States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA [30 U.S.C. 1292(d)] provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 9, 1994.

Robert J. Biggi,

Acting Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 914—INDIANA

1. The authority citation for part 914 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. In § 914.15, paragraph (aaa) is added to read as follows:

§ 914.15 Approval of regulatory program amendments.

* * * * *

(aaa) The following amendment (Program Amendment Number 93–3) to the Indiana program as submitted to OSM on April 2, 1993, and clarified on September 21, 1993, and March 28, 1994, is approved effective July 15, 1994: 310 IAC 0.6–1–2 concerning applicability of the rule; 310 IAC 0.6–1–2.5 concerning ultimate authority for the Indiana Department of Natural Resources; 310 IAC 0.6–1–9 concerning defaults, dismissals, agreed orders, and consent decrees, and 310 IAC 0.6–1–17 concerning record of the director for surface coal mining permits.

[FR Doc. 94–17283 Filed 7–14–94; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD09–94–019]

RIN 2115–AE47

Drawbridge Operation Regulations; Saginaw River, MI

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: This amendment removes the regulations for the I–75 highway drawbridge, mile 14.5 across the Saginaw River at Zilwaukee, Michigan, because a fixed span replacement bridge has been constructed and the bascule bridge has been removed. A notice of proposed rulemaking has not been issued for this regulation because the bascule bridge is no longer in existence, eliminating the need for regulation.

EFFECTIVE DATE: This rule becomes effective on August 15, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. Robert W. Bloom, Jr., Chief, Bridge Branch, Ninth Coast Guard District, at (216) 522–3993.

SUPPLEMENTARY INFORMATION:

Drafting Information

The principal person involved in drafting this document is Mr. Fred H. Mieser, Project Manager.

Background and Purpose

The bascule bridge across the Saginaw River, mile 14.5, at Zilwaukee, Michigan, was replaced by a high level fixed bridge at mile 14.61 from the mouth of the river. The bascule bridge has been removed; therefore, the need for 33 CFR 117.647(c) has been eliminated. This action has no economic consequences. It merely removes regulations for a bridge that no longer exists.

This action necessitates redesignating the regulations listed in 33 CFR 117.647 (d), (e), and (f) for the Sixth Avenue bridge, mile 17.1, Chessie System railroad bridge, mile 18.0, and Grand Trunk Western railroad bridge, mile 19.2 all across the Saginaw River within the State of Michigan.

Regulatory Evaluation

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not

significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. We conclude this because the rule which is being changed is for a drawbridge that has been removed from the waterway and no longer exists.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this action will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632).

Since the I–75 drawbridge has been removed and replaced by a fixed bridge, the rule governing the I–75 drawbridge is no longer appropriate. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Federalism

The Coast Guard has analyzed this action under the principles and criteria contained in Executive Order 12612 and has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under section 2.B.2.g.5 of Commandant Instruction M16475.1B, promulgation of operating requirements or procedures for drawbridges is categorically excluded from further environmental documentation. A Categorical Exclusion Determination Statement has been prepared and placed in the docket.

List of Subjects in 33 CFR Part 117

Bridges.

For reasons set out in the preamble, the Coast Guard is amending 33 CFR Part 117 as follows:

PART 117—DRAWBRIDGE OPERATING REGULATIONS

1. The authority citation for part 117 continues to read as follows.

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g).

2. In § 117.647, paragraph (c) is removed and paragraphs (d), (e), and (f) are redesignated as paragraphs (c), (d), and (e) respectively.

Dated: July 5, 1994.

Rudy K. Peschel,

Rear Admiral, U.S. Coast Guard Commander, Ninth Coast Guard District.

[FR Doc. 94–17274 Filed 7–14–94; 8:45 am]

BILLING CODE 4910–14–M

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

Subsistence Management Regulations for Federal Public Lands in Alaska; Customary and Traditional Use Eligibility Determinations; Review Policies

AGENCY: Forest Service, USDA; Fish and Wildlife Service, Interior.

ACTION: Review policies.

SUMMARY: Pursuant to the regulatory authority found at 36 CFR 242.10(a), 242.18(b), 50 CFR 100.10(a), and 100.18(b), the Federal Subsistence Board (Board) provides notice of a priority list and associated schedule for reviewing customary and traditional use eligibility determinations, and details the associated administrative process, under the Federal Subsistence Management Program.

EFFECTIVE DATE: The Federal Subsistence Board policies shall be effective July 15, 1994.

ADDRESSES: Any comments concerning this notice may be sent to the Chair, Federal Subsistence Board, c/o Richard S. Pospahala, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, Alaska 99503.

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o Richard S. Pospahala, Office of Subsistence Management, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, Alaska 99503; telephone (907) 786–3447. For questions specific to National Forest System lands, contact Norman R. Howse, Assistant Director Subsistence, USDA, Forest Service, Alaska Region, P.O. Box 21628, Juneau, Alaska 99802–1628; telephone (907) 586–8890.

SUPPLEMENTARY INFORMATION:

Background

In 1990, the Board assumed subsistence management responsibilities on Federal public lands and adopted the existing State of Alaska customary and traditional use eligibility determinations. Such determinations identified customary and traditional subsistence uses of certain fish and wildlife resources by specific communities and areas in Alaska. Due to changes in the rural status of some communities, public comments on the draft environmental impact statement "Subsistence Management for Federal Public Lands in Alaska" (October 7, 1991), comments received on temporary and implementing subsistence regulations, and customary and traditional use eligibility determination appeals submitted under the temporary subsistence regulations, the Board recognized the need for new assessments of existing customary and traditional use eligibility determinations. However, the Board deferred action on customary and traditional use eligibility until after July 1, 1992 (the effective date of final implementing rules for the Federal subsistence program) and indicated that a customary and traditional use determination process and schedule would be developed and published. Customary and traditional use eligibility determination assessments were begun in regard to the Kenai Peninsula and Upper Tanana areas in 1992, and the Copper River Basin more recently. These areas were prioritized based upon public comments received during the environmental impact statement process and subsequent Board meetings. This notice sets forth an initial customary and traditional use eligibility determination schedule to be updated on a routine basis dependent upon input from the public and Federal Subsistence Regional Advisory Councils (Regional Councils). Details of the administrative process involved in customary and traditional assessments, public and advisory council input opportunities, and decision making steps, are also set forth.

Customary and Traditional Use Eligibility Determination Procedures

The Board will implement a systematic program for review of customary and traditional use eligibility

determinations. As a priority consideration, the Board will focus its determinations on community or area uses of large mammals (ungulates and bears). Nevertheless, the Board recognizes that subsistence is in large part exemplified by reliance upon, and traditional use of, a multitude of fish and wildlife species, and consequently even the Board's initial large mammal assessments will examine information on subsistence uses of varied species. Furthermore, the Board retains the authority to initiate assessments and make eligibility determinations related to the customary and traditional use of any species as recommended by Regional Councils or as necessary for proper administration of the program. The Board will examine uses of species of large mammals by communities or areas rather than focus on individual herds.

The Board recognizes that subsistence resource use patterns of neighboring communities are often interrelated and should be analyzed concurrently. The Board has identified 26 areas in Alaska where neighboring communities are thought to have similar patterns of resource uses. In identifying these "analysis areas" the distribution of Federal public lands and associated jurisdictions of Regional Councils were taken into account. The 26 analysis areas constitute geographically distinct regions of Alaska within which customary and traditional use patterns of a community or communities will be documented and analyzed. Within each analysis area, the determinations will focus primarily on the customary and traditional uses of large mammals by the communities located within that analysis area. Existing eligibility determinations regarding communities and areas adjacent to the area under analysis will not be revised unless a full assessment and review of those areas or communities have occurred.

Existing regulations at 36 CFR 242.16(b) and 50 CFR 100.16(b) identify eight factors that exemplify customary and traditional subsistence uses of a community or area. The Board will base its determination of customary and traditional use eligibility on the extent to which a community, group of communities, or area meet the characteristics of these identified factors. The eight factors are as follows:

1. A long-term consistent pattern of use, excluding interruptions beyond the control of the community or area;

2. A pattern of use recurring in specific seasons for many years;

3. A pattern of use consisting of methods and means of harvest which are characterized by efficiency and economy of effort and cost, conditioned by local characteristics;

4. The consistent harvest and use of fish or wildlife as related to past methods and means of taking; near, or reasonably accessible from the community or area;

5. A means of handling, preparing, preserving, and storing fish or wildlife which has been traditionally used by past generations, including consideration of alteration of past practices due to recent technological advances, where appropriate;

6. A pattern of use which includes the handing down of knowledge of fishing and hunting skills, values and lore from generation to generation;

7. A pattern of use in which the harvest is shared or distributed within a definable community of persons; and

8. A pattern of use which relates to reliance upon a wide diversity of fish and wildlife resources of the area and which provides substantial cultural, economic, social and nutritional elements to the community or area.

To reach final decisions on customary and traditional use eligibility, several steps in the process of initiating, preparing, reviewing, noticing, evaluating public comments, and acting on each customary and traditional use assessment will have to be accomplished. All participating Federal agencies and the Regional Councils have substantial roles in the completion of these tasks and eventual customary and traditional use eligibility determinations. In addition, customary and traditional use eligibility determinations will be subject to Federal rulemaking procedures for which considerable public review and comment opportunities are afforded.

The following steps form the framework of the administrative process which will be applied in reaching customary and traditional use eligibility determinations:

Scoping—Define, in consultation with pertinent Regional Councils, affected rural communities within or adjacent to the analysis area that will be part of the assessment. Consult with local residents, Regional councils, and local advisory committees for input on methodology of assessment, special public participation needs, and other local insight.

Information Collection—Collect and analyze available literature, harvest reports, interviews, and other available information. Determine if available information is adequate to make determinations. Recommend and/or plan for additional information gathering or studies if needed.

Analysis—Analyze information as related to eight regulatory factors identified in the Federal Subsistence Management Program regulations. Prepare and present an assessment report including conclusions on needed changes to existing determinations to pertinent Regional Council, and other entities as requested, and take comments on adequacy of analysis; revise analysis as necessary.

Regional Council Review—Prepare and present to the pertinent Regional Council, initial staff recommendations relative to use eligibility determinations. These recommendations will be reviewed by all affected Regional Councils.

Proposed Rule—Revise the staff recommendations in consideration of the Regional Council comments and publish a proposed rule in the **Federal Register**.

Public Review—Hold public meetings and accept comments from the public, Regional Councils, local advisory committees, and affected communities. Regional Councils will review public comments and develop recommendations for Board consideration.

Board Decision—Board receives Regional Council recommendations and makes customary and traditional use eligibility determinations, subsequently published as a final rule in the **Federal Register**. New, customary and traditional use eligibility determinations will be scheduled to take effect at the beginning of a Federal subsistence regulatory year (July 1).

These steps have been developed as a result of experience, and Regional Council input regarding the Kenai Peninsula and Upper Tanana areas' customary and traditional use eligibility determinations which were begun in 1992. The determination process for both of those areas is well along, with determinations expected to be completed during 1995.

Depending on the complexity of the issues and area under review, the scoping, information collection, and analysis portions of each customary and traditional use eligibility determination action are expected to take at least a year. In most instances it is foreseen that public involvement may extend the period required for each determination to greater than a year.

Customary and Traditional Use Determination Priorities

In order to provide for an adequate review of customary and traditional use eligibility, the Board recognizes that not all customary and traditional use eligibility determination requests and

agency assessments could be addressed at the same time. Consequently, the Board has established customary and traditional use eligibility determination priorities which are based on public requests, recommendations of Regional Councils and Federal land management agencies, and the availability of personnel and financial resources to conduct the work. At the present time, the Board has established priorities for customary and traditional use assessments for 1994–1995.

Assessments begun in 1992 regarding the Kenai Peninsula and Upper Tanana areas are nearing completion. In contemplation of those customary and traditional use eligibility determinations which will be completed after 1995, the Board intends to continue to review requests submitted from the public, and recommendations from the Regional Councils and Federal agencies, and any additional information which might be pertinent. As necessary, an updated customary and traditional use eligibility determination schedule will be published in the **Federal Register** in ensuing years. In addition, the Board retains the flexibility to respond to management problems as needed, including those instances in which customary and traditional use eligibility determinations may need modification on an urgent basis.

The current schedule and priority list for making customary and traditional use eligibility determinations is as follows:

Analysis area and priority order	Regional advisory council	Unit	Year of completion
1. Upper Tanana	Eastern Interior	12	1995
2. Kenai Peninsula	Southcentral	7, 15	1995
3. Copper River Basin	Southcentral	11, 13(A–D)	1996
4. Yukon-Kuskokwim Delta	Western Interior	18	1995
5. Minto	Eastern Interior	20(A), (B), (D), (F); 25 (C)	1996
6. Yukon Flats	Eastern Interior	25(A), (B), (D)	1995
7. Eastern North Slope	North Slope	26(B), (C)	1995
Completion dates of the following prioritized areas to be determined:			
Stikine	Southeast	1(B), 3	.....
Denali/Parks Highway	Eastern Interior	20(A), (C), 13(E), 16	.....
Eastern Interior	Eastern Interior	20(E)	.....
Iditarod-George	Western Interior	19, 21(E)	.....
Chatham	Southeast	1(C), (D), 4; 5(A), (B)	.....
Prince William Sound	Southcentral	6	.....
Ketchikan	Southeast	1(A), 2	.....
Bristol Bay	Bristol Bay	17	.....
Middle Yukon	Western Interior	21(A), (B), (C), (D)	.....
Kodiak	Kodiak/Aleutians	8	.....
Brooks Range	Western Interior	24	.....
Lake Clark	Bristol Bay	9(A), (B), (C)	.....
Alaska Peninsula	Bristol Bay	9(D) & (E)	.....
Seward Peninsula	Seward Peninsula	22(C), (D), (E)	.....
Kotzebue Sound	Northwest Arctic	23	.....
Norton Sound	Seward Peninsula	22(A), (B)	.....
Western North Slope	North Slope	26(A)	.....
Aleutians	Kodiak/Aleutians	10	.....
Talkeetna	Southcentral	14	.....

Drafting Information

This policy was drafted under the guidance of Richard S. Pospahala, U.S. Fish and Wildlife Service, Alaska Regional Office, Office of Subsistence Management, Anchorage, Alaska. The primary authors were Taylor Brelsford and William Knauer of the same office; John Hiscock of the National Park Service, Alaska Regional Office; Tom Boyd, Bureau of Land Management, Alaska State Office; and Norm Howse, USDA-Forest Service, Alaska Regional Office.

Dated: June 16, 1994.

William L. Hensley,

Chair, Federal Subsistence Board.

Dated: June 24, 1994.

Robert W. Williams,

Acting Regional Forester, USDA-Forest Service.

[FR Doc. 94–17041 Filed 7–14–94; 8:45 am]

BILLING CODE 3410–11–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 55

[FRL–5013–2]

Outer Continental Shelf Air Regulations; Delegation of Authority; South Coast Air Quality Management District, State of California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Delegation of authority.

SUMMARY: The Regional Administrator for EPA Region 9, San Francisco, has delegated authority to implement and enforce the requirements of the Outer Continental Shelf (OCS) program within 25 miles of the state's seaward boundary to the South Coast Air Quality Management District (SCAQMD or District), California. EPA reviewed the

District's rules and regulations and has found them to be adequate for delegation, provided that the District meets the requirements of 40 CFR 51.161(b) and 40 CFR part 124 by amending Rule 212, Standards for Approving Permits, to incorporate public notice and comment procedures for permitting of OCS facilities.

