

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 455

[CMS-6034-P]

RIN 0938-AQ19

Medicaid Program; Recovery Audit Contractors

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would provide guidance to States related to Federal/State funding of State start-up, operation and maintenance costs of Medicaid Recovery Audit Contractors (Medicaid RACs) and the payment methodology for State payments to Medicaid RACs in accordance with section 6411 of the Affordable Care Act. In addition, this rule proposes requirements for States to assure that adequate appeal processes are in place for providers to dispute adverse determinations made by Medicaid RACs. Finally, the rule proposes that States and Medicaid RACs coordinate with other contractors and entities auditing Medicaid providers and with State and Federal law enforcement agencies.

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 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-6034-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-6034-P,
P.O. Box 8016,
Baltimore, MD 21244-8016.

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 to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-6034-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 before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey 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.)

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

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.

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

FOR FURTHER INFORMATION CONTACT:

Joanne Davis, (410)786-5127.

SUPPLEMENTARY INFORMATION:

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.regulations.gov>. Follow the search instructions 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

The Medicaid program is a cooperative Federal/State program designed to allow States to receive matching funds from the Federal government to finance medical assistance to eligible low income beneficiaries. Medicaid was enacted in 1965 by the passage of Title XIX of the Social Security Act (the Act).

States may choose to participate in the Medicaid program by submitting a State plan for medical assistance that is approved by the Secretary. Although States are not required to participate in the Medicaid program, all States, the District of Columbia, and the territories do participate. Once a State elects to participate in the program, it is required to comply with its State plan, as well as the requirements imposed by the Act and applicable Federal regulations.

CMS is the primary Federal agency providing oversight of State Medicaid activities and facilitating program integrity efforts. Our administration of the Medicaid program requires that we expend billions of dollars in Federal matching payments to States for Medicaid expenditures. We also have an obligation to prevent, identify, and recover improper payments to individuals, contractors, and organizations.

In November 2009, the President signed Executive Order (E.O.) 13520 in an effort to reduce improper payments by increasing transparency in government and holding agencies accountable for reducing improper payments. On March 22, 2010, the Office of Management and Budget (OMB) issued guidance for agencies regarding the implementation of E.O. 13520 entitled Part III to OMB Circular A-123, Appendix C (Appendix C). Appendix C outlines the responsibilities of agencies, determines the programs subject to E.O. 13520, defines supplemental measures and targets for high priority programs, and establishes reporting requirements under E.O. 13520 and procedures to identify entities with outstanding payments.

Section 6411 of the Patient Protection and Affordable Care Act (Pub. L. 111-148, enacted on March 23, 2010) (the Affordable Care Act) requires States to establish programs in which they would contract with 1 or more Recovery Audit Contractors (Medicaid RACs) by December 31, 2010. The Medicaid RACs would review Medicaid claims submitted by providers of services for which payment may be made under section 1902(a) of the Act or a waiver of the State plan. Medicaid RACs would identify underpayments, and identify and collect overpayments from providers.

Section 6411(a)(1) of the Affordable Care Act amends section 1902(a)(42) of the Act to provide that "the State

shall establish a program under which the State contracts (consistent with State law and in the same manner as the Secretary enters into contracts with recovery audit contractors under section 1893(h) . . .) with 1 or more recovery audit contractors for the purpose of identifying underpayments and overpayments and recouping overpayments” To offer context for our proposed approach to the Medicaid RAC program, we provide background discussion on the Medicare RAC program.

B. Medicare RACs

Medicare RACs are private entities with which CMS contracts to identify and collect improper payments made in Medicare's fee-for-service program. Initially authorized by the Congress as a 3-year demonstration program by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8, 2003) (MMA), Medicare RACs were permanently authorized in the Tax Relief and Health Care Act of 2006 (Pub. L. 109-432, enacted on December 20, 2006) (TRHCA). The TRHCA directed CMS to expand the Medicare RAC program nationwide by January 1, 2010.

During the Medicare RAC demonstration period, we contracted with RACs to review claims from Medicare participating providers and suppliers in New York, Florida, California, Arizona, Massachusetts, and South Carolina. From 2005 through 2008, the Medicare RACs identified and collected

or corrected over \$1 billion in improper payments. The majority, or 96 percent, of the improper payments were overpayments, while the remaining 4 percent were underpayments. As a result of the demonstrated cost effectiveness of the Medicare RACs, the TRHCA required CMS to implement a nationwide Medicare RAC program.

