ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 289–0451b; FRL–7784–1]

Revisions to the California State Implementation Plan, Monterey Bay Unified and Santa Barbara Air Pollution Control Districts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Monterey Bay Unified Air Pollution Control District (MBUAPCD) and Santa Barbara County Air Pollution Control District (SBCAPCD) portions of the California State Implementation Plan (SIP). These revisions concern definitions. We are proposing to approve local rules to regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: Any comments on this proposal must arrive by August 23, 2004.

ADDRESSES: Send comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901 or e-mail to *steckel.andrew@epa.gov,* or submit comments at *http://www.regulations.gov.*

You can inspect copies of the submitted SIP revisions, EPA's technical support documents (TSDs), and public comments at our Region IX office during normal business hours by appointment. You may also see copies of the submitted SIP revisions by appointment at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 ''I'' Street, Sacramento, CA 95814

Monterey Bay Unified Air Pollution Control District, 24580 Silver Cloud Ct., Monterey, CA 93940–6536

Santa Barbara County Air Pollution Control District, 260 North San Antonio Road, Suite A, Santa Barbara, CA 93110–1315

A copy of the rule may also be available via the Internet at *http://www.arb.ca.gov/drdb/drdbltxt.htm.* Please be advised that this is not an EPA Web site and may not contain the same version of the rule that was submitted to EPA.

FOR FURTHER INFORMATION CONTACT: Cynthia G. Allen, EPA Region IX, (415) 947–4120, *allen.cynthia@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposal addresses the following local rules: MBUAPCD Rule 101 and SBCAPCD Rule 102. In the Rules and Regulations section of this **Federal Register**, we are approving these local rules in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: June 15, 2004.

Wayne Nastri,

Regional Administrator, Region IX.

[FR Doc. 04–16567 Filed 7–22–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 402

[CMS–6146–P]

RIN 0938–AL53

Medicare Program; Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish the procedures for imposing exclusions for certain violations of the Medicare program. These procedures are based on the procedures that the Office of Inspector General has published for civil money penalties, assessments, and exclusions under their delegated authority. These regulations would protect beneficiaries from health care providers and entities found in noncompliance with Medicare rules and regulations and would otherwise improve the safeguard provisions under the Medicare statute.

DATES: To be assured consideration, comments must be received at the appropriate address, as provided below, no later than 5 p.m. on September 21, 2004.

ADDRESSES: In commenting, please refer to file code CMS–6146–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6146–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Joel Cohen, (410) 786–3349.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–6146–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are processed, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7197.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order

payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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

I. Background

[If you choose to comment on issues in this section, please include the caption ''Background'' at the beginning of your comments.]

Section 2105 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35) added section 1128A to the Social Security Act (the Act) to authorize the Secretary of Health and Human Services to impose civil money penalties, assessments, and/or exclusion from the Medicare program for certain health care facilities, practitioners, suppliers or other entities under prescribed circumstances. Exclusion provides the ultimate enforcement tool for agencies attempting to establish compliance with legal and program standards, and is used in addition to potential civil, criminal, and/or administrative proceedings.

Since 1981, the Congress has significantly increased both the number and types of circumstances under which the Secretary may impose an exclusion of a provider or an entity from the Medicare and State health care programs. The Secretary has delegated the authority for these provisions to either the Office of Inspector General (OIG) or the Centers for Medicare & Medicaid Services (CMS) (59 FR 52967, October 20, 1994). The exclusion authorities delegated to the OIG address fraud, misrepresentation, or falsification, while those that address noncompliance with programmatic or regulatory requirements are delegated to CMS. However, the OIG has the authority to impose an exclusion and to prosecute cases involving exclusions that were delegated to CMS if CMS and the OIG jointly determine it to be in the interest of economy, efficiency, or effective coordination of activities. The determination may be made either on a case-by-case basis, or for all cases brought under a particular listed authority.

On December 14, 1998, we published a final rule in the **Federal Register** (63 FR 68687), delineating the procedures for pursuing civil money penalties (CMPs) and assessments. That final rule added a new part 402 to title 42, chapter IV of the Code of Federal Regulations (CFR) to incorporate our CMP and assessment authorities. We did not address exclusions in that final rule, but did reserve subpart C to incorporate this information at a future date.

In the December 14, 1998 rule, we indicated that our procedures for imposing the CMPs and assessment authorities delegated to CMS were based on the procedures that the OIG has delineated in 42 CFR part 1003. We also made the OIG's hearing and appeal procedures set forth in 42 CFR part 1005 effective for the CMP, assessment, and exclusion authorities delegated to CMS.

II. Provisions of the Proposed Rule

This proposed rule would amend part 402, subpart C, Exclusions, to incorporate the rules concerning exclusions associated with the CMP violations identified in part 402. Subpart C contains the general requirements and procedures that are common to the imposition of an exclusion from Medicare, Medicaid, and, where applicable, other Federal health care programs. These regulations would not materially impact the hearing and appeal procedures currently available to any person on whom we could impose an exclusion.

Specifically, we are proposing to add the following provisions to subpart C:

• *Section 402.200, Basis and purpose.*

[If you choose to comment on issues in this section, please include the caption ''Basis and purpose'' at the beginning of your comments.]