EFFECTIVE DATES: The effective date of the delegation of authority for SCAQMD is May 9, 1994.

ADDRESSES: Copies of the request for delegation of authority and EPA's letter of delegation are available for public inspection at EPA's Region 9 office during normal business hours and at the following location:

South Coast Air Quality Management District, 21865 East Copley Drive, Diamond Bar, CA 91765–4182.

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, Rulemaking Section (A–5–3), Air and Toxics Division, 75 Hawthorne Street, San Francisco, CA 94105. (415) 744–1197.

SUPPLEMENTARY INFORMATION: The U.S. Environmental Protection Agency has delegated the authority to implement and enforce the requirements of the OCS rule (40 CFR part 55) to the SCAQMD. The final OCS rule was promulgated by EPA on September 4, 1992 pursuant to section 328 of the Clean Air Act (the Act). (57 FR 40792).

Under section 328(a) of the Act, EPA may delegate authority to implement and enforce the OCS air regulations to a state if that state is adjacent to an OCS source and the Administrator determines that the state's regulations are adequate. The State of California is adjacent to a number of OCS sources and the District's regulations have been reviewed by EPA. The following criteria for delegation are set forth at 40 CFR 55.11:[1] (1) the state has adopted the appropriate portions of 40 CFR part 55 into law; (2) the state has adequate authority under state law to implement and enforce the requirements of part 55; (3) the state has adequate resources to implement and enforce the requirements of part 55; and (4) the state has adequate administrative procedures to implement and enforce the requirements of part 55, including public notice and comment procedures.

The following delegation agreement represents the terms and conditions of the delegation to the SCAQMD:

U.S. EPA—South Coast Air Quality Management District, Agreement for Delegation of Authority for Outer Continental Shelf Air Regulations (40 CFR Part 55)

The undersigned, on behalf of the South Coast Air Quality Management District ("SCAQMD" or "the District") and the United States Environmental Protection Agency ("EPA"), hereby agree to the delegation of authority from EPA to the SCAQMD to implement and enforce the requirements of the Outer Continental Shelf ("OCS") Air Regulations (40 CFR part 55) within 25 miles of the state's seaward boundary, pursuant to section 328(a)(3) of the Clean Air Act ("the Act"), subject to the terms and conditions below. EPA has reviewed SCAQMD's request for delegation and has found that SCAQMD's regulations meet the requirements for delegation set forth at 40 CFR 55.11, provided that the District meets the requirements of 40 CFR 51.161(b) and 40 CFR part 124 by amending Rule 212, Standards for Approving Permits, to incorporate public notice and comment procedures for permitting of OCS facilities. Until the District Board approves an amended Rule 212 that meets the requirements of 40 CFR 51.161(b) and 40 CFR part 124, the District shall interpret the current Rule 212 to incorporate the requirements of 40 CFR 51.161(b) and 40 CFR part 124. In addition, the District shall provide a copy of its Rule 212 interpretation to all OCS sources regulated by the District, and a copy to the Administrator through the EPA Regional Office (Attn: A–5–1). The public notice distribution, for purposes of all major modifications to off-shore sources, shall be to the broadest possible scope of interested parties and shall include as a minimum:

- Availability for public inspection in at least one location in the area affected of the information submitted by the owner or operator and of the State or local agency's analysis of the effect on air quality;
- A 30-day period for submittal of public comment; and
- A notice by prominent advertisement in the area affected of the location of the source information and the analysis of the effect on air quality.

This delegation includes authority for the following sections of the Outer Continental Shelf Air Regulations:

Section	Title
55.1	Statutory authority and scope.
55.2	Definitions.
55.3	Applicability.
55.4	Requirements to submit a notice of intent.
55.6	Permit requirements.
55.7	Exemptions.
55.8	Monitoring, reporting, inspections, and compliance.
55.9	Enforcement.
55.10	Fees.
55.13	Federal requirements that apply to OCS sources.
55.14	Requirements that apply to OCS sources located within 25 miles of states' seaward boundaries by state.

EPA is not delegating the authority to implement and enforce sections 55.5 (Corresponding onshore area designation), 55.11 (Delegation), and 55.12 (Consistency updates), as authority for these sections is reserved to the Administrator. The District has also adopted Appendix A to 40 CFR part 55, Listing of State and Local Requirements Incorporated by Reference into part 55, by State. The authority to revise or amend this section is reserved to EPA Region 9. In addition, SCAQMD has not yet received delegation of authority from EPA for implementation and enforcement of the federal Prevention of Significant Deterioration Program (PSD). Therefore, EPA shall retain authority for the PSD provisions of part C of the Act and the regulations promulgated thereunder at 40 CFR 52.21.

Under section 328(a)(3) of the Act, EPA may delegate authority to implement and enforce the OCS air regulations to a state if that state is adjacent to an OCS source and the Administrator determines that the state's regulations are adequate. The State of California is adjacent to a number of OCS sources. For the OCS sources for which the South Coast has been designated the corresponding onshore area (COA), the State has submitted SCAQMD's regulations to EPA and requested that EPA delegate to SCAQMD authority to implement and enforce the OCS air regulations. SCAQMD's regulations have been reviewed by EPA and, in conjunction with the District's commitment to amend Rule 212 to (1) incorporate public notice and comment procedures for OCS facilities; and (2) to interpret the current Rule 212 to incorporate public notice and comment procedures for OCS facilities until Rule 212 is amended, EPA determined the regulations to be adequate for implementing and enforcing the delegable sections of 40 CFR part 55.

The OCS air regulations set forth the following criteria for delegation at 40 CFR 55.11:

(1) The state has adopted the appropriate portions of 40 CFR part 55 into state law—SCAQMD adopted Rule

[1] The term "state" as used in the delegation criteria refers to the local air pollution permitting agency—SCAQMD.

1183, Outer Continental Shelf Air Regulations, on March 12, 1993. This rule incorporates the provisions of 40 CFR part 55 that EPA is delegating to the District. (NOTE: §§ 55.5 (corresponding onshore area designations), 55.11 (delegation), 55.12 (consistency updates), Appendix A (Listing of State and Local Requirements) were adopted by SCAQMD but EPA will not delegate authority for these sections, as provided by § 55.11(a)).

(2) The state has adequate authority under state law to implement and enforce the requirements of part 55—According to a letter dated January 25, 1993 and forwarded to EPA from the State Attorney General, SCAQMD has the authority to implement and enforce the requirements of part 55.

(3) The state has adequate resources to implement and enforce the requirements of part 55—SCAQMD has submitted information documenting that the District has adequate resources to implement and enforce the requirements of part 55.

(4) The state has adequate administrative procedures to implement and enforce the requirements of this part, including public notice and comment procedures—SCAQMD's administrative procedures have been reviewed by EPA and found to be adequate assuming that the District: (1) amends Rule 212 for OCS sources in accordance with 40 CFR § 51.161(b) and 40 CFR 124; and (2) interprets the current Rule 212 for OCS sources in accordance with 40 CFR 51.161(b) and 40 CFR 124.

EPA is delegating authority to implement and enforce part 55 pursuant to the SCAQMD's use of the following administrative and procedural rules:

Regulation I—General Provisions		
Rule 104 ...	Reporting of Source Test Data and Analysis	January 9, 1976.
Rule 105 ...	Authority to Arrest	January 9, 1976.
Rule 106 ...	Increments of Progress	January 9, 1976.
Rule 109 ...	Recordkeeping for Volatile Organic Compounds	March 6, 1992.
Rule 110 ...	Rule Adoption Procedure to Assure Protection and Enhancement of The Environment	October 7, 1988.
Regulation II—Permits		
Rule 201 ...	Permit to Construct	January 5, 1990.
Rule 203 ...	Permit to Operate	January 5, 1990.
Rule 204 ...	Permit Conditions	March 6, 1992.
Rule 210 ...	Applications	January 5, 1990.
Rule 212 ...	Standards for Approving Permits (provided the Rule is interpreted and implemented to require public notice and comment for OCS sources).	September 6, 1991.
Rule 214 ...	Denial of Permits	January 5, 1990.
Rule 216 ...	Appeals	January 5, 1990.
Rule 221 ...	Plans	January 4, 1985.
Regulation III—Fees		
Rule 301 ...	Permit Fees	June 11, 1993.
Rule 303 ...	Hearing Board Fees	June 6, 1992.
Rule 306 ...	Plan Fees	July 6, 1990.
Regulation IV—Prohibitions		
Rule 430 ...	Breakdown Provisions	May 5, 1978.
Regulation V—Procedure Before the Hearing Board		
Rule 501 ...	General	February 5, 1988.
Rule 502 ...	Filing Petitions	July 10, 1992.
Rule 503 ...	Petitions for Variances and Appeals	February 5, 1988.
Rule 503.1	Ex Parte Petitions for Variances	February 5, 1988.
Rule 504 ...	Rules from which Variances are not allowed	January 5, 1990.
Rule 506 ...	Failure to Comply with Rules	February 5, 1988.
Rule 507 ...	Pleadings	August 1, 1995.
Rule 510 ...	Notice of Hearing	February 5, 1988.
Rule 511 ...	Evidence	February 5, 1988.
Rule 511.1	Subpoenas	February 5, 1988.
Rule 513 ...	Administrative Notice	February 5, 1988.
Rule 514 ...	Continuances	February 5, 1988.
Rule 515 ...	Findings and Decisions	March 6, 1992.
Rule 517 ...	Emergency Variances—Procedures—Breakdown	February 5, 1998.
Regulation VII—Emergencies		
Rule 703 ...	Episode Criteria	April 4, 1980.
Rule 704 ...	Episode Declaration	July 9, 1982.
Rule 706 ...	Episode Notification	April 4, 1980.
Rule 708 ...	Plans	July 9, 1982.

Regulation VIII—Orders for Abatement		
Rule 802 ...	Order of Abatement	August 1, 1975.
Rule 803 ...	Filing Petitions	February 5, 1988.
Rule 806 ...	Findings	February 5, 1988.
Rule 814 ...	Official Notice	August 1, 1975.
Rule 816 ...	Order and Decisions	February 5, 1988.
Rule 817 ...	Effective Date of Decision	August 1, 1975.
Regulation IX—New Source Performance Standards		
	April 9, 1993.	
Regulation XII—Rules of Practice and Procedures Health and Safety Code Section 40509		
	June, 1985.	
Regulation XIII—New Source Review		
	June 28, 1990.	
Regulation XVII—Prevention of Significant Deterioration		
	January 6, 1989.	

The District may use any administrative procedures it has under State law to implement and enforce the requirements of part 55. However, as stated in the preamble to part 55, as onshore, a variance will not shield a source from enforcement action by EPA.

Permits

Pursuant to § 55.6:

(1) SCAQMD will require that the Applicant send a copy of any permit application required by 40 CFR 55.6 to the Administrator through the EPA Regional Office (Attn: A–5–1) at the same time as the application is submitted to SCAQMD.

(2) SCAQMD shall send a copy of any public comment notice required under §§ 55.6, 55.13 or 55.14 to the Administrator through the EPA Regional Office (Attn: A–5–1) and to the Minerals Management Service.

(3) SCAQMD shall send a copy of any preliminary determination and any final permit action required under §§ 55.6, 55.13, or 55.14 to the Administrator through the EPA Regional Office (Attn: A–5–1) at the time of the determination and shall make available to the Administrator any materials used in making the determination.

(4) SCAQMD shall provide written notice of any permit application from a source, the emissions from which may affect a Class I area, to the Federal Land Manager of that area.

(5) The District shall request EPA guidance on any matter involving the interpretation of section 328 of the Act, the delegated sections of the OCS regulations or any other provision of 40 CFR part 55 to the extent that implementation, review, administration or enforcement of these provisions has not been covered by determinations or guidance sent to the District.

(6) Pursuant to its authority under the Clean Air Act, EPA may review permits issued by the District under this agreement to ensure that the District's implementation of Rule 1183 is consistent with the time frames and requirements of the Federal regulations (40 CFR part 55).

Exemptions

Pursuant to § 55.7:

(1) SCAQMD shall transmit to the Administrator (through the Regional Office), the Minerals Management Service, and the U.S. Coast Guard, a copy of the permit application that includes an exemption request, or the request for exemption if no permit is required, within 5 days of its receipt.

(2) SCAQMD shall consult with the Minerals Management Service of the U.S. Department of the Interior and the U.S. Coast Guard to determine whether the exemption will be granted or denied.

(3) If SCAQMD, the Minerals Management Service, and the U.S. Coast Guard do not reach a consensus decision within 90 days from the day the SCAQMD received the exemption request, the request shall automatically be referred to the Administrator, who will process the referral in accordance with 40 CFR 55.7(f)(3). SCAQMD shall transmit to the Administrator, within 91 days of its receipt, the exemption request and all materials submitted with the request, such as the permit application or the compliance plan, and any other information considered or developed during the consultation process.

(4) SCAQMD will process exemption requests submitted with an approval to construct or permit to operate application in accordance with the procedures outlined in 40 CFR part 55.

Monitoring, Reporting, Inspections, and Compliance

SCAQMD may use any authority it possesses under state law to require monitoring and reporting, and to conduct inspections. The Administrator or SCAQMD shall consult with the Minerals Management Service and the U.S. Coast Guard prior to inspections. This shall in no way interfere with the ability of EPA or SCAQMD to conduct unannounced inspections.

General Conditions

(1) SCAQMD shall implement and enforce the Federal requirements of 40 CFR 55.13 as well as the applicable state and local requirements contained in 40 CFR 55.14. Notwithstanding the above, EPA retains authority for implementation and enforcement of the PSD requirements of part C of the Act and 40 CFR 52.21. The District shall notify sources that may be subject to part C of the Act and 40 CFR 52.21 that they must apply to EPA for a permit. The District's failure to notify sources shall not affect EPA's exercise of its enforcement and implementation authority.

(2) The primary responsibility for enforcement of the OCS air regulations delegated to the District shall rest with the SCAQMD. Nothing in this

agreement shall prohibit EPA from enforcing the OCS requirements of the Clean Air Act, the OCS regulations, or the terms and conditions of any permit issued by the District pursuant to this agreement.

(3) In the event that the District is unwilling or unable to enforce a provision of this delegation with respect to a source subject to the OCS air regulations, the District will immediately notify the EPA Region 9 Regional Administrator. Failure to notify the Regional Administrator does not preclude EPA from exercising its enforcement authority.

(4) EPA shall retain authority to implement and enforce all requirements for OCS sources located beyond 25 miles from the state's seaward boundaries.

(5) This delegation may be amended at any time by the formal written agreement of both the SCAQMD and EPA including amendments to add, change, or remove conditions or terms of this agreement.

(6) If SCAQMD adopts revisions to the District regulations reviewed by EPA and found to meet the requirements set forth at 40 CFR 55.11 for delegation, the parties may amend the agreement pursuant to condition 5 above, or EPA may take steps to revoke the delegation in whole or in part pursuant to condition 7 below. Any amendments to regulations submitted by the District to meet the requirements of 40 CFR 55.11 shall not be applied under this agreement until EPA has reviewed such amendments and determined that they are still adequate to implement and enforce the delegable portions of 40 CFR part 55.

(7) This delegation, after consultation with the SCAQMD, may be revoked in whole or in part if EPA determines that the SCAQMD no longer meets the requirements for delegation set forth at 40 CFR 55.11(b)(1–4). Any such revocation shall be effective as of the date specified in a Notice of Revocation to the SCAQMD. In addition, this agreement shall be revoked if: (1) the District does not amend Rule 212, Standards for Approving Permits, to incorporate public notice and comment requirements for OCS sources by August 15, 1994; (2) the District fails to interpret the current Rule 212 to incorporate public notice and comment for OCS sources.