In our evaluation of the Medicare RAC demonstration, providers surveyed identified to CMS a number of concerns and processes needing improvement. For example, Medicare RACs were reportedly inconsistent in documenting their "good cause" for reviewing a claim. In addition, providers complained that a lack of physician presence on Medicare RAC staffs contributed to Medicare claims incorrectly being denied. As a result, we met with stakeholders, including the provider community, and made a number of changes to improve the Medicare RAC program. In the permanent Medicare RAC program, we directed Medicare RACs to consistently document their "good cause" for reviewing a claim. We now require each Medicare RAC to hire a physician Medical Director to oversee the medical record review process; assist nurses, therapists, and certified coders upon request; manage quality assurance procedures; and maintain relationships with provider associations.

Both the MMA and the TRHCA authorized CMS to pay Medicare RACs on a contingency fee basis. Currently, we pay Medicare

RACs a contingency fee rate ranging between 9 and 12.50 percent. These contingency fees are not initially fixed by CMS, but are established by the contractors through a bidding process with CMS. Providers may appeal Medicare RAC determinations through the established Medicare appeals process. During the demonstration period, Medicare RACs were required to return contingency fees if the claim determination was overturned on the first level appeal. However, Medicare RACs were entitled to retain contingency fees if the determination was overturned on subsequent levels of appeal. In the permanent Medicare RAC program, we now require Medicare RACs to return the contingency fee payment if the determination is overturned at any stage of the appeals process.

C. Existing State Contingency Fee Contracts

There is precedent for State Medicaid contingency fee contracts for purposes of recovering Medicaid overpayments subject to third party liability (TPL) requirements. Section 1902(a)(25) of the Act requires States to take all reasonable measures to determine the legal liability of third parties to pay for medical assistance furnished to a Medicaid recipient under the State plan. In addition, several States currently contract with contingency fee contractors to recover Medicaid overpayments unrelated to TPL. In a memorandum to CMS' Regional Administrators dated November 7, 2002, we revised our

policy prohibiting Federal financial participation (FFP) for States to pay costs to contingency fee contractors, unrelated to TPL. The revised policy allows contingency fee payments if the following conditions are met: (1) The intent of the contingency fee contract must be to produce savings or recoveries in the Medicaid program; (2) the savings upon which the contingency fee payment is based must be adequately defined and the determination of fee payments documented to CMS's satisfaction.

D. Medicaid RACs

Section 6411(a) of the Affordable Care Act amends and expands section 1902(a)(42) of the Act to require States to establish programs by December 31, 2010, to contract with 1 or more Medicaid RACs to audit Medicaid claims and to identify underpayments and overpayments. While States are required to establish their Medicaid RAC programs by December 31, 2010, via the State plan amendment process, such programs need not be implemented by this date. Instead, absent an exception, States must fully implement their Medicaid RAC programs by April 1, 2011. We solicit comments on the proposed implementation date. States would be required to report to CMS certain elements describing the effectiveness of their Medicaid RAC programs. These elements would include, but not be limited to general program descriptors (for example, contract periods of performance, contractors' names,) and

program metrics (for example, number of audits conducted, recovery amounts, number of cases referred for potential fraud). To implement this provision, we propose to add a new subpart F to 42 CFR part 455.

Medicaid RACs would review post-payment claims for improper payments, overpayments, as well as underpayments consistent with State laws and regulations. Medicaid RACs are a supplemental approach to Medicaid program integrity efforts already underway to ensure that States make proper payments to providers. Medicaid RACs do not replace any existing State program integrity or audit initiatives or programs. States must maintain their existing program integrity efforts uninterrupted with respect to levels of funding and activity. Should we detect evidence of fraud, waste, and abuse that goes unreported by the Medicaid RACs, we would work closely with States to identify focus areas for Medicaid RACs to improve their efficacy.

The Affordable Care Act requires all States to establish Medicaid RAC programs, subject to such exceptions and requirements as the Secretary may require. This provision enables CMS to vary the Medicaid RAC program requirements, or exempt a State from establishing a Medicaid RAC program if inconsistent with State law. For example, we may exempt a State from the requirement to pay Medicaid RACs on a contingent basis for collecting overpayments when State law

expressly prohibits contingency fee contracting. However, some other fee structure could be required under any such exception.

