

(17) The boundary proceeds east-northeasterly approximately 10,000 feet in a straight line to the southeast corner of section 34, Township 12 North, Range 10 West.

(18) On the U.S.G.S. Topographical Map of Sonoma County, California, the boundary proceeds north along the east boundary of section 34, Township 12 North, Range 10 West, to the Sonoma County-Mendocino County line.

(19) The boundary follows the Sonoma County-Mendocino County line west then south to the southwest corner of Section 34, Township 12 North, Range 11 West.

(20) The boundary proceeds in a straight line east southeasterly to the southeast corner of section 2, Township 11 North, Range 11 West.

(21) The boundary proceeds in a straight line south southeasterly to the southeast corner of section 24, Township 11 North, Range 11 West.

(22) The boundary proceeds in a straight line southeasterly across sections 30, 31 and 32 in Township 11 North, Range 10 West, to the point at 38°45' North latitude parallel and 123°00' East longitude in section 5, T. 10 N., R. 10 W.

Signed: July 14, 1986.

W.T. Drake,
Acting Director.

Approved August 5, 1986.

Francis A. Keating, II,
Assistant Secretary (Enforcement).

[FR Doc. 86-19139 Filed 8-25-86; 8:45 am]

BILLING CODE 4810-31-M

DEPARTMENT OF EDUCATION

34 CFR Part 674

Postsecondary Education; National Direct Student Loan Program

Correction

In FR Doc. 86-17690, beginning on page 28312, in the issue of Wednesday, August 6, 1986, make the following corrections:

§ 674.6a [Corrected]

1. On page 28314, first column, in amendatory instruction 3, "674.6" should read "674.6a".

2. On the same page, first column, in the section heading, "§ 673.6a" should read "§ 674.6a".

3. On the same page, first column, § 674.6a(a) third line, after "subsequent" insert "award years".

4. On the same page, first column, § 674.6a(c)(1), third line, "in" should read "to".

5. On the same page, first column, § 674.6a(c)(2), fourth line, "repayments" was misspelled.

6. On the same page, second column, § 674.6a(c)(3)(ii), first line, "Subtracting" was misspelled.

BILLING CODE 1505-01-M

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 261

Prohibitions; Fossil Collecting

AGENCY: Forest Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: In keeping with the language of the Archaeological Resources Protection Act of 1979 and in response to informal comments from the scientific and academic communities, the Forest Service is clarifying its regulations concerning fossil collecting on National Forest System lands. The language on "paleontological resources" is being moved to a separate paragraph and the requirement for permits is being limited specifically to vertebrate fossils and commercial activities.

DATES: Effective date: August 26, 1986. Comments due on or before October 27, 1986.

ADDRESSES: Send written comments to R. Max Peterson, Chief (2800), Forest Service, USDA, P.O. Box 2417, Washington, DC 20013.

The public may inspect comments received on this interim rule in the office of the Director, Minerals and Geology Management Staff, Room 606, 1621 North Kent Street, Rosslyn, Virginia 22209, from the hours of 8:30 a.m. and 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Tom King, Minerals and Geology Management Staff, USDA, P.O. Box 2417, Washington, DC 20013. (703-235-9745).

SUPPLEMENTARY INFORMATION: Current regulations prohibit the excavation and removal of any paleontological object from National Forest System lands without first obtaining a special use authorization in accordance with 36 CFR 261.1a. The regulations define a paleontological resource as "... evidence of fossilized remains of multicellular invertebrate and vertebrate animals and multicellular plants, including imprints thereof" Moreover, the language of The Archaeological Resources Protection Act of 1979 (16 U.S.C. 470bb)

distinguishes between "archaeological" and "paleontological" resources, which we interpret to mean that Federal land management agencies are not mandated to exercise the same degree of protection for the two resources.

The collection of paleontological objects on National Forest System lands is a legitimate scientific and educational pursuit and there is no evidence of widespread conflicts or problems that would require a blanket prohibition on all activities as currently provided in 36 CFR 261.9. Vertebrate fossils have traditionally been accorded special significance and will remain subject to regulation. Where there is a need to protect other paleontological resources at a unique site, land managers may issue special closure orders pursuant to 36 CFR 261.53(c).

Paleontological objects found in an archaeological context are considered part of the archaeological resource and would remain subject to the prohibitions at 36 CFR 261.9 and 36 CFR 296.4.

Since the field season for scientific and academic research is already underway, there is a need to make this interim rule effective immediately. However, public comments are invited and will be fully considered in developing a final rule.