This section provides the basis and purpose for the imposition of an exclusion from Medicare, Medicaid, and, where applicable, other Federal health care programs for noncompliance with the respective provisions of the Act specified in § 402.1(e). This subpart also sets forth the appeal rights of persons subject to exclusion, and the procedures for reinstatement following exclusion. This subpart is based on § 1003.102, § 1003.105, § 1003.107, and § 1003.109 of the OIG's regulations.

• *Section 402.205, Length of exclusion.*

[If you choose to comment on issues in this section, please include the caption ''Length of exclusion'' at the beginning of your comments.]

This section describes the duration of exclusion from Medicare, Medicaid, and, where applicable, other Federal health care programs for the applicable violation. Currently, there are four general categories for which violations may cause exclusions. These categories involve non-compliance with assignment billings, non-compliance with charge or service limits, failure to provide information or improperly providing information, or non-compliance with Medigap or Medicare Select. Some exclusion provisions provide that the exclusion is imposed in accordance with section 1842(j)(2) of the Act. Section 1842(j)(2) provides for exclusion from participation in the programs under the Act. These exclusions may not exceed 5 years. For these exclusion provisions, CMS proposes to use its discretion to set a duration for the exclusion, up to 5 years, after considering aggravating and mitigating circumstances as described in this proposed rule. By contrast, many other exclusion provisions extend to all Federal health care programs, and do not address the minimum or maximum duration of the exclusion, but instead simply refer to applying the provisions of section 1128A of the Act, or section 1128(c) of the Act for imposition of the exclusion. However, neither section 1128A, nor section 1128(c) addresses the specific duration of an exclusion for any of the title XVIII exclusion provisions described in this proposed rule. Therefore, where the duration of an exclusion is not specifically addressed by statute for a specific exclusion provision, CMS proposes to use its discretion to apply a time period it believes is justified, taking into account appropriate aggravating and mitigating factors as described in this proposed rule.

While several provisions of title 18 of the Act refer on their face only to CMPs, they also make cross-references to section 1128A of the Act, from which we assert that our exclusion authority derives. For example, several provisions within section 1882 of the Act refer to CMPs. Each of these provisions incorporates by reference portions of section 1128A, articulating with precise specificity which provisions of section 1128A are applicable. In each case, this includes section 1128A's exclusion authority found in section 1877, though there the exclusion authority is made even more clear with the term ''exclusion'' being found in the section heading. The applicable provision of section 1128A is that provision's last sentence, explicitly made applicable to all the foregoing, which provides that the Secretary ''may make a determination in the same [CMP]

proceeding to exclude the person from participation in * * * Federal health care programs * * *''

• *Section 402.208, Factors considered in determining whether to exclude, and the length of exclusion.*

[If you choose to comment on issues in this section, please include the caption ''Factors considered'' at the beginning of your comments.]

The statute specifies the grounds for imposition of the various exclusions, but offers little detail regarding the adjudicatory processes inherent in administering them. Instead, the statute vests CMS with broad administrative discretion. We are sensitive to the fact that the nature of the grounds for imposition of exclusions vary widely.

This section describes the specific details of the aggravating or mitigating circumstances that may be considered. This section is based on corresponding sections of 42 CFR parts 1001 and 1003. We note that our application of aggravating and mitigating factors flows both as a natural result of a statutory scheme that contemplates exclusions of varying lengths, as well as the Secretary's rulemaking authority specified in section 1871 of the Act.

• *Section 402.209, Scope and effect of exclusion.*

[If you choose to comment on issues in this section, please include the caption ''Scope and effect'' at the beginning of your comments.]

This section describes the general scope and effect of an exclusion. Generally, an excluded provider or supplier may not directly or indirectly submit claims, or cause claims to be submitted, to the Medicare program. Providers who submit, or cause to be submitted, claims during the course of an exclusion risk other possible sanctions, including criminal and civil liability. Medicare will not pay claims for beneficiaries who elect to see excluded providers, except, perhaps, for the first claim, which will be accompanied by a notification to the beneficiary that the provider/supplier has been excluded from participation in Medicare and that no further Medicare payments will be made on the beneficiary's behalf. This section is based on § 1001.1901. We note that in § 402.209(b)(3), whereas in some cases the maximum exclusion time limit may preclude us from applying the specified prohibited conduct as the basis for denying reinstatement to the Medicare program, the fact that an excluded provider has engaged in such prohibited conduct may give rise to a new exclusion action by the initiating agency (CMS or OIG), the practical effect of which would be to deny reinstatement into the Medicare program.

• *Section 402.210, Notice of exclusion.*

[If you choose to comment on issues in this section, please include the caption ''Notice of exclusion'' at the beginning of your comments.]

This section describes the contents of the respective notices, and, specifically the timing for release of (a) the written notice of intent to exclude (that is, the proposed determination), and (b) the written notice of exclusion. At a minimum, the written notice of intent to exclude provides the person with such information as to the reason why the person is noncompliant with the statute, the length of the proposed exclusion, and instructions for responding to this notice, including providing argument to the exclusion for the agency to consider. The written notice to exclude is sent to the person in the same manner as the written notice of intent to exclude if the agency determines the exclusion is warranted. This notice will also provide the person with information on their appeal rights to the exclusion. This section is based on the notices provided by the OIG in § 1001.2001, § 1001.2002, § 1001.2003, and § 1003.109.

