

showing no more than one exceedance per year is required to redesignate from unclassifiable to attainment. The data for three years have been presented and are satisfactory and complete. To redesignate the Androscoggin Valley Interstate Area from unclassifiable to attainment does not involve any regulatory change. The formal table in the Code of Federal Regulations containing the designation status is not changed since the attainment and unclassifiable designations are combined for ozone.

Final Action: EPA is approving the redesignation to attainment of the NAAQS for ozone in the New Hampshire portion of the Androscoggin Valley Interstate AQCR, submitted on October 2, 1986.

Since EPA views the redesignation as noncontroversial, we are taking this action without prior proposal. This action will be effective August 11, 1987. However, if EPA is notified within 30 days that adverse or critical comments will be submitted, we will withdraw this action and publish a new rulemaking proposing the action and establishing a comment period.

Under 5 U.S.C. 605(b), the Administrator has certified that SIP approvals do not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 11, 1987. This action may not be challenged later in proceedings to enforce its requirements (see 307(b)(2)).

List of Subjects in 40 CFR Part 81

Air pollution control.

Authority: 42 U.S.C. 7401-7642.

Dated: April 22, 1987.

Lee M. Thomas,

Administrator.

[FR Doc. 87-13471 Filed 6-11-87; 8:45 am]

BILLING CODE 5560-50-M

40 CFR Part 272

[FRL-3217-4]

Tennessee; Final Authorization of State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Tennessee has applied for final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has reviewed Tennessee's application and has made a decision, subject to public review and comment, that Tennessee's hazardous waste program revision for the hazardous components of radioactive mixed wastes satisfies all of the requirements necessary to qualify for final authorization. Thus, EPA intends to approve Tennessee's hazardous waste program revision for the hazardous components of radioactive mixed wastes. Tennessee's application for program revision is available for public review and comment.

DATES: Final authorization for Tennessee shall be effective August 11, 1987, unless EPA publishes a prior Federal Register action withdrawing this immediate final rule. All comments on Tennessee's program revision application must be received by the close of business June 30, 1987.

ADDRESSES: Copies of Tennessee's program revision application are available during 8:30 A.M. to 4:30 P.M., Monday through Friday, at the following addresses for inspection and copying: Division of Solid Waste Management, Tennessee Department of Health and Environment, 701 Broadway, Nashville, Tennessee 37219; US EPA Headquarters Library, PM 211A, 401 M Street, SW., Washington, DC 20460, Phone: 202/382-5926; US EPA, Region IV, Library, 345 Courtland St., NE., Atlanta, Georgia 30365, Phone: 404/347-4216, Gayle Alston, Librarian. Written comments should be sent to Otis Johnson, Jr., 345 Courtland St., NE., Atlanta, Georgia 30365, Phone: 404/347-3016.

FOR FURTHER INFORMATION CONTACT: Otis Johnson, Jr., 345 Courtland St., NE., Atlanta, Georgia 30365, Phone: 404/347-3016.

SUPPLEMENTARY INFORMATION:

A. Background

States with final authorization under section 3006(b) of the Resource Conservation and Recovery Act ("RCRA") or "the Act", 42 U.S.C. 6929(b), have a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. In addition, as an interim measure, the Hazardous and Solid Waste Amendments of 1984 (Pub. L. 98-616, November 8, 1984, hereinafter "HSWA") allows States to revise their programs to become

substantially equivalent instead of equivalent to RCRA requirements promulgated under HSWA authority. States exercising the latter option receive "interim authorization" for the HSWA requirements under section 3006(g) of RCRA, 42 U.S.C. 6926(g), and later apply for final authorization for the HSWA requirements.

Revisions to State hazardous waste programs are necessary when Federal or State statutory or regulatory authority is modified or when certain changes occur. Most commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR Parts 260 through 266 and 124 and 270.

B. Tennessee

Tennessee initially received final authorization on February 5, 1985. On March 12, 1987, Tennessee submitted a program revision application for additional program approval for the hazardous components of radioactive mixed wastes. Today, Tennessee is seeking approval of its program revision in accordance with 40 CFR 271.21(b)(3).

EPA has reviewed Tennessee's application, and has made an immediate final decision that Tennessee's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Consequently, EPA intends to grant final authorization for the additional program modifications to Tennessee. The public may submit written comments on EPA's immediate final decision up until June 30, 1987. Copies of Tennessee's application for program revision are available for inspection and copying at the locations indicated in the "ADDRESSES" section of this notice.

Approval of Tennessee's program revision for the hazardous components of radioactive mixed wastes shall become effective in 60 days unless an adverse comment pertaining to the State's revision discussed in this notice is received by the end of the comment period. If an adverse comment is received EPA will publish either (1) a withdrawal of the immediate final decision or (2) a notice containing a response to comments which either affirms that the immediate final decision takes effect or reverses the decision.

The State of Tennessee has issued one storage permit to the US Department of Energy (DOE) at Oak Ridge, Tennessee which allows the facility to store certain specific hazardous wastes. Although the Region does not believe that any radioactive mixed wastes are currently stored at this facility, their RCRA permit does not preclude them from storing the

specific hazardous wastes covered by their permit if the waste is also radioactively contaminated. This permit will continue in force and will be considered the RCRA permit.

The State of Tennessee anticipates issuing in the very near future, the public notice of the draft permit for the DOE K-1435 incinerator at Oak Ridge. The K-1435 incinerator, if permitted, will incinerate hazardous wastes which are radioactive and nonradioactive, as well as PCBs and other solid wastes.

