Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FR–7003–5]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) Region VIII proposes to delete the residential soil portions of the Jacobs Smelter Superfund Site, Utah, known as Operable Unit One (OU1), from the National Priorities List and requests public comment on this action. The NPL constitutes Appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR Part 300, which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). This action is being taken because EPA, with concurrence from the Utah Department of Environmental Quality (UDEQ), has determined that all appropriate response actions have been taken and that no further response at OU1 is appropriate.

A detailed rationale for this Proposal to Delete is set forth in the direct final rule which can be found in the Rules and Regulations section of this Federal Register. The direct final rule is being published because EPA views this deletion action as a noncontroversial revision and anticipates no significant adverse or critical comments. If no significant adverse or critical comments are received, no further activity is contemplated. If EPA receives significant adverse or critical comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period.

Any parties interested in commenting should do so at this time.

DATES: Comments concerning this action must be received by EPA on or before August 6, 2001.

ADDRESSES: Comments may be mailed to: Mr. Jim Christiansen, Remedial Project Manager, U.S. EPA Region VIII, EPR–SR, 999 18th Street, Suite 300, Denver, CO 80202, (303) 312–6748. Email: christiansen.jim@epa.gov.

Information Repositories: Comprehensive information on the Jacobs Smelter Site as well as information specific to this proposed partial deletion is available for review at EPA’s Region VIII office in Denver, Colorado. The Administrative Record for OU1 and the Deletion Docket for this partial deletion are maintained at the following information repositories: U.S. EPA Region VIII, Superfund Records Center, 5th Floor, 999 18th Street, Denver, Colorado, 80202, (303) 312–6473, Hours of Operation: M–F 8:00 a.m. to 4:30 p.m. Tooele County Library, 100 West Vine Street, Tooele, Utah, 84074.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Christiansen, Remedial Project Manager, U.S. EPA Region VIII, EPR–SR, 999 18th Street, Suite 300, Denver, CO 80202, (303) 312–6748. Email: christiansen.jim@epa.gov.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is located in the Rules and Regulations section of this Federal Register.


Patricia D. Hull,

Acting Regional Administrator, U.S. Environmental Protection Agency, Region VIII.

[FR Doc. 01–16435 Filed 7–3–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 416, 482, and 485

[HCFA–3070–P]

RIN 0938–AK95

Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the physician supervision requirement for certified registered nurse anesthetists furnishing anesthesia services in hospitals, critical access hospitals, and ambulatory surgical centers that participate in the Medicare and Medicaid programs. Under this proposed rule, the current physician supervision requirement would be maintained, unless the Governor of a State, in consultation with the State’s Boards of Medicine and Nursing, exercises the option of exemption from this requirement, consistent with State law.

These proposed changes are an integral part of our efforts to improve the quality of care furnished through Federal programs, while at the same time recognizing a State’s traditional domain in establishing professional licensure and scope-of-practice laws. It will give States the flexibility to improve access and address safety issues.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on September 4, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address only: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–3070–P, P.O. Box 8013, Baltimore, MD 21207–8013.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them. If you prefer, you may deliver (by hand or courier) your written comments (1 original and 3 copies) to one of the

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3070–P. For information on viewing public comments see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Stephanie Dyson, RN (410) 786–9226. Jeannie Miller, RN (410) 786–3164.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at 7500 Security Blvd, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. by calling (410) 786–7197.

To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or MasterCard number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the Federal Register documents at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

This Federal Register document is also available from the Federal Register online database through GPO Access, a service of the U.S. Government Printing Office. The Website address is: http://www.access.gpo.gov/naara/index.html.

I. Background

A. Statutory Provisions

Sections 1861(e)(1) through (e)(8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet other requirements that we find necessary in the interest of the health and safety of the hospital's patients. Section 1820 of the Act contains criteria that a critical access hospital (CAH) must meet in order to be designated as a CAH by a State. Sections 1832(a)(2)(F)(i) and 1833(i) of the Act provide coverage requirements for ambulatory surgical centers (ASCs). Section 1861(bb) of the Act defines "certified registered nurse anesthetists" (CRNAs) and their services.

B. General

On December 19, 1997, we published a proposed rule entitled, "Hospital Conditions of Participation, Provider Agreements and Supplier Approval", (62 FR 66726) in the Federal Register.

The final rule was published January 18, 2001 (66 FR 4674) and was to have been effective March 19, 2001. This rule eliminated the federal physician supervision requirement for CRNAs furnishing anesthesia services in participating hospitals, ASCs, and CAHs. Instead, under the January 2001 rule, the level of supervision of CRNAs in participating Medicare facilities would be determined according to state law. On March 19, 2001, the effective date was delayed 60 days in accordance with the memorandum to the President from the Chief of Staff, dated January 20, 2001, and published in the Federal Register (see 66 FR 27598). On May 18, the rule was further delayed for 180 days in order to explore alternatives for implementation (see 66 FR 27598).

