

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 455

[CMS-2264-P]

RIN 0938-A088

Medicaid Integrity Program; Limitation on Contractor Liability

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

ACTION: Proposed rule.

SUMMARY: Section 6034 of the Deficit Reduction Act of 2005 established the Medicaid Integrity Program to promote the integrity of the Medicaid program by authorizing the Centers for Medicare and Medicaid Services (CMS) to enter into contracts with contractors that will (1) review the actions of individuals or entities furnishing items or services (whether fee-for-service, risk, or other basis) for which payment may be made under an approved State plan and/or any waiver of the plan approved under section 1115 of the Social Security Act; (2) audit claims for payment of items or services furnished, or administrative services furnished, under a State plan; (3) identify overpayments of individuals or entities receiving Federal funds; and (4) educate providers of services, managed care entities, beneficiaries,

and other individuals with respect to payment integrity and quality of care. This proposed rule would set forth limitations on a contractor's liability while performing these services under the Medicaid Integrity Program.

This proposed rule would provide for limitation of a contractor's liability for actions taken to carry out a contract under the Medicaid Integrity Program. The proposed rule would, to the extent possible, employ the same or comparable standards and other substantive and procedural provisions as are contained in section 1157 (Limitation on Liability) of the Social Security Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 30 days after date of publication in the **Federal Register**.]

ADDRESSES: In commenting, please refer to file code CMS-2264-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-2264-P,
P.O. Box 8014,
Baltimore, MD 21244-8014.

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-2264-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.

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-2064-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. 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). The Centers for Medicare and Medicaid Services (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) established the Medicaid Integrity Program (the Program), within CMS to combat Medicaid fraud and abuse. For the first time, the Program authorizes the Federal government to directly identify, recover, and prevent inappropriate Medicaid payments. It would also 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 our first comprehensive 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 amended title XIX of the Social Security Act (the Act), (42 U.S.C. 1396 et seq.) by redesignating the old section 1936 as section 1937; and inserting the new section 1936 "Medicaid Integrity Program."

The new section 1936 of the Act states that the Secretary promote the integrity of the Medicaid program by entering into contracts with eligible entities to carry out the following activities:

1. 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 this plan approved under section 1115 of the Act) to determine whether fraud, waste, and/or abuse has occurred, or is likely to occur, or whether these actions have any potential for resulting in an expenditure of funds under title XIX in a manner that is not intended under the provisions of title XIX.
2. 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.

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

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

Section 6034 of the DRA also mandated that the Secretary will by regulation provide for the limitation of a contractor's liability for actions taken to carry out a contract under the Medicaid Integrity Program.

II. Provisions of the Proposed Rule

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

Limitations on Contractor Liability

Contractors that perform activities under the Medicaid Integrity Program (the Program), would be reviewing activities of providers and others seeking Medicaid payment for providing services to Medicaid beneficiaries. In an effort to reduce or eliminate the Program contractor's exposure to possible legal action from entities it reviews, section 6034 of the DRA requires that we, by regulation,

limit the Program contractor's liability for actions taken in carrying out its contract. We must establish, to the extent we find appropriate, standards and other substantive and procedural provisions that are the same as, or comparable to, those contained in section 1157 of the Act.

Section 1157 of the Act states that any organization having a contract with the Secretary, its employees, fiduciaries, and anyone who furnishes professional services to these organizations are protected from civil and criminal liability in performing their duties under the Act or their contract, provided these duties are performed with due care.

Following the mandate of section 6034 of the DRA, this proposed rule, in §455.1, Basis and scope, would add a new paragraph (c) stating that subpart C implements section 1936 of the Act. Section 1936 of the Act 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 subpart C. In addition, new subpart C, §455.200(a), would specify the statutory basis of proposed new subpart C, which would implement section 1936 of the Act, which states that the Secretary will promote the integrity of the Medicaid program by entering into contracts with eligible

entities to carry out the activities under subpart C. Section 455.200(b) would provide the scope for the limitation on a contractor's liability to carry out a contract under the Medicaid Integrity Program as proposed under new §455.202. Section 455.202(a) would protect Program contractors from liability in the performance of their contracts provided they carry out their contractual duties with due care.

In accordance with section 6034 of the DRA, we propose to employ the same standards for payment of legal expenses as are contained in section 1157(d) of the Act. Therefore, §455.202(b) would provide that we would make payment to Program contractors, their members, employees, and anyone who provides legal counsel or services to them, for expenses incurred in the defense of any legal action related to the performance of the Program contract. We also propose that any and all payment(s) and the amount of each payment(s) if any, would be determined exclusively by us, and conditioned upon (1) the reasonableness of the expense(s); (2) the amount of government funds available for payment(s); and (3) whether the payment(s) is(are) allowable under the terms of the contract.

In drafting §455.202, we considered employing a standard for the limitation of liability other than the due

care standard. We considered whether it would be appropriate to provide that a contractor would not be civilly liable by reason of the performance of any duty, function, or activity under its contract provided the contractor was not grossly negligent in that performance. However, section 6034 of the DRA requires that we employ the same or comparable standards and provisions as are contained in section 1157 of the Act. This approach is consistent with a similar approach taken in the Medicare Integrity Program (see 70 FR 35204), which has virtually identical statutory limitations on contractor liability language. Therefore, we do not believe that it would be appropriate to expand the scope of immunity to a standard of gross negligence, as it would not be a comparable standard to that set forth in section 1157(b) of the Act.

III. Collection of Information Requirements

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

IV. Response to Comments

Because of the large number of 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 million to \$29 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 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 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 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. In §455.1, add new paragraph (c) to read as follows:

§455.1 Basis and scope.

* * * * *

(c) Subpart C implements section 1936 of the Act. It 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 of subpart C.

3. New subpart C, consisting of §455.200 and §455.202, is added to part 455 to read as follows:

Subpart C-Medicaid Integrity Program

Sec.

455.200 Basis and scope.

455.202 Limitation on contractor liability.

Subpart C-Medicaid Integrity Program

§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.

§455.202 Limitation on contractor liability.

(a) A program contractor, a person, or an entity employed by, or having a fiduciary relationship with, or who furnishes professional services to a program contractor will not be held to have violated any criminal law and will not be held liable in any civil action, under any law of the United States or of any State (or political subdivision thereof), by reason of the performance of any duty, function, or activity required or authorized under this subpart or under a valid contract entered into under this subpart, provided due care was exercised in that performance and the contractor has a contract with CMS under this

subpart.

(b) CMS pays a contractor, a person, or an entity described in paragraph (a) of this section, or anyone who furnishes legal counsel or services to a contractor or person, a sum equal to the reasonable amount of the expenses, as determined by CMS, incurred in connection with the defense of a suit, action, or proceeding, if the following conditions are met:

(1) The suit, action, or proceeding was brought against the contractor, person or entity by a third party and relates to the contractor's, person's or entity's performance of any duty, function, or activity under a contract entered into with CMS under this subpart.

(2) The funds are available.

(3) The expenses are otherwise allowable under the terms of the contract.

CMS-2264-P 19
(Catalog of Federal Domestic Assistance Program No. 93.778,
Medical Assistance Program)

Dated: _____

Leslie V. Norwalk,
Acting Administrator,
Centers for Medicare & Medicaid
Services.

Approved: _____

Michael O. Leavitt,
Secretary.

BILLING CODE 4120-01-P