

*E. Executive Order 13132: Federalism*

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This action merely proposes to determine that the Imperial County area has not attained by its applicable attainment date, and to reclassify the Imperial County area as a moderate ozone nonattainment area and to adjust applicable deadlines. Thus, Executive Order 13132 does not apply to this rule.

*F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This action does not have "Tribal implications" as specified in Executive Order 13175. This action merely proposes to determine that the Imperial County area has not attained by its applicable attainment date, and to reclassify the Imperial County area as a moderate ozone nonattainment area and to adjust applicable deadlines. The Clean Air Act and the Tribal Authority Rule establish the relationship of the Federal government and Tribes in developing plans to attain the NAAQS, and this rule does nothing to modify that relationship. Thus, Executive Order 13175 does not apply to this rule.

*G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks*

Executive Order 13045, "Protection of Children From Environmental Health

and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have disproportionate effects on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This action is not subject to Executive Order 13045 because it is not economically significant as defined in E.O. 12866, and because the Agency does not have reason to believe the environmental health risks or safety risks addressed by this rule present a disproportionate risk to children. This action merely proposes to determine that the Imperial Valley area has not attained the standard by the applicable attainment date, and to reclassify the Imperial Valley area as a moderate ozone nonattainment area and to adjust applicable deadlines.

*H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211, "Actions That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer Advancement Act*

As noted in the proposed rule, section 12(d) of the National Technology Transfer Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS. This action merely proposes to determine that the Imperial County area has not attained by the applicable attainment date, and to reclassify the Imperial County area as a moderate ozone nonattainment area and to adjust applicable deadlines. Therefore, EPA

did not consider the use of any voluntary consensus standards.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This action merely proposes to determine that the Imperial County area did not attain the 8-hour ozone NAAQS by the applicable attainment date, to reclassify the Imperial County area as a moderate ozone nonattainment area and to adjust applicable deadlines.

**List of Subjects in 40 CFR Part 81**

Environmental protection, Air pollution control.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: November 14, 2007.

**Laura Yoshii,**

*Acting Regional Administrator, Region IX.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Part 455**

[CMS-2271-P]

RIN 0938-AO97

**Medicaid Integrity Program; Eligible Entity and Contracting Requirements for the Medicaid Integrity Audit Program**

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

**ACTION:** Proposed rule.

**SUMMARY:** Section 1936 of the Social Security Act (the Act) (as added by section 6034 of the Deficit Reduction Act of 2005 (DRA)) established the Medicaid Integrity Program to promote the integrity of the Medicaid program by requiring CMS to enter into contracts with eligible entities to: Review the actions of individuals or entities furnishing items or services (whether on a fee-for-service, risk, or other basis) for which payment may be made under an approved State plan and/or any waiver of such plan approved under section 1115 of the Act; audit claims for payment of items or services furnished, or administrative services rendered, under a State plan; identify overpayments to individuals or entities receiving Federal funds; and educate providers of services, managed care entities, beneficiaries, and other individuals with respect to payment integrity and quality of care.

This proposed rule would provide requirements for an eligible entity to enter into a contract under the Medicaid integrity audit program. The proposed rule would also establish the contracting requirements for eligible entities. The requirements would include procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement; competitive procedures to be used; and procedures under which a contract may be renewed.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 24, 2007.

**ADDRESSES:** In commenting, please refer to file code CMS-2271-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2271-P, P.O. Box 8010, Baltimore, MD 21244-1850. Please allow sufficient time for

mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2271-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-8148 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.) Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

*Submission of comments on paperwork requirements.* You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

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

**FOR FURTHER INFORMATION CONTACT:** Barbara Rufo, 410-786-5589 or Crystal High, 410-786-8366.

**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-2271-P.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments

received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, 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 1-800-743-3951.

**I. Background**

*A. Current Law*

States and the Federal government share in the responsibility for safeguarding Medicaid program integrity. States must comply with Federal requirements designed to ensure that Medicaid funds are properly spent (or recovered, when necessary). CMS is the primary Federal agency responsible for providing oversight of States' activities and facilitating their program integrity efforts.