Similarly, some State legislatures must enact legislation before amending their State plans. Because the establishment of a Medicaid RAC program is accomplished by State plan amendment (SPA), many State legislatures will not have the opportunity to convene and enact such an amendment to their State plans prior to December 31, 2010, those States would need to submit justifications to defer establishing Medicaid RAC programs until after those State legislatures have met. For States that require a State legislative change granting authority to establish a Medicaid RAC program, a SPA should be submitted indicating that the Medicaid RAC program cannot be established until legislative authority is granted.

Finally, there may be circumstances, unrelated to the examples above, where a State would seek to be excepted from some or all of the requirements of the Medicaid RAC program. Accordingly, we propose at §455.516 that States seeking exceptions from contracting with Medicaid RACs must submit to CMS a written justification for the request. We anticipate granting complete Medicaid RAC program exceptions rarely, and only under the most compelling of circumstances.

Section 6411(a) of the Affordable Care Act amends section 1902(a)(42) of the Act, which requires States to make the following assurances to CMS regarding Medicaid RAC programs:

- Under section 1902(a)(42)(B)(ii)(I) of the Act, payments shall be made to a Medicaid RAC contractor under contract with a State only from amounts recovered. As discussed more fully below, we interpret this to mean that payments to Medicaid RACs may not exceed the total amounts recovered. Additionally, we interpret this to mean that payments to contractors may not be made based upon amounts merely identified but not recovered, or amounts that may initially be recovered but that subsequently must be repaid due to determinations made in appeals proceedings.

The payment methodology determination for States, as well as when Medicaid RACs should be paid by States for their work are separate, but closely related issues. The distinction between amounts recovered and amounts identified has implications for how States would structure and administer payment agreements with Medicaid RACs, as well as the timing of Medicaid RACs' receipt of payments. The options below illustrate two ways that States could structure payments, though they are not exhaustive.

In option one, for example, State A pays RAC B its fee when RAC B identifies and recovers an overpayment. If provider C appeals and wins at any stage, RAC B would be

required to return any portion of the contingency fee that corresponds to the amount of an overpayment that is overturned on appeal.

In a second option, State D determines it would pay RAC E its contingency fee at the point at which the recovery amount is fully adjudicated; that is, at the conclusion of any and all appeals available to provider F. At that point, State D would pay RAC E a contingency fee based on the amount recovered.

- Under section 1902(a)(42)(B)(ii)(II)(aa) of the Act, payments to a Medicaid RAC contractor shall be made on a contingent basis for collecting overpayments from the amounts recovered. We are aware that the proposed Medicaid RAC program, by virtue of the differences between the Medicare and Medicaid programs, would not operate identically to the Medicare RAC program. Recognizing that each State must tailor its Medicaid RAC activities to the uniqueness of its own State, we are not proposing to prescribe a set contingency fee rate for States. Instead, we are proposing certain guidelines based upon section 1902(a)(42)(B) of the Act and our experience with the Medicare RAC program, but allowing States the discretion to set their fees within those guidelines.

The Medicaid RACs would contract with States and territories to identify and collect overpayments, and would be paid on a contingency fee basis by the States. In the

Medicare RAC program, CMS contracts with Medicare RACs to identify and recover overpayments from Medicare providers, and to identify and pay underpayments to Medicare providers. We recognize the differences among States and territories when it comes to the issue of coordinating with RACs the collection of overpayments. The statute requires Medicaid RACs to collect overpayments. However, some States may not be able to delegate the collection of overpayments to contractors, while other States may have other restrictions. In keeping with the statutory language that States must establish RAC programs consistent with State law, we propose to provide States with the flexibility of coordinating RAC collections of overpayments.

Currently, there are 4 Medicare RAC contractors operating. Those RACs are paid an average contingency fee rate of 10.86 percent by CMS, with the highest rate being 12.50 percent. We interpret the statutory language that States must establish a Medicaid RAC program "in the same manner as the Secretary enters into contracts with" Medicare RACs to mean that some of the provisions of the Medicare RAC program, generally, should serve as a model for the proposed Medicaid RAC program. Accordingly, in §455.510(b)(3) and (b)(4), we are proposing that we would not provide Federal financial participation (FFP) with respect to any amount of a State's contingency fee in excess of the then highest Medicare

RAC contingency fee rate unless a State requests an exception from CMS and provides an acceptable justification.