Regulatory Impacts and Review

This interim rule has been reviewed under Executive Order 12291, The Regulatory Flexibility Act (5 U.S.C. 601, et seq.), and implementing Departmental procedures. The Assistant Secretary of Agriculture for Natural Resources and Environment has determined that the regulation is not a major rule and will not have a significant economic impact on a number of small entities. It will have little or no effect on the economy because it affects only Forest Service land managers. The regulation may reduce administrative costs for analysis of permit conditions, permit issuance and administration, law enforcement, and other legal actions previously required to control fossil collecting.

Based on both past experience and environmental analysis, this interim rule will have no significant effect on the human environment, individually or cumulatively. Therefore, it is categorically excluded from documentation in an environmental assessment or an environmental impact statement (40 CFR 1508.4).

This interim rule contains no information collection requirements as defined in 5 CFR Part 1320.

List of Subjects in 36 CFR Part 261

Law enforcement, National Forests.

Therefore, for the reasons, set forth above, Part 261 of Chapter II of Title 36 of the Code of Federal Regulations is hereby amended as follows:

PART 261—[Amended]

1. The authority citation for Part 261 continues to read as follows:

Authority: 30 Stat. 35, as amended (16 U.S.C. 551); Sec. 1, 33 Stat. 628 (16 U.S.C. 472); 50 Stat. 526, as amended (7 U.S.C. 101, (f)); 82 Stat. 916 (16 U.S.C. 1246, (f)); 92 Stat. 1650 as amended (16 U.S.C. 1133 (c)-(d)(1)), unless otherwise noted.

2. Paragraphs (g) and (h) are revised and a new paragraph (i) is added to § 261.9 to read as follows:

§ 261.9 Property.

(g) Digging in, excavating, disturbing, injuring, destroying, or in any way damaging any prehistoric, historic, or archaeological resource, structure, site, artifact, or property.

(h) Removing any prehistoric, historic, or archaeological resource, structure, site, artifact, property.

(i) Excavating, damaging, or removing any vertebrate fossil or removing any paleontological resource for commercial purposes without a special use authorization.

Dated: July 26, 1986.

George S. Dunlop,

Assistant Secretary, Natural Resources and Environment.

[FR Doc. 86-19151 Filed 8-25-86; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 405

[HSQ-115-F]

Medicare Program; End Stage Renal Disease Program; Redesignation of Networks and Reorganization of Network Organizations

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the requirements in current regulations pertaining to the End-Stage Renal Disease (ESRD) networks and organizations and establishes provisions for new, more efficient network organizations. This rule removes the criteria that define existing networks, removes the requirement that HCFA change designations of ESRD networks through rulemaking, and removes the list of currently-designated networks that

now appears in regulations. It is intended that these amendments will increase the efficiency and effectiveness of the ESRD program by instituting a faster process for changing network designations and organizations as program needs arise. These amendments also permit the reduction of the number of existing networks to as few as 14, which is consistent with section 9214 of Pub. L. 99-272, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA).

DATES: These regulations are effective September 25, 1986.

FOR FURTHER INFORMATION CONTACT: Spencer Colburn (301) 594-3413.

SUPPLEMENTARY INFORMATION:

I. Background

The Social Security Amendments of 1972 (Pub. L. 92-603) extended Medicare coverage to individuals with end-stage renal disease (ESRD) who require dialysis or transplantation. At that time, the broad array of professionals and facilities involved in the treatment of persons with ESRD indicated the need for a system to promote effective coordination. We believed that the integration of hospitals and other health facilities into organized networks was the most effective way to assure the delivery of needed ESRD care. Therefore, on July 1, 1975, we published proposed regulations (40 FR 27782) and final regulations on June 3, 1976 (41 FR 22502) that included provisions for implementing the existing ESRD networks.

Those regulations—

- Required that ESRD facilities be organized into coordinated systems ("networks") for the delivery of ESRD care;
- Required that the "networks" organize themselves through the establishment of a network coordinating council for each network area, with representation from all ESRD facilities in each network;
- Required that each network coordinating council appoint a medical review board to review the appropriateness of ESRD patient care and services;
- Required that a network and its coordinating council act as liaison between the Federal government and the available community resources, with the coordinating council supplying the Secretary information which the Secretary could use to make determinations, and make recommendations to member facilities as needed to achieve the objectives of the network;

- Specified the membership requirements and responsibilities of medical review boards;

- Provided for a relationship between networks and health care review organizations and health service planning organizations;

- Identified minimal utilization rates and the requirements for approval of facilities with respect to such rates;

- Outlined general requirements for all facilities furnishing ESRD services; and

- Contained a list of designated network areas.