*B. Medicaid Integrity Program*

Section 6034 of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109-171, enacted on February 8, 2006) added a new section 1936 to the Act that established the Medicaid Integrity Program, referenced as the "Program" hereafter, to combat Medicaid fraud and abuse. The Program is intended to identify, recover, and prevent Medicaid overpayments. It is also intended to support the efforts of the State Medicaid agencies through a combination of oversight and technical assistance.

Although individual States work to ensure the integrity of their respective Medicaid programs, the Program represents CMS' first national strategy to detect and prevent Medicaid fraud and abuse. The Program would provide CMS with the ability to more directly ensure the accuracy of Medicaid payments and to deter those who would exploit the program.

Section 6034 of the DRA amends title XIX of the Act by redesignating the former section 1936 as section 1937; and inserting the new 1936 "Medicaid Integrity Program." The new section 1936 states the Secretary will promote the integrity of the Medicaid program by entering into contracts with eligible

entities to carry out the following activities:

Review of actions of individuals or entities furnishing items or services (whether on a fee-for-service, risk, or other basis) for which payment may be made under the State plan approved under title XIX (or under any waiver of such plan approved under section 1115 of the Act) to determine whether fraud, waste, or abuse has occurred, or is likely to occur, or whether such actions have a potential for resulting in an expenditure of funds under title XIX in a manner which is not intended under the provisions of title XIX.

Audit of claims for payment for items or services furnished, or administrative services rendered, under a State plan under title XIX, including cost reports, consulting contracts, and risk contracts under section 1903(m) of title XIX.

Identification of overpayments to individuals or entities receiving Federal funds under title XIX.

Education of providers of services, managed care entities, beneficiaries, and other individuals with respect to payment integrity and quality of care.

Section 1936 of the Act also mandates that the Secretary will by regulation establish procedures which will include the following:

- Procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement.

- Competitive procedures to be used when entering into new contracts under this section; when entering into contracts that may result in the elimination of responsibilities under section 202(b) of the Health Insurance Portability and Accountability Act of 1996; and any other time considered appropriate by the Secretary.

- Procedures under which a contract under this section may be renewed without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

CMS has determined not to address in this proposed rule the above bullet that references the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We have determined that section 202(b) of HIPAA addressed certain Medicare contracting issues which, because of structural differences between the Medicare and Medicaid programs, such as the fact that the Federal government does not utilize carriers or fiscal intermediaries in the Federal administration of the Medicaid program, do not pertain to the Medicaid contracting environment. Moreover, we

have also determined that the provisions of the Social Security Act established by section 202(b) of HIPAA have since been repealed by section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. We invite public comment on this approach.

## II. Provisions of the Proposed Regulations

In accordance with section 1936 of the Act, we would, through this proposed rule at new subpart D, § 455.200, define eligible entities that may enter into contracts under this Program to carry out activities as described above as well as establish contracting requirements for such entities. The approach taken in this proposed rule is consistent with a similar approach taken in the Medicare Integrity Program, which has very similar statutory requirements.

### A. Basis and Scope

Following the mandate of section 1936 of the Act, this proposed rule, in subpart C, § 455.200(b), Basis and Scope, would add additional language stating that part of the Medicaid Integrity Program's scope is to carry out the Medicaid integrity audit functions. Subpart C would apply to entities that seek to compete for, or receive an award of, a contract under section 1936 of the Act.

### B. Definition of Eligible Entity

In accordance with section 1936 of the Act, the proposed § 455.230 would describe that an eligible entity may enter into a Medicaid integrity audit program contract if it:

- Demonstrates the capability to carry out the contractor activities;

- In carrying out such activities, agrees to cooperate with the Inspector General of the Department of Health and Human Services, the Attorney General, and other law enforcement agencies, as appropriate, in the investigation and deterrence of fraud and abuse in relation to title XIX and in other cases arising out of such activities;

- Maintains an appropriate written code of conduct and compliance policies that include, without limitation, an enforced policy on employee conflicts of interest;

- Complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement; and,

- Meets other requirements the Secretary may impose.

It would not be possible to identify in this rule every possible contractor requirement that may appear in a future

solicitation. In order to permit maximum flexibility to tailor our contractor eligibility requirements to specific solicitations while satisfying section 1936 of the Act, any additional requirements would be contained in the applicable solicitation.