In the absence of an approved exception, a State may only pay a RAC contractor, from the overpayments collected, a contingency fee up to the highest Medicare RAC contingency rate. Any additional payment from the State to the RAC must be made using State-only funds. FFP is not available for administrative expenditure claims for the marginal difference between the highest Medicare fee and the State's contingency fee. For example, unless an exception applies, if the highest Medicare RAC contingency fee is 12.50 percent and the State pays a Medicaid RAC 14 percent, we would not pay the Federal match on the 1.50 percent difference. The State would use State-only funds to make up the difference between the State's 14 percent contingency fee and the 12.50 percent contingency fee ceiling.

Currently, the Medicare RAC contracts have an established period of performance of up to 5 years, beginning in 2009. Initially, the maximum contingency rate for which FFP would be available for States to pay Medicaid RACs would be the highest Medicare RAC contingency fee, which is 12.50 percent. That fee would be the maximum rate when States implement their RAC programs no later than April 1, 2011. Subsequently, we would make States aware of any modifications to payment methodology for contingency fees and Medicaid RAC maximum contingency

rates for which FFP would be available by publishing in a **Federal Register** notice, by December 31, 2013, the maximum Medicare contingency fee rate, which would apply to FFP availability for any Medicaid RAC contracts covering the period of performance beginning on July 1, 2014. The established rate would be in place for 5 years or until we publish a new maximum rate in the **Federal Register**. We solicit public comments on this approach.

The Medicare RAC program is still a relatively new program. We will apply the lessons learned from the Medicare RAC Demonstration, as well as from the current program in providing States technical support and assistance in their efforts to implement their programs. For example, States would require Medicaid RACs to employ trained medical professionals to review Medicaid claims, as CMS now requires the Medicare RACs to do. Additionally, States may consider establishing requirements regarding the documentation of good cause to review a claim. States should also be cognizant of potential organizational conflicts of interest, and should take affirmative steps to identify and prevent any such conflicts of interest.

The Office of the Inspector General of U.S. Department of Health and Human Services (HHS-OIG) recently reported that the Medicare RACs identified over \$1 billion in improper payments, but referred only two cases of potential fraud to CMS.

HHS-OIG opined that Medicare RACs are disincentivized to make referrals because the RACs receive contingency fees. As we learn from the lessons of Medicare RACs, we caution States, in their design of Medicaid RAC programs, to ensure that the Medicaid RACs report instances of fraud and/or criminal activity in addition to the pursuit of overpayments. At §455.508(b), we propose that whenever RACs have reasonable grounds to believe that fraud or criminal activity has occurred, they must report it to the appropriate law enforcement officials. We solicit comments on these and other issues that States should consider in the design of their RAC programs. At §455.508(c), we propose that Medicaid RACs must meet the additional requirements that States may establish.

- Under section 1902(a)(42)(B)(ii)(II)(bb) of the Act, payment to a Medicaid RAC may be made in the amounts as the State may specify for identifying underpayments from the amounts recovered. Currently, Medicare RACs are paid a contingency fee to identify underpayments, similar to the way in which they are paid to identify and recover overpayments. With respect to Medicaid RACs, a State may elect to use a similar approach, or elect to establish a set fee or some other fee structure for the identification of underpayments. Consistent with a State's obligation to ensure that it pays the right amount to the right provider for the right service at the right time for the right recipient, whatever

methodology a State chooses must adequately incentivize the detection of underpayments. In §455.510(c), we are proposing to grant States the flexibility to specify the underpayment fee for Medicaid RACs. Additionally, we would monitor the methodologies and amounts paid by States to Medicaid RACs to identify underpayments, and may consider future additional regulation depending on what data reveals over time. We solicit public comments on the proposal of allowing States this flexibility.

The Affordable Care Act requires that payments to a Medicaid RAC can only come from amounts recovered. Federal matching payments are not available for RAC fees paid in excess of the overpayment amounts collected. The total fees paid to a Medicaid RAC include both the amounts associated with (1) identifying and recovering overpayments; and (2) identifying underpayments. Due to the Affordable Care Act's requirement that contingency fees only come from amounts recovered, total fees must not exceed the amounts of overpayments collected.