(8) This delegation of authority becomes effective upon the date of the signature of both parties to this Agreement.

(9) A notice of this delegated authority will be published in the **Federal Register**.

Dated: May 9, 1994.

John Wise,

Acting Regional Administrator, Region 9.

Dated: May 3, 1994.

Dr. James Lents,

Executive Officer, South Coast Air Quality Management District.

Dated: May 2, 1994.

Peter M. Greenwald,

District Counsel, SCAQMD.

EPA Action

The EPA hereby notifies the public that it has delegated the authority to implement and enforce the requirements of the OCS air regulations (40 CFR part 55) promulgated by EPA on September 4, 1992 to the above-referenced local agency.

The Office of Management and Budget has exempted this rulemaking from the requirements of section 6 of Executive Order 12866.

This notice is issued under the authority of section 328 of the Clean Air Act, 42 U.S.C. 7627.

Dated: June 16, 1994.

John Wise,

Acting Regional Administrator, Region 9.

[FR Doc. 94–17296 Filed 7–14–94; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405 and 414

[BPD–770–CN]

RIN 0938–AG22

Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1994

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

ACTION: Correction of final rule with comment period.

SUMMARY: This document corrects technical errors that appeared in the final rule with comment period published in the **Federal Register** on December 2, 1993 (58 FR 63626) entitled "Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1994."

EFFECTIVE DATE: January 1, 1994.

FOR FURTHER INFORMATION CONTACT: Elizabeth Holland, (410) 966–1309.

SUPPLEMENTARY INFORMATION: In **Federal Register** Document [93–29362] beginning on page 63626, in the issue of December 2, 1993, make the following corrections:

A. *Page 63626*

1. In the **ADDRESSES** section, in column 2, in line 12, the telephone number is corrected to read "(202) 690–7890."

2. In column 3, in line 10, the **Federal Register** citation is corrected to read "(57 FR 55914)."

B. *Page 63628*

In column 3, in line 4, the **Federal Register** citation is corrected to read "(56 FR 59502)."

C. *Page 63642*

In column 2, in the paragraph designated I., the number of the fourth code in the listing is corrected to read "84182."

D. *Page 63652*

In column 2, in the paragraph designated 2.a., the **Federal Register** citation is corrected to read "(57 FR 55938)."

E. *Pages 63653 and 63662, Table 3*

1. On page 63653, the following codes are corrected to read:

HCPCS+	MOD description	RUC recommended work RVUs	Specialty recommended work RVUs	HCFA decision
*15788	Chemical peel, face, epiderm	None	5.00	Decreased.
*15789	Chemical peel, face, dermal	None	6.59	Decreased.

HCPCS+	MOD description	RUC recommended work RVUs	Specialty recommended work RVUs	HCFA decision
*15792	Chemical peel, nonfacial	None	4.00	Decreased.
*15793	Chemical peel, nonfacial	None	5.34	Decreased.

2. On page 63662, the following codes are corrected to read:

HCPCS+	MOD description	RUC recommended work RVUs	Specialty recommended work RVUs	HCFA decision
97545	Work hardening	None	1.70	(b).
97546	Work hardening	None	.85	(b).

F. Pages 63722 through 63836, Addendum B

1. On page 63722, the following codes are corrected to read:

HCPCS[1]	MOD status	Description	Work RVUs	Practice expense RVUs[2]	Malpractice RVUs	Total	Global period	Update
33401	C	Valvuloplasty, open	0.00	0.00	0.00	0.00	090	S
33403	C	Valvuloplasty, w/cp bypass	.00	.00	.00	.00	090	S
33406	C	Replacement, aortic valve	.00	.00	.00	.00	090	S
33413	C	Replacement, aortic valve	.00	.00	.00	.00	090	S
33414	C	Repair, aortic valve	.00	.00	.00	.00	090	S
33471	C	Valvotomy, pulmonary valve	.00	.00	.00	.00	090	S
33475	C	Replacement, pulmonary valve	.00	.00	.00	.00	090	S
33505	C	Repair artery w/tunnel	.00	.00	.00	.00	090	S
33506	C	Repair artery, translocation	.00	.00	.00	.00	090	S
33600	C	Closure of valve	.00	.00	.00	.00	090	S
33602	C	Closure of valve	.00	.00	.00	.00	090	S
33606	C	Anastomosis/artery-aorta	.00	.00	.00	.00	090	S
33608	C	Repair anomaly w/conduit	.00	.00	.00	.00	090	S
33610	C	Repair by enlargement	.00	.00	.00	.00	090	S

[1] All numeric CPT HCPCS Copyright 1993 American Medical Association.
[2]* Indicates reduction of Practice Expense RVUs as a result of OBRA 1993.

2. On page 63723, the following codes are corrected to read:

HCPCS[1]	MOD status	Description	Work RVUs	Practice expense RVUs[2]	Malpractice RVUs	Total	Global period	Update
33611	C	Repair double ventricle	0.00	0.00	0.00	0.00	090	S
33612	C	Repair double ventricle	.00	.00	.00	.00	090	S
33615	C	Repair (simple fontan)	.00	.00	.00	.00	090	S
33617	C	Repair by modified fontan	.00	.00	.00	.00	090	S
33619	C	Repair single ventricle	.00	.00	.00	.00	090	S
33692	C	Repair of heart defects	.00	.00	.00	.00	090	S
33697	C	Repair of heart defects	.00	.00	.00	.00	090	S
33698	C	Repair of heart defects	.00	.00	.00	.00	090	S
33722	C	Repair of heart defect	.00	.00	.00	.00	090	S
33732	C	Repair heart-vein defect	.00	.00	.00	.00	090	S
33736	C	Revision of heart chamber	.00	.00	.00	.00	090	S
33766	C	Major vessel shunt	.00	.00	.00	.00	090	S
33767	C	Atrial septectomy/septostomy	.00	.00	.00	.00	090	S
33770	C	Repair great vessels defect	.00	.00	.00	.00	090	S
33771	C	Repair great vessels defect	.00	.00	.00	.00	090	S
33853	C	Repair septal defect	.00	.00	.00	.00	090	S

[1] All numeric CPT HCPCS Copyright 1993 American Medical Association.
[2]* Indicates reduction of Practice Expense RVUs as a result of OBRA 1993.

3. On page 63724, the following codes are corrected to read:

HCPCS[1]	MOD status	Description	Work RVUs	Practice expense RVUs[2]	Malpractice RVUs	Total	Global period	Update
33917	C	Repair pulmonary artery	0.00	0.00	0.00	0.00	090	S
33918	C	Repair pulmonary atresia	.00	.00	.00	.00	090	S
33919	C	Repair pulmonary atresia	.00	.00	.00	.00	090	S
33920	C	Repair pulmonary atresia	.00	.00	.00	.00	090	S
33922	C	Transect pulmonary artery	.00	.00	.00	.00	090	S

[1] All numeric CPT HCPCS Copyright 1993 American Medical Association.
[2]* Indicates reduction of Practice Expense RVUs as a result of OBRA 1993.

4. On page 63733, HCPCS code 43248 is corrected to read as follows:

HCPCS[1]	MOD status	Description	Work RVUs	Practice expense RVUs[2]	Malpractice RVUs	Total	Global period	Update
43248	A	Upper GI endoscopy/guidewire	3.18	*4.14	0.34	7.66	000	N

[1] All numeric CPT HCPCS Copyright 1993 American Medical Association.
[2]* Indicates reduction of Practice Expense RVUs as a result of OBRA 1993.

5. On page 63749, the third appearance of HCPCS code 59020 is corrected to read as follows:

HCPCS[1]	MOD status	Description	Work RVUs	Practice expense RVUs[2]	Malpractice RVUs	Total	Global period	Update
59020	A	Fetal contract stress test	0.67	*0.87	0.19	1.73	000	S

[1] All numeric CPT HCPCS Copyright 1993 American Medical Association.
[2]* Indicates reduction of Practice Expense RVUs as a result of OBRA 1993.

6. On page 63764, the following code is corrected to read:

HCPCS[1]	MOD status	Description	Work RVUs	Practice expense RVUs[2]	Malpractice RVUs	Total	Global period	Update
70551	A	Magnetic image, brain (MRI)	1.50	0.67	0.10	2.27	XXX	N

[1] All numeric CPT HCPCS Copyright 1993 American Medical Association.
[2]* Indicates reduction of Practice Expense RVUs as a result of OBRA 1993.

7. On page 63799, the following code is added to read:

HCPCS[1]	MOD status	Description	Work RVUs	Practice expense RVUs[2]	Malpractice RVUs	Total	Global period	Update
86423	D	Radioimmunosorbent test IGE	0.00	0.00	0.00	0.00	XXX	O

[1] All numeric CPT HCPCS Copyright 1993 American Medical Association.
[2]* Indicates reduction of Practice Expense RVUs as a result of OBRA 1993.

8. On page 63836, the following codes are corrected to read:

HCPCS[1]	MOD status	Description	Work RVUs	Practice expense RVUs[2]	Malpractice RVUs	Total	Global period	Update
J7030	E	Infusion, normal saline solution	0.00	0.00	0.00	0.00	XXX	O
J7040	E	Infusion, normal saline solution	.00	.00	.00	0.00	XXX	O
J7042	E	5% dextrose/normal saline	.00	.00	.00	0.00	XXX	O
J7050	E	Infusion, normal saline solution	.00	.00	.00	0.00	XXX	O
J7051	E	Sterile saline or water	.00	.00	.00	0.00	XXX	O
J7060	E	5% dextrose/water	.00	.00	.00	0.00	XXX	O
J7070	E	Infusion, d5w	.00	.00	.00	0.00	XXX	O
J7120	E	Ringers lactate infusion	.00	.00	.00	0.00	XXX	O

[1] All numeric CPT HCPCS Copyright 1993 American Medical Association.
[2]* Indicates reduction of Practice Expense RVUs as a result of OBRA 1993.

(Section 1848 of the Social Security Act (42 U.S.C. 1395w–4))
(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 5, 1994.

Neil J. Stillman,

Deputy Assistant Secretary for Information Resources Management.

[FR Doc. 94–17222 Filed 7–14–94; 8:45 am]

BILLING CODE 4120–01–P

Office of the Secretary

42 CFR Parts 417, 431, 434, and 1003

RIN 0991–AA44

Medicare and State Health Care Programs: Fraud and Abuse, Civil Money Penalties and Intermediate Sanctions for Certain Violations by Health Maintenance Organizations and Competitive Medical Plans

AGENCY: Office of the Secretary, HHS, Office of Inspector General (OIG) and the Health Care Financing Administration (HCFA).

ACTION: Final rule.

SUMMARY: This final rule implements sections 9312(c)(2), 9312(f), and 9434(b) of Public Law 99–509, section 7 of Public Law 100–93, section 4014 of Public Law 100–203, sections 224 and 411(k)(12) of Public Law 100–360, and section 6411(d)(3) of Public Law 101–239. These provisions broaden the Secretary's authority to impose intermediate sanctions and civil money penalties on health maintenance organizations (HMOs), competitive medical plans, and other prepaid health plans contracting under Medicare or Medicaid that (1) substantially fail to provide an enrolled individual with required medically necessary items and services; (2) engage in certain marketing, enrollment, reporting, or claims payment abuses; or (3) in the case of Medicare risk-contracting plans, employ or contract with, either directly or indirectly, an individual or entity excluded from participation in Medicare. The provisions also condition Federal financial participation in certain State payments on the State's exclusion of certain prohibited entities from participation in HMO contracts and waiver programs. This final rule is intended to significantly enhance the protections for Medicare beneficiaries and Medicaid recipients enrolled in a HMO, competitive medical plan, or other contracting organization under titles XVIII and XIX of the Social Security Act.

EFFECTIVE DATE: These rules are effective September 13, 1994.

FOR FURTHER INFORMATION, CONTACT:

Zeno W. St. Cyr, II, Legislation, Regulations, and Public Affairs Staff, OIG, (202) 619–3270 or

Marty Abeln, Office of Managed Care, HCFA, (202) 205–9582 or

Mike Fiore, Medicaid Bureau, HCFA, (410) 966–4460

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

Managed care plans, such as health maintenance organizations (HMOs), competitive medical plans (CMPs), and health insuring organizations (HIOs) are entities that provide enrollees with comprehensive, coordinated health care in a cost-efficient manner. Payment for these plans is generally made on a prepaid, capitation basis. The goal of prepaid health care delivery is to control health care costs while at the same time providing enrollees with affordable, coordinated, quality health care services. Titles XVIII and XIX of the Social Security Act (the Act) authorize contracts with managed health care plans for the provision of covered health services to Medicare beneficiaries and Medicaid recipients.

B. Medicare

Section 1876 of the Act provides for Medicare payment at predetermined rates to eligible organizations that have entered into risk contracts with HFCA, or for payment of reasonable costs to eligible organizations that have entered into cost contracts. Eligible organizations include HMOs that have been federally qualified under section 1310(d) of title XIII of the Public Health Service Act, and CMPs that meet the requirements of section 1876(b)(2) of the Act.

Medicare enrollees of risk-contracting CMPs or HMOs are required to receive covered services only through the organization, except for emergency services and urgently needed out-of-area services. In the case of a cost contract, the Medicare beneficiary may also receive services outside the organization, with Medicare paying for the services through the general Medicare fee-for-service system. If an HMO or CMP fails to comply with a contract provision, the Secretary may decide to not renew or to terminate the contract. Regulations governing nonrenewal of a contract are found at 42 CFR 417.492, and regulations governing termination of a contract are at 42 CFR 417.494.

C. Medicaid

Section 1903(m) of the Act contains requirements that apply to State Medicaid contracts for the provision, on a risk basis, either directly or through arrangements, of at least certain specified services ("comprehensive services"). HCFA regulations at 42 CFR part 434 implement the requirements in section 1903(m) and contain other requirements applicable to Medicaid contracts generally. Section 434.70 provides that HCFA may withhold Federal matching payments, known as Federal financial participation (FFP), for State expenditures for services provided to Medicaid recipients when either party to a contract substantially fails to carry out the terms of the contract.

D. New Legislation

1. The Omnibus Budget Reconciliation Act of 1986

Section 9312(c)(2) of Public Law 99–509, the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), added section 1876(f)(3) to the Act. This provision authorizes the Secretary to suspend enrollment of Medicare beneficiaries by an HMO/CMP or to suspend payment to the HMO/CMP for individuals newly enrolled, after the date the Secretary notifies the organization of noncompliance with the requirement in section 1876(f)(1) that limits enrollment to no more than 50 percent Medicare beneficiaries and Medicaid recipients. Prior to OBRA 86, HCFA's only recourse against an organization for noncompliance with any contract provisions was to non-renew or initiate termination of the contract. The new authority provides alternative remedies that may be used in place of or in addition to contract nonrenewal or termination for organizations that do not comply with the enrollment composition requirement.

Additionally, sections 9312(f) and 9434(c) of OBRA 86 added sections 1876(i)(6) and 1903(m)(5), respectively, to the Act. These provisions authorize a civil money penalty not greater than $10,000 for each instance of failure by an organization with a Medicare risk contract, or certain organizations with a comprehensive risk contract under Medicaid, to provide required medically necessary items or services to Medicare or Medicaid enrollees if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee.