As proposed in the January 2001 final rule, we identified two important questions that were not raised and thus not addressed previously.

- One question concerned the States' reliance on Medicare physician supervision requirements in establishing State scope-of-practice laws and monitoring practices. In some cases, State laws and regulations may have been written with the assumption that Medicare would continue its longstanding policy requiring physician supervision of the anesthesia care provided by CRNAs. Eliminating the federal CRNA supervision requirements for participating Medicare facilities could mean that some States would change their supervision practices without considering their potential safety impact. In the absence of federal regulations, we were concerned that States might have promulgated different laws or different monitoring practices.

- The second question was whether a prospective study or monitoring should be undertaken to assess the impact in those States where CRNAs practice without physician supervision, or where physicians practice without the assistance of CRNAs. To date, no study has definitively addressed these issues, although the literature we reviewed indicated that the anesthesia-related death rate is extremely low, and that the administration of anesthesia in the United States is safe relative to surgical risk. However, in the absence of clear research evidence it is impossible to definitively document outcomes related to these practices.

We have concluded that we must resolve these implementation questions before we will consider eliminating entirely the federal CRNA supervision requirement. At the same time, however, we wish to give States the flexibility they need to ensure that their citizens have appropriate access to quality anesthesia services.

Accordingly, we again have delayed the effective date of the final rule and are proposing an alternative method in lieu of proposing an immediate removal of the federal supervision requirement. Our alternative proposed method would be to—

(1) Establish an exemption from the physician supervision requirement by recognizing a Governor's written request to us attesting that, after consultation with the State's Boards of Medicine and Nursing on issues related to access to and the quality of anesthesia services, and consistent with state law, he or she is aware of the State's right to an exemption from the requirement and has determined that it is in the best interests of the State's citizens to exercise this exemption, and

(2) Have the Agency for Health Research and Quality (AHRQ), with input from HCFA and that of other stakeholders, including anesthesiologists and CRNAs, design and conduct a prospective study or monitoring effort to assess outcomes of care issues relating to CRNA practice and involvement. One approach that we are seeking comment on would be to create a voluntary registry that could prospectively monitor these practices. We are interested in comments on other approaches, as well.

The Secretary is specifically seeking comments on both aspects of our alternative implementation approach.

II. Provisions of the Proposed Regulations

A. Overview

Under the proposal, we would continue to require CRNA supervision by a physician in hospitals, CAHs, and ASCs that participate in the Medicare program. However, we would add a new standard, entitled "State Exemptions."
This new standard would allow State Governors, following consultation with the State’s Boards of Medicine and Nursing on issues related to access to and the quality of anesthesia services, and consistent with state law, to exercise their option of exemption from the physician supervision requirement in anesthesia administration through a letter of attestation. The Governor seeking such an exemption would be required to submit a letter to us, attesting that it is in the best interests of the State’s citizens to opt-out of the requirement of physician supervision, and that such an opt-out is consistent with State law. We are developing a model letter of attestation that a Governor may send to the HCFA Administrator to signify that the State is exempt from the physician supervision requirement. The request to opt-out, and any withdrawal of a request to opt-out, would both be automatic and effective upon submission to HCFA. As with the current conditions of participation, the exemption would apply to all patients receiving anesthesia services in Medicare participating hospitals, CAHs, and ASCs, assuring that Medicare patients would not receive a different level of care from non-Medicare patients.

B. Discussion

We continue to believe that States are best positioned to regulate practitioners’ scope-of-practice and that our proposal is most appropriately designed to allow States to exercise authority over anesthesia services. It will effectively provide greater discretion to State authorities that are experienced at regulating the licensing, education, training, and performance of the professionals practicing under their purview, without the burden associated with duplicative regulatory oversight. Allowing States to make determinations about health care professional standards of practice, and hospitals, CAHs, and ASCs to make decisions regarding the delivery of care, assures that those closest to, and who know the most about, the health care delivery system are accountable for the outcomes of that care. Since the January 2001 rule is not yet effective, the regulatory changes we are proposing here are drafted as revisions to the 2000 CFR.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This rule is not considered to have a significant economic impact on hospitals and, therefore, is not considered a major rule. There are no requirements for hospitals, CAHs, and ASCs to initiate new processes of care, reporting, or to increase the amount of time spent on providing or documenting patient care services. This proposed rule would provide hospitals, CAHs, and ASCs with more flexibility in how they provide quality anesthesia services, and encourage implementation of the best practice protocols.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $25 million to $25 million or less annually (65 FR 69432). For purposes of the RFA, all non-profit hospitals, CAHs, and other hospitals with revenues of $25 million or less annually are considered to be small entities. Ambulatory surgical centers with revenues of $7.5 million or less annually are also considered to be small entities. Individuals and States are not included in the definition of small entities. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, that exceeds the inflation-adjusted threshold of $110 million. This rule places no additional costs for implementation on the governments mentioned. It will allow the Governor through a letter to us, to opt-out of the physician supervision requirement for CRNAs and allow the CRNAs to practice independently where State law permits. This change is consistent with our policy of respecting State control and oversight of health care professions by deferring to State laws to regulate professional practice. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on States and local governments. Consequently, it need not be reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 416

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.
§ 416.42 Condition for coverage—Surgical services.