Our experience with Medicare RAC contractors is that overpayment recoveries exceed underpayment identification by more than a 9:1 ratio. Therefore, it is not anticipated that States would need to maintain a reserve of recovered overpayments to fund Medicaid RAC costs associated with identifying underpayments. However, States must maintain an

accounting of amounts recovered and paid. Further, States must also ensure that they do not pay in total RAC fees more than the total amount of overpayments collected.

States must report overpayments to CMS based on the net amount remaining after all fees are paid to the Medicaid RAC. Medicaid RACs may only receive payments through the contingency fee arrangement made in accordance with these requirements and the limitations discussed relating to the maximum contingency fee amount. No additional FFP is available for any other State payment made to the RACs. This treatment of the fees and expenditures is directly linked to the specific statutory language implementing Medicaid RAC requirements. It does not apply to Medicaid overpayment recoveries in other contexts.

For example, RAC X's fee for overpayment identification is 10 percent of the recovery amount. The fee for identification of underpayments is 10 percent of the amount identified. If an overpayment amount is \$100, and the total amount of underpayment is \$20, the total fees paid to the Medicaid RAC would be \$12 (\$10 for the identification of the overpayment and \$2 for the identification of the underpayment). From the remaining amount of the \$88 overpayment, the State would report, and the Federal share of the identified overpayment amount would be based upon, the appropriate State match rate for FFP. If the State pays a

provider based on the Medicaid RAC-identified underpayment, and that expenditure is claimed in accordance with timely filing requirements, the \$20 expenditure would be matched at the regular FMAP, or the appropriate FFP rate.

Currently, §433.312 requires States to refund the Federal share of overpayments, regardless of whether the State actually recovers the overpayments from the provider. This requirement, and all other requirements relating to overpayments, would apply to Medicaid RAC identified overpayments. Therefore, if a Medicaid RAC identifies an overpayment to a provider, the State is required to refund the Federal share of the overpayment amount to the Federal government net of any contingency fee paid, as discussed above.

- Under section 1902(a)(42)(B)(ii)(III) of the Act, States must have an adequate appeals process for entities to challenge adverse Medicaid RAC determinations. Each State already has in place an administrative appeals infrastructure, whereby a provider may avail itself of its due process rights in an administrative or judicial setting, depending on State law or administrative rule, with attendant procedures for notice and an opportunity to be heard. States may utilize the existing appeals infrastructure to adjudicate Medicaid RAC appeals. States would be required to submit to CMS a proposal

describing the appeals process, which must be approved prior to implementing their RAC programs.

Alternatively, a State may elect to establish a separate appeals process for RAC determinations, which must also ensure providers adequate due process in pursuing an appeal. Accordingly, at §455.512 we propose to offer States the flexibility to determine the appeals process that would be available to providers who seek review of adverse RAC determinations.

Finally, it is important to note that the potential length of a State's administrative appeals process may have an impact on the methodology/structure of the payment agreement between a State and a Medicaid RAC. For example, in a contract between State X and RAC Y, where State X's administrative appeal process can extend for 2 years, RAC Y may not receive payment for an extended period of time. Accordingly, RAC Y's contingency fee rate will most likely reflect operating, maintenance and legal costs over that period. Alternatively, in State Z, completion of the administrative appeals process takes 9 months. A contract between State Z and RAC V may reflect a different contingency fee rate.

- Under section 1902(a)(42)(B)(ii)(IV)(aa) of the Act, for purposes of section 1903(a)(7) of the Act, expenditures made by the State to carry out the Medicaid RAC program are

necessary for the proper and efficient administration of the State plan or waiver of the plan. We interpret this reference to section 1903(a)(7) of the Act to mean that amounts expended by a State to establish and operate the Medicaid RAC program (aside from fee payments, the treatment of which is discussed elsewhere in this preamble) are to be shared by the Federal government at the 50 percent administrative rate. We propose in §455.514(b) that FFP would be available to States for administrative costs subject to reporting requirements.