2. The Medicare and Medicaid Patient and Program Protection Act of 1987

Section 7 of Public Law 100–93, the Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA), added section 1902(p) of the Act, which grants States the authority to exclude individuals or entities from participation in their Medicaid programs for any of the reasons that constitute a basis for exclusion from Medicare under sections 1128, 1128A, or 1866(b)(2) of the Act. In addition, section 7 of MMPPPA established a new condition that States must meet in order to receive FFP for

payments to HMOs or entities furnishing services under a waiver approved under section 1915(b)(1) of the Act. The latter provision conditioned FFP upon a State's providing that it will exclude from participation, as an HMO or an entity furnishing services under a section 1915(b)(1) waiver, any entity that could be excluded under section 1128(b)(8) of the Act (that is, any individual or entity against whom criminal or civil penalties have been imposed). FFP is also conditioned upon a State excluding an entity that has, directly or indirectly, a substantial contractual relationship with a person described in section 1128(b)(8)(B) of the Act.

3. The Omnibus Budget Reconciliation Act of 1987

Section 4014 of Public Law 100–203, the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), provides the Department with increased penalty amounts and greater statutory authority and flexibility to take action against HMOs or CMPs that commit certain abuses. This authority also may be exercised in addition to or in place of initiating contract termination proceedings. Section 4014 of OBRA 87 amends section 1876(i)(6) of the Act to authorize the Secretary to impose civil money penalties, suspend enrollment, and suspend payments for newly enrolled individuals in the case of an organization with a Medicare contract (both risk and cost contract) that the Secretary determines has (1) failed substantially to provide required medically necessary items and services to Medicare enrollees if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee; (2) imposed premiums on Medicare enrollees in excess of permitted premium amounts; (3) acted to expel or refused to reenroll an individual in violation of section 1876 of the Act; (4) engaged in any practice that can reasonably be expected to deny or discourage enrollment (except as permitted under section 1876) by Medicare enrollees whose medical condition or history indicates a need for substantial future medical services; (5) misrepresented or falsified information provided under section 1876 to the Secretary, an individual, or any other entity; or (6) fails to comply with the requirements of section 1876(g)(6)(A) regarding prompt payment of claims. Under OBRA 87, the maximum allowable civil money penalty that can be imposed for each determination of a violation is increased to $25,000, or $100,000 in the case of a HMO or CMP determined to have committed acts in (4) above or for misrepresenting or falsifying information furnished to the Secretary under section 1876.

4. The Medicare Catastrophic Coverage Act of 1988

The Medicare Catastrophic Coverage Act of 1988 (MCCA), Public Law 100–360, amended sections 1876 and 1903(m) of the Act by adding new civil money penalty authority for violations occurring within the Medicare program and by applying the OBRA 87 HMO and CMP intermediate sanction and civil money penalty authority to the Medicaid program.

Section 224 of MCCA amended section 1876(i)(6)(B)(i) of the Act. In addition to other civil money penalties, in cases where Medicare enrollees are charged more than the allowable premium, section 224 imposes a penalty which doubles the amount of excess premium charged by the HMO or CMP. The excess premium amount is deducted from the penalty and returned to the Medicare enrollee. Section 224 also imposes a $15,000 penalty for each individual not enrolled if it is determined that the HMO or CMP engaged in any practice which denied or discouraged enrollment (except as permitted under section 1876 of the Act) by Medicare enrollees whose medical condition or history indicated a need for substantial future medical services.

Section 411(k)(12) of MCCA amended section 1903(m)(5) of the Act to provide the Secretary with authority to impose civil money penalties on contracting organizations, and to deny payments for new enrollees of contracting organizations, in cases where the Secretary determines that an organization has (1) failed substantially to provide required medically necessary items and services to Medicaid enrollees if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee; (2) imposed premiums on Medicaid enrollees in excess of premium amounts permitted under title XIX of the Act; (3) discriminated among individuals in violation of the provisions of section 1903(m)(2)(A)(v) of the Act, including expelling or refusing to reenroll an individual or engaging in any practice which could reasonably be expected to deny or discourage enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicates a need for substantial future medical services; or (4) misrepresented or falsified information provided under section 1903 of the Act to the Secretary, State, an individual, or any other entity.

Under the amendments to section 1903(m)(5) made by MCCA, the maximum allowable civil money penalty that can be imposed for each determination of a violation is increased to $25,000, or $100,000 in the case of a determination that a contracting organization has (1) violated the provisions of section 1903(m)(2)(A)(v) by expelling or refusing to reenroll an individual or by engaging in a practice which denied or discouraged enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicated a need for substantial future medical services; or (2) misrepresented or falsified information furnished to the Secretary or State under section 1903(m).

Additionally, in cases where Medicaid enrollees are charged more than the allowable premium, section 411(k)(12) of MCCA amended section 1903(m)(5) of the Act to authorize imposition of an additional penalty which doubles the amount of excess premium charged by the contracting organization, with the excess premium amount deducted from the penalty and returned to the Medicaid enrollee. Imposition of an additional $15,000 penalty is authorized for each individual not enrolled if it is determined that the contracting organization has violated the provisions of section 1903(m)(2)(A)(v) by expelling or refusing to reenroll an individual or by engaging in any practice which denied or discouraged enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicated a need for substantial future medical services.

5. The Omnibus Budget Reconciliation Act of 1989

Public Law 101–239, the Omnibus Budget Reconciliation Act of 1989 (OBRA 89), amended sections 1876 and 1902(p) of the Act to provide the Secretary with an additional civil money penalty and intermediate sanction authority for violations occurring within the Medicare program and with additional conditions for FFP.

Section 6411(d)(3)(A) of OBRA 89 amended section 1876(i)(6)(A) of the Act to authorize the Secretary to restrict enrollment in, suspend payment to, and impose a civil money penalty against an organization with a risk contract that (1) employs or contracts with any individual or entity excluded from Medicare participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or (2) employs or contracts with any entity for the

provision of such services (directly or indirectly) through an excluded individual or entity. The maximum allowable civil money penalty that may be imposed for each determination of a violation of this nature is $25,000.

Section 6411(d)(3)(B) of OBRA 89 amended section 1902(p)(2) of the Act to condition FFP in payments to HMOs, or to entities furnishing services under a § 1915(b)(1) waiver, upon the State's barring the following entities from participation as HMOs or section 1915(b)(1) waiver participants: (1) Any organization that employs or contracts with any individual or entity excluded from Medicaid participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or (2) any organization that employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity.

II. Provisions of the Proposed Rule

On July 22, 1991, we published a proposed rule with a 60-day comment period (56 FR 33403) that would amend 42 CFR Part 417, Subpart C; Part 431, Subpart B; Part 434, Subparts C, D, E, and F; and Part 1003 specifically by establishing sanctions and civil money penalties which may be imposed on contracting organizations that substantially fail to provide an enrollee with required medically necessary items and services or that engage in certain marketing, enrollment, reporting, claims payment, employment, or contracting abuses.

In the July 1991 proposed rule, we proposed to incorporate the Medicare sanction provisions of OBRA 86, OBRA 87, MCCA, and OBRA 89 into agency regulations largely without substantial modifications. Under the proposed regulations, after HCFA (or a State) determines that a contracting organization has committed a violation under sections 1876(i)(6)(A) or 1903(m)(5)(A), information pertaining to the violation would be provided to the OIG.

Briefly, our proposed changes to the regulations were designed to implement the Department's new authorities by detailing HCFA's (and States') role in imposing intermediate sanctions, and the OIG's role in imposing civil money penalties, for certain abuses committed by contracting organizations providing health care items or services to Medicare beneficiaries or Medicaid recipients. We proposed that—

- Once it is determined that a Medicare contracting organization has committed a violation, and in place of initiating contract termination proceedings, HCFA may:
  - —Require the contracting organization to suspend enrollment of Medicare beneficiaries;
  - —Suspend payments to the contracting organization for individuals enrolled after a specified date.
- If a State Medicaid agency determines that a Medicaid contracting organization has committed a violation, it may, in place of terminating the contract, recommend to HCFA that HCFA's intermediate sanction authority be exercised to deny payment to the contracting organization for Medicaid recipients enrolled with the organization after a specified date. This recommendation takes effect absent HCFA action.
- In addition to or in place of other remedies available under law, the OIG may:
  - —Impose a penalty of up to $25,000 for each determination that a contracting organization has—
    - (1) Failed substantially to provide an enrollee with required medically necessary items and services, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee; or
    - (2) Committed enrollment, marketing, claims payment, or certain reporting violations;
  - —Impose a penalty of up to $25,000 for each determination that a contracting organization with a Medicare risk-sharing contract employs or contracts with—
    - (1) Individuals or entities excluded from participation in Medicare, under sections 1128 or 1128A of the Act, for the provision of health care, utilization review, medical social work, or administrative services; or
    - (2) Any entity for the provision of such services (directly or indirectly) through an excluded individual or entity; and
  - —Impose a penalty of up to $100,000 for each determination that a contracting organization has—
    - (1) Misrepresented or falsified information furnished under the provisions of the statute to the Secretary or State; or
    - (2) Expelled or refused to reenroll an individual or engaged in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by statute) by enrollees whose medical condition or history indicates a need for substantial future medical services.
- In cases where a civil money penalty is imposed against a plan for charging enrollees more than the allowable premium, the OIG will impose an additional penalty equal to double the amount of excess premium charged by the contracting organization. The excess premium amount will be deducted from the penalty and returned to the enrollee.
- The OIG will impose an additional $15,000 penalty for each individual not enrolled if it is determined that a contracting organization expelled or refused to reenroll an individual or engaged in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by statute) by enrollees whose medical condition or history indicates a need for substantial future medical services.
- The provisions also condition FFP in certain State payments on the State's exclusion of certain entities excluded (or excludable) from Medicare.

III. Analysis of and Responses to Public Comments

In response to the July 22, 1991 proposed rule, we received 14 timely items of correspondence. The comments were from group health associations, State agencies, health insurance plans, and law firms. A summary of these comments are discussed below:

A. Intermediate Sanctions

Comment: Several commenters wanted clarification on how § 417.495(a)(1), which describes the first basis for the imposition of intermediate sanctions, will be defined. There was particular interest expressed about the criteria by which the terms "fails substantially" and "medically necessary" will be evaluated.

Response: In determining if an organization has violated § 417.495(a)(1), HCFA and State Medicaid agencies will make a comprehensive three-part evaluation. Specifically, this will involve determining if the organization has: (1) *Failed substantially* to provide *medically necessary* items or services and this has (3) *adversely affected* (or has the *substantial likelihood* of adversely affecting) the enrollee. To determine if the three principal requirements of § 417.495(a)(1) have been violated, HCFA and State Medicaid agencies will have recourse to a number of sources of information and guidance. For Medicare, the information sources include the attending physician, other health care personnel, the HMO or CMP, utilization reviewers, the Peer Review Organization (PRO), the Medicare enrollee or authorized representatives, and internal or possibly

third-party expertise. Additional sources of guidance will include clinical practice standards; guidelines or advisories promulgated by authoritative bodies; and Medicare law, regulations, and manuals.

States, in making an initial finding on Medicaid contractor violations, also have a number of sources of information available to them. These include health care experts conducting the required periodic medical audits; the health professionals under contract to the State to perform the annual quality review of services delivered by HMOs and HIOs; other health consultants to the State agency; clinical practice standards, guidelines, or advisories promulgated by authoritative bodies; and Medicaid law, regulations, and manuals.

In making determinations of "substantial failure," consideration will be given to the impact on the health status of a Medicare or Medicaid enrollee of not having received covered items and services and, in cases where patterns of withholding items and services are identified, the frequency of the events and the resulting impact on the health status of enrollees.

In making determinations of "medical necessity," HCFA and the States will rely on their respective coverage or payment requirements but will also utilize various sources of expert opinion (as described above) in order to determine if required medically necessary care has either been denied or inappropriately provided.

Comment: A commenter asked whether the same criteria used for "medical necessity" for Medicare and Medicaid coverage of services will be used to determine medical necessity under the final rule.

Response: In making medical necessity decisions, Medicare and Medicaid will continue to utilize the current oversight processes and coverage and payment criteria. Under the intermediate sanction, however, HCFA and States will also have recourse, on a case by case basis, to other sources of expert information and guidance (as described in the previous response) in making medical necessity decisions.

Comment: A number of commenters wanted changes made to the definition of "adverse affect." One commenter suggested that the definition is too narrow, and unreasonably requires the patient to suffer a high degree of risk to his or her health before a sanction can be applied. Another commenter said that the definition was too vague and suggested amending the definition to indicate that adverse effect is limited to the withholding of or failure to provide medically necessary care covered by the contract. Another commenter expressed concern that the definition of adverse affect appears to be lacking in that it addresses only those instances in which care has been withheld and fails to address those instances where substandard or inappropriate care has been delivered. Still another commenter believed the regulation should provide a definition for "adverse affect" that specifically includes sanctions against HMOs that fail to provide timely and adequate prenatal and children's preventive care.

Response: The expertise needed to determine what constitutes "adverse effect" are similar to those previously discussed which are needed to evaluate "substantial failure" and "medically necessary." HCFA and States will rely on the same sources of information and guidance (as previously described) to determine when an enrollee has been adversely affected by the failure to provide the required medically necessary services.

It should be noted that in addition to a substantial failure to provide medically necessary services, "adverse effect" may also be found to be the result of providing inappropriate or substandard care. Specifically, for medical services that are Medicare or Medicaid approved and are found to be medically necessary, if HCFA or the State determines that a failure to appropriately provide required services has adversely affected (or has a substantial likelihood of adversely affecting) an enrollee, then this will constitute a violation. This includes Medicaid required prenatal and children's preventive care.

Comment: One commenter stated that "adversely affects" should be defined in terms of a detrimental effect on the condition(s) for which the person is seeking treatment.

Response: HCFA and State Medicaid agencies will not limit a determination of adverse effect to only those conditions for which the person is seeking treatment. For example, instances may arise where beneficiaries are seeking treatment for one condition and the physician will determine that another condition is actually the cause of their symptoms.

Comment: One commenter stated that the penalties should apply only to instances where the plan acts negligently or with intent to wrongfully deny medically necessary services. Similarly, a few commenters believed that any sanctions and/or civil money penalties should apply only when an organization has knowingly and willfully violated the law. Two of those commenters suggested that we add a requirement that any violations must be "knowingly and willfully" committed before we impose a sanction.

Response: Sanctions will not be limited to instances where plans act negligently or with wrongful intent. Aggravating and mitigating factors, such as the degree of culpability of the organization, will be considered in determining any sanction or civil money penalty. As in all our determinations on intermediate sanctions, the scope, and duration of the violation, as well as the level of threat to enrollee health and safety, will be evaluated in determining the severity of a particular sanction. Further, we believe that an absolute requirement for "knowingly and willfully" violations is more stringent than the law anticipated. We will consider evidence that an organization has willfully violated the statute as an aggravating circumstance. Nevertheless, we will not add the requirement that violations must be "knowingly and willfully" committed before the imposition of a sanction.

Comment: One commenter asked whether it would be considered a failure to provide medically necessary services if an HMO determined, according to its standard procedures, that a particular service did not qualify as an emergency or out-of-area urgently needed care and denied the service. This commenter recommended that the regulation exclude from any definition of "substantial failure to provide medically necessary services" those circumstances in which care is not provided based upon a medical judgment made in accord with the HMO's standard operating policies determining coverage. In addition, the commenter asked under what circumstances the failure of a physician, with whom the HMO contracts on an independent contractor basis, to furnish a medically necessary item or service can be imputed to the HMO, absent a clear showing that the HMO knowingly contracted with a physician (or other provider) with a history of improper treatment of patients.