EPA's intent is to authorize Tennessee for radioactive mixed hazardous wastes before they issue the final permit for this incinerator so the K-1435 incinerator permit will be the RCRA permit. Tennessee is not seeking authorization to operate in Indian lands.

C. Decision

I conclude that Tennessee's application for program revision meets all of the statutory and regulatory requirements established by RCRA. Accordingly, Tennessee is granted final authorization to operate its hazardous waste program as revised. Tennessee now has responsibility for permitting treatment, storage, and disposal facilities within its borders and carrying out other aspects of the RCRA-program, subject to the limitation of its revised program application and previously approved authorities. Tennessee also has primary enforcement responsibilities, although EPA retains the right to conduct inspections under section 3007 of RCRA and to take enforcement actions under section 3008, 3013 and 7003 of RCRA.

Compliance With Executive Order 12291:

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Certification Under the Regulatory Flexibility Act:

Pursuant to the provisions of 4 U.S.C. 605(b), I hereby certify that this authorization will not have a significant economic impact on a substantial number of small entities. This authorization effectively suspends the applicability of certain Federal regulations in favor of Tennessee's program, thereby eliminating duplicative requirements for handlers of hazardous waste in the State. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 272

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This notice is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: May 21, 1987.

Jack E. Ravan,

Regional Administrator.

[FR Doc. 87-13472 Filed 6-11-87; 8:45am]

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40 CFR Part 716

[OPTS-84026A; FRL-3217-5]

Addition of Chemicals to the Preliminary Assessment Information and Health and Safety Data Reporting Rule; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; Correction.

SUMMARY: This document corrects the CAS number entry for ethylbenzene listed under § 716.120 which was incorrectly listed.

DATE: This document is effective June 12, 1987.

FOR FURTHER INFORMATION CONTACT: John A. Richards (TS-788B), Federal Register Staff, Environmental Protection Agency, 401 M St., SW., Rm. NE-G009, Washington, DC 20460, (202)-382-3415.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 20, 1987, (52 FR 19027), in FR Doc. 87-11479, EPA added four substances to two model information-gathering rules: The Toxic Substances Control Act (TSCA) section 8(a) Preliminary Assessment Information Rule and the TSCA section 8(d) Health and Safety Data Reporting Rule. The CAS number for ethylbenzene was incorrectly listed under the 8(d) amendment.

Dated: June 3, 1987.

Joseph J. Merenda,

Director, Existing Chemical Assessment Division, Office of Toxic Substances.

PART 716—[AMENDED]

Therefore, 40 CFR 716.120(a)(1) is corrected by revising the CAS number entry for ethylbenzene to read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

(a) * * *

(1) * * *

CAS No.	Substances	Special Exemptions	Effective date	Sunset date
100-41-4	Ethylbenzene	* * *	6/19/87	6/19/97

[FR Doc. 87-13474 Filed 6-11-87; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 416, 420, 431, 485, 489, 498, 1001 and 1004

[BERC-371-FC]

Medicare Program; Appeals Procedures for Determinations That Affect Participation in Medicare

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

ACTION: Final rule with comment period.

SUMMARY: These rules update and clarify policy and appeals from determinations that affect participation of providers, suppliers, and practitioners in the Medicare program. This policy is currently set forth in Subpart O of Part 405 of the Medicare rules. Revision is needed to conform these rules with changes that have been made in other regulations and in the delegations of authority since Subpart O was published. The purpose is to achieve internal consistency of all Medicare rules and to ensure that users of our regulations are not misled or confused by language that does not reflect current policy and delegations of authority.

DATES: 1. These rules are effective on June 12, 1987.

2. To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on August 11, 1987.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-371-FC, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

If you comment on the information collection requirements, please send a copy of those comments directly to: Office of Information and Regulatory Affairs, Attention: Allison Herron, HCFA Desk Officer, New Executive Office Building, Room 3208, Washington, DC 20503.

In commenting, please refer to BERC-371-FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT:

Luisa V. Iglesias, (202) 245-0383.

SUPPLEMENTARY INFORMATION: In order to conform and clarify these rules, we found it necessary to—

1. Revise and reorganize the content of several sections in order to eliminate unnecessary repetition and clarify the appeal rights of providers, suppliers, practitioners, and nonparticipating hospitals that furnish emergency services. (§§ 498.2 and 498.5)

2. Reflect changes in delegations of authority whereby the Department's Office of the Inspector General (OIG), rather than HCFA, is responsible for certain initial determinations. (§ 498.3(c))

3. Add the following to the list of determinations that are subject to the provisions of Part 498:

a. The determination to impose sanctions on a practitioner or provider for violation of statutory obligations. (This reflects policy contained in Part 1004 of the OIG rules, published on September 30, 1986 at 51 FR 34764.)

b. Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services. (This change corrects the unintentional omission of two practitioners who, in practice, have the same appeal rights as suppliers because they must meet special Medicare qualification requirements not applicable to other practitioners.)

c. The cancellation of the approval of a Medicaid SNF or ICF by HCFA, under section 1910(c) of the Act. Section 1910(c):

• Authorizes the Secretary (who has delegated responsibility to HCFA) to

cancel the approval of a Medicaid SNF or ICF that is found not to meet the requirements for participation; and

• Gives the affected facility the right to a hearing and to judicial review to the extent provided in sections 205(b) and 205(g) of the Act, respectively. Since the Part 498 appeals procedures are also based on those sections (as cited in section 1869(c) of the Act), those procedures are made applicable to the Medicaid facilities whose approval is cancelled.

d. Whether an ESRD facility is considered to be hospital-based or independent. This type of determination was established by § 405.439(c)(2) of the rules on prospective payment to ESRD facilities, published on May 11, 1983 at 48 FR 21254 and redesignated as § 413.170 on September 30, 1986 at 51 FR 34793.