In addition, we propose that a contractor under section 1936 of the Act may perform any or all of the contractor functions as are listed and described under "contractor functions."

### C. Contractor Functions

In accordance with section 1936 of the Act, section 455.232 would identify the functions of the Medicaid integrity audit program contractor as follows:

- Review of the actions of individuals or entities furnishing items or services (whether on a fee-for-service, risk, or other basis) for which payment may be made under a State plan approved under title XIX (or under any waiver of such plan approved under section 1115 of the Act) to determine whether fraud, waste, or abuse has occurred, is likely to occur, or whether such actions have the potential for resulting in an expenditure of funds under title XIX in a manner which is not intended under the provisions of title XIX.

- Audit of claims for payment for items or services furnished, or administrative services rendered, under a State plan under title XIX, including (a) cost reports; (b) consulting contracts; and (c) risk contracts under section 1903(m) of the Act.

- Identification of overpayments to individuals or entities receiving Federal funds under title XIX.

- Educating providers of service, managed care entities, beneficiaries, and other individuals with respect to payment integrity and quality of care.

### D. Competitive Procedures and Requirements

Section 455.234 would specify that a Medicaid integrity audit contract will be awarded in accordance with 48 CFR chapters 1 and 3 (the Federal Acquisition Regulation (FAR) and the Health and Human Services Acquisition Regulation, respectively), this subpart, and all other applicable laws and regulations. In accordance with section 1936 of the Act, we would specify that these competitive procedures and requirements will be used as follows:

- When entering into new contracts under this section.

- At any other time considered appropriate by the Secretary. In addition, we propose to specify in § 455.234 that an entity must meet the eligibility requirements established in proposed § 455.230 to become eligible to

be awarded a Medicaid integrity audit program contract.

#### E. Renewal of Contracts

Renewing a contract, when appropriate, results in continuity for both CMS and the contractor and can be in the best interest of the Program. If a contract is not renewed, we must ensure that sufficient time is provided to transfer and reassign the Medicaid integrity audit program functions as described in this subpart. Therefore, in § 455.236, we would specify that an initial contract term will be defined in the Medicaid integrity audit program contract and a renewal clause may be included in the contract. We also would specify that we may, but are not required to, renew the Medicaid integrity audit program contracts without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

In accordance with sections 1936(c)(2) and (3) of the Act, we would specify in § 455.236(b) that we may renew a Medicaid integrity audit program contract without competition if the contractor continues to meet all requirements of the proposed subpart C, the contractor meets or exceeds the performance requirements established in its current contract, and it is in the best interest of the government.

At § 455.236(a) we propose that if CMS does not renew a contract, the contract will end in accordance with its terms. The contractor will not have a right to a hearing or judicial review regarding our renewal decision.

#### F. Conflict of Interest

This proposed rule would establish at § 455.238 the process for identifying, evaluating, and resolving conflicts of interest as mandated by sections 1936(c)(2) and (3) of the Act. Establishing such a process would ensure that business arrangements of potential contractors do not inhibit competition between providers, suppliers, or other types of business related to the Medicaid program, or have the potential of harming the government's interests.

We would adhere to the requirements of the FAR's organizational conflict of interest requirements found at 48 CFR subpart 9.5 when soliciting contracts for the Medicaid integrity audit program. Due to the sensitive nature of the work to be performed under the contract, the need to preserve public trust, and the history of fraud and abuse in the Medicaid program, we would maintain the presumption that each prospective

contract involves a significant potential organizational conflict of interest.

Prior to awarding a Medicaid integrity audit program contract, the contracting officer will draft an organizational conflict of interest clause specific to the contractor for inclusion in the contract. In general we would not enter into a Medicaid integrity audit program contract with an offeror or an existing Medicaid integrity audit program contractor that has been determined to have, or that has the potential for, an unresolved organizational conflict of interest.

At § 455.238(a), we would specify that an offeror for a Medicaid integrity audit program contract is, and the Medicaid integrity audit program contractors are, subject to the conflict of interest standards and requirements of the FAR organizational conflict of interest guidance found at 48 CFR subpart 9.5, and the requirements and standards that are contained in each individual contract awarded to perform the functions described under section 1936 of the Act.