Response: In general, an organization which reasonably follows approved guidelines and policies in making medical care decisions will not be found to have denied medically necessary services. It is important to emphasize that we expect medical care decisions to be made judiciously and appropriately. There may be instances when the organization's rules are inadequate; in such circumstances we expect the organization to protect the welfare of the beneficiary.

With respect to an HMO contracting with an independent contractor physician, we consider the HMO responsible for the quality of care its members receive. The HMO has a duty to ensure that the care enrollees receive is appropriate, whether the physician or provider is an employee of the HMO or an independent contractor. If a HMO knowingly contracts with a provider that has a history of improper treatment toward patients, we would consider this a serious aggravating circumstance in determining a sanction or civil money penalty.

Comment: One commenter pointed out that not all HMOs offer all routine covered services in their own health care centers, and therefore must contract out with other providers to offer those services. If it occurs that routine services cannot be scheduled without some minor delay, under what circumstances would such a delay result in a determination that the HMO failed substantially to provide medically necessary services?

Response: Such a situation will be evaluated based on the judgement of experts with whom HCFA will consult and in accordance with Medicare law and regulations. As previously noted, these experts include physicians, other medical personnel, the PRO, and utilization reviewers. Factors such as the effect of delays on the beneficiary's health and whether such delays are reasonable given the type of service and the needs of the beneficiary will be considered. An HMO that contracts for various services remains responsible for the quality and timeliness of those services.

Comment: Several commenters wanted more guidance as to what constitutes an excess premium for purposes of imposing intermediate sanctions in § 434.67(a)(2). One commenter suggested that the regulation include language stating that HCFA approval of the premium amount is consistent with the statutory requirement. Another commenter believed that penalties in premium setting should be limited to instances in which plans knowingly and intentionally seek to overcharge beneficiaries.

Response: In Medicare contracting organizations the premiums and other charges for Medicare enrollees are required to be the actuarial equivalent of what a Medicare beneficiary would pay in fee-for-service for Medicare covered services (section 1876(e)). Premium charges in excess of the HCFA approved amount would be considered excessive.

Although premiums are not typically employed for Medicaid contracting HMOs for Medicaid enrollees, if the State and the HMO/HIO agreed to do so, the use of the premiums would have to be explicitly described in the HMO/HIOs contract with the State. The use of premiums in this way would also have to be described in the State plan, and could not exceed the actual value of deductibles and co-payment amounts provided for under the State plan. Both the State plan provision and the contract terms are required to have the approval of HCFA. Therefore any use of premiums which is not explicitly provided for in an HMO's or HIO's contract with the State, which has been approved by HCFA, would be in excess of a permitted premium.

Comment: Proposed § 417.495(a)(8), which we have designated as § 417.500(a)(8) in this final rule, prohibits Medicare risk contractors from employing or contracting with or through individuals or entities (either directly or indirectly) which have been excluded from participating in Medicare. One commenter believed this provision placed an onerous burden on the risk contractor to conduct extensive inquiries into the background of each of its participating providers and subcontractors, as well as imposing an obligation to obtain from HCFA the most recent information regarding excluded entities. In addition, this commenter wanted clarification of the meaning of "employing or contracting * * * (directly or indirectly) through an excluded individual or entity," so the risk contractor will know the extent of background information it must require of participating providers and others. Further, the commenter suggested that HCFA implement this provision by, (1) providing the risk contractor with a periodic listing of all excluded entities; and (2) specifying that the statutory obligation is satisfied if the risk contractor requests the background information, checks the information furnished by the subcontractor against the most recent list of excluded entities provided by HCFA, and the contracting entity or entities are not on the list.

Response: As part of its current operating procedures, HCFA makes available to Medicare contractors the Medicare/Medicaid Sanction-Reimbursement Report, which lists entities, contractors, and providers excluded from Medicare. While we consider review of the sanction report a critical step in complying with the requirement prohibiting contracting with an excluded individual or entity, it is not conclusive proof of having satisfied the legal obligation. In general, beyond reviewing the sanction report, we expect a reasonable effort to comply with this requirement. This would include reasonable activities to verify provider credentials, and review of other relevant State and professional records. We do not require or expect contracting organizations to go beyond making a reasonable and conscientious effort to comply with this requirement.

Comment: Many commenters wanted more than 15 days to respond to the notice of intermediate sanctions. The suggested time limits ranged from 30 to 60 days with the option of additional extensions.

Response: We agree that allowing more time for an organization to respond to a notification of sanction may be necessary in some instances. We have revised our regulations at § 417.500(b)(2) and § 434.67(c) to permit a 15 day extension to the original 15 days if HCFA approves a written request from the organization. The request for an extension must provide a credible explanation of why additional time is needed and must be received by HCFA or the State agency, as appropriate, before the end of the 15 day period following the organization's date of notification of sanction. An extension will not be available in instances where HCFA, or HCFA in consultation with the State agency, finds that the organization's conduct poses a serious threat to an enrollees' health and safety or if HCFA or the State agency, as appropriate, judges the additional 15 days to be unnecessary for the organization to respond.

Comment: Two commenters wanted the regulation to specify the information that would be provided in the notice of intermediate sanctions. Another commenter suggested the following information be provided: (1) The sanction or sanctions to be imposed; (2) the effective date and duration of the sanction; (3) the authority for the sanction; (4) the reason for the sanction; (5) specific information regarding the organization's right to contest the determination, including timeframes for submission of the organization's request for reconsideration, the permissible content of the request and supporting materials, and to whom the request should be submitted; and (6) information regarding any rights to hearing or appeal, including judicial review, that the organization may have if the sanction is imposed. In addition, the organization should be provided with copies of any documents on which HCFA or the State Agency relied in determining that a violation occurred.

Response: Confidentiality may not allow the release of certain documents which have influenced HCFA's decision to impose a sanction. However, most of

the information listed above will be provided to an organization in the notification of sanction. Specifically, the notice of sanction will provide: (1) The sanction or sanctions to be imposed, (2) the reason for the sanction, (3) the authority for the sanction, (4) the effective date of the sanction, and (5) the time available for submission of the request for reconsideration and to whom the request should be submitted.

HCFA will specify the above information in operating procedures rather than in the regulations. Under the intermediate sanctions, appeal rights will be limited to the reconsideration period.

Comment: One commenter wanted the following information provided by HCFA following a reconsideration: (1) Whether the intermediate sanction will be imposed; (2) the reasons for imposing the sanction, addressing the evidence and arguments submitted by the organization; (3) the effective date and duration of the sanction; and (4) specific information regarding the organization's right to appeal the imposition of a sanction.

Response: We will provide this information at the conclusion of a reconsideration, with two exceptions. First, the duration of the sanction will depend largely on the organization's corrective action plan and willingness and ability to resolve the problem(s). An organization that cannot immediately correct a deficiency for which it has been sanctioned will be expected to submit a corrective action plan to HCFA. This plan will be the organization's description of how and when it will resolve the problems that caused the sanctions to be imposed. Because each corrective action plan is unique, the duration of the sanction cannot be specified at the time it is imposed. Second, there will not be additional appeal steps beyond the initial reconsideration. HCFA will, however, act as quickly as possible when an organization believes it has resolved the violation(s) and wishes to be re-evaluated.

Comment: One commenter recommended that the Medicaid regulations contain minimum standards for the State review procedure. In addition, this commenter believed that an organization sanctioned by a State should have an opportunity for a separate review determination on the Federal level which would supersede any State determination.

Response: State Medicaid agencies are currently responsible for establishing and implementing procedures to monitor HMO and HIO contracts. The areas States monitor through these procedures are broader than the areas identified in this rule. Because States already have these monitoring and review procedures in place, we prefer to allow States to implement these additional responsibilities within their current activities. We will not, in these regulations, specify national standards for this one aspect of the overall monitoring and review of HMO and HIO contracts conducted by States.

In response to the second comment, the Medicaid program is administered by States as opposed to the Federal government. We stated in the preamble of the proposed rule that we believe that States are in the best position to monitor the identified violations and to make a determinations as to whether a violation has occurred. The proposed rule and this final rule offer an additional opportunity for an HMO or HIO to receive a reconsideration of a State's determination. We do not see the need for a third level of review and determination.

Comment: A commenter recommended that HCFA require States to collect information quarterly from Medicaid participating HMOs on the timeliness and frequency of prenatal visits for each Medicaid enrollee. The commenter also recommended requiring States to annually submit data to HCFA demonstrating that the State's rates for prenatal and Early Periodic Screening Diagnosis and Testing (EPSDT) services are adequate to ensure access under Medicaid's statutory requirements.

Response: This comment goes beyond the scope of this rulemaking, which implements legislative authority for intermediate sanctions and civil money penalties for HMOs (and some HIOs). HMOs and HIOs are not yet obligated to pay EPSDT providers State rates. The adequacy of such State rates is not relevant in the case of HMO enrollees. Note, however, section 1926(a) of the Social Security Act requires that State Medicaid agency payments must be sufficient to enlist enough providers to ensure that obstetric and pediatric services are available to Medicaid recipients at least to the same extent available to the general population. HCFA is developing a proposed rule which would implement the provisions of section 1926(a) in regulations.

Comment: One commenter believed that, without additional FFP, the Federal requirements mandating additional specific monitoring functions under this regulation would be burdensome for the States.

Response: HCFA expects States to integrate these new areas of monitoring into their existing monitoring and review activities; for example, those required for monitoring an HMO's enrollment and termination practices and grievance procedures. There will continue to be FFP in the costs for conducting these activities at each State's current Federal matching rate.

Comment: One commenter recommended that HCFA affirmatively adopt those State decisions with which it agrees. The commenter believes this will mean that HCFA will more closely examine State agency determinations or decisions if it is required to formally adopt them.

Response: The regulation at § 434.67(b) provides for a mechanism whereby HCFA must uphold or reject a State decision that a sanction be or not be imposed. We believe that HCFA's consequent imposition of a sanction or decision not to impose a sanction provides sufficient formal affirmative adoption or rejection of a State's recommendation.

Comment: One commenter recommended that the final regulation should specify that the informal appeal must be conducted by an official "experienced and knowledgeable" about contracting under sections 1876 or 1903(m) of the Act.

Response: HCFA will ensure that sanction reconsiderations are evaluated by qualified HCFA officials. However, we do not believe it is necessary to mandate specific qualifications in the regulation.

Comment: A number of commenters were interested in HCFA's approach to beneficiary complaints. HCFA was encouraged to add provisions to the intermediate sanctions establishing timeframes and methodologies for the investigation of complaints. A specific recommendation was made to amend 42 CFR part 417 to require HCFA to have procedures to monitor and investigate violations of section 1876 of the Act. Other commenters believed that HCFA should require contracting organizations to publicize the availability of intermediate sanctions along with information on how to file complaints. Another commenter suggested the rules specify that the complainant receive: (1) Verification of receipt of the complaint; (2) a copy of the notice of intermediate sanction; (3) a copy of the HMOs response, if any, and; (4) a copy of the reconsideration determination. Finally, two commenters wanted a time limit placed on HCFA's investigation and review of beneficiary complaints, suggesting a 60-day deadline for processing the initial complaint and informing the complainant on the outcome of the investigation.

Response: The purpose of the intermediate sanction is to provide more

tools and authority to protect the Medicare beneficiary or Medicaid recipient. HCFA already has procedures in the regional offices and State Medicaid agencies for reporting and responding to beneficiary or recipient complaints. In addition, we already require that HMOs have a formal appeals process through which Medicare enrollees may submit complaints to HCFA. Information about this process must be included in written marketing materials, as set forth in § 417.426. Thus, if an HMO or competitive medical plan denies a service or payment for a service to a Medicare enrollee, the HMO or competitive medical plan must advise the enrollee of his or her rights under Medicare that afford the beneficiary the right to appeal the denial to HCFA. Establishing a separate complaint mechanism for the intermediate sanctions regulation would only serve to divert scarce resources from oversight and enforcement activities. Nevertheless, enrollee complaints will continue to be used as a key indicator of potential problems in Medicare or Medicaid contracting plans as well as identifying potential problems where intermediate sanctions or civil money penalties would be effective.

Comment: One commenter stated that an appropriate sanction for marketing abuse would be to require future marketing materials and/or membership materials to publicize the imposition of sanctions.

Response: This goes beyond our legislative authority. We are constrained, by the provisions of the enabling legislation, in the sanctions we may apply.

Comment: Two commenters were concerned that if the informal reconsideration results in a reversal of the initial determination, there is no provision to ensure that notice of the decision to reverse is provided to the OIG.

Response: We agree that it is important that OIG be notified by HCFA if, in the course of reconsideration or at a later time, a sanction is rescinded. The single determination applies to the initial determination and HCFA will promptly forward to the OIG information on reversals or termination of sanctions. Generally, HCFA will only notify OIG of an intermediate sanction after HCFA has confirmed the imposition of a sanction. This confirmation of sanction will occur at the conclusion of the notification of sanction period or at the end of a reconsideration.

Comment: One commenter believed that the sanctions available to HCFA were too limited and recommended that this final regulation include a third category of sanctions to include such additional sanctions as HCFA considers appropriate and as justice requires. Another commenter specifically suggested we broaden the intermediate sanctions to include sanctions for inappropriate marketing activities and noncompliance with appeal timeframes.

Response: We cannot broaden the intermediate sanctions regulation by introducing a third new category of sanctions that would be determined by what HCFA would consider "appropriate and as justice requires." To do so would exceed our statutory authority.

With regard to applying the intermediate sanctions to marketing violations, section 1876(i)(6)(A)(V) of the Act authorizes HCFA to impose sanctions if an HMO/CMP misrepresents or falsifies information that it furnishes under section 1876 of the Act to HCFA, an individual, or to any other entity. We believe this provides us authority to address a wide range of potential marketing abuses. One of the sanctions provided by the statute is the suspension of enrollment Medicare beneficiaries by the HMO/CMP (section 1876(i)(B)(ii)). Because we consider marketing activities to be an integral part of the enrollment process, we believe the statute gives HCFA the authority to require the offending HMO/CMP to suspend marketing activities directed to Medicare beneficiaries. Therefore, in this final rule, we clarify this by adding a new § 417.500(d)(3). Accordingly, §§ 417.500 (d)(1)–(d)(3) require the sanctioned HMO/CMP to stop accepting applications for enrollment made by Medicare beneficiaries, suspend payment to the HMO/CMP for Medicare beneficiaries enrolled during the sanction period, and, finally, requires the HMO/CMP to suspend all marketing activities to Medicare beneficiaries.

Additionally, we believe that, even in cases where HCFA imposes the suspension of payment sanction, HCFA may require the HMO/CMP to suspend marketing activities to Medicare beneficiaries. We believe that, if HCFA could suspend all enrollment entirely at its discretion, conditions could be attached to a decision to permit an HMO/CMP to continue to enroll new members—namely that actual marketing to new members cease until the sanction is lifted.

Noncompliance with appeal time frames may also be a violation of section 1876(i)(6)(A)(v) if, for example, HCFA finds that an HMO/CMP is misrepresenting information regarding its appeal process or is providing beneficiaries inaccurate information regarding appeal time frames. In addition, since the Medicare appeals process protects the Medicare enrollee's right to appeal an HMO's or competitive medical plan's decision not to furnish or pay for services, a violation of the appeals process is a failure to substantially provide required medically necessary items and services.

