you have any additional questions, please call Kay Hall (214) 767-4405 or Rachel McCarty at (214) 767-2082.

Sincerely,

(Signature)

Calvin Cline, Branch Chief
Survey and Certification Operations Branch