4. Include hospices and rural health clinics, which were unintentionally omitted from the rules, even though in practice they have the same appeals rights as other providers and suppliers. (Because Subpart O contained 63 repetitious list of providers and suppliers to which the rules apply, adding a new provider or supplier has in the past required 63 changes in the rules. We will be taking advantage of this opportunity to simplify the regulations by adding definitions and eliminating the lists.)

5. Transfer, from Subpart F of Part 405 of the Medicare regulations to the new part 498, the special rules for notice of certain initial determinations that affect independent laboratories and suppliers of portable X-ray services (current § 405.640).

6. Conform language that describes the effect of determinations and decisions to the Social Security Administration (SSA) rules at 20 CFR Part 404, Subpart J, because it is the SSA Office of Hearings and Appeals that handles these Medicare appeals.

Because the transfer described under item 5. above left a single section in Subpart F (dealing with the general aspects of agreements with State survey agencies), we took advantage of this opportunity to—

• Transfer the content of that remaining § 405.685 to § 405.1902, which deals with survey agency functions and procedures; and

• Vacate and reserve Subpart F.

Note.—Paragraph (c) of § 405.685 is not repeated in the amendments to § 405.1902, but is subsumed in paragraph (b)(3).

We have also corrected cross-references and redesignated the content of Subpart O as a new Part 498, in accordance with the overall plan to

assign a separate part for each major aspect of the Medicare program. A redesignation table at the end of this preamble will enable the reader to identify the source of each section in new Part 498.

Regulatory Impact Statement

Because these rules merely update, clarify and redesignate existing rules, we anticipate slight, if any, economic impact or impact on small entities such as some of the providers and suppliers that have long been subject to the provisions of Subpart O of Part 405 of the Medicare rules. For that reason, we have determined that a regulatory analysis under Executive Order 12291 is not required. We have also determined, and the Secretary certifies, that analysis under the Regulatory Flexibility Act (5 U.S.C. 601 through 612) is not required because this rule will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act of 1980 (Pub. L. 96-511)

Sections 498.22(c), 498.40 (b) and (c), 498.58(c) and 498.82(b) of these redesignated rules contain information collection requirements that are subject to approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 and are being submitted to OMB for that purpose. When approval is obtained, we will publish a notice to that effect in the Federal Register.

Waiver of Notice of Proposed Rulemaking and Delayed Effective Date

These rules clarify and update content that deals with procedural rather than substantive aspects of the Medicare program. They conform that content with practices that are already in effect and are not intended to make any substantive change, except as required by change in the delegation of authority. Accordingly, we find that notice and delayed effective date are unnecessary.

Response to Comments

Although this regulation is final, we will consider any comments, including comments from anyone who believes that, in the process of clarification and redesignation, we have made substantive changes other than the one discussed above as required by the change in the delegation of authority.

Because of the many letters we receive in response to publication in the Federal Register, we cannot acknowledge or respond to them individually. However, if we revise Part 498, in response to comments, or for any

other reason, we will discuss and respond to the comments in the preamble to that revision.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 420

Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicare.

42 CFR Part 498

Administrative practice and procedure, Appeals, Medicare Practitioners, providers, and suppliers.

Redesignation Table for 42 CFR Part 405, Subparts F and O

Old section	New section
405.640.....	498.20(a)(2).
405.685.....	405.1902(b).
405.1501(a).....	Removed as duplicative of § 405.1502.
405.1501(b), (c), and (e).	498.5.
405.1501(d).....	498.3(e).
405.1502.....	498.3(b).
405.1503.....	498.20(a).
405.1504.....	498.20(b).
405.1505.....	498.3(c).
405.1510.....	498.22(a).
405.1511(a).....	498.22(c).
405.1511(b).....	498.22(b).
405.1512.....	498.22(b)(2).
405.1513.....	498.23.
405.1514.....	498.24.
405.1515.....	498.24.
405.1516.....	498.25(a).
405.1517.....	498.25(b).
405.1518.....	498.22(d).
405.1519.....	498.30.
405.1520.....	498.32(a).
405.1521.....	498.32(b).
405.1530.....	Removed as duplicative of § 405.1531.
405.1531.....	498.40.
405.1532.....	498.42.
405.1533.....	498.44.
405.1534.....	498.45.
405.1535.....	498.47.
405.1536.....	498.48.
405.1537.....	498.49.
405.1538.....	498.50.
405.1539.....	498.50.
405.1540.....	498.52.
405.1541.....	498.53.
405.1542.....	498.56.
405.1543.....	498.54.
405.1544.....	498.58.
405.1545.....	498.60.
405.1546.....	498.61.
405.1547.....	498.62.
405.1548.....	498.63.

Old section	New section
405.1549.....	498.64.
405.1550.....	498.66.
405.1551.....	498.68.
405.1552.....	498.69.
405.1553.....	498.70.
405.1554.....	498.71.
405.1555.....	498.71.
405.1556.....	498.72.
405.1557.....	498.74.
405.1558.....	498.74.
405.1559.....	498.76.
405.1560.....	498.78.
405.1561.....	498.80.
405.1562.....	498.82.
405.1563.....	498.83.
405.1564.....	498.85.
405.1565.....	498.86.
405.1566.....	498.88.
405.1567.....	498.90.
405.1568.....	498.83.
405.1569.....	498.95.
405.1570.....	498.100.
405.1571.....	498.102.
405.1572 and 405.1571(c).	498.103.
405.1590.....	498.10.
405.1591.....	498.11.
405.1592.....	498.13.
405.1593.....	498.15.
405.1594.....	498.11(b).
405.1595.....	498.17.