Comment: One commenter requested that an organization which is under the sanction of suspension of new enrollment applications also be prohibited from any new subscriber marketing activities. Another commenter asked what the implications for the organization are if an intermediate sanction of suspension of enrollment is imposed. Does the organization still have an obligation to conduct the annual open enrollment period if it occurs during the sanction period? Also, if the sanction is the suspension of payments for new enrollees, will the organization still be required to accept new enrollees and provide health services for which they may not be paid?

Finally, one commenter asked for a specific definition of "suspension." For example, if payments are suspended, the commenter wanted to know whether the organization can recover for services furnished during the sanction period after the sanction is lifted. The commenter also asked whether the organization may engage in marketing activities during the suspension period, holding applications in abeyance until the sanction is removed.

Response: Based on the authority granted the Secretary under section 1876(f)(3) of the Act and established in this regulation at §§ 417.500 (d)(1) through (d)(3), HCFA has the authority to impose the following penalties on offending HMOs or CMPs:

1. Require the HMO or CMP to suspend the enrollment of Medicare beneficiaries during the sanction period; or

2. Suspend payments to the organization for Medicare beneficiaries enrolled during the sanction period.

Depending on the severity and nature of the violation, HCFA will determine which of the two penalties available under the intermediate sanctions is appropriate. A discussion of the two penalties under the intermediate sanctions available to HCFA follows.

Suspension of new Medicare enrollments: Under this sanction, HCFA requires the HMO or CMP to cease all enrollments of Medicare beneficiaries. On the date the sanction is effective, the plan would be prohibited from

accepting applications or otherwise enrolling any new Medicare beneficiaries in the plan. However, individuals already enrolled in the plan and who become Medicare eligible (age in) while the plan is under the suspension of new enrollments, may be enrolled, if they choose, in the plan during the sanction period. Under this sanction, the plan would also be prohibited from engaging in any marketing activities directed to Medicare beneficiaries.

The organization would continue to be paid by HCFA for beneficiaries enrolled before the imposition of this sanction.

Suspension of payments: Under the suspension of payments penalty, the HMO or CMP may continue to enroll beneficiaries but would not be paid for those beneficiaries during the sanction period. Once the sanction period ends, there will be a retroactive payment for beneficiaries enrolled during the sanction period. Thus, this penalty is purely a financial one, affecting only the withholding of the HMO's or competitive medical plan's capitation payment for new medicare enrollees during the sanction period.

Enrollment of new members would be allowed to continue; thus the plan would not necessarily "lose" potential enrollees who would enroll with another HMO or CMP if enrollment was suspended under section 1876(i)(6)(B)(iii) of the Act. As was described in a previous response to a comment, at the time an HMO or CMP is notified that it is subject to the intermediate sanctions, the notice of sanction will inform the plan what specific intermediate sanction has been imposed, including what the plan must do to comply with the sanction, and the effective date of the sanction. In addition to whatever sanction HCFA imposes, the HMO or CMP may also be subject to civil money penalties levied by the Office of Inspector General.

Comment: Several commenters suggested that the informal reconsideration be required to be conducted promptly, for example, within 30 or 60 days of receipt of the organization's evidence. In addition, one commenter requested that the review be expedited if the organization demonstrates that there is a pressing need for swift action.

Response: It is our intent to conduct reconsiderations promptly. The purpose of an intermediate sanction is to allow us to resolve a problem quickly. Nevertheless, we do not choose to specify a time limit. We encourage organizations to inform us of any circumstances that require expedited reconsideration.

Comment: One commenter stated that the language in proposed § 417.495(e)(1), now designated as § 417.500(e)(1), implies that HCFA's reconsideration will inevitably result in upholding the initial determination. They recommended the language of this paragraph be revised to clarify that the sanctions are effective only if HCFA decides to uphold the initial determination.

Response: We disagree with the commenters interpretation of § 417.500(e)(1) and we do not believe the recommended clarification is necessary. We believe it is clear that the provision on the effective date for a sanction only applies when a final decision to impose a sanction is made. The reconsideration process is meant to be a serious assessment of the response by the sanctioned organization. As such, HCFA will not inevitably uphold its initial decision. If HCFA reverses its initial decision, § 417.500(e)(1) would have no applicability.

Comment: One commenter noted that the regulation allows HCFA to make the intermediate sanction effective immediately if the organization's conduct poses a serious threat to an enrollee's health and safety. The commenter stated that if the health and safety of enrollees is at issue, HCFA should take steps to terminate the contract in its entirety, and that intermediate sanctions are not appropriate in such critical circumstances.

Response: There may be instances in which HCFA will impose the intermediate sanction to stop the organization from enrollment and marketing activities at the same time a termination action is being initiated. We believe it is in the best interest of the enrollee that we maintain our authority to respond simultaneously with both actions.

Comment: Three commenters wanted to know if the intermediate sanctions could be imposed retroactively.

Response: Intermediate sanctions will always be imposed prospectively. Civil money penalties, on the other hand, may be imposed for conduct which has already occurred.

Comment: One commenter asked that we clarify what "generally" means as it appears in proposed §§ 417.495(e)—now § 417.500(e)—and 434.67(f)(1). These sections specify that if an HMO seeks reconsideration of a HCFA sanction, "the intermediate sanction generally will be effective on the date the organization is notified of HCFA's decision."

Response: The notice of intermediate sanction, (or notice of reconsideration of an intermediate sanction) will specify the effective date. Usually this will be on the date of the reconsideration notice. We have revised these sections, however, to more clearly state that the sanction is effective on the date specified in the sanction notice or reconsideration notice, respectively.

Comment: One commenter suggested a definition of "substantial" contractual relationship under a Medicaid contract. The commenter proposed that the regulation define "substantial" as greater than 5 percent of the total annual volume of payments for categories of services under the program.

Response: We considered use of a quantitative approach to defining a "substantial" contractual relationship—either a numerical dollar amount or, as suggested by the commenter, expressed as a percent. We dismissed such approaches because contracts of seemingly small financial value could still have a significant effect on Medicare or Medicaid enrollees. Furthermore, if an organization is large, with a substantial contracting budget, even a small percent, such as 5 percent, could involve substantial sums of money. We are therefore adhering to the definition of a "substantial" contractual relationship contained in the proposed rule. Nevertheless, we will consider relative size as a factor in our determination of whether to impose intermediate sanctions or civil money penalties.

Comment: A number of commenters believed that the imposition and duration of sanctions in both Medicare and Medicaid should be subject to a formal review instead of the proposed informal review process. One commenter stated that the formal review steps should consist of an independent review by an administrative law judge (ALJ), with review by the Departmental Appeals Board and, finally, judicial review; with sanctions not taking effect until all appeals are exhausted.

Response: The legislative intent for the intermediate sanctions is to provide HCFA with the authority to respond in a flexible and timely manner to violations of contracting organizations. Allowing the sanction process to become linked to extended review procedures would not serve the interests of the beneficiary or meet the intent of legislation. We believe that the reconsideration process will provide organizations ample opportunity to explain their position.

Comment: Two commenters stated that, if a pre-sanction hearing was not allowed, there should be a post-sanction

hearing before an ALJ or other impartial body, held as soon as possible after the imposition of any sanctions.

Response: As was stated previously, the intent of the statutory provisions implemented in this regulation is to allow HCFA to respond quickly to a problem. During the reconsideration process the decision to impose or not impose a sanction will be made judiciously. In the event a sanction is applied, HCFA will work with the organization to resolve the problem as rapidly as possible. We expect sanctions to be of short duration. If the violation persists, the likely outcome would be termination of the contract rather than an indefinite sanction. We believe that additional hearings would only serve to delay the resolution of problems.

Comment: One commenter stated that an organization should have an "opportunity to cure" by which the organization could avoid the imposition of sanctions by demonstrating not only that the alleged violation had not occurred, but that any prior violation already had been remedied.

Response: We agree that an organization which has received a notice of sanction should have a reasonable opportunity to present its position. In the event the risk contractor demonstrates during the reconsideration period that the sanction is not appropriate, the sanction will not be imposed. The organization's prior contract performance will be considered as we determine whether to impose a sanction and the amount of any civil money penalty.

Comment: One commenter requested than an organization be allowed to submit both documentary evidence, including statements and affidavits, and written arguments in response to a notice that HCFA intends to impose an intermediate sanction.

Response: We agree. The rule provides for the submission of such information as part of the reconsideration process. (See §§ 417.500 (b) (proposed § 417.495(b)) and 434.67(c))

Comment: One commenter expressed concern about the potential duration of an intermediate sanction and recommended a procedure by which, once a sanction is imposed, it will remain in effect until the organization submits a credible allegation of compliance. The commenter defined this as a senior officer's written statement that the organization has taken steps to ensure alleged violations have been examined and, where necessary, corrected. The commenter stated that HCFA should then have 14 days to determine whether the sanction should be terminated. If HCFA is unable to make a determination within 14 days, then the commenter believes that the intermediate sanction should be removed.

Response: We disagree with the recommendation. Our review and decision if we should end a sanction will be done as quickly as possible, but the timing will depend largely on the complexity of the problem and responsiveness of the organization. If a sanction is imposed, the sanctioned organization will develop a corrective action plan, effectively setting their own timetable for the removal of sanctions. HCFA will respond as quickly as possible to review an organization that believes it has corrected its deficiencies.

Comment: Several commenters wanted some means available to ensure prompt reevaluation of an existing sanction and a time limit placed on the duration of a sanction. A related comment was that any renewal of a contract should constitute ratification of the organization's performance under the contract and, thus, the end of the sanction period.

Response: In the event a sanction is applied to an organization, HCFA will respond as quickly as possible to their request for a re-evaluation. We, however, will not set specific limits on the timing or frequency of our reevaluations, or view contract renewal as HCFA's acknowledgement that sufficient corrective action has been taken.

Comment: One commenter pointed out what was believed to be an error in proposed § 434.67(f)(1). The last sentence of this citation in the proposed rule referred to "the date the organization is notified of HCFA's decision under paragraph (d)(1)(ii) of this section." However, paragraph (d)(1)(ii) of that section does not relate to a notification of a decision following reconsideration by HCFA, but rather to a decision by a State agency.

Response: We have modified § 434.67(d)(2) to clarify that the State agency decision to impose a sanction becomes HCFA's decision except in instances where HCFA decides to modify or reverse that agency decision. We also have revised § 434.67(f) so that it, (1) refers in paragraph (f)(1) to the date the HMO is "notified * * * under paragraph (c)," rather than "under paragraph (d)(1)(ii);" and, (2) refers in paragraph (f)(2) to "the date specified in HCFA's reconsideration notice."

B. Factors To be Considered in Levying Civil Money Penalties

Comment: One commenter believed that the proposed "Factors To Be Considered in Levying Civil Money Penalties" greatly dilutes the effectiveness of the penalties by creating many opportunities for HMOs to argue for minimal fines. The commenter stated that the imposition of a full penalty is tied to proof that the HMO engaged in prohibited behavior on a repeated and knowing basis—which is excessively difficult to prove. The commenter suggested that the deterrent effect of the civil money penalties should be preserved by imposing maximum fines for all violations that come to light.

Response: The intent of penalties is to quickly bring about corrective action on the part of a sanctioned organization and to deter further violations. The OIG will use the "Factors to Be Considered in Levying Civil Money Penalties" as a guide in determining the appropriate amount of any civil money penalty. Organizations that have made honest errors and are responsive to HCFA regulators will face less severe penalties than organizations that demonstrate a pattern of knowingly committing violations. We believe that, in performing our oversight responsibilities, it is important to retain flexibility in responding to violations. However, once all evidence has been evaluated and weighed, the OIG will act on the facts of the case in the manner it believes will best achieve the objectives of enrollee protection and regulatory compliance.

Comment: One commenter had several suggestions regarding the enumeration of specific mitigating and aggravating circumstances for the imposition of civil money penalties.

The commenter stated that the statute and regulation establish sanctions that can be imposed against organizations that charge enrollees premiums in excess of those permitted. The commenter believed it should be a mitigating circumstance if the premiums were only incidentally in excess of those permitted; it should be an aggravating circumstance if the premiums were greatly in excess of those permitted.

The commenter stated that the statute and regulations also provide sanctions for contracting with excluded individuals or entities. The commenter believed it should be an aggravating circumstance if the entity was excluded because of its dealings with the HMO and the excluded entity is contracting with the HMO for health care services. The commenter believed it should be a mitigating circumstance if the—

(1) Entity was excluded because of activities unrelated to its dealings with the HMO.

(2) Contract with the excluded entity is unrelated to the delivery of health care services.

(3) Violation is confined to a particular service area of the HMO.

Response: We do not agree with these comments. We believe that the current factors listed under proposed § 1003.106(a)(4) provide for sufficient consideration of the circumstances surrounding violations where premiums in excess of the allowable amount are charged by a contracting organization. Therefore, a separate factor addressing such a violation is unnecessary. With regard to the second comment, we believe that this goes beyond the scope of the statute. The enabling legislation provides for imposition of a civil money penalty without regard to the specific activities which resulted in an individual being excluded from the Medicare program. Additionally, since the statute provides that the penalty may be imposed in instances where excluded individuals are contracted to provide other than patient care, we see no need to mitigate this circumstance. Finally, we believe that the current factors listed under § 1003.106(a)(4) provide for sufficient consideration of the scope of a violation. Therefore, an amendment addressing violations that may be confined to a particular service are not necessary.

Comment: One commenter wanted the OIG to consider prior offenses for which the organization was not assessed any sanctions or money penalties. The commenter believed that even if prior violations had not been sanctioned, a pattern of violations should be considered more serious and dealt with more harshly. The commenter also suggested that proposed § 1003.106(a)(4)(vii), which concerns the history of prior offenses, should be amended to include, in the list of factors to be considered, whether there were any prior offenses by the organization, regardless of administrative or civil sanctions assessed.

Response: In making a determination on the imposition of sanctions we will consider an organization's pattern of conduct. A background of repeated violations would be considered an aggravating circumstance. We believe the current provisions in proposed § 1003.106 allow the OIG to consider the prior conduct of an organization in levying civil money sanctions. Therefore, an amendment is unnecessary.

Comment: One commenter stated that the standards in § 1003.106 relating to determinations regarding the amount of the penalty and assessment are subjective criteria which could result in arbitrary determinations by the OIG.

Response: We disagree with this comment. Congress authorized a maximum penalty amount for certain violations contained in the underlying statutes. The proposed factors listed in § 1003.106 represent an attempt to provide a measure for impartially determining a penalty amount against a culpable organization. Moreover, the public is afforded an opportunity to comment on the proposed factors before their adoption in final regulations. This process is intended to inform the public about what factors will be used in determining penalty amounts, and, to the extent possible, remove subjectivity from penalty determination decisions.

Comment: One commenter wanted to add the "enrollee's compliance with rules and protocols of the contracting organization" as a factor in our determination of imposing civil money penalties.

Response: We believe that the current factors listed under proposed § 1003.106(a)(4) provide for sufficient consideration of the commenter's concerns. Specifically, in paragraph (a)(4)(ii) the factor is the degree of culpability of the contracting organization. Under this factor, in determining whether or not to impose a penalty, as well as in determining the amount of any penalty which may be imposed, consideration will be given to the enrollee's culpability for the violation, including compliance with rules and protocols of the contracting organization. Therefore, a separate factor addressing this issue is unnecessary.