• *Section 402.212, Response to notice of proposed exclusion.*

[If you choose to comment on issues in this section, please include the caption ''Response to notice'' at the beginning of your comments.]

This section describes the general process and procedure for the respondent to follow when presenting an oral or written response to the notice of intent to exclude (that is, the proposed determination). The agency will accept for consideration any supportive information the respondent provides. The agency does not limit nor suggest what type of information should be presented. The burden to present convincing information is left to the discretion of the respondent. This section is based on the process and procedures delineated by the OIG in § 1003.109. However, to encourage timely communication between the respondent and the initiating agency, we have added an additional element whereby the initiating agency will contact the respondent within 15 days of receipt of the respondent's request to establish a mutually agreed upon time and place for the hearing of oral arguments.

• *Section 402.214, Appeal of exclusion.*

[If you choose to comment on issues in this section, please include the caption ''Appeal of exclusion'' at the beginning of your comments.]

This section describes the general appeal process (as referenced in § 1005) for requesting a hearing before an administrative law judge and details the required elements of the written request for appeal. Generally, the elements of the written request must include the basis for the disagreement with the exclusion, the general basis for the defense of the respondent, reasons why the proposed length of exclusion should be modified. This section is based on § 1001.2003 and § 1001.2007.

• *Section 402.300, Request for reinstatement.*

[If you choose to comment on issues in this section, please include the caption ''Request for reinstatement'' at the beginning of your comments.]

In proposed § 402.300, we discuss the request for reinstatement. In § 402.300(a), we describe the written request for reinstatement. We discuss that an excluded person may submit a written request for reinstatement to the initiating agency no sooner than 120 days prior to the terminal date of exclusion as specified in the notice of exclusion. The written request for reinstatement would be required to include documentation demonstrating that the person has met the standards set forth in § 402.302. We also state that obtaining or reactivating a Medicare provider number (or equivalent) would not constitute reinstatement.

Section 402.300(b) discusses that, upon receipt of a written request for reinstatement, the initiating agency may require the person to furnish additional, specific information, and authorization to obtain information from private health insurers, peer review organizations, and others as necessary to determine whether reinstatement is granted.

In § 402.300(c), we discuss that failure to submit a written request for reinstatement and/or to furnish the required information or authorization would result in the continuation of the exclusion, unless the exclusion had been in effect for 5 years. In that case, reinstatement would be automatic.

Section 402.300(d) discusses that, if a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the excluded person would be permitted to request and apply for reinstatement within 120 days of the expiration of the reduced exclusion period. A written request for the reinstatement would include the same standards as noted in paragraph (b) of this section. This section is based on § 1001.3001.

• *Section 402.302, Basis for reinstatement.*

[If you choose to comment on issues in this section, please include the caption ''Basis for reinstatement'' at the beginning of your comments.]

In § 402.302, we discuss that the initiating agency would authorize reinstatement if the agency determined that-

(1) The period of exclusion had expired;

(2) There were reasonable assurances that the types of actions that formed the basis for the original exclusion did not recur and would not recur; and

(3) There is no additional basis under title XVIII of the Act that would justify the continuation of the exclusion.

We are also discussing that the initiating agency would not authorize reinstatement if it determined that submitting claims or causing claims to be submitted or payments to be made by the Medicare program for items or services furnished, ordered, or prescribed, would serve as a basis for denying reinstatement. This section would apply regardless of whether the excluded person had obtained a Medicare provider number (or equivalent), either as an individual or as a member of a group, before being reinstated.

In making a determination regarding reinstatement, the initiating agency would consider—(1) The conduct of the excluded person occurring before the date of the notice of the exclusion, if that conduct was not known to the initiating agency at the time of the exclusion; (2) the conduct of the excluded person after the date of the exclusion; (3) whether all fines and all debts due and owing (including overpayments) to any Federal, State, or local government that relate to Medicare, Medicaid, or, where applicable, any Federal, State, or local health care program were paid in full, or satisfactory arrangements were made to fulfill these obligations; (4) whether the excluded person complied with, or had made satisfactory arrangements to fulfill, all of the applicable conditions of participation or conditions of coverage under the Medicare statutes and regulations; and (5) whether the excluded person had, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by Medicare, Medicaid, and, where applicable, any other Federal health care program, for items or services furnished, ordered, or prescribed, and the conditions under which these actions occurred.

CMS proposes that reinstatement would not be effective until the initiating agency granted the request and provided notice under § 402.304. Reinstatement would be effective as provided in the notice.

A determination for a denial of reinstatement would not be appealable or reviewable except as provided in § 402.306.

We also discuss that an ALJ cannot require reinstatement of an excluded person according to this chapter. The content of this section is based on the criteria provided by the OIG in § 1001.3002.

• *Section 402.304, Approval of request for reinstatement.*

[If you choose to comment on issues in this section, please include the caption ''Approval of request'' at the beginning of your comments.]