(b) Standard: Administration of anesthesia. Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or
(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthetist’s assistant as defined in § 410.68(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthetist’s assistant, under the supervision of an anesthesiologist. 

(d) Standard: State exemption. (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to HCFA signed by the Governor, following consultation with the State’s Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State’s citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

1. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395), unless otherwise noted.

2. In § 485.639, paragraph (c) is revised and new paragraph (e) is added to read as follows:

§ 485.639 Condition of participation: Surgical services.

(c) Administration of anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only—

(i) A qualified anesthesiologist;
(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;
(iii) A doctor of dental surgery or dental medicine;
(iv) A doctor of podiatric medicine;
(v) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;
(vi) An anesthesiologist’s assistant, as defined in § 410.69(b) of this chapter; or
(vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist’s assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(e) Standard: State exemption. (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to HCFA signed by the Governor, following consultation with the State’s
Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State’s citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)


Thomas A. Scully, Administrator, Health Care Financing Administration.

[FR Doc. 01–16964 Filed 7–3–01; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2, 25, 101

[IB Docket No. 97–95; FCC 01–182]

Allocation and Designation of Spectrum in the 36.0–43.5 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Further notice of proposed rulemaking.

SUMMARY: This document proposes rule changes to the domestic frequency spectrum plan to provide satellite and terrestrial operators greater certainty about the scope of operations in the 36.0–43.5 GHz band. This document also proposes to adopt specific power flux-density limits on satellite operations in portions of this band. The proposed rules reflect decisions reached at the 2000 World Radiocommunication Conference (WRC–2000) in Istanbul, Turkey.


FOR FURTHER INFORMATION CONTACT: Troy Hanbury, Planning and Negotiations Division, International Bureau (202) 418–0766 or via electronic mail: ghbanbury@fcc.gov, or Charles Breig, Planning and Negotiations Division, International Bureau (202) 418–2156 or via electronic mail: cbreig@fcc.gov.


Summary of the Further Notice of Proposed Rulemaking

This document seeks comment on proposed modifications to the 36.0–43.5 GHz portion of the band plan that would harmonize the domestic band plan with the international sharing arrangement established at WRC–2000 and promote spectrum efficiency. In general, the Commission proposes to designate the 37.0–40.0 GHz band and the 42.0–42.5 GHz band for wireless services and to designate the 40.0–42.0 GHz band for satellite services. Specifically, the Commission proposes: (1) To re-designate the 41.0–42.0 GHz band for satellite services and the 37.6–38.6 GHz band for wireless services; and (2) to add a designation to the 40.5–41.0 GHz band for MSS. The Commission also proposes to adopt or to consider several changes to the table of frequency allocations, including the following: (1) Adding a Fixed-Satellite Service (FSS) allocation in the 37.5–37.6 GHz band; (2) shifting the Mobile-Satellite Service (MSS) allocation from the 39.5–40.0 GHz band to the 40.5–41.0 GHz band; (3) adding a primary Government FSS allocation to the 40.5–41.0 GHz band; (4) adding a primary FSS allocation in the 41.0–42.0 GHz band; (5) considering the addition of fixed and mobile for non-Government use to the 42.5–43.5 GHz band; and (6) providing additional protection to Radio Astronomy in the 42.5–43.5 GHz band. Finally, the Commission proposes to better define the spectrum designations that the Commission chose for the 36.0–51.4 GHz band. The Commission seeks comment on the general approach to the proposed domestic implementation of the U.S. achievements at WRC–2000 and on each of the proposals individually. While the proposed band plan alters the layout of satellite and terrestrial service designations in the band to recognize the U.S. achievements at WRC–2000, the proposed band plan would not change the total spectrum currently designated for use by satellite and terrestrial wireless services.

Paperwork Reduction Act Analysis

Because there are no new or modified paperwork requirements in the proposed rules, there is no increase in paperwork burden associated with this rulemaking.

Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act (RFA), the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this Further Notice of Proposed Rulemaking. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the Further Notice of Proposed Rulemaking. The Commission will send a copy of the Further Notice of Proposed Rulemaking, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. See 5 U.S.C. 603(a).

A. Need for and Objectives of the Proposed Rules

In this Further Notice of Proposed Rulemaking, the Commission proposes to modify the band segmentation plan governing operations in the 36.0–43.5 GHz band to reflect decisions reached at the 2000 World Radiocommunication Conference (WRC–2000). To provide satellite and terrestrial operators with greater certainty about the scope of operations in this band, the Commission also proposes specific power flux density (PFD) limits on satellite operations in portions of this band. In the Further Notice of Proposed Rulemaking, the Commission proposes to re-designate the 41.0–42.0 GHz band...