Comment: One commenter asked if proposed § 1003.103(c)(1)(iv), now designated as § 1003.103(e)(1)(iv), establishes degrees or levels of misrepresentation and falsification of information that will be subject to varying amounts of civil money penalties. In addition, the commenter wanted a distinction to be made in the regulation between a misrepresentation and falsification and a mistake with no fraudulent intent.

Response: Concerning a violation of this nature, we believe that once all pertinent information is examined, any reasonable person could discern the difference between a "misrepresentation" and "a mistake with no fraudulent intent." Therefore, we believe that the language in § 1003.103(c)(1)(iv) is sufficient as written.

Comment: Section 1003.103(c)(1)(v) specifies that the failure to comply with prompt payment of claims as established in section 1876(g)(6)(A) of the Act is the basis for a money penalty. A commenter asked what constitutes a violation of timely claims payment, whether it is one late claim or a percentage of claims beyond the standard. In addition, this commenter questioned whether late claims will be determined from a monthly report, Medicare carriers, on-site review, or beneficiary or provider complaints and asked whether this includes claims from nonparticipating providers.

Response: Section 1876(g)(6)(A) of the Act contains a cross-reference to sections 1816(c)(2) and 1842(c)(2) of the Act, which describe prompt payment. These sections require that 95 percent of claims be paid within a specified time period (currently 24 calendar days after receipt). As a result, a definition in this regulation is unnecessary.

Comment: One commenter questioned whether Qualified Medicare Beneficiaries (QMBs) are subject to this rule.

Response: This rule applies to plans that have a Medicare or Medicaid contract. QMBs could be enrolled (or want to enroll) in these plans, and thus, could be affected by these rules.

Comment: One commenter wanted to know what constitutes "discouraging enrollment." Another commenter stated that a penalty should be imposed for discouraging enrollment only if a beneficiary is discouraged from enrolling because of a medical condition or a future need for substantial services.

Response: It is not possible to set out all the possible ways that enrollments in a contracting organization might be discouraged. Essentially, such a determination would be made after judging all the facts and circumstances surrounding an alleged violation. We agree, however, that violations of this nature pertain to certain circumstances. The statute specifically authorizes imposition of a penalty in those instances in which, except as permitted by law, a contracting organization expels or refuses to reenroll an individual or engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by enrollees whose medical condition or history indicate a need for substantial future medical services.

Comment: One commenter stated that § 434.80 would require a State agency to exclude from participation, as a Medicaid contractor, any HMO that is controlled or owned by an individual who has been convicted of a criminal offense relating to financial misconduct. The commenter said that this provision amounts to a lifetime ban on participation in Medicaid for

individuals who may have committed an offense only marginally related to the delivery of health care. The commenter recommended that this prohibition not be a lifetime ban, but that the prohibitions be restricted in their effect to criminal offenses which occurred within the past 10 years. The commenter also stated that the relationship of the criminal offense to the delivery of health care services should be a factor applied by the State agency in determining the fitness of the HMO contractor.

Response: This requirement is based on the requirement in 1902(p)(2) of the Act. The law does not provide authority for the Department to either grant exceptions to this requirement or make this requirement effective for only a specified time period.

Comment: A commenter noted that proposed § 1003.106(a)(1) refers to determining the amount of a penalty under § 1003.103(a), (b) and (c)(1) through (c)(3), and proposed § 1003.106(a)(4) refers to factors for the OIG to consider in determining the penalty under § 1003.103(b)(4) [sic]. The commenter states that there is no § 1003.103(b)(4), and believes that both of these references are incorrect.

Response: We agree. Several sections were incorrectly referenced in §§ 1003.106(a)(1) and 1003.106(a)(4) and we are revising the regulations accordingly. Numerous revisions to referenced sections are made in this final rule because of the publication of final OIG regulations since this HMO regulation was published as a proposed rule.

IV. Provisions of the Final Regulations

After consideration of the comments received and our further analysis of specific issues, we are publishing as final the July 22, 1991, proposed regulations with the revisions identified below. We have also made numerous editorial changes to improve the readability of the proposed text, without changing its substance.

On October 17, 1991 HCFA published a final rule (56 FR 51984) that amended part 417 to simplify, clarify, and update regulations on prepaid health care. Among other changes, that rule designated the contents of Subpart C—Health Maintenance Organization and Competitive Medical Plans as Subpart L—Medicare Contract Requirements. In the July 1991 proposed rule, we proposed to add a new § 417.495, "Sanctions against the organizations" to subpart C. Therefore, as a change from the proposed rule, we are designating proposed § 417.495 as 417.500 and adding it to subpart L.

As discussed in section III of this preamble, we have revised proposed §§ 417.495(b) and 434.67(c), which concern the time limit for seeking a reconsideration, to allow an additional 15 days under certain circumstances. (Proposed § 417.495(b) is now § 417.500(b).)

In addition to changes to improve its readability, proposed § 417.495(e), which concerns the effective date of a sanction, is revised to replace the inexplicit phrase "generally will be effective on the date the organization is notified of HCFA's decision." In this final rule, we specify that, if an organization seeks a reconsideration, the sanction is effective on the date specified in HCFA's notice of reconsidered determination. (Proposed § 417.495(e) is now § 417.500(e). Proposed § 431.55 is revised to improve its readability.)

On January 29, 1992, the OIG published a final rule (57 FR 3298) that amended, among other parts, part 1003. As a result of the publication of the January 29, 1992 rule, we have made changes from our July 22, 1991 proposed rule as follows:

- The substance of proposed §§ 1003.100(b)(1)(i) and (b)(1)(ii), which concern the purpose of part 1003, were incorporated into regulations at §§ 100.100(b)(1)(i) and (b)(1)(iv), respectively, by the January 29 rule. Therefore, proposed § 1003.100(b)(1)(i) is not included in this final rule. Section 1003.100(b)(1)(iv) is included in this final rule solely to make technical corrections.
- Proposed § 1003.100(b)(1)(iii), which also concerns the purpose of part 1003, is designated as § 1003.100(b)(1)(vi) by this final rule.
- The substance of proposed § 1003.102(b)(1), which identifies those individuals against whom the OIG may impose a penalty, was incorporated at §§ 1003.102(b)(1) through (b)(3) by the January 29, 1992 rule. Therefore, it is not included in this rule.
- Proposed § 1003.102(b)(2), which concerns the imposition of penalties against contracting organizations, is designated as § 1003.102(b)(8) by this final rule.
- In § 1003.103, which concerns the amount of a penalty, proposed paragraph (c) is designated as paragraph (e). Further, paragraph (a) as established by the January 29 rule is revised to include a reference to the newly-established paragraph (e).
- Also in § 1003.103, subparagraph (e)(3)(ii) is revised to more clearly reflect the penalty amount stipulated under the statute.
- In § 1003.106, which concerns determining the amount of a penalty and assessment, we have replaced the phrase "person or contracting organization" with the phrase "person." "Person," as it is broadly defined in § 1003.101, includes contracting organizations. Therefore, the phrase was replaced in the final rule.

As discussed in section III of this preamble, we have included, at § 1003.106(d), provisions regarding mitigating and aggravating circumstances to be considered in determining the amount of any penalty.

V. Information Collection Requirements

This final rule contains no information collection requirements. Consequently, this final rule need not be reviewed by the Executive Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Statement

This final rule implements sections of OBRA 1986, sections of the Medicare and Medicaid Patient and Program Protection Act of 1987, sections of the Medicare Catastrophic Coverage Act of 1988, and a section of OBRA 1989. This final rule will implement the Secretary's broadened authority to impose intermediate sanctions and civil money penalties on HMOs and other prepaid health plans contracting under Medicare or Medicaid that substantially fail to provide an enrolled individual with required medically necessary items and services, engage certain marketing, enrollment, reporting, or claims payment abuses, or, in the case of Medicare, employ or contract with, either directly or indirectly, an individual or entity excluded from participation in Medicare.

This regulation is the result of statutory changes and serves to clarify departmental policy with respect to the imposition of intermediate sanctions and civil money penalties. We believe the majority of plans, practitioners and providers do not engage in the prohibited activities and practices discussed in this final rule. In addition, we believe this final rule will have a deterrent effect upon providers and practitioners. Therefore, we expect that the aggregate economic impact would be minimal, affecting only those engaged in the prohibited behavior in violation of this final rule.

The Office of Management and Budget has reviewed this final rule in accordance with the provisions of Executive Order 12866.

We generally prepare a regulatory flexibility analysis that is consistent

with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all HMOs, competitive medical plans and other contracting organizations to be small entities.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final 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 604 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 50 beds.

We do not have data to assist us in estimating the number of contracting organizations that will be affected by this final rule or the magnitude of any penalties that will be imposed. Nevertheless, any impact will be minimal because we believe the number of providers and practitioners engaged in prohibited activities are few. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act since we have determined, and the Secretary certifies, that this final rule will not result in a significant economic impact on a substantial number of small entities and will not have a significant impact on the operations of a substantial number of small rural hospitals.

List of Subjects

42 CFR Part 417

Administrative practice and procedure; Grant programs—health; Health care; Health facilities; Health insurance; Health Maintenance Organizations (HMO); Loan programs—health; Medicare; Reporting and recordkeeping requirements.

42 CFR Part 431

Grant Programs—Health; Health facilities; Medicaid; Privacy; Reporting and recordkeeping requirements.

42 CFR Part 434

Grant Programs—Health; Health Maintenance Organizations (HMO); Medicaid; Reporting and recordkeeping requirements.

42 CFR Part 1003

Administrative practice and procedure; Fraud; Grant Programs—Health; Health facilities; Health professions; Maternal and child health; Medicaid; Medicare; Penalties.

A. 42 CFR part 417 is amended as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 is revised to read as follows:

Authority: Secs. 1102, 1833(a)(1)(A), 1861(s)(2)(H), 1871, 1874, and 1876 of the Social Security Act (42 U.S.C. 1302, 1395l(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, and 1395mm); sec. 114(c) of Pub. L. 97–248 (42 U.S.C. 1395mm note); section 9312(c) of Pub. L. 99–509 (42 U.S.C. 1395mm note); and secs. 215, 353, and 1301 through 1318 of the Public Health Service Act (42 U.S.C. 216, 263a, and 300e through 300e–17) and 31 U.S.C. 9701, unless otherwise noted.

Subpart L—Medicare Contract Requirements

2. In subpart L, a new section 417.500 is added to read as follows:

§ 417.500 Sanctions against HMOs and CMPs.

(a) *Basis for imposition of sanctions.* HCFA may impose the intermediate sanctions specified in paragraph (d) of this section, as an alternative to termination, if HCFA determines that an HMO or CMP with a contract under this subpart does one or more of the following:

(1) Fails substantially to provide the medically necessary services required to be provided to a Medicare enrollee and the failure adversely affects (or has a substantial likelihood of adversely affecting) the enrollee.

(2) Requires Medicare enrollees to pay amounts in excess of premiums permitted.

(3) Acts, in violation of the provisions of this part, to expel or to refuse to reenroll an individual.

(4) Engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals whose medical conditions or histories indicate a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes under this part to HCFA, an individual, or to any other entity.

(6) Fails to comply with the requirements of section 1876(g)(6)(A) of the Act relating to the prompt payment of claims.

(7) Fails to meet the requirement in section 1876(f)(1) of the Act that not more than 50 percent of the organization's enrollment be Medicare beneficiaries and Medicaid recipients.

(8) Has a Medicare risk contract and—

(i) Employs or contracts with individuals or entities excluded from participation in Medicare under section 1128 or section 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of those services (directly or indirectly) through an excluded individual or entity.

(b) *Notice of sanction.* (1) Before imposing the intermediate sanctions specified in paragraph (d) of this section, HCFA—

(i) Sends a written notice to the HMO or CMP stating the nature and basis of the proposed sanction; and

(ii) Sends the OIG a copy of the notice (other than a notice regarding the restriction on Medicare and Medicaid enrollees as described in paragraph (a)(7) of this section), once the sanction has been confirmed following the notice period or the reconsideration.

(2) HCFA allows the HMO or CMP 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with a requirement described in paragraph (a) of this section, as applicable. HCFA may allow a 15-day addition to the original 15 days upon receipt of a written request from the HMO or CMP. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by HCFA before the end of the 15-day period following the date of receipt of the sanction notice. HCFA does not grant an extension if it determines that the HMO's or CMP's conduct poses a threat to an enrollee's health and safety.

(c) *Informal reconsideration.* If, consistent with paragraph (b)(2) of this section, the HMO or CMP submits a timely response to HCFA's notice of sanction, HCFA conducts an informal reconsideration that:

(1) Consists of a review of the evidence by a HCFA official who did not participate in the initial decision to impose a sanction; and

(2) Gives the HMO or CMP a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(d) *Specific sanctions.* If HCFA determines that an HMO or CMP has acted or failed to act as specified in paragraph (a) of this section and affirms this determination in accordance with paragraph (c) of this section, HCFA may—

(1) Require the HMO or CMP to suspend acceptance of applications for

enrollment made by Medicare beneficiaries during the sanction period;

(2) Suspend payments to the HMO or CMP for Medicare beneficiaries enrolled during the sanction period; and

(3) Require the HMO or CMP to suspend all marketing activities to Medicare enrollees.

(e) *Effective date and duration of sanctions*—(1) *Effective date.* Except as provided in paragraph (e)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the HMO or CMP timely seeks reconsideration under paragraph (c) of this section, on the date specified in the notice of HCFA's reconsidered determination.

(2) *Exception.* If HCFA determines that the HMO's or CMP's conduct poses a serious threat to an enrollee's health and safety, HCFA may make the sanction effective on a date before issuance of HCFA's reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until HCFA notifies the HMO or CMP that HCFA is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

(f) *Termination by HCFA.* In addition to or as an alternative to the sanctions described in paragraph (d) of this section, HCFA may decline to renew a HMO's or CMP's contract in accordance with § 417.492(b), or terminate the contract in accordance with § 417.494(b).

(g) *Civil money penalties.* If HCFA determines that a HMO or CMP has committed an act or failed to comply with a requirement described in paragraph (a) of this section (with the exception of the requirement to limit the percentage of Medicare and Medicaid enrollees described in paragraph (a)(7) of this section), HCFA notifies the OIG of that determination. HCFA also conveys to the OIG information when it reverses or terminates a sanction imposed under this subpart. In accordance with the provisions of 42 CFR part 1003, the OIG may impose civil money penalties on the HMO or CMP in addition to or in place of the sanctions that HCFA may impose under paragraph (d) of this section.

B. 42 CFR part 431 is amended as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 431.55 is amended by adding a sentence at the end of paragraph (a) and adding new paragraph (h) to read as follows:

§ 431.55 Waiver of other Medicaid requirements.

(a) Statutory basis. * * *. Section 1902(p)(2) of the Act conditions FFP in payments to an entity under a section 1915(b)(1) waiver on the State's provision for exclusion of certain entities from participation.

* * * * *

(h) *Waivers approved under section 1915(b)(1) of the Act*—(1) Basic Rules. (i) An agency must submit, as part of it's waiver request, assurance that the entities described in paragraph (h)(2) of this section will be excluded from participation under an approved waiver.

(ii) FFP is available in payments to an entity that furnishes services under a section 1915(b)(1) waiver only if the agency excludes from participation any entity described in paragraph (h)(2) of this section.

(2) Entities that must be excluded. The agency must exclude an entity that meets any of the following conditions:

(i) Could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(ii) Has a substantial contractual relationship (direct or indirect) with an individual convicted of certain crimes, as described in section 1128(b)(8)(B) of the Act.