Subsequently, the End-Stage Renal Disease Amendments of 1978 (Pub. L. 95-292), amended title XVIII of the Social Security Act (the Act) by adding section 1881; section 1881(c) statutorily authorizes the establishment of ESRD network areas and network organizations, consistent with criteria the Secretary finds appropriate to assure the effective and efficient administration of ESRD program benefits.

With respect to ESRD networks, section 1881(c) of the Act requires the Secretary to—

- Establish ESRD network areas and organizations;
- Prescribe in regulations requirements with respect to membership in network organizations by individuals having financial or control relationships with ESRD providers and facilities;
- Take into account the network goals and performance in determining whether to certify new or expanded facilities in the network area and to terminate or withhold certification of a facility for failure to cooperate with network goals; and
- Provide guidelines for the planning and delivery of services as necessary to assist the network organizations in developing their goals to promote the use of self-dialysis and transplantation.

Section 1881(c) further requires the Secretary to establish a national ESRD medical information system to assure the effective and efficient administration of Medicare benefits. The existing networks have been receiving copies of the national medical information forms from ESRD facilities prior to submitting the forms to us.

Section 1881(c) of the Act also specifies that the network organizations for each area—

- Include a coordinating council, an executive committee, and a medical review board;
- Include at least one patient as a member on each coordinating council and executive committee;

- Encourage the use of treatment settings most compatible with the successful rehabilitation of the patient;
- Develop criteria and standards relating to the quality and appropriateness of patient care;
- Develop network goals for the placement of patients in self-care settings and for transplantation;
- Evaluate the procedures used in the network to assess the appropriateness of patients for proposed treatment modalities;
- Identify those network members that are not cooperating with network goals and assist those facilities to develop appropriate plans of correction; and
- Submit an annual report on July 1 of each year that includes the network goals, data on the network's performance in meeting its goals (including data on the comparative performance of network members), identification of facilities that have consistently failed to cooperate with network goals and recommendations with respect to the need for additional or alternative services in the network area including self-dialysis training, transplantation and organ procurement facilities.

In summary, the amendments made to section 1881(c) of the Act did not include all of the provisions related to networks which had been included in the final regulations published on June 3, 1976 (41 FR 22502). These regulations were more prescriptive than the statute. The requirements contained in the 1976 regulations that were not statutorily required included the following:

- Specific criteria for designating network areas (§ 405.2110).
- Representation from all ESRD facilities on each network coordinating council (§ 405.2111).
- Review of the appropriateness of ESRD patient care and service by medical review boards (§ 405.2111).
- Membership of network coordinating councils by professional disciplines (§ 405.2111).
- Specific initial functions of network coordinating councils (§ 405.2111).
- Specific ongoing functions of network coordinating councils and network executive committees (§ 405.2112).
- Relationship of network coordinating councils with the Federal government and the available community resources (§ 405.2112).
- Membership requirements of specific disciplines for medical review boards (§ 405.2113).
- Current responsibilities of medical review boards (§ 405.2113).

- Reporting requirements of medical review boards (§ 405.2113).
- Relationship of ESRD networks to health care review organizations and health service planning organizations (§ 405.2114).

On April 7, 1986, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) was enacted which requires the Secretary to maintain renal disease network organizations as authorized under section 1881(c) of the Act, and not merge the network organizations into other organizations or entities. The Secretary may consolidate network organizations, but only if such consolidation does not result in fewer than 14 such organizations being permitted to exist.

II. Notice of Proposed Rulemaking

On April 15, 1986, we published a notice of proposed rulemaking to implement section 9214 of Pub. L. 99-272 (51 FR 12714). Briefly, the major provisions of the notice proposed to:

- Remove the definition of "Network Coordinating Council" (§ 405.1202).
- Redefine "Network, ESRD" as all Medicare-approved ESRD facilities in a geographic area that we designate and define "Network Organization" as the administrative governing body to the network and liaison to the Federal government (§ 405.2102).
- Delete the requirements for publishing network designations in regulations, and remove the criteria for designating networks which would result in reducing the number of network organizations to a minimum number (but not fewer than 14) (§ 405.2110).
- Delete the specific membership requirements for the network coordinating council in § 405.2111 that go beyond the statutory requirements and include the remaining requirements of that section as new network organization requirements in § 405.2112.
- Specify the duties, responsibilities and functions of the new network organizations (§ 405.2112).
- Delete the requirements that specific professional medical and social service personnel be members of the medical review board and the specific functions required of the medical review board (§ 405.2113).
- Remove the requirements for network coordinating councils to enter into working arrangements with health care review organizations and health service planning organizations (§ 405.2114).
- Delete the requirement that information obtained from network coordinating councils be used in the utilization rate determination (§ 405.2121).