In § 455.238(b), we would include post award discussions. We would specify that we consider that a post award conflict of interest has developed if, during the term of the contract, the contractor or any of its employees, agents, or subcontractors received, solicited, or arranged to receive any fee, compensation, gift, payment of expenses, offer of employment, or any other thing of value from any entity that is reviewed, audited, investigated, or contacted during the normal course of performing activities under a Medicaid integrity audit program contract. We incorporate the definition of "gift" from the Standards of Ethical Conduct for Employees of the Executive Branch [5 CFR 2635.203(b)].

In addition, in § 455.238(c) we propose that if CMS has determined that a contractor's activities are creating a conflict, then a conflict of interest has occurred during the term of the contract. If such an event has occurred, among other actions, we may, as we deem appropriate:

- Not renew the contract for an additional term;
- Modify the contract; or
- Terminate the contract.

The proposed provisions do not describe all of the information that may be required, or the level of detail that would be required. We wish to have the flexibility to tailor the requirements to each individual procurement. Because potential offerors may have questions about whether information submitted in response to a solicitation, including information regarding potential conflicts

of interest, may be redisclosed under the Freedom of Information Act (FOIA), we provide the following information.

To the extent that a proposal containing information is submitted to us as a requirement of a competitive solicitation under 41 U.S.C. Chapter 4, Subchapter IV, we would withhold the proposal when requested under the FOIA. This withholding is based upon 41 U.S.C. 253b(m). However, there is one exception to this policy. It involves any proposal that is set forth or incorporated by reference in the contract awarded to the proposing offeror. Such a proposal may not receive categorical protection. Rather, we would withhold, under 5 U.S.C. 552(b)(4), information within the proposal that is required to be submitted that constitutes trade secrets or commercial or financial information that is privileged or confidential, provided the criteria established by *National Parks & Conservation Association v. Morton*, 498 F.2d 765 (D.C. Cir. 1974), as applicable, are met. For any such proposal, we would follow pre-disclosure notification procedures set forth at 45 CFR 5.65(d).

Any proposal containing the information submitted to us under an authority other than 41 U.S.C. Chapter 4, Subchapter IV, and any information submitted independent of a proposal would be evaluated solely on the criteria established by *National Parks & Conservation Association v. Morton* and other appropriate authorities to determine if the proposal in whole or in part contains trade secrets or commercial or financial information that is privileged or confidential and protected from disclosure under 5 U.S.C. 552(b)(4). Again, for any such proposal, we would follow pre-disclosure notification procedures set forth at 45 CFR 5.65(d) and will also invoke 5 U.S.C. 552(b)(6) to protect information that is of a highly sensitive personal nature. It should be noted that the protection of proposals under FOIA does not preclude us from releasing contractor proposals when necessitated by law, such as in the case of a lawful subpoena.

#### G. Conflict of Interest Resolution

We propose to describe at § 455.240(a) how a conflict of interest may be resolved. We would state that a Conflicts of Interest Review Board may be established and convened at any time during the term of the contract, as well as during the procurement process, to evaluate and assist the contracting officer in resolving conflicts of interest. We would determine when or if the Board will be convened. We would, at § 455.240(b), specify that a resolution of

an organizational conflict of interest is a determination by the contracting officer that:

- The conflict is mitigated;
- The conflict precludes award of a contract to the offeror;
- The conflict requires that we modify an existing contract;
- The conflict requires that we terminate an existing contract; or
- It is in the best interest of the government to contract with the offeror or contractor even though the conflict of interest exists.

An offeror's or contractor's method of mitigating conflicts of interest will be evaluated on a case by case basis. We have provided examples of methods an offeror or contractor may use to mitigate organizational conflicts of interest. The examples are not an all-inclusive list of possible methods of mitigation nor are we obligated to approve a mitigation method that uses one of the provided examples. Possible methods of mitigation include:

- Divestiture, or reduction in the amount, of the financial relationship the organization has in another organization to a level acceptable to us and appropriate for the situation.
- If shared responsibilities create the conflict, a plan, subject to our approval, to separate lines of business and management or critical staff from work on the Medicaid integrity audit program contract.
- If the conflict exists because of the amount of financial dependence upon the Federal Government, negotiating a phasing out of other contracts or grants that continue in effect at the start of the Medicaid integrity audit program contract.
- If the conflict exists because of the financial relationships of individuals within the organization, divestiture of the relationships by the individual involved.
- If the conflict exists because of an individual's indirect interest, divestiture of the interest to levels acceptable to us or removal of the individual from the work under the Medicaid integrity audit program contract.