In regard to approval of a request for reinstatement (§ 402.304), we discuss that, if the initiating agency would grant a request for reinstatement, the initiating agency would—

(1) Give written notice to the excluded person specifying the date of reinstatement; and

(2) Notify appropriate Federal and State agencies, and, to the extent possible, all others that were originally notified of the exclusion, that the person had been reinstated into the Medicare program.

A determination by the initiating agency to reinstate an excluded person would have no effect if Medicare, Medicaid, or, where applicable, any other Federal health care program had imposed a longer period of exclusion under its own authorities. The content of this section is based on the procedures provided by the OIG in § 1001.3003.

• *Section 402.306, Denial of request for reinstatement.*

[If you choose to comment on issues in this section, please include the caption ''Denial of request'' at the beginning of your comments.]

In § 402.306, Denial of request for reinstatement, we discuss that, if a request for reinstatement is denied, the initiating agency would provide written notice to the excluded person. Within 30 days of the date of this notice, the excluded person could submit to the initiating agency—

(1) Documentary evidence and a written argument challenging the reinstatement denial; or

(2) A written request to present written evidence and/or oral argument to an official of the initiating agency.

If this written request were received timely by the initiating agency, the initiating agency, within 15 days of receipt of the excluded person's request, would initiate communication with the excluded person to establish a time and place for the requested meeting.

In addition, we discuss that, after evaluating any additional evidence submitted by the excluded person (or at the end of the 30-day period described above, if no documentary evidence or written request were submitted), the initiating agency would send written notice to the excluded person either confirming the denial, or approving the reinstatement as set forth in § 402.304. If the initiating agency would elect to uphold its denial decision, the written notice would also indicate that a subsequent request for reinstatement would not be considered until at least 1 year after the date of the written denial notice.

The decision to deny reinstatement would not be subject to administrative review. The content of this section is based on the procedures provided by the OIG in § 1001.3004.

III. Collection of Information Requirements

While this regulation contains information collection requirements, these requirements are exempt from the Paperwork Reduction Act as stipulated in 5 CFR 1320.4(a)(2) (collection of information to conduct a civil or administrative action, investigation, or audit involving an agency against specific individuals or entities).

IV. Response to Comments

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

V. Regulatory Impact Statement

Overall Impact

[If you choose to comment on issues in this section, please include the caption ''Regulatory Impact Statement'' at the beginning of your comments.]

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13132 (August 4, 1999, Federalism), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532).

Executive Order 12866 directs agencies taking ''significant regulatory action'' to reflect consideration of all

costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This proposed rule is not a significant regulatory action as defined by section 3(f) of Executive Order 12866. We believe that there are no significant costs associated with this proposed rule that would impose any mandates on State, local or tribal governments, or the private sector that would result in an expenditure of $100 million in any given year. We expect that all program participants would comply with the statutory and regulatory requirements making unnecessary the imposition of an exclusion from Medicare, Medicaid and, where applicable, other Federal health care programs. Therefore, we do not anticipate more than a *de minimis* economic impact as a result of this proposed rule. Further, any impact that may occur would only affect those limited few individuals or entities that engage in prohibited behavior. We do not anticipate any savings or costs as a result of this proposed rule.

The RFA (15 U.S.C. 603(a)), as modified by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), requires agencies to determine whether the proposed rule would have a significant economic impact on a substantial number of small entities and, if so, to identify in the notice of proposed rulemaking any regulatory options that could mitigate the impact of the proposed regulation on small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and small government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $26 million or less annually. Individuals and States are not included in the definition of a small entity. We believe that any impact as a result of the proposed rule would be minimal, since, as mentioned above, the only individuals or entities affected would be those limited few who engage in prohibited conduct. Since the vast majority of program participants comply with statutory and regulatory requirements, any aggregate economic impact would not be significant.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We do not believe a regulatory impact analysis is required here because, for the reasons stated above concerning our obligations under the RFA and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121), this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We believe that there are no significant costs associated with this technical rule that would impose any mandates on State, local, or tribal governments, or the private sector that would result in an expenditure of $110 million in any given year. As was previously mentioned, since the majority of program participants comply with statutory and regulatory requirements, any aggregate economic impact would not be significant.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this proposed rule would not significantly affect the rights, roles, or responsibilities of the States. This rule would not impose substantial direct requirement costs on State or local governments, preempt State law, or otherwise implicate Federalism.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 402

Administrative practice and procedure, Health facilities, Health professions, Medicaid, Medicare, Penalties.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV, part 402 as set forth below:

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

1. The authority citation for part 402 continues to read as follows:

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

Subpart A—General Provisions

2. In § 402.3, the introductory text is republished and a new definition for ''initiating agency'' is added in alphabetical order to read as follows:

§ 402.3 Definitions.

For purposes of this part:

* * * * *

Initiating agency means whichever agency (CMS or the OIG) initiates the interaction with the person.

* * * * *

3. In part 402, a new subpart C is added to read as follows:

Subpart C—Exclusions

Sec.

Subpart C—Exclusions

§ 402.200 Basis and purpose.

(a) *Basis.* This subpart is based on the sections of the Act that are specified in § 402.1(e).