- Delete the requirement that an ESRD facility must provide evidence of service needs in a network for additional dialysis services (§ 405.2132).

- Remove the requirements for membership and representation in the network (§ 405.2134).
- Make conforming regulation changes concerning the roles of the network organization, network executive committee and medical review board (§§ 405.2136 and 405.2138).
- Delete the Appendix to Subpart U that provides the list of designated ESRD networks.

III. Analysis of and Responses to Public Comments

We received 192 pieces of correspondence from 18 of the 32 existing ESRD network, 3 hospitals, 104 ESRD facility staff, 11 ESRD patients, 3 ESRD patient advocacy groups, and 3 members of Congress. In addition, we received comments from ESRD facility chain organizations, State Health Departments, physician and nurse associations, hospital associations, a health systems agency, the Forum of ESRD Networks, medical schools, physicians, nurses, social workers, and other interested parties. The comments and our responses to those comments are discussed below.

A. Consolidation of Networks

Comment: A number of commenters opposed consolidation of the current ESRD network organizations. These commenters suggested that new larger organizations would lose the personal contact that has been established among the facilities, eliminate the authority and capability to fulfill the statutory mandates, and be unable to address the problems unique to a small geographic area. The commenters also suggested that there are financial disincentives to consolidation (for example, start-up costs of new organizations, increased travel and meeting expenses, and increased costs due to lack of voluntary participation in the organization).

Several commenters were in favor of consolidating the 32 networks to streamline the ESRD program and to concentrate on the quality assurance activities.

Response: We agree that initial phase-in of the new contract organizations will result in changes in the working relationships between ESRD facilities and the new network organizations. This effect can be expected from any reorganization of an existing program. However, prudent management of the networks requires that the networks be

designated in the most efficient structure possible to meet the organization goals.

B. Elimination of Networks

Comment: A few commenters stated that the concept of networks, while originally a good idea, is no longer valid and that the networks should be eliminated.

Response: The maintenance of ESRD networks is mandated by section 1881(c) of the Act, and we do not have statutory authority to eliminate them.

C. Provisions of Pub. L. 99-272

Comment: A few commenters believe that the proposed regulations did not take into account the provisions of Pub. L. 99-272. The commenters believe that the intent of Pub. L. 99-272 requires that the regulations define specifically the criteria for the new organizations, explain the transition from 32 networks to as few as 14, provide information on the projected level of funding, better define the functions of the new organizations, and describe the raw data that will be gathered for quality assurance studies.

Response: Section 9214 of Pub. L. 99-272 specifies that the Secretary will maintain renal disease networks as authorized under section 1881(c) of the Act, and may not merge the network organizations into other organizations or entities. The statute further provides that the Secretary may consolidate the network organizations, but only if the consolidation does not result in fewer than 14 such organizations being permitted to exist.

These regulations require specifically that the network organizations perform the network functions as mandated by section 1881(c) of the Act. In addition, we intend to award contracts for at least 14 organizations in keeping with the provisions of Pub. L. 99-272. We do not believe it necessary to specify in regulations the number of network organizations. We also do not believe it appropriate to explain the network transition process, the funding mechanism or other administrative functions in regulations. The level of funding, number of facilities or networks, and the size of the patient population are all subject to change, and the regulations process does not permit timely and rapid response to these changes. We will respond to these changes administratively to assure the flexibility to accomplish the goals of the statute.

D. Quality Assurance, Patient Health and Safety

Comment: A number of commenters expressed concern that the network

organizations would no longer conduct quality assurance activities and that only the current ESRD networks can evaluate care and assure patient health and safety in the specialized environment of ESRD facilities.

Response: We will require the new network organizations to develop criteria and standards relating to the quality and appropriateness of care and to evaluate the procedures used by the facilities in the network in accessing patients for placement in appropriate treatment modalities to ensure the quality of care. We will include these activities in the contracts with the network organizations and monitor them as appropriate.