- Section 1902(a)(42)(B)(ii)(IV)(bb) and section 1903(d) of the Act applies to amounts recovered (not merely identified) under the Medicaid RAC program. We propose that a State must refund the Federal share of the net amount of overpayment recoveries after deducting a RAC's fee payments (in conformance with the restrictions discussed above, including the maximum allowed RAC contingency fee and the exception process). In other words, a State would take a RAC's fee payment "off the top" before calculating the Federal share of the overpayment recovery to be returned to CMS. Such amounts recovered would be subject to a State's quarterly expenditure estimates and the funding of the State's share.

Additionally, we note that the territories operate under a separate funding authority that is statutorily-capped. Because of the limitations placed on FFP by section 1108(g) of the Act, territories must assess the feasibility of

implementing and funding Medicaid RAC contractors in their jurisdictions. We would provide technical assistance to the territories on how to implement the provisions in sections 1902(a)(42)(B)(ii)(I), (II), (III) and (IV) of the Act. We solicit public comment on the impact and feasibility of such provisions on the territories.

- Under section 1902(a)(42)(B)(ii)(IV)(cc) of the Act, States and their Medicaid RACs must coordinate their efforts with other contractors or entities performing audits of entities receiving payments under the State plan or waiver in the State, including State and Federal law enforcement agencies. We emphasize that Medicaid RACs are not intended to, and do not, replace any State program integrity or audit initiatives or programs. We propose in §455.508(b) that an entity that wishes to enter a contract with a State to perform the functions of a Medicaid RAC must agree to the coordination efforts.

Although overlapping or multiple provider audits may be necessary, we hope to minimize the likelihood of overlapping audits. The Affordable Care Act requires that States assure CMS that they will coordinate Medicaid RAC audit activity with an array of other stakeholders that also conduct audits. We anticipate working systematically, both internally and with States. We recognize that providers are currently subject to audits by the States' routine program integrity audits, CMS'

Medicaid Integrity Contractors' audits, as well as audits conducted by other State and Federal entities.

In addition to the obligation to coordinate auditing efforts to reduce the overburdening of Medicaid providers, we also want to ensure coordination between Medicaid RACs and law enforcement organizations so that suspected cases of fraud and abuse are processed through the appropriate channels. Law enforcement organizations that may conduct audits or investigations include, but are not limited to, the HHS-OIG, the U.S. Department of Justice, including the Federal Bureau of Investigation, State Medicaid Fraud Control Units, other Federal and State law enforcement agencies as appropriate and CMS. One approach to ensure this coordination is for States to establish Memoranda of Understanding (MOUs) with their State Medicaid Fraud Control Units (MFCUs), program integrity units or other law enforcement agencies. Nothing would preclude a State from agreeing to pay the Medicaid RAC a contingency fee from funds ultimately recovered and returned to the State as the State share of an overpayment (or restitution) at the close of the civil or criminal proceeding.

Finally, coordination may be a challenge because of the number of other agencies or entities that may be conducting audits, but States are obligated to ensure that Medicaid RACs do not duplicate or compromise the efforts of other entities

performing audits, including law enforcement that may be investigating fraud and abuse.

II. Provisions of the Proposed Regulations

In the section that follows, we discuss the proposed changes to the regulations in part 455 governing the Program Integrity--Medicaid.

We propose to add a new "Subpart F--Medicaid Recovery Audit Contractors Program" that would implement section 1902(a)(42)(B) of the Act. Section 1902(a)(42)(B) sets forth provisions relating to States establishing recovery audit contractor programs in which States will contract with 1 or more Medicaid RACs to audit Medicaid claims and to identify underpayments and identify and recover overpayments. We propose to add the following sections:

A. Purpose (§455.500)

Proposed §455.500 sets forth the purpose of the new subpart F. The regulations would implement section 1902(a)(42)(B) of the Act that establishes the Medicaid RAC program.

B. Establishment of program (§455.502)

At proposed §455.502, we would establish the Medicaid RAC program as a measure for States to promote the integrity of Medicaid program, and require that States enter into contracts with one or more RACs to carry out the activities described in

§455.506, and require that States report on certain elements describing the effectiveness of their Medicaid RAC program.

C. Definitions (§455.504)

We are proposing to define the Medicaid RAC program as a recovery audit contractor administered by a State to identify overpayments and underpayments and recoup overpayments.

We are proposing to define the Medicare RAC program as a recovery audit contractor program administered by CMS to identify overpayments and underpayments and recoup overpayments.