(b) *Purpose.* This subpart—

(1) Provides for the imposition of an exclusion from the Medicare and Medicaid programs (and, where applicable, other Federal health care programs) against persons that violate the provisions of the Act provided in § 402.1(e) (and further described in § 402.1(c)); and

(2) Sets forth the appeal rights of persons subject to exclusion and the procedures for reinstatement following exclusion.

§ 402.205 Length of exclusion.

The length of exclusion from participation in Medicare, Medicaid, and, where applicable, other Federal health care programs is contingent on the specific violation of the Medicare statute. A full description of the specific violations identified in the sections of

the Act are cross-referenced in the regulatory sections listed in the table below.

(a) In no event will the period of exclusion exceed 5 years for violation of the following sections of the Act:

Social Security Act paragraph	Code of Federal Regulations section
1833(h)(5)(D) in repeated cases.	§ 402.1(c)(1)
1833(q)(2)(B) in repeated cases.	§ 402.1(c)(3)
1834(a)(11)(A)	§ 402.1(c)(4)
1834(a)(18)(B)	§ 402.1(c)(5)
1834(b)(5)(C)	§ 402.1(c)(6)
1834(c)(4)(C)	§ 402.1(c)(7)
1834(h)(3)	§ 402.1(c)(8)
1834(j)(4)	§ 402.1(c)(10)
1834(k)(6)	§ 402.1(c)(31)
1834(l)(6)	§ 402.1(c)(32)
1842(b)(18)(B)	§ 402.1(c)(11)
1842(k)	§ 402.1(c)(12)
1842(l)(3)	§ 402.1(c)(13)
1842(m)(3)	§ 402.1(c)(14)
1842(n)(3)	§ 402.1(c)(15)
1842(p)(3)(B) in repeated cases.	§ 402.1(c)(16)
1848(g)(1)(B) in repeated cases.	§ 402.1(c)(17)
1848(g)(3)(B)	§ 402.1(c)(18)
1848(g)(4)(B)(ii) in repeated cases.	§ 402.1(c)(19)
1879(h)	§ 402.1(c)(23)

(b) For violation of the following sections, there is no maximum time limit for the period of exclusion.

Social Security Act paragraph	Code of Federal Regulations section
1834(a)(17)(c) for a pattern of contacts.	§ 402.1(e)(2)(i)
1834(h)(3) for a pattern of contacts.	§ 402.1(e)(2)(ii)
1877(g)(5)	§ 402.1(c)(22)
1882(a)(2)	§ 402.1(c)(24)
1882(p)(8)	§ 402.1(c)(25)
1882(p)(9)(C)	§ 402.1(c)(26)
1882(q)(5)(C)	§ 402.1(c)(27)
1882(r)(6)(A)	§ 402.1(c)(28)
1882(s)(4)	§ 402.1(c)(29)
1882(t)(2)	§ 402.1(c)(30)

(c) For a person excluded under any of the grounds specified in paragraph (a) of this section, notwithstanding any other requirements in this section, reinstatement occurs—

(1) At the expiration of the period of exclusion, if the exclusion was imposed for a period of 5 years; or

(2) At the expiration of 5 years from the effective date of the exclusion, if the exclusion was imposed for a period of less than 5 years and the initiating agency did not receive the appropriate written request for reinstatement as specified in § 402.300.

§ 402.208 Factors considered in determining whether to exclude, and the length of exclusion.

(a) *General factors.* In determining whether to exclude a person and the length of exclusion, the initiating agency considers the following:

(1) The nature of the claims and the circumstances under which they were presented.

(2) The degree of culpability, the history of prior offenses, and the financial condition of the person presenting the claims.

(3) The total number of acts in which the violation occurred.

(4) The dollar amount at issue (Medicare Trust Fund dollars and/or beneficiary out-of-pocket expenses).

(5) The prior history of the person insofar as its willingness or refusal to comply with requests to correct said violations.

(6) Any other facts bearing on the nature and seriousness of the person's misconduct.

(7) Any other matters that justice may require.

(b) *Criteria to be considered.* As a guideline for taking into account the general factors listed in paragraph (a) of this section, the initiating agency may consider any one or more of the circumstances listed in paragraphs (b)(1) and (b)(2) of this section, as applicable. The respondent, in his or her written response to the notice of intent to exclude (that is, the proposed exclusion), may provide information concerning potential mitigating circumstances:

(1) *Aggravating circumstances.* An aggravating circumstance may be any of the following:

(i) The services or incidents were of several types and occurred over an extended period of time.

(ii) There were numerous services or incidents, or the nature and circumstances indicate a pattern of claims or requests for payment or a pattern of incidents, or whether a specific segment of the population was targeted.

(iii) Whether the person was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for health care items or services at any time before the incident or whether the person presented any claim or made any request for payment that included an item or service subject to a determination under § 402.1.

(iv) There is proof that the person engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs and in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings at section 1128A(c)(1) of the Act, does not apply to proof of other wrongful conducts as an aggravating circumstance.

(v) The wrongful conduct had an adverse impact on the financial integrity of the Medicare program or its beneficiaries.

(vi) The person was the subject of an adverse action by any other Federal, State, or local government agency or board, and the adverse action is based on the same set of circumstances that serves as a basis for the imposition of the exclusion.

(vii) The noncompliance resulted in a financial loss to the Medicare program of at least $5,000.