We continue to believe that ensuring patient health and safety in ESRD facilities is the responsibility of the State survey agencies and HCFA regional offices. These organizations have the experience and expertise to evaluate compliance with health and safety requirements by all types of Medicare providers, including ESRD facilities. In addition, we are developing an outcome-oriented survey process for ESRD facilities to provide a more valid and reliable assessment of the care being furnished to patients and to assure that the facilities are meeting the needs of their patients.

E. Patient Access and Health Planning

Comment: Two commenters suggested that changes to the present network system would limit patient access to care and compromise health planning activities in areas without a certificate of need program.

Response: The regulations provide specifically that designation of ESRD networks does not require a patient to seek care only in facilities in the network area where the patient lives, or limit patient choice of physicians or facilities, or limit patient referral by physicians to facilities in another network. We do not believe the regulations will in any way compromise patients' access to care. Networks do not have the authority to participate directly in the health planning process. Networks have provided necessary data to the authorized health planning agencies and will continue to do so.

F. Area Designation Process

Comment: Several commenters objected to the removal of the current requirement that ESRD networks be designated through rulemaking. The commenters believe that there should be an opportunity to comment on network area designations and that the provider community should be consulted about network configurations.

Response: Because of the dynamic nature of the ESRD program, as evidenced by the rapid growth of both facilities and the patient population, the rulemaking process is inadequate to address properly program needs with respect to the designation of ESRD networks. Section 1881(c) of the Act provides the Secretary with broad authority to designate ESRD networks in accordance with any criteria the Secretary believes appropriate. Therefore, the Secretary may choose network configurations that would best serve ESRD patients, the facilities and the ESRD program. We do not wish to exclude the concerns of patients or providers with respect to this issue, but we do not believe it is necessary to include network designations in regulations. Any comments that we have received have been given extensive consideration and any future recommendations regarding network designations will be given full consideration prior to the designation of networks.

G. Network Organization Duties

Comment: A few commenters suggested that the regulations do not provide specific functions and duties for the network organizations. One commenter suggested that networks be given a specific consultative role to Utilization and Quality Control Peer Review Organizations (PROs) and Health Systems Agencies (HSAs).

Response: We intend to remove burdensome requirements that were not statutorily mandated. We have specified in § 405.2112 the network functions that are authorized by the statute. As we stated in the proposed rule (51 FR 12715), we believe the duties and responsibilities contained in the current regulations are burdensome and obsolete. By requiring network organizations to perform only those duties specified in the statute, we believe we are providing for more effective and efficient administration of network activities. If it becomes necessary to require network organizations to pursue additional activities (such as the data collection activities discussed below), we will amend the contract with the network organizations to include those activities. In addition, we have revised § 405.2112 to reflect the statutory requirement that networks develop criteria and standards to evaluate the quality and appropriateness of care that we included in our preamble discussion in the proposed rule but inadvertently omitted from the regulation section.

We agree that it may be desirable for some of the network organizations to have formal arrangements with HSAs or PROs. However, we have not included this requirement in regulations because it may not be necessary for each network organization to maintain formal arrangements with HSAs or PROs. We will monitor network organizations and include the requirement as appropriate in contracts.

H. Network Data Activities

Comment: Two-thirds of all commenters expressed concern about the role of networks in data collection and validation. Many of the commenters believe that removing network organizations from these activities would seriously compromise the integrity of the national medical information data system and possibly hinder the network organizations in their medical review activities.

Response: We agree with the commenters that removal of the network organizations from the various data activities would, at least temporarily, affect the high degree of compliance currently exhibited by ESRD facilities in supplying complete, valid data to the medical information system. Therefore, we will retain the network data collection and validation functions for the new network organizations. Contracts will specify the necessary data collection functions and provide mechanisms for monitoring those functions.

I. Appointed Panels

Comment: Several commenters expressed concerns regarding the appointment of the network coordinating council, executive committee and medical review board by the network organization. The commenters believe that there should be universal participation on the network coordinating council by all providers and that elected, rather than appointed, bodies will elicit better participation by member facilities.

Response: The network organizations, under contract to HCFA, will be responsible for naming the members of these three entities, assigning them specific duties and monitoring their performance. As stated in the proposed rule (51 FR 12717), the mechanism used to identify and recruit these members, and the delineation of their duties, will be addressed by the potential network organizations in their contract proposals. This does not preclude the contractors from having full participation on the network coordinating council if they believe that

this would most effectively address the contract's task.