By providing a process for the identification, evaluation, and resolution of conflicts of interest, we not only protect the government's interests but help to ensure that the contractors do not hinder competition in their service areas by misusing their position as a Medicaid integrity audit program contractor.

### III. Collection of Information Requirements

This document does not impose any information collection and

recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

### IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, 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, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

### V. Regulatory Impact Statement

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

We have examined the impact of this 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), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule would not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6.5 million to \$31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory

impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this 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 whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This proposed rule would not exceed this established threshold level. This rule would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation would not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

### List of Subjects in Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR chapter IV as set forth below:

### PART 455—PROGRAM INTEGRITY; MEDICAID

1. The authority citation for part 455 continues to read as follows:

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

2. A new § 455.200 is added to read as follows:

**§ 455.200 Basis and scope.**

(a) *Statutory basis.* This subpart implements section 1936 of the Act that establishes the Medicaid Integrity Program, under which the Secretary will promote the integrity of the program by entering into contracts with eligible entities to carry out the activities under this subpart C.

(b) *Scope.* This subpart provides for the limitation on a contractor's liability to carry out a contract under the Medicaid Integrity Program and to carry out the Medicaid integrity audit program functions.

3. A new § 455.230 is added to read as follows:

**§ 455.230 Eligibility requirements.**

CMS may enter into a contract with an entity to perform the activities described at § 455.232, if it meets the following conditions:

(a) The entity has demonstrated capability to carry out the activities described below.

(b) In carrying out such activities, the entity agrees to cooperate with the Inspector General of the Department of Health and Human Services, the Attorney General, and other law enforcement agencies, as appropriate, in the investigation and deterrence of fraud and abuse in relation to Title XIX of the Social Security Act and in other cases arising out of such activities.

(c) Maintains an appropriate written code of conduct and compliance policies that include, without limitation, an enforced policy on employee conflicts of interest.

(d) The entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement.

(e) The entity meets such other requirements the Secretary may impose.

4. A new § 455.232 is added to read as follows:

**§ 455.232 Medicaid integrity audit program contractor functions.**

The contract between CMS and a Medicaid integrity audit program contractor specifies the functions the contractor will perform. The contract may include any or all of the following functions:

(a) Review of the actions of individuals or entities furnishing items or services (whether on a fee-for-service, risk, other basis) for which payment may be made under a State Plan approved under title XIX of the Act (or under any waiver of such plan approved under section 1115 of the Act) to determine whether fraud, waste, or abuse has occurred, is likely to occur, or whether such actions have the potential

for resulting in an expenditure of funds under title XIX in a manner which is not intended under the provisions of title XIX.

(b) Auditing of claims for payment for items or services furnished, or administrative services rendered, under a State Plan under title XIX to ensure proper payments were made. This includes: Cost reports, consulting contracts, and risk contracts under section 1903(m) of the Act.

(c) Identifying if overpayments have been made to individuals or entities receiving Federal funds under title XIX.

(d) Educating providers of service, managed care entities, beneficiaries, and other individuals with respect to payment integrity and quality of care.

5. A new § 455.234 is added to read as follows:

**§ 455.234 Awarding of a contract.**

(a) CMS awards and administers Medicaid integrity audit program contracts in accordance with acquisition regulations set forth at 48 CFR chapters 1 and 3, this subpart, and all other applicable laws and regulations. These competitive procedures and requirements for awarding Medicaid integrity audit program contracts are to be used as follows:

(1) When entering into new contracts under this section.

(2) At any other time considered appropriate by the Secretary.

(b) An entity is eligible to be awarded a Medicaid integrity audit program contract only if it meets the eligibility requirements established in § 455.202, 48 CFR chapter 3, and all other applicable laws and requirements.