(viii) The number of instances for which full, accurate, and complete disclosure was not made as required, or provided as requested, and the significance of the undisclosed information.

(2) *Mitigating circumstances.* A mitigating circumstance may be any of the following:

(i) All incidents of noncompliance were few in nature and of the same type, occurred within a short period of time, and the total amount claimed or requested for the items or services provided was less than $1,500.

(ii) The claim(s) or request(s) for payment for the item(s) or service(s) provided by the person were the result of an unintentional and unrecognized error in the person's process for presenting claims or requesting payment, and the person took corrective steps promptly after the error was discovered.

(iii) Previous cooperation with a law enforcement or regulatory entity resulted in convictions, exclusions, investigations, reports for weaknesses, or civil money penalties against other persons.

(iv) Alternative sources of the type of health care items or services furnished by the person are not available to the Medicare population in the person's immediate area.

(v) The person took corrective action promptly upon learning of the noncompliance from the person's employee or contractor, or by the Medicare contractor.

(vi) The person had a documented mental, emotional, or physical condition before or during the commission of the noncompliant act(s) and that condition reduces the person's culpability for the acts in question.

(vii) The completeness and timeliness of refunding to the Medicare Trust Fund or Medicare beneficiaries any inappropriate payments.

(viii) The degree of culpability of the person in failing to provide timely and complete refunds.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interest of justice, those circumstances require either a reduction or increase in the sanction in order to ensure achievement for the purposes of this subpart.

(c) *Limitations.* (1) The standards set forth in this section are binding on the person, except to the extent that their application results in an imposition of an amount that exceeds the limits imposed by the United States Constitution.

(2) Nothing in this section limits the authority of the initiating agency to settle any issue or case as provided by § 402.17, or to compromise any penalty and assessment as provided by § 402.115.

§ 402.209 Scope and effect of exclusion.

(a) *Scope of exclusion.* Under this title, persons may be excluded from the Medicare, Medicaid, and, where applicable, any other Federal health care programs.

(b) *Effect of exclusion on a person(s).* (1) Unless and until an excluded person is reinstated into the Medicare program, no payment is made by Medicare, Medicaid, and, where applicable, any other Federal health care programs for any item or service furnished by the excluded person or at the direction or request of the excluded person when the person furnishing the item or service knew or had reason to know of the exclusion, on or after the effective date of the exclusion as specified in the notice of exclusion.

(2) An excluded person may not take assignment of a Medicare beneficiary's claim on or after the effective date of the exclusion.

(3) An excluded person that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act. In addition, submission of claims, or the causing of claims to be submitted for items or services furnished, ordered, or prescribed, by an excluded person may serve as the basis for denying reinstatement to the Medicare program.

(c) *Exceptions to paragraph (b)(1) of this section.* (1) If a Medicare beneficiary or other person (including a supplier) submits an otherwise payable claim for items or services furnished by an excluded person, or under the medical direction or on the request of an excluded person after the effective date of the exclusion, CMS pays the first claim submitted by the beneficiary or other person and immediately notify the claimant of the exclusion. CMS does not pay a beneficiary or other person (including a supplier) for items or services furnished by, or under the medical direction of, an excluded person, more than 15 days after the date on the notice to the beneficiary or other person (including a supplier), or after the effective date of the exclusion, whichever is later.

(2) Notwithstanding the other provisions of this section, payment may be made for certain emergency items or services furnished by an excluded person, or under the medical direction or on the request of an excluded person during the period of exclusion. To be payable, a claim for the emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services, specifying the nature of the emergency and the reason that the items or services were not furnished by a person eligible to furnish or order the items or services. No claim for emergency items or services is payable if those items or services were provided by an excluded person that, through employment, contractual, or under any other arrangement, routinely provides emergency health care items or services.

§ 402.210 Notice of exclusion.

(a) *Notice of proposed determination.* When the initiating agency proposes to exclude a person from participation in a Federal health care program in accordance with this part, notice of the intent to exclude must be given in writing, and delivered or sent by certified mail, return receipt requested. The written notice must include, at a minimum, the following:

(1) Reference to the statutory basis for the exclusion.

(2) A description of the claims, requests for payment, or incidents for which the exclusion is proposed.

(3) The reason why those claims, requests for payments, or incidents subject the person to an exclusion.

(4) The length of the proposed exclusion.

(5) A description of the circumstances that were considered when determining the period of exclusion.

(6) Instructions for responding to the notice, including a specific statement of the person's right to submit documentary evidence and a written response concerning whether the exclusion is warranted, and any related issues such as potential mitigating circumstances. The notice must specify that—

(i) The person has the right to request an opportunity to present oral argument to an official of the initiating agency.

(ii) The request for oral argument must be submitted within 30 days of the receipt of the notice of intent to exclude.

(7) If a person fails, within the time permitted under § 402.212, to exercise the right to respond to the notice of intent to exclude, the initiating agency may initiate actions for the imposition of the exclusion.

(b) *Notice of exclusion.* Once the initiating agency determines that an exclusion is warranted, a written notice of exclusion is sent to the person in the same manner as described in paragraph (a) of this section. The exclusion is effective 20 days from the date of the notice. The written notice must include, at a minimum, the following:

(1) The basis for the exclusion.