In addition all ESRD facilities are required, by virtue of their Medicare certification, to participate in network activities and pursue network goals. Finally, we are developing regulations to implement intermediate reimbursement sanctions against facilities that fail to cooperate with network goals.

J. Requirements for Representation by Specific Disciplines

Comment: A few commenters believe it is appropriate to retain the current regulatory requirements that specific health disciplines be represented on the network coordinating council and medical review board. They contend that these individuals are best qualified to evaluate the quality and appropriateness of care and to resolve patient grievances.

Response: We do not agree that it is necessary to retain these prescriptive requirements in regulations. We will include in the contract with the new network organizations a requirement that members of the medical review board be individuals qualified to evaluate the quality and appropriateness of care delivered to ESRD patients. We will also require network organizations to develop a patient grievance protocol. As stated above, the mechanism for identifying potential board members and their actual appointment is subject to approval by us through the contracting process. We believe that these provisions adequately address the concerns raised regarding this issue.

K. Patient Representation

Comment: Several commenters expressed concern over consumer representation on network committees. Many believe that the requirement for one patient representative will limit patient participation and patient services such as health education and review of grievances.

Response: We do not intend to diminish consumer participation in network activities. The proposed rule specifies that the network coordinating council and executive committee must include at least one patient representative; that requirement is mandated by section 1881(c) of the Act. There is nothing to preclude a network organization from appointing additional patient representatives if necessary or appropriate.

L. Contracting Process

Comment: A number of commenters opposed the use of competitive contracts for funding the organizations.

They believe that competitive contracts would substantially reduce voluntary participation in network activities and that potential contractors would be less committed to renal patients and facilities. The commenters are concerned that the new network organizations would not take advantage of existing network expertise. The commenters are also concerned that the current organizations would be precluded from participating in the competitive bid process.

One commenter supports the contracting process but believes it should be subject to public comment.

Response: The competitive bidding process will take into account potential contractors' technical capabilities, experience and proposed plans for performing the requirements of the contract. We believe these elements will assure that network contracts are awarded to organizations that are fully committed to meeting the needs of the ESRD program. We further believe that the competitive bidding process will result in a more effective and more efficient delivery of the network services and enhance our monitoring capability of network organizations. There will be nothing in the request for proposals that will preclude existing networks from submitting proposals for the new networks organizations.

We will specify in contracts the details of the duties and responsibilities of the network organizations. However, we believe that the substance of the contracts has already been subject to notice and public comment through our publication of the April 15, 1986 proposed rule and this final rule.

M. Extension of Comment Period

Comment: Two commenters requested that we extend the public comment period, so that they may thoroughly consider the long-term implications the proposed rule would have on the ESRD program.

Response: We believe that the 30-day period was sufficient time for receipt of comments on the proposed regulation changes and the number, diversity, and detail of the comments received support our belief.

N. Consideration of Public Comments

Comment: Two members of Congress requested that we consider comments submitted by an ESRD network in promulgating the final regulations.

Response: We wish to assure all commenters that we gave every timely comment we received thorough consideration and careful deliberation in formulating this final rule. We believe

that our discussion of the specific comments provides adequate rationale for the changes we made from the proposed rule and those instances where we maintained the position stated in the proposed rule.

O. Withdrawal of Regulation Changes

Comment: Several commenters suggested that our proposed rule be withdrawn, primarily because it did not retain the network data collection function. A few commenters expressed general opposition to any changes in the current network system.

Response: We continue to believe that this final rule will result in more efficient network organizations that will better address the needs of ESRD patients and the renal community. To the extent that network performance relative to available resources is enhanced, the entire ESRD program will benefit. As mentioned previously, we will include, as a task for the contractors, the network data collection and validation activities.

IV. Summary of Changes in the Final Regulations

A. Network Data Activities

After reviewing the public comments, we have decided to retain the network data functions that network organizations have been performing. The existing networks have been receiving copies of the national medical information forms from ESRD facilities for validation, analysis, and support of network activities prior to submitting the forms to us. We will specify these functions, and any additional data collection activities, in our contracts with the new network organizations, and we will continue to monitor network performance regarding these functions.

B. Technical Correction

In the proposed rule, we included mention in the preamble of the statutory requirement for network organizations to develop criteria and standards relating to the quality and appropriateness of patient care (51 FR 12715) and inadvertently omitted the requirement from the regulations text. We have revised § 405.2112 to add a new paragraph (c) to include this requirement as a function of a network organization.

V. Final Notice and Request for Proposals

We are developing separately a list of the consolidated ESRD network boundaries that we will be publishing

shortly as a final notice in the **Federal Register**.