42 CFR Chapter IV is amended as set forth below:

PART 405—[AMENDED]

A. Part 405 is amended as set forth below:

1. Subparts F and O are removed and reserved and the table of contents is amended to reflect this change.

2. Section 405.1902 is amended to redesignate paragraphs (b) and (c) as (c) and (d), add a new paragraph (b), revise the caption of redesignated paragraph (c) and provide a caption for redesignated paragraph (d). As amended, § 405.1902 reads as follows:

§ 405.1902 State survey agency review.

(b) *Functions of survey agencies.* State and local agencies that have agreements under section 1864(a) of the Act—

(1) Survey and make recommendations regarding the issues listed in paragraph (a)(1) of this section;

(2) Conduct validation surveys as provided in paragraph (a)(3) of this section;

(3) Perform other surveys and other appropriate activities and certify their findings to HCFA; and

(4) Review statements obtained from each SNF, setting forth (from payroll records) the average numbers and types of personnel (in full-time equivalents) on

each tour of duty during at least 1 week of each quarter, such week to be selected by the survey agency and to occur irregularly in each quarter of the year.

(c) *Effect of survey agency certification.* * * *

(d) *Effect of PRO review.* * * *

B. The content removed from § 405.640 and Subpart O of Part 405 is redesignated as a new Part 498 and revised to read as follows:

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM

Subpart A—General Provisions

Sec.	
498.1	Statutory basis.
498.2	Definitions.
498.3	Scope and applicability.
498.5	Appeal rights.
498.10	Appointment of representatives.
498.11	Authority of representatives.
498.13	Fees for services of representatives.
498.15	Charge for transcripts.
498.17	Filing of briefs with the ALJ or Appeals Council and opportunity for rebuttal.

Subpart B—Initial, Reconsidered, and Revised Determinations

498.20	Notice and effect of initial determination.
498.22	Reconsideration.
498.23	Withdrawal of request for reconsideration.
498.24	Reconsidered determination.
498.25	Notice and effect of reconsidered determination.

Subpart C—Reopening of Initial or Reconsidered Determinations

498.30	Limitation on reopening.
498.32	Notice and effect of reopening and revision.

Subpart D—Hearings

498.40	Request for hearing.
498.42	Parties to the hearing.
498.44	Designation of hearing official.
498.45	Disqualification of Administrative Law Judge.
498.47	Prehearing conference.
498.48	Notice of prehearing conference.
498.49	Conduct of prehearing conference.
498.50	Record, order, and effect of prehearing conference.
498.52	Time and place of hearing.
498.53	Change in time and place of hearing.
498.54	Joint hearings.
498.56	Hearing on new issues.
498.58	Subpoenas.
498.60	Conduct of hearings.
498.61	Evidence.
498.62	Witnesses.
498.63	Oral and written summation.
498.64	Record of hearing.
498.66	Waiver of right to appear and present evidence.
498.68	Dismissal of request for hearing.
498.69	Dismissal for abandonment.

- Sec.
 498.70 Dismissal for cause.
 498.71 Notice and effect of dismissal and right to request review.
 498.72 Vacating a dismissal of request for hearing.
 498.74 Administrative Law Judge's decision.
 498.76 Removal of hearing to Appeals Council.
 498.78 Remand by Administrative Law Judge.

Subpart E—Appeals Council Review

- 498.80 Right to request Appeals Council review of Administrative Law Judge's decision or dismissal.
 498.82 Request for Appeals Council review.
 498.83 Appeals Council action on request for review.
 498.85 Procedures before the Appeals Council on review.
 498.86 Evidence admissible on review.
 498.88 Decision or remand by the Appeals Council.
 498.90 Effect of Appeals Council decision.
 498.95 Extension of time for seeking judicial review.

Subpart F—Reopening of Decisions Made by Administrative Law Judges or the Appeals Council

- 498.100 Basis, timing, and authority for reopening an ALJ or Council decision.
 498.102 Revision of reopened decision.
 498.103 Notice and effect of revised decision.

Authority: Secs. 205(a), 1102, 1869(c) 1871, and 1872 of the Social Security Act (42 U.S.C. 405(a), 1302, 1395 ff(c), 1395hh and 1395ii), unless otherwise noted.)

Subpart A—General Provisions

§ 498.1 Statutory basis.

(a) Section 1869(c) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Section 1128 (a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

(e) Section 1862(d) of the Act provides for the exclusion of individuals or entities that submit false claims, bill excessive charges or furnish substandard care.

(f) HCFA is responsible for implementing section 1869(c) of the Act, and section 1866 (b)(2), except subparagraphs (D), (E), and (F). The OIG

is responsible for implementing the other cited sections.

(g) Although sections 1866 and 1869 of the Act are silent regarding appeal rights for suppliers and practitioners, the rules in this part include procedures for review of determinations that affect those two groups.

§ 498.2 Definitions.

As used in this part—

"Affected party" means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and *"party"* means the affected party or HCFA (or the OIG), as appropriate. *"ALJ"* stands for Administrative Law Judge.

"Appeals Council" or *"Council"* means the Appeals Council of the Office of Hearings and Appeals of the Social Security Administration.

"OHA" stands for the Social Security Administration's Office of Hearings and Appeals.

"OIG" stands for the Department's Office of the Inspector General.