(2) The length of the exclusion and, when applicable, the factors considered in setting the length.

(3) The effect of exclusion.

(4) The earliest date on which the initiating agency considers a request for reinstatement.

(5) The requirements and procedures for reinstatement.

(6) The appeal rights available to the excluded person under part 1005 of this title.

(c) *Amendment to the notice.* No later than 15 days before the final exhibit exchanges required under § 1005.8 of this title, the initiating agency may amend the notice of exclusion if information becomes available that justifies the imposition of a period of exclusion other than the one proposed in the original written notice.

§ 402.212 Response to notice of proposed exclusion.

(a) A person that receives a notice of intent to exclude (that is, the proposed determination) as described in § 402.210, may present to the initiating agency a written response arguing whether the proposed exclusion is warranted, and may present additional supportive documentation. The person must submit this response within 60 days of the receipt of notice. The initiating agency reviews the materials presented and initiate a response to the person regarding the argument presented, and any changes to the determination, if appropriate.

(b) The person is also afforded an opportunity to be heard by the initiating agency in order to present oral argument

concerning whether the proposed exclusion is warranted and any related matters. The person must submit this request within 60 days of the receipt of notice. Within 15 days of receipt of the person's request, the initiating agency initiates communication with the person to establish a mutually agreed upon time and place for the requested hearing.

§ 402.214 Appeal of exclusion.

(a) The procedures in part 1005 of this title apply to all appeals of exclusions. References to the Inspector General in that part apply to the initiating agency.

(b) A person excluded under this subpart may file a request for a hearing before an administrative law judge (ALJ) only on the issues of whether—

(1) The basis for the imposition of the exclusion exists; and

(2) The duration of the exclusion is unreasonable.

(c) When the initiating agency imposes an exclusion for a period of 1 year or less, paragraph (b)(2) of this section does not apply.

(d) The excluded person must file a request for a hearing within 60 days from the receipt of notice of exclusion. The effective date of an exclusion is not delayed beyond the date stated in the notice of exclusion simply because a request for a hearing is timely filed (see paragraph (g) of this section).

(e) A timely filed written request for a hearing must include—

(1) A statement as to the specific issues or findings of fact and conclusions of law in the notice of exclusion with which the person disagrees.

(2) Basis for the disagreement.

(3) The general basis for the defenses that the person intends to assert.

(4) Reasons why the proposed length of exclusion should be modified.

(5) Reasons, if applicable, why the health or safety of Medicare beneficiaries receiving items or services does not warrant the exclusion going into or remaining in effect before the completion of an ALJ proceeding in accordance with part 1005 of this title.

(f) If the excluded person does not file a written request for a hearing as provided in paragraph (d) of this section, the initiating agency notifies the excluded person, by certified mail, return receipt requested, that the exclusion goes into effect or continues in accordance with the notice of exclusion. The excluded person has no right to appeal the exclusion other than as described in this section.

(g) If the excluded person files a written request for a hearing, and asserts in the request that the health or safety of Medicare beneficiaries does not warrant the exclusion going into or remaining in effect before completion of an ALJ hearing, then the initiating agency may make a determination as to whether the exclusion goes into effect or continues pending the outcome of the ALJ hearing.

§ 402.300 Request for reinstatement.

(a) An excluded person may submit a written request for reinstatement to the initiating agency no sooner than 120 days prior to the terminal date of exclusion as specified in the notice of exclusion. The written request for reinstatement must include documentation demonstrating that the person has met the standards set forth in § 402.302. Obtaining or reactivating a Medicare provider number (or equivalent) does not constitute reinstatement.

(b) Upon receipt of a written request for reinstatement, the initiating agency may require the person to furnish additional, specific information, and authorization to obtain information from private health insurers, peer review organizations, and others as necessary to determine whether reinstatement is granted.

(c) Failure to submit a written request for reinstatement and/or to furnish the required information or authorization results in the continuation of the exclusion, unless the exclusion has been in effect for 5 years. In this case, reinstatement is automatic.

(d) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the excluded person may request and apply for reinstatement within 120 days of the expiration of the reduced exclusion period. A written request for the reinstatement includes the same standards as noted in paragraph (b) of this section.

§ 402.302 Basis for reinstatement.

(a) The initiating agency authorizes reinstatement if it determines that—

(1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion did not recur and will not recur; and

(3) There is no additional basis under title XVIII of the Act that justifies the continuation of the exclusion.

(b) The initiating agency does not authorize reinstatement if it determines that submitting claims or causing claims to be submitted or payments to be made by the Medicare program for items or services furnished, ordered, or prescribed, may serve as a basis for denying reinstatement. This section applies regardless of whether the excluded person has obtained a Medicare provider number (or equivalent), either as an individual or as a member of a group, before being reinstated.