6. A new § 455.236 is added to read as follows:

**§ 455.236 Renewal of a contract.**

(a) CMS specifies the initial contract term in the Medicaid integrity audit program contract. CMS may, but is not required to, renew a Medicaid integrity audit program contract without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

(b) CMS may renew a Medicaid integrity audit program contract without competition if all of the following conditions are met:

(1) The Medicaid integrity audit program contractor continues to meet the requirements established in this subpart.

(2) The Medicaid integrity audit program contractor meets or exceeds the performance requirements established in its current contract.

(3) It is in the best interest of the government.

(c) If CMS does not renew a contract, the contract will end in accordance with its terms. The contractor will not have a right to a hearing or judicial review regarding CMS' renewal or non-renewal decision.

7. A new § 455.238 is added to read as follows:

**§ 455.238 Conflict of interest.**

(a) Offerors for Medicaid integrity audit program contracts, and Medicaid integrity audit program contractors, are subject to the following requirements:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation organizational conflict of interest guidance, found under 48 CFR subpart 9.5.

(2) The standards and requirements that are contained in each individual contract awarded to perform activities described under section 1936 of the Act.

(b) Post-award conflicts of interest: CMS considers that a post-award conflict of interest has developed if, during the term of the contract, one of the following occurs:

(1) The contractor or any of its employees, agents, or subcontractors received, solicited, or arranged to receive any fee, compensation, gift (defined at 5 CFR 2635.203(b)), payment of expenses, offer of employment, or any other thing of value from any entity that is reviewed, audited, investigated, or contacted during the normal course of performing activities under the Medicaid integrity audit program contract.

(2) CMS determines that the contractor's activities are creating a conflict of interest.

(c) If CMS determines that a conflict of interest exists during the term of the contract, among other actions, CMS may:

(1) Not renew the contract for an additional term.

(2) Modify the contract.

(3) Terminate the contract.

8. A new § 455.238 is added to read as follows:

**§ 455.240 Conflict of interest resolution.**

(a) Review Board: CMS may establish a Conflicts of Interest Review Board to assist in resolving organizational conflicts of interest.

(b) Resolution: Resolution of an organizational conflict of interest is a determination by the contracting officer that:

(1) The conflict is mitigated.

(2) The conflict precludes award of a contract to the offeror.

(3) The conflict requires that CMS modify an existing contract.

(4) The conflict requires that CMS terminate an existing contract.

(5) It is in the best interest of the government to contract with the offeror or contractor even though the conflict of interest exists and a request for waiver is approved in accordance with 48 CFR 9.503.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: June 15, 2007.

**Leslie V. Norwalk,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: August 20, 2007.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. E7-22773 Filed 11-21-07; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 483

[CMS-2266-P]

RIN 0938-AO82

#### Medicare and Medicaid Programs; Waiver of Disapproval of Nurse Aide Training Program in Certain Cases and Nurse Aide Petition for Removal of Information for Single Finding of Neglect

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would permit a waiver of nurse aide training disapproval as it applies to skilled nursing facilities, in the Medicare program, and nursing facilities, in the Medicaid program, that are assessed a civil money penalty of at least \$5,000 for noncompliance that is not related to quality of care. This is a statutory provision enacted by section 932 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted December 8, 2003.)

In addition, this proposed rule would codify an additional statutory provision enacted by section 4755 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33, enacted on August 5, 1997) that requires the State to establish a procedure to permit a nurse aide to petition the State to have a single finding of neglect removed from the nurse aide registry if the State determines that the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior

or neglect and the neglect involved in the original finding was a single occurrence.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 24, 2007.

**ADDRESSES:** In commenting, please refer to file code CMS-2266-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2266-P, P.O. Box 8017, Baltimore, MD 21244-8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2266-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and

retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

*Submission of comments on paperwork requirements.* You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

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

**FOR FURTHER INFORMATION CONTACT:** Pat Miller, (410) 786-6780.

#### **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-2266-P and the specific "issue identifier" that precedes the section on which you choose to comment.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, 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 1-800-743-3951.

### **I. Background**

#### *A. Waiver of Disapproval of Nurse Aide Training Program in Certain Cases*

To participate in the Medicare and Medicaid programs, long-term care facilities must be certified as meeting Federal participation requirements. Long-term care facilities include skilled nursing facilities (SNFs) for Medicare and nursing facilities (NFs) for Medicaid. The Federal participation