Additionally, we will publish an announcement of a request for proposals (RFP) in the Commerce Business Daily (CBD) that will appear for 15 consecutive days. During those 15 days, interested parties may request copies of the RFP. On the fifteenth day the announcement appears in the CBD, we will distribute copies of the RFP to existing organizations that we feel currently have the expertise to perform network organization functions and any other parties that request copies. We will accept proposals within 30 days from the date that we issue copies of the RFP.

VI. Regulatory Impact Statement

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any "major rule" that is likely to have an annual effect on the economy of \$100 million or more, result in a major increase in costs or prices for consumers, any industries, government agencies or geographic regions, or meet other threshold criteria that are specified in that order. In addition, consistent with the Regulatory Flexibility Act of 1980 (5 U.S.C. 601-12), we prepare and publish a regulatory flexibility analysis for regulations unless the Secretary certifies that the regulations will not have a significant economic impact on a substantial number of small entities.

Because ESRD networks are such a small activity, with a total FY 1986 budget of less than \$5 million, these changes do not meet any of the criteria for a major rule under Executive Order 12291, and a regulatory impact analysis is not required. However, the planned reductions in numbers of network areas and organizations will clearly affect all or almost all existing network organizations. Since these organizations are a creation of the government and are funded by us solely to fulfill the requirements of the law, they are not the kind of small entities to which the Regulatory Flexibility Act is usually considered to apply. Nonetheless, they are small organizations, and a substantial number of them would experience a significant adverse economic effect as a result of our changes. Therefore, the following discussion, in combination with the other sections of the preamble of this rule, serves as a voluntary regulatory flexibility analysis.

As previously noted, this rule will expedite the ESRD network designation or redesignation process by eliminating the requirement that such designation be accomplished through rulemaking. This

rule will also delete the network criteria from the current regulations and provide for the reorganization of network organizations in each designated network. These procedural changes will not have any economic impact in themselves.

Existing network organizations will be affected only when we actually redesignate networks and make arrangements with new network organizations. We do not expect this redesignation to have an adverse effect on ESRD facilities or beneficiaries. Rather, to the extent that network performance relative to available resources is enhanced, the entire ESRD program will benefit.

We intend to replace existing network organizations with a more effective and efficient system. We believe that at this time there is no need for a narrow geographic focus and that essential functions may be best accomplished by the smallest number of entities. The health care delivery system generally is capable of accomplishing operational coordination of the delivery of needed services without reliance on special additional organizations such as the ESRD networks. As a desirable by-product, these changes will reduce the regulatory burden on the suppliers of ESRD services, while continuing to assure the health and safety of Medicare beneficiaries.

In conclusion, we believe that the adverse economic impact of our reductions will be limited to the affected entities and their immediate employees. Such adverse consequences as may be anticipated will not be of sufficient magnitude to offset the advantages to be gained by anticipated improvements in efficiency, effectiveness, economy, and quality of care.

VII. Information Collection Requirements

Sections 405.2112(f) and 405.2136(c)(3) of this final rule contain information collection requirements that are subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). A notice will appear in the **Federal Register** when approval is obtained.

If you wish to submit comments on the information collection requirements contained in this final rule, you may submit comments to:

Desk Officer, Office of Information and Regulatory Affairs, Room 3208, New Executive Office Building, Washington, DC 20503.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Chapter IV is amended as set forth below.

Part 405 is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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

1. The authority citation for Part 405 Subpart U is revised to read as follows:

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

2. The table of contents for Subpart U is amended by removing the section numbers and titles for §§ 405.2111, 405.2114 and 405.2132; revising the titles of §§ 405.2112 and 405.2134 to read "ESRD network organizations," and "Condition: Participation in network activities," respectively; and removing the reference to the APPENDIX.

3. Section 405.2100 is revised to correct the statutory reference in paragraph (a) and to remove references to ESRD networks and coordinating councils as follows:

§ 405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in § 405.2101, and general definitions are contained in § 405.2102. The provisions of §§ 405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the

establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

4. Section 405.2102 is amended by removing the lower-case, lettered paragraph designations and placing the definitions in alphabetical order, revising the definitions of "Network, ESRD" and removing the definition of "Network Coordinating Council", and adding, in alphabetical order, a definition of "Network Organization" to read as follows:

§ 405.2102 Definitions.

Network. ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by HCFA.

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

5. Section 405.2110 is revised to read as follows:

§ 405.2110 Designation of ESRD networks.