(c) In making a determination regarding reinstatement, the initiating agency considers the following—

(1) Conduct of the excluded person occurring before the date of the notice of the exclusion, if that conduct was not known to the initiating agency at the time of the exclusion;

(2) Conduct of the excluded person after the date of the exclusion;

(3) Whether all fines and all debts due and owing (including overpayments) to any Federal, State, or local government that relate to Medicare, Medicaid, or, where applicable, any Federal, State, or local health care program are paid in full, or satisfactory arrangements are made to fulfill these obligations;

(4) Whether the excluded person complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or conditions of coverage under the Medicare statutes and regulations; and

(5) Whether the excluded person has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by Medicare, Medicaid, and, where applicable, any other Federal health care program, for items or services furnished, ordered, or prescribed, and the conditions under which these actions occurred.

(d) Reinstatement is not effective until the initiating agency grants the request and provide notices under § 402.304. Reinstatement is effective as provided in the notice.

(e) A determination for a denial of reinstatement is not appealable or reviewable except as provided in § 402.306.

(f) An ALJ may not require reinstatement of an excluded person in accordance with this chapter.

§ 402.304 Approval of request for reinstatement.

(a) If the initiating agency grants a request for reinstatement, the initiating agency—

(1) Gives written notice to the excluded person specifying the date of reinstatement; and

(2) Notifies appropriate Federal and State agencies, and, to the extent possible, all others that were originally notified of the exclusion, that the person is reinstated into the Medicare program.

(b) A determination by the initiating agency to reinstate an excluded person has no effect if Medicare, Medicaid, or,

where applicable, any other Federal health care program has imposed a longer period of exclusion under its own authorities.

§ 402.306 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, the initiating agency provides written notice to the excluded person. Within 30 days of the date of this notice, the excluded person may submit to the initiating agency—

(1) Documentary evidence and a written argument challenging the reinstatement denial; or

(2) A written request to present written evidence and/or oral argument to an official of the initiating agency.

(b) If a written request as described in paragraph (a)(2) of this section is received timely by the initiating agency, the initiating agency, within 15 days of receipt of the excluded person's request, initiates communication with the excluded person to establish a time and place for the requested meeting.

(c) After evaluating any additional evidence submitted by the excluded person (or at the end of the 30-day period described in paragraph (a) of this section, if no documentary evidence or written request is submitted), the initiating agency sends written notice to the excluded person either confirming the denial, or approving the reinstatement in the manner set forth in § 402.304. If the initiating agency elects to uphold its denial decision, the written notice also indicates that a subsequent request for reinstatement will not be considered until at least 1 year after the date of the written denial notice.

(d) The decision to deny reinstatement is not subject to administrative review.

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

Dated: September 5, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare and Medicaid Services.

Dated: March 15, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 04–16791 Filed 7–22–04; 8:45 am]

BILLING CODE 4120–01–U

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

RIN 1018–AT40

2004–2005 Refuge-Specific Hunting and Sport Fishing Regulations; Correction

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Correction to proposed regulations.

SUMMARY: This document contains corrections to the proposed regulations which were published June 30, 2004, (69 FR 39552). The proposed regulations related to the addition of 10 refuges and wetland management districts to the list of areas open for hunting and/or sport fishing programs and increase the activities available at 7 other refuges. We also develop pertinent refuge-specific regulations for those activities and amend certain regulations on other refuges that pertain to migratory game bird hunting, upland game hunting, big game hunting, and sport fishing for the 2004–2005 season.

DATES: We must receive your comments on or before July 30, 2004.

FOR FURTHER INFORMATION CONTACT: Leslie Marler, (703) 358–2397.

SUPPLEMENTARY INFORMATION:

Background

We issue refuge-specific regulations when we open wildlife refuges to migratory game bird hunting, upland game hunting, big game hunting, or sport fishing. These regulations list the wildlife species that you may hunt or fish, season, bag or creel limits, methods of hunting or sport fishing, descriptions of areas open to hunting or sport fishing, and other provisions as appropriate. The regulations that are the subject of these corrections increase opportunity to hunt upland game only at Big Oaks National Wildlife Refuge in the State of Indiana.

Need for Correction

We provided information in the **SUPPLEMENTARY INFORMATION** section indicating that Big Oaks National Wildlife Refuge was opening for the first time to migratory bird and upland game. The refuge is not opening to migratory bird hunting. The ''X'' will be removed from the chart in the **SUPPLEMENTARY INFORMATION** on page 39553 under migratory bird hunting, and the amendatory text under § 32.33 for that refuge should continue to reflect that migratory bird hunting is reserved and that we are opening to upland game hunting.

Correction of Publication

Accordingly, the publication on June 30, 2004, of the proposed regulations is corrected as follows:

PART 32—[CORRECTED]

§ 32.33 [Corrected]

1. Direction #15 on page 39595 in the third column is corrected by adding instruction c. as follows: c. Revising paragraph B. of ''Big Oaks National Wildlife Refuge.''

2. The listing for Big Oaks National Wildlife Refuge should be inserted on page 39595 in the third column in § 32.33 before the listing for ''Muscatatuck National Wildlife Refuge''. The listing reads as follows:

Big Oaks National Wildlife Refuge

* * *

B. Upland Game Hunting. We allow hunting of squirrel in accordance with State regulations subject to the following condition: We require a refuge permit.

* * * * *

Dated: July 19, 2004.

Susan Wilkinson,

Fish and Wildlife Service, Federal Register Liaison.

[FR Doc. 04–16763 Filed 7–22–04; 8:45 am]

BILLING CODE 4310–55–P