"Provider" means a hospital, skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), or hospice, that has in effect an agreement to participate in Medicare, or a clinic, rehabilitation agency, or public health agency that has a similar agreement but only to furnish outpatient physical therapy or outpatient speech pathology services, and *"prospective provider"* means any of the listed entities that seeks to participate in Medicare as a provider.

"Supplier" means an independent laboratory, supplier of portable X-ray services, rural health clinic (RHC), ambulatory surgical center (ASC), or end-stage renal disease (ESRD) treatment facility that is approved by HCFA as meeting the conditions for coverage of its services, and

"Prospective supplier" means any of the listed entities that seeks to be approved for coverage of its services under Medicare. However, for purposes of the sanctions and penalties that may be imposed by the OIG, the term *"supplier"* has the meaning specified in § 1001.2 of this title.

§ 498.3 Scope and applicability.

(a) *Scope.* This part sets forth procedures for reviewing initial determinations that HCFA makes with respect to the matters specified in paragraph (b) of this section and that the OIG makes with respect to matters specified in paragraph (c) of this section.

(b) *Initial determinations by HCFA.* HCFA makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(3) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(4) Whether a prospective supplier meets the appropriate conditions for coverage of its services, as set forth in Part 405 (§ 405.152, Subpart M, N, Q, or U), Part 416, or Part 491 of this chapter).

(5) Whether the services of a supplier continue to meet the conditions for coverage.

(6) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services as set forth in §§ 405.1730 through 405.1737 or in § 410.22 of this chapter, respectively.

(7) The termination of a provider agreement in accordance with § 489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with § 405.2404 of this chapter.

(8) The cancellation of the approval of a Medicaid SNF or ICF by HCFA under section 1910(c) of the Act.

(9) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospital-based or independent.

(c) *Initial determinations by the OIG.* The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with Part 1001, Subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with Part 1001, Subpart B of this title.

(3) The imposition of sanctions in accordance with Part 1004 of this title.

(d) *Administrative actions that are not initial determinations.* Administrative actions other than those specified in paragraphs (b) and (c) of this section are not initial determinations and thus are not subject to this part.

Administrative actions that are not initial determinations include, but are not limited to, the following:

(1) The finding that a provider or supplier determined to be in compliance

with the conditions of participation or the conditions for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth in Part 405 (Subpart K, L, or Q), Part 482 or Part 485 of this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in Subpart S of Part 405 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider has been adjudged insolvent or bankrupt under Federal or State law, or insolvency or bankruptcy proceedings are pending.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution—

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to a SNF that is not in compliance with a condition of participation—

(i) The finding that the SNF's deficiencies pose immediate jeopardy to patients' health and safety; and

(ii) When the SNF's deficiencies do not pose immediate jeopardy, the decision to deny payment for new admissions.

(e) *Exclusion of civil rights issues.* The procedures in this subpart do not apply to the adjudication of issues relating to a provider's compliance with civil rights requirements that are set forth in Part 489 of this chapter. Those issues are handled through the Department's Office of Civil Rights.

§ 498.5 Appeal rights.

(a) *Appeal rights of prospective providers.* (1) Any prospective provider dissatisfied with an initial determination or revised initial determination that it does not qualify as a provider may request reconsideration in accordance with § 498.22(a).

(2) Any prospective provider dissatisfied with a reconsidered determination under paragraph (a)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(b) *Appeal rights of providers.* Any provider dissatisfied with an initial determination to terminate its provider agreement is entitled to a hearing before an ALJ.

(c) *Appeal rights of providers and prospective providers.* Any provider or prospective provider dissatisfied with a hearing decision may request Appeals Council review and has a right to seek judicial review of the Council's decision.

(d) *Appeal rights of prospective suppliers.* (1) Any prospective supplier dissatisfied with an initial determination or a revised initial determination that its services do not meet the conditions for coverage may request reconsideration in accordance with § 498.22(a).

(2) Any prospective supplier dissatisfied with a reconsidered determination under paragraph (d)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(e) *Appeal rights of suppliers.* Any supplier dissatisfied with an initial determination that the services subject to the determination no longer meet the conditions for coverage, is entitled to a hearing before an ALJ.

(f) *Appeal rights of suppliers and prospective suppliers.* (1) Any supplier or prospective supplier dissatisfied with the hearing decision may request Appeals Council review of the ALJ's decision.

(2) Suppliers and prospective suppliers do not have a right to judicial review except as provided in paragraph (i) of this section.

(g) *Appeals rights for certain practitioners.* A physical therapist in

independent practice or a chiropractor dissatisfied with a determination that he or she does not meet the requirements for coverage of his or her services has the same appeal rights as suppliers have under paragraphs (d), (e) and (f) of this section.

(h) *Appeal rights for nonparticipating hospitals that furnish emergency services.* A nonparticipating hospital dissatisfied with a determination or decision that it does not qualify to elect to claim payment for all emergency services furnished during a calendar year has the same appeal rights that providers have under paragraph (a), (b), and (c) of this section.

(i) *Appeal rights for suspended or excluded practitioners, providers, or suppliers.* (1) Any practitioner, provider, or supplier who has been suspended, or whose services have been excluded from coverage in accordance with § 498.3(c)(2), or has been sanctioned in accordance with § 498.3(c)(3), is entitled to a hearing before an ALJ.

(2) Any suspended or excluded practitioner, provider, or supplier dissatisfied with a hearing decision may request Appeals Council review and has a right to seek judicial review of the Council's decision by filing an action in Federal district court.

(j) *Appeal rights for Medicaid SNFs and ICFs terminated by HCFA.* (1) Any Medicaid SNF or ICF that has had its approval cancelled by HCFA in accordance with § 498.3(b)(8) has a right to a hearing before an ALJ, to request Appeals Council review of the hearing decision, and to seek judicial review of the Council's decision.