(iii) Employs or contracts directly or indirectly with one of the following:

(A) Any individual or entity that, under section 1128 or section 1128A of the Act, is precluded from furnishing health care, utilization review, medical social services, or administrative services.

(B) Any entity described in paragraph (h)(2)(i) of this section.

(3) Definitions. As used in this section, substantial contractual relationship means any contractual relationship that provides for one or more of the following services:

(i) The administration, management, or provision of medical services.

(ii) The establishment of policies, or the provision of operational support, for the administration, management, or provision of medical services.

C. 42 CFR part 434 is amended as set forth below:

PART 434—CONTRACTS

1. The authority citation for part 434 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart C—Contracts with HMOs and PHPs: Contract Requirements

2. In subpart C, a new § 434.22 is added to read as follows:

§ 434.22 Application of sanctions to risk comprehensive contracts.

A risk comprehensive contract must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by HCFA under § 434.67(e).

Subpart D—Contracts With Health Insuring Organizations

3. In subpart D, a new § 434.42 is added to read as follows:

§ 434.42 Application of sanctions to risk comprehensive contracts.

A risk comprehensive contract must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by HCFA under § 434.67(e).

Subpart E—Contracts With HMOs and PHPs: Medicaid Agency Responsibilities

4. In subpart E, § 434.63 is revised to read as follows:

§ 434.63 Monitoring procedures.

The agency must have procedures to do the following:

(a) Monitor enrollment and termination practices.

(b) Ensure proper implementation of the contractor's grievance procedures.

(c) Monitor for violations of the requirements specified in § 434.67 and the conditions necessary for FFP in contracts with HMOs specified in § 434.80.

Subpart E—Contracts With HMOs and PHPs: Medicaid Agency Responsibilities

5. In subpart E, a new § 434.67 is added to read as follows:

§ 434.67 Sanctions against HMOs with risk comprehensive contracts.

(a) *Basis for imposition of sanctions.* The agency may recommend that the intermediate sanction specified in paragraph (e) of this section be imposed if the agency determines that an HMO with a risk comprehensive contract does one or more of the following:

(1) Fails substantially to provide the medically necessary items and services required under law or under the contract to be provided to an enrolled recipient and the failure has adversely

affected (or has substantial likelihood of adversely affecting) the individual.

(2) Imposes on Medicaid enrollees premium amounts in excess of premiums permitted.

(3) Engages in any practice that discriminates among individuals on the basis of their health status or requirements for health care services, including expulsion or refusal to reenroll an individual, or any practice that could reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1903(m) of the Act) by eligible individuals whose medical conditions or histories indicate a need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes, under section 1903(m) of the Act to HCFA, the State agency, an individual, or any other entity.

(b) *Effect of an agency determination.* (1) When the agency determines that an HMO with a risk comprehensive contract has committed one of the violations identified in paragraph (a) of this section, the agency must forward this determination to HCFA. This determination becomes HCFA's determination for purposes of section 1903(m)(5)(A) of the Act, unless HCFA reverses or modifies the determination within 15 days.

(2) When the agency decides to recommend imposition of the sanction specified in paragraph (e) of this section, this recommendation becomes HCFA's decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, unless HCFA rejects this recommendation within 15 days.

(c) *Notice of sanction.* If a determination to impose a sanction becomes HCFA's determination under paragraph (b)(2) of this section, the agency must send a written notice to the HMO stating the nature and basis of the proposed sanction. A copy of the notice is forwarded to the OIG at the same time it is sent to the HMO. The agency allows the HMO 15 days from the date it receives the notice to provide evidence that it has not committed an act or failed to comply with a requirement described in paragraph (a) of this section, as applicable. The agency may allow a 15-day addition to the original 15 days upon receipt of a written request from the organization. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by HCFA before the end of the 15-day period following the date the organization received the sanction notice. An extension is not granted if HCFA determines that the organization's conduct poses a threat to an enrollee's health and safety.

(d) *Informal reconsideration.* (1) If the HMO submits a timely response to the agency's notice of sanction, the agency conducts an informal reconsideration that includes—

(i) Review of the evidence by an agency official who did not participate in the initial recommendation to impose the sanction; and

(ii) A concise written decision setting forth the factual and legal basis for the decision.

(2) The agency decision under paragraph (d)(1)(ii) of this section is forwarded to HCFA and becomes HCFA's decision unless HCFA reverses or modifies the decision within 15 days from the date of HCFA's receipt of the agency determination. In the event HCFA modifies or reverses the agency decision, the agency sends the HMO a copy of HCFA's decision under this paragraph.

(e) *Denial of payment.* If a HCFA determination that a HMO has committed a violation described in paragraph (a) of this section is affirmed on review under paragraph (d) of this section, or is not timely contested by the HMO under paragraph (c) of this section, HCFA, based upon the recommendation of the agency, may deny payment for new enrollees of the HMO under section 1903(m)(5)(B)(ii) of the Act. Under §§ 434.22 and 434.42, HCFA's denial of payment for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.

(f) *Effective date and duration of sanction.* (1) Except as specified in paragraphs (f)(2) and (f)(3) of this section, a sanction is effective 15 days after the date the HMO is notified of the decision to impose the sanction under paragraph (c) of this section.

(2) If the HMO seeks reconsideration under paragraph (d) of this section, the sanction is effective on the date specified in HCFA's reconsideration notice.

(3) If HCFA, in consultation with the agency, determines that the HMO's conduct poses a serious threat to an enrollee's health and safety, the sanction may be made effective on a date prior to issuance of the decision under paragraph (d)(1)(ii) of this section.

(g) *Civil money penalties.* If a determination that an organization has committed a violation under paragraph (a) of this section becomes HCFA's determination under paragraph (b)(1) of this section, HCFA conveys the determination to the OIG. In accordance with the provisions of 42 CFR part 1003, the OIG may impose civil money penalties on the organization in addition to or in place of the sanctions that may be imposed under this section.

(h) *HCFA's role.* HCFA retains the right to independently perform the functions assigned to the agency in paragraphs (a) through (f) of this section.

(i) *State Plan requirements.* The State Plan must include a plan to monitor for violations specified in paragraph (a) of this section and for implementing the provisions of this section.

6. In subpart F, a new § 434.80 is added to read as follows:

Subpart F—Federal Financial Participation

§ 434.80 Condition for FFP in contracts with HMOs.

(a) *Basic rule.* FFP in payments to an HMO is available only if the agency excludes from participation as such an entity any entity described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(2), either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, with one of the following:

(i) Any individual or entity excluded from Medicaid participation under section 1128 or section 1128A of the Act for the furnishing of health care, utilization review, medical social work, or administrative services.

(ii) Any entity for the provision through an excluded individual or entity of services described in paragraph (b)(3)(i) of this section.

D. 42 CFR part 1003 is amended as set forth below:

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

1. The authority citation for part 1003 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7a, 1320b–10, 1395mm, 1395ss(d), 1395u(j), 1395u(k), 1396b(m), 11131(c) and 11137(b)(2).

2. Section 1003.100 is amended by revising paragraph (a); republishing paragraph (b)(1) introductory text; revising paragraphs (b)(1)(iv) and

(b)(1)(v); and adding a new paragraph (b)(1)(vi) to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128, 1128(c), 1128A, 1140, 1842(j), 1842(k), 1876(i)(6), 1882(d), and 1903(m)(5) of the Social Security Act, and sections 421(c) and 427(b)(2) of Public Law 99–660 (42 U.S.C. 1320a–7, 1320a–7a, 1320a–7(c), 1320b–10, 1395mm, 1395ss(d), 1395u(j), 1395u(k), 1396b(m), 11131(c) and 11137(b)(2)).

(b) *Purpose.* * * *

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

* * * * *

(iv) Fail to report information concerning medical malpractice payments or who improperly disclose, use or permit access to information reported under part B of title IV of Public Law 99–660, and regulations specified in 45 CFR part 60;

(v) Misuse certain Medicare and social security program words, letters, symbols and emblems; or

(vi) Substantially fail to provide an enrollee with required medically necessary items and services, or that engage in certain marketing, enrollment, reporting, claims payment, employment, or contracting abuses.

* * * * *

3. Section 1003.101 is amended by adding, in alphabetical order, definitions for the terms "adverse effect," "contracting organization," and "enrollee" to read as follows:

§ 1003.101 Definitions.

* * * * *

Adverse effect means medical care has not been provided and the failure to provide such necessary medical care has presented an imminent danger to the health, safety, or well-being of the patient or has placed the patient unnecessarily in a high-risk situation.

* * * * *

Contracting organization means a public or private entity, including of a health maintenance organization (HMO), competitive medical plan, or health insuring organization (HIO) which meets the requirements of section 1876(b) of the Act or is subject to the requirements in section 1903(m)(2)(A) of the Act and which has contracted with the Department or a State to furnish services to Medicare beneficiaries or Medicaid recipients.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization that contracts with the Department under title XVIII or title XIX of the Act.

* * * * *

4. Section 1003.102, paragraph (b) introductory text is republished and a new paragraph (b)(8) is added to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

* * * * *

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

* * * * *

(8) Is a contracting organization that HCFA determines has committed an act or failed to comply with the requirements set forth in § 417.500(a) or § 434.67(a) of this title or failed to comply with the requirement set forth in § 434.80(c) of this title.

* * * * *

5. Section 1003.103 is amended by revising paragraph (a) and adding new paragraph (e) to read as follows:

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) through (e) of this section, the OIG may impose a penalty of not more than $2,000 for each item or service that is subject to a determination under § 1003.102.

* * * * *

(e)(1) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization has:

(i) Failed substantially to provide an enrollee with required medically necessary items and services and the failure adversely affects (or has the likelihood of adversely affecting) the enrollee;

(ii) Imposed premiums on enrollees in excess of amounts permitted under section 1876 or Title XIX of the Act;

(iii) Acted to expel or to refuse to re-enroll a Medicare beneficiary in violation of the provisions of section 1876 of the Act and for reasons other than the beneficiary's health status or requirements for health care services;

(iv) Misrepresented or falsified information furnished to an individual or any other entity under section 1876 or section 1903(m) of the Act; or

(v) Failed to comply with the requirements of section 1876(g)(6)(A) of the Act regarding prompt payment of claims.

(2) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization with a contract under section 1876 of the Act:

(i) Employs or contracts with individuals or entities excluded, under section 1128 or section 1128A of the Act, from participation in Medicare for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of services (directly or indirectly) through an excluded individual or entity.

(3) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $100,000 for each determination that a contracting organization has:

(i) Misrepresented or falsified information furnished to the Secretary under section 1876 of the Act or to the State under section 1903(m) of the Act; or

(ii) Acted to expel or to refuse to reenroll a Medicaid recipient because of the individual's health status or requirements for health care services, or engaged in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1876 or section 1903(m) of the Act) with the contracting organization by Medicare beneficiaries and Medicaid recipients whose medical condition or history indicates a need for substantial future medical services.

(4) If enrollees are charged more than the allowable premium, the OIG will impose an additional penalty equal to double the amount of excess premium charged by the contracting organization. The excess premium amount will be deducted from the penalty and returned to the enrollee.

(5) The OIG will impose an additional $15,000 penalty for each individual not enrolled when HCFA determines that a contracting organization has committed a violation described in paragraph (e)(3)(ii) of this section.

(6) For purposes of paragraph (e) of this section, a violation is each incident where a person has committed an act listed in § 417.500(a) or § 434.67(a) of this title or failed to comply with a requirement set forth in § 434.80(c) of this title.

6. Section 1003.106 is amended by adding new paragraph (a)(4); redesignating paragraph (d) as paragraph (e) and republishing it; and adding a new paragraph (d) to read as follows:

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) * * *

(4) In determining the appropriate amount of any penalty in accordance with § 1003.103(e), the OIG will consider as appropriate—

(i) The nature and scope of the required medically necessary item or service not provided and the circumstances under which it was not provided;

(ii) The degree of culpability of the contracting organization;

(iii) The seriousness of the adverse effect that resulted or could have resulted from the failure to provide required medically necessary care;

(iv) The harm which resulted or could have resulted from the provision of care by a person that the contracting organization is expressly prohibited, under section 1876(i)(6) or section 1903(p)(2) of the Act, from contracting with or employing;

(v) The harm which resulted or could have resulted from the contracting organization's expulsion or refusal to reenroll a Medicare beneficiary or Medicaid recipient;

(vi) The nature of the misrepresentation or fallacious information furnished by the contracting organization to the Secretary, State, enrollee, or other entity under section 1876 or section 1903(m) of the Act;

(vii) The history of prior offenses by the contracting organization or principals of the contracting organization, including whether, at any time prior to determination of the current violation or violations, the contracting organization or any of its principals was convicted of a criminal charge or was held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services; and

(viii) Such other matters as justice may require.

* * * * *

(d) In considering the factors listed in paragraph (a)(4) of this section, for violations subject to a determination under § 1003.103(e), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(1) Nature and circumstances of the incident. It would be considered a mitigating circumstance if, where more than one violation exists, the appropriate items or services not provided were:

(i) Few in number, or

(ii) Of the same type and occurred within a short period of time.

It would be considered an aggravating circumstance if such items or services were of several types and occurred over a lengthy period of time, or if there were many such items or services (or the nature and circumstances indicate a pattern of such items or services not being provided).

(2) Degree of culpability. It would be considered a mitigating circumstance if the violation was the result of an unintentional, unrecognized error, and corrective action was taken promptly after discovery of the error.

(3) Failure to provide required care. It would be considered an aggravating circumstance if the failure to provide required care was attributable to an individual or entity that the contracting organization is expressly prohibited by law from contracting with or employing.

(4) Use of excluded individuals. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in the prohibited practice of contracting or employing, either directly or indirectly, individuals or entities excluded from the Medicare program under section 1128 or section 1128A of the Act.

(5) Routine practices. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in any discriminatory or other prohibited practice which has the effect of denying or discouraging enrollment by individuals whose medical condition or history indicates a need for substantial future medical services.

(6) Prior offenses. It would be considered an aggravating circumstance if at any time prior to determination of the current violation or violations, the contracting organization or any of its principals was convicted on criminal charges or held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services. The lack of prior liability for criminal, civil, or administrative sanctions by the contracting organization, or the principals of the contracting organization, would not necessarily be considered a mitigating circumstance in determining civil money penalty amounts.

(e) (1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this section will limit the authority of the Department to settle any issue or case as provided by § 1003.126, or to compromise any penalty and assessment as provided by § 1003.128.

Dated: March 30, 1994.

June Gibbs Brown,

Inspector General.

Dated: April 12, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Approved: July 7, 1994.

Donna E. Shalala,

Secretary, Department of Health and Human Services.

[FR Doc. 94–17221 Filed 7–14–94; 8:45 am]

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 322

RIN 3067–AC27

Defense Production: Priorities and Allocations Authority; Removal of CFR Part

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: This rule removes 44 CFR 322, Defense Production: Priorities and Allocations Authority (DMO–3), the authority for which was superseded by Executive Order 12919 of June 3, 1994.

EFFECTIVE DATE: July 15, 1994.

FOR FURTHER INFORMATION CONTACT: Larry Hall, Preparedness, Training and Exercises Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3520.

SUPPLEMENTARY INFORMATION: On June 3, 1994, the President signed Executive Order 12919, National Defense Industrial Resources Preparedness, 59 FR 29525, June 7, 1994, which delegated authorities under the Defense Production Act and revoked and superseded certain authorities that were the basis for 44 CFR part 322. This rule removes part 322 to comply with Executive Order 12919.

List of Subjects in 44 CFR Part 322

Authority delegations (Government agencies), National defense.