HCFA designated ESRD networks in which the approved ESRD facilities 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.* HCFA 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.

§ 405.2111 [Removed]

6. Section 405.2111 is removed.

7. Section 405.2112 is revised to read as follows:

§ 405.2112 ESRD network organizations.

HCFA 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.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care.

(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 HCFA an annual report that contains the following information:

(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; and

(ii) Transplantation.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section.

(4) 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 coordinating council, executive committee (each including at least one patient representative), and a medical review board, and supporting and coordinating the activities of each.

8. Section 405.2113 is revised to read as follows:

§ 405.2113 Medical review board.

(a) *General.* The medical review board must be composed of individuals qualified to evaluate the quality and appropriateness of care delivered to ESRD patients.

(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).

§ 405.2114 [Removed]

9. Section 405.2114 is removed.

§ 405.2120 [Amended]

10. Section 405.2120 is amended by removing the reference "Section 226(g) of the Social Security Act (42 U.S.C. 426(g))" and inserting in its place, the correct reference "Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1))".

§ 405.2121 [Amended]

11. Section 405.2121 is amended by removing paragraph (a) and redesignating paragraphs (b), (c) and (d) as (a), (b) and (c), respectively.

§ 405.2122 [Amended]

12. Section 405.2122(b)(2)(ii) is amended by removing the reference "§ 405.2102(r)(7)" and inserting, in its place, the reference "§ 405.2102".

§ 405.2132 [Removed]

13. Section 405.2132 is removed.

14. Section 405.2134 is revised to read as follows:

§ 405.2134 Conditions: Participation in network activities.

Each facility must participate in network activities and pursue network goals.

15. Section 405.2136 is amended by revising the introductory paragraph, removing paragraph (b)(5), and revising paragraph (c) introductory text, reprinting paragraph (c)(3) introductory text unchanged for the convenience of the reader, and revising paragraphs (c)(3)(v), (c)(3)(vi), and (h) to read as follows:

§ 405.2136 Condition: Governing body and management.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, 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. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer who is responsible for the overall management of the facility.

(c) *Standard: chief executive officer.* The governing body appoints a qualified

chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

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(3) The responsibilities of the chief executive officer include but are not limited to:

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(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contracts.

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(h) *Standard: medical staff.* The governing body of the ESRD facility designates a qualified physician (see § 405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

§ 405.2138 [Amended]

16. Section 405.2138(e) is amended by removing the words "Network Council" and inserting in their place, the words "network organization".

§ 405.2161 [Amended]

17. Section 405.2161(a) is amended by removing the reference "§ 405.2102(r)(5)" and inserting in its place, the reference "§ 405.2102".

§ 405.2162 [Amended]

18. Sections 405.2162 (a) and (c) are amended by removing the reference

"§ 405.2102(r)(4)" and inserting in its place, the reference "§ 405.2102".

§ 405.2163 [Amended]

19. Sections 405.2163 (c) and (d) are amended by removing the references "§ 405.2102(r)(6)" and "§ 405.2102(r)(2)" and inserting in their places, the references "§ 405.2102" and "§ 405.2102", respectively.

§ 405.2164 [Amended]

20. Section 405.2164(a) is amended by removing the phrase "§§ 405.2132, 405.2134, and 405.2137.", and inserting in its place, the phrase "§§ 405.2134 and 405.2137 that relate to participation in the network activities and patient long-term programs."

§ 405.2170 [Amended]

21. Section 405.2170 is amended by removing the references "§ 405.2102(r)(7)" and "§ 405.2102(r)(5)" and inserting in their places, the reference "§ 405.2102".

§ 405.2171 [Amended]

22. Sections 405.2171 (b) and (c) are amended by removing the references "§ 405.2102(r)(6)" and "§ 405.2102(r)(2)" and inserting in their places, the reference "§ 405.2102".

23. The Appendix to Subpart U is removed.

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare Hospital Insurance and No. 13.774, Supplementary Medical Insurance)

Dated: July 11, 1986.

William L. Roper,
Administrator, Health Care Financing
Administration.

Approved: July 25, 1986.

Otis R. Bowen,
Secretary.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[GEN Docket 84-801; FCC 86-350]

Exemptions from Technical Standards for Computing Devices

AGENCY: Federal Communications Commission.

ACTION: Clarification of final rule; notice of availability.

SUMMARY: The Commission gives notice of availability of a clarification of its exemptions from the computing devices rules under Part 15, Subpart J. This