(2) The Medicaid agreement remains in effect until the period for requesting a hearing has expired or, if the facility requests a hearing, until a hearing decision is issued, unless HCFA—

(i) Makes a written determination that continuation of provider status for the SNF or ICF constitutes an immediate and serious threat to the health and safety of patients and specifies the reasons for that determination; and

(ii) Certifies that the facility has been notified of its deficiencies and has failed to correct them.

§ 498.10 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with HCFA, the ALJ, or the Appeals Council.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 498.11 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 498.10 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 498.13 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 498.10 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 498.15 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Council review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Appeals Council, as appropriate.

§ 498.17 Filing of briefs with the ALJ or Appeals Council, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and one copy to the ALJ or the Appeals Council, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and one copy with the ALJ or the Council and furnish a copy to the other party.

(2) The ALJ or the council will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

Subpart B—Initial, Reconsidered, and Revised Determinations

§ 498.20 Notice and effect of initial determinations.

(a) *Notice of initial determination—*

(1) *General rule.* HCFA or the OIG, as appropriate, mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to reconsideration, if applicable, or to a hearing.

(2) *Special rules: Independent laboratories and suppliers of portable x-ray services.* If HCFA determines that an independent laboratory or a supplier of portable x-ray services no longer meets the conditions for coverage of some or all of its services, the notice—

(i) Specifies an effective date of termination of coverage that is at least 15 days after the date of the notice;

(ii) Is also sent to physicians, hospitals, and other parties that might use the services of the laboratory or supplier; and

(iii) In the case of laboratories, specifies the categories of laboratory tests that are no longer covered.

(3) *Special rules: Nonparticipating hospitals that elect to claim payment for emergency services.* If HCFA determines that a nonparticipating hospital no longer qualifies to elect to claim payment for all emergency services furnished in a calendar year, the notice—

(i) States the calendar year to which the determination applies;

(ii) Specifies an effective date that is at least 5 days after the date of the notice; and

(iii) Specifies that the determination applies to services furnished, in the specified calendar year, to patients accepted (as inpatients or outpatients) on or after the effective date of the determination.

(4) *Other special rules.* Additional rules pertaining, for example, to content and timing of notice, notice to the public and to other entities, and time allowed for submittal of additional information, are set forth elsewhere in this chapter, as follows:

Part 405 Subpart X—for rural health clinics.

Part 416—for ambulatory surgical centers.

Part 489—for providers, when their provider agreements have been terminated.

Part 1001, Subpart B—for excluded or suspended providers, suppliers, physicians, or practitioners.

Part 1001, Subpart C—for providers, when their provider agreements are terminated by the OIG.

Part 1004—for sanctioned providers and practitioners.

(b) *Effect of initial determination.* An initial determination is binding unless it is—

(1) Reconsidered in accordance with § 498.24;

(2) Reversed or modified by a hearing decision in accordance with § 498.78; or

(3) Revised in accordance with § 498.32 or § 498.100.

§ 498.22 Reconsideration.

(a) *Right to reconsideration.* HCFA reconsiders any initial determination that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section. (None of the determinations made by the OIG are subject to reconsideration.)

(b) *Request for reconsideration: Manner and timing.* The affected party specified in paragraph (a) of this section, if dissatisfied with the initial determination may request reconsideration by filing the request—

(1) With HCFA or with the State survey agency;

(2) Directly or through its legal representative or other authorized official; and

(3) Within 60 days from receipt of the notice of initial determination, unless the time is extended in accordance with paragraph (d) of this section. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later.

(c) *Content of request.* The request for reconsideration must state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement.

(d) *Extension of time to file a request for reconsideration.* (1) If the affected party is unable to file the request within the 60 days specified in paragraph (b) of this section, it may file a written request with HCFA, stating the reasons why the request was not filed timely.

(2) HCFA will extend the time for filing a request for reconsideration if the affected party shows good cause for missing the deadline.

§ 498.23 Withdrawal of request for reconsideration.

A request for reconsideration is considered withdrawn if the requestor files a written withdrawal request before HCFA mails the notice of reconsidered determination, and HCFA approves the withdrawal request.

§ 498.24 Reconsidered determination.

When a request for reconsideration has been properly filed in accordance with § 498.22, HCFA—

(a) Receives written evidence and statements that are relevant and material to the matters at issue and are submitted within a reasonable time after the request for reconsideration;

(b) Considers the initial determination, the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other written evidence submitted under paragraph (a) of this section, taking into account facts relating to the status of the prospective provider or supplier subsequent to the initial determination; and

(c) Makes a reconsidered determination, affirming or modifying the initial determination and the findings on which it was based.

§ 498.25 Notice and effect of reconsidered determination.

(a) *Notice.* (1) HCFA mails notice of a reconsidered determination to the affected party.

(2) The notice gives the reasons for the determination.

(3) If the determination is adverse, the notice specifies the conditions or requirements of law or regulations that the affected party fails to meet, and informs the party of its right to a hearing.

(b) *Effect.* A reconsidered determination is binding unless—

(1) HCFA or the OIG, as appropriate, further revises the revised determination; or

(2) The revised determination is reversed or modified by a hearing decision.

Subpart C—Reopening of Initial or Reconsidered Determinations**§ 498.30 Limitation on reopening.**

An initial or reconsidered determination that a prospective provider is a provider or that a hospital qualifies to elect to claim payment for all emergency services furnished in a calendar year may not be reopened. HCFA or the OIG, as appropriate, may on its own initiative, reopen any other initial or reconsidered determination,

within 12 months after the date of notice of the initial determination.

