

## §§ 405.2100–405.2101

a decision by a reviewing entity after the determination or decision is reopened as provided in §405.1885 of this subpart, the revision must be considered a separate and distinct determination or decision to which the provisions of §§ 405.1811, 405.1834, 405.1835, 405.1837, 405.1875, 405.1877 and 405.1885 of this subpart are applicable.

(b)(1) Only those matters that are specifically revised in a revised determination or decision are within the scope of any appeal of the revised determination or decision.

(2) Any matter that is not specifically revised (including any matter that was reopened but not revised) may not be considered in any appeal of the revised determination or decision.

[73 FR 30266, May 23, 2008]

### Subparts S–T [Reserved]

## Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

**AUTHORITY:** Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

**SOURCE:** 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

## §§ 405.2100–405.2101 [Reserved]

### § 405.2102 Definitions.

As used in this subpart, the following definitions apply:

*Network, ESRD.* All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

*Network organization.* The administrative governing body to the network and liaison to the Federal government.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6547, Mar. 1, 1988; 55 FR 9575, Mar. 14, 1990; 72 FR 15273, Mar. 30, 2007; 73 FR 20473, Apr. 15, 2008; 79 FR 66261, Nov. 6, 2014]

### § 405.2110 Designation of ESRD networks.

CMS designated ESRD networks in which the approved ESRD facilities

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collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.* The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in §405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

### § 405.2111 [Reserved]

### § 405.2112 ESRD network organizations.

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:

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(1) A statement of the network goals.  
(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

- (i) Self-care;
- (ii) Transplants; and
- (iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

### § 405.2113 Medical review board.

(a) *General.* The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) *Restrictions on medical review board members.* (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional

involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

### § 405.2114 [Reserved]

### §§ 405.2131–405.2184 [Reserved]

## Subparts V–W [Reserved]

## Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

*AUTHORITY:* Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

*SOURCE:* 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

### § 405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act:

(a) Section 1833—Amounts of payment for supplementary medical insurance services.

(b) Section 1861(aa)—Rural health clinic services and Federally qualified health center services covered by the Medicare program.

(c) Section 1834(o)—Federally qualified health center prospective payment system beginning October 1, 2014.

[79 FR 25473, May 2, 2014]

### § 405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

*Allowable costs* means costs that are incurred by a RHC or FQHC that is authorized to bill based on reasonable costs and are reasonable in amount and proper and necessary for the efficient delivery of RHC and FQHC services.

*Beneficiary* means an individual enrolled in the Supplementary Medical