§ 498.32 Notice and effect of reopening and revision.

(a) *Notice.* (1) HCFA or the OIG, as appropriate, gives the affected party notice of reopening and of any revision of the reopened determination.

(2) The notice of revised determination states the basis or reason for the revised determination.

(3) If the determination is that a supplier or prospective supplier does not meet the conditions for coverage of its services, the notice specifies the conditions with respect to which the affected party fails to meet the requirements of law and regulations, and informs the party of its right to a hearing.

(b) *Effect.* A revised determination is binding unless

(1) The affected party requests a hearing before an ALJ; or

(2) HCFA or the OIG further revises the revised determination.

Subpart D—Hearings**§ 498.40 Request for hearing.**

(a) *Manner and timing of request.* (1) An affected party entitled to a hearing under § 498.5 may file a request for a hearing with HCFA or the OIG, as appropriate, or with OHA.

(2) The affected party or its legal representative or other authorized official must file the request in writing within 60 days from receipt of the notice of initial, reconsidered, or revised determination unless that period is extended in accordance with paragraph (c) of this section. (Presumed date of receipt is determined in accordance with § 498.22(b)(3)).

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for contending that the findings and conclusions are incorrect.

(c) *Extension of time for filing a request for hearing.* If the request was not filed within 60 days—

(1) The affected party or its legal representative or other authorized official may file with the ALJ a written request for extension of time stating the reasons why the request was not filed timely.

(2) For good cause shown, the ALJ may extend the time for filing the request for hearing.

§ 498.42 Parties to the hearing.

The parties to the hearing are the affected party and HCFA or the OIG, as appropriate.

§ 498.44 Designation of hearing official.

(a) The Associate Commissioner for Hearings and Appeals, or his or her delegate designates an ALJ or a member or members of the Appeals Council to conduct the hearing.

(b) If appropriate, the Associate Commissioner or the delegate may substitute another ALJ or another member or other members of the Appeals Council to conduct the hearing.

(c) As used in this part, "ALJ" includes a member or members of the Appeals Council who are designated to conduct a hearing.

§ 498.45 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Appeals Council as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 498.47 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 498.48 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 498.49 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the HCFA or OIG representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 498.50 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.*

(1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.*

(1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 days to file objections to the order.

(3) After the 10 days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.*

The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 498.52 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 498.53 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 498.54 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 498.56 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if HCFA or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Time limits.* The ALJ will not consider any issue that arose on or after any of the following dates:

(1) The effective date of the termination of a provider agreement.

(2) The date on which it is determined that a supplier no longer meets the conditions for coverage of its services.

(3) The effective date of the notice to a hospital of its failure to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished to Medicare beneficiaries during the calendar year.

(4) The effective date of the suspension, or of the exclusion from coverage of services furnished by a

suspended or excluded practitioner, provider, or supplier.

(c) *Notice and conduct of hearing on new issues.* (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 498.52.

(2) After giving notice, the ALJ will, except as provided in paragraph (d) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(d) *Remand to HCFA or the OIG.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (c) of this section, the ALJ may remand the case to HCFA or the OIG for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct HCFA or the OIG to return the case to the ALJ for further proceedings.

§ 498.58 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary, who pays the cost of issuance and the fees and mileage of any subpoenaed witnesses.

§ 498.60 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence

available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 498.61 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 498.62 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 498.63 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 498.17.

§ 498.64 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 498.66 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) HCFA or the OIG shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to

appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 498.69.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(3) *Handling of briefs and related statements.* If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 498.17.

§ 498.68 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 498.69 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 days after the ALJ sends a "show cause" notice, with a showing of good cause.

§ 498.70 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 498.71 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 498.72.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Appeals Council.

§ 498.72 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 days from receipt of the notice of dismissal and shows good cause for vacating the dismissal. (Date of receipt is determined in accordance with § 498.22(b)(3).)

§ 498.74 Administrative Law Judge's decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Appeals Council within the stated time period, and the Council reviews the case;

(2) The Appeals Council denies the request for review and the party seeks judicial review by filing an action in a Federal district court;

(3) The decision is revised by an ALJ or the Appeals Council; or

(4) The decision is a recommended decision directed to the Council.

§ 498.76 Removal of hearing to Appeals Council.

(a) At any time before the ALJ receives oral testimony, the Council may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Council conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 498.78 Remand by the Administrative Law Judge.

(a) If HCFA or the OIG requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to HCFA or the OIG for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

Subpart E—Appeals Council Review**§ 498.80 Right to request Appeals Council review of Administrative Law Judge's decision or dismissal.**

Either of the parties has a right to request Appeals Council review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 498.82 Request for Appeals Council review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Appeals Council.

(2) The requesting party or its representative or other authorized official must file the request with the OHA within 60 days from receipt of the notice of decision or dismissal, unless the Council, for good cause shown by the requesting party, extends the time for filing. The rules set forth in § 498.40(c) apply to extension of time for requesting Appeals Council review. (The date of receipt of notice is determined in accordance with § 498.22(c)(3).)

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 498.83 Appeals Council action on request for review.

(a) *Request by HCFA or the OIG.* The Appeals Council may dismiss, deny, or grant a request made by HCFA or the OIG for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Council will grant the affected party's request for review unless it dismisses the request for one of the following reasons:

- (1) The affected party requests dismissal of its request for review.
- (2) The affected party did not file timely or show good cause for late filing.
- (3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Council review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Appeals Council review is binding and not subject to further review.

(d) *Review panel.* If the Council grants a request for review of the ALJ's decision, the review will be conducted by a panel of at least two members of the Council, designated by the Chairperson or Deputy Chairperson, and one individual designated by the Secretary from the U.S. Public Health Service.

§ 498.85 Procedures before the Appeals Council on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Appeals Council to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 498.17.

§ 498.86 Evidence admissible on review.

(a) The Appeals Council may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Council considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Council that additional relevant evidence is available, the Council will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Council, a transcript is prepared and made available to any party upon request.

§ 498.88 Decision or remand by the Appeals Council.

(a) When the Appeals Council reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Council may either issue a decision or remand the case to an ALJ for a hearing and decision or a

recommended decision for final decision by the Council.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Council in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Council, certifies the case to the Council with a recommended decision.

(d) The parties have 20 days from the date of a notice of a recommended decision to submit to the Council any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-day period, the Council issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Council does not remand the case to an ALJ, the following rules apply:

(1) The Council's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Council receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Council's decision is mailed to each party.

§ 498.90 Effect of Appeals Council decision.

(a) The decision of the Appeals Council is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a district court of the United States; or

(2) The Council reopens and revises its decision in accordance with § 498.102.

(b) Section 498.5 specifies the circumstances under which an affected party has a right to seek judicial review.

§ 498.95 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Appeals Council decision and is entitled to judicial review must commence civil action within 60 days from receipt of the notice of the Council's decision (as determined under § 498.22(c)(3)), unless the Council extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Council before the 60-day period ends.

(c) For good cause shown, the Council may extend the time for commencing civil action.

Subpart F—Reopening of Decisions Made by Administrative Law Judges or the Appeals Council

§ 498.100 Basis, timing, and authority for reopening an ALJ or Council decision.

(a) *Basis and timing for reopening.* An ALJ of Appeals Council decision may be reopened, within 60 days from the date of the notice of decision, upon the motion of the ALJ or the Council or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Appeals Council may be reopened only by the Appeals Council.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Appeals Council. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 498.102 Revision of reopened decision.

(a) *Revision based on new evidence.* If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Appeals Council—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Council revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Appeals Council, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Appeals Council may review that revised decision at the request of either party or on its own motion.

§ 498.103 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Appeals Council review of an ALJ revised decision, or to judicial review of a Council reviewed decision.

(b) *Effect—(1) ALJ revised decision.* An ALJ revised decision is binding

unless it is reviewed by the Appeals Council.

(2) *Appeals Council revised decision.* A Council revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 498.95.

C. Correction of Cross References

References to Subpart O of Part 405 of this chapter are corrected or, if unnecessary or inappropriate, are removed as follows:

§ 405.705 [Amended]

1. In paragraph (b), the parenthetical reference to "see Subpart O of this Part 405" is removed.

§ 405.1901 [Amended]

2. In paragraph (e)(6), the parenthetical reference to "See § 405.1505(m)" is removed.

§ 405.1905 [Amended]

3. In paragraph (b), the parenthetical reference is revised to read "[Appeals procedures are set forth in Part 498 of this Chapter.]".

§ 405.2402 [Amended]

4. In paragraph (f), "Subpart O of this part." is changed to "Part 498 of this chapter."

§ 405.2404 [Amended]

5. In paragraph (b)(3), "Subpart O of this part." is changed to "Part 498 of this chapter."

§ 416.25 [Amended]

6. In paragraph (f), "Part 405, Subpart O of this chapter." is changed to "Part 498 of this chapter."

§ 416.35 [Amended]

7. In paragraph (b)(3), "Part 405, Subpart O of this chapter." is changed to "Part 498 of this chapter."

§ 420.3 [Amended]

8. In paragraph (a), "Subpart O of Part 405 of this chapter" is changed to "Part 498 of this chapter".

§ 431.153 [Amended]

9. In paragraph (d)(1), "Part 405, Subpart O of this title" is changed to "Part 498 of this chapter".

§ 485.74 [Amended]

10. "Part 405, Subpart O of this chapter," is changed to "Part 498 of this chapter".

§ 489.16 [Amended]

11. In paragraph (c)(2), "Part 405, Subpart O of this chapter." is changed to "Part 498 of this chapter".

§ 489.53 [Amended]

12. In paragraph (d), "Subpart O of Part 405 of this chapter." is changed to "Part 498 of this chapter".

§ 1001.3 [Amended]

13. In the first line, "Subpart O of Part 405 of this title" is changed to "Part 498 of this title".

§ 1001.128 [Amended]

14. a. In paragraph (b), the cross reference is changed to "Subpart D of Part 498 of this title".

b. In paragraph (c), the cross-reference is changed to "Subpart E of Part 498 of this title".

§ 1001.134 [Amended]

15. In paragraph (b)(2)(ii), "Subpart O of Part 405 of this title" is changed to "Part 498 of this title".

§ 1001.201 [Amended]

16. In paragraph (c), "Subpart O of Part 405 of this title" is changed to "Part 498 of this title".

§ 1004.100 [Amended]

17. In paragraph (g), "Subpart O of Part 405 of this title" is changed to "Part 498 of this title".

§ 1004.130 [Amended]

18. In paragraph (a)(1), the cross reference is changed to "Part 498 of this title".

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

Dated: March 4, 1987.

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

Approved: March 13, 1987.

Otis R. Bowen,

Secretary.

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DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 11

Superfund and Clean Water Act; Natural Resource Damage Assessments Response to Comments

AGENCY: Department of the Interior.

ACTION: Notice of response to comments.

SUMMARY: This notice responds to the comments received by the Department on whether an amendment should be