D. Activities to be conducted by Medicaid RACs (§455.506)

We propose at §455.506(a), to require States to contract with one or more RACs to engage in reviews of Medicaid claims submitted by providers of services or other individuals furnishing items and services for which payment has been made under section 1902(a) of the Act to determine whether providers have been underpaid or overpaid, and to recover any overpayments identified. We propose at §455.506(b), to leave to the States' discretion the manner in which they will coordinate with Medicaid RACs' recoupment of overpayments.

E. Eligibility Requirements for Medicaid RACs (§455.508)

We propose at §455.508 to provide that in order to be eligible to contract with a State to perform the functions of a Medicaid RAC, an entity must have technical capability to carry out the activities described in §455.506, including

employing trained medical professionals to review Medicaid claims. An entity must also agree to coordinate with State and Federal agencies, and meet any such other requirements as the State may establish.

F. Payments to RACs (§455.510)

We propose at §455.510(a) that fees paid to RACs shall be made only from amounts recovered. We propose at §455.510(b)(1) to require that the contingency fee paid to Medicaid RACs be based on a percentage of the recovered overpayment amount. We propose at §455.510(b)(2), that States shall determine at what stage of the audit process Medicaid RACs will receive their contingency fee. We propose at §455.510(b)(3) that, except as provided in paragraph (b)(4), CMS will not provide FFP for any amount of contingency fee that exceeds the then highest contingency fee rate paid to a Medicare RAC. We propose at §455.514(b)(4), that, on a case-by-case basis, CMS will review and consider substantially justified requests from States to pay Medicaid RAC(s) a contingency fee higher than the highest Medicare RAC contingency fee. We propose at §455.510(c) to require that States determine the fee paid to Medicaid RACs to identify underpayments.

G. Medicaid RAC Provider Appeals (§455.512)

We propose at §455.512 to require States to provide a process for provider appeals of adverse Medicaid RAC determinations.

H. Federal Share of State Expense for the Medicaid RAC Program (§455.514)

We propose at §455.514(a) that funds expended by the State to carry out the Medicaid RAC program shall be considered necessary for the proper and efficient administration of the State plan or a waiver of the plan.

We propose at §455.514(a) that the Federal share of State expense does not include fees paid.

We propose at §455.514(b) that FFP is available to States for administrative costs of operation and maintenance of Medicaid RACs, subject to CMS' reporting requirements.

I. Exceptions from Medicaid RAC Programs (§455.516)

We propose at §455.516, that States that seek to be excepted from any of the requirements of the Medicaid RAC program must submit to CMS a written justification for the request and get CMS approval.

J. Applicability to the territories (§455.518)

We propose at §455.518 that the provisions in §455.500 through §455.516 are applicable to Guam, Puerto Rico, U.S. Virgin Islands, American Samoa and the Commonwealth of the Northern Mariana Islands.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

- A. ICRs Regarding State Submission of Certain Elements Describing the Effectiveness of their Medicaid RAC Programs (§455.502(c))

Section 455.502(c) would require States to submit certain elements describing the effectiveness of their Medicaid RAC programs. These elements will include, but not be limited to general program descriptors and program metrics evaluating effectiveness. The burden associated with this requirement is the time and effort put forth by the State to aggregate existing data that will be part of the process of establishing their RAC program. We estimate it would take 1 State 2 hours to perform this task. The total annual burden for this requirement is 112 hours.

B. ICRs Regarding State Justifications to Pay Higher Contingency Fees (§455.510(b)(4))

Section 455.510(b)(4) would require States to submit justifications to CMS to pay Medicaid RACs a contingency fee higher than the highest Medicare RAC.

The burden associated with this requirement is the time and effort put forth by the State to prepare and submit a justification. We estimate it would take 1 State 60 hours to perform this task. The total annual burden for this requirement is 1680 hours.

C. ICRs Regarding Medicaid RAC Provider Appeals (§455.512)

Section 455.512 would require States to provide administrative appeal procedures for Medicaid providers that seek review of an adverse Medicaid RAC determination.

The burden associated with this requirement is the time and effort put forth by the State to prepare and provide administrative appeal procedures. We estimate it would take 1 State 60 hours to perform these tasks. The total annual burden for this requirement is 3,360 hours.

D. ICRs Regarding Federal Share of State expense for the Medicaid RAC Program (§455.514(b))

Section 455.514(b), FFP would be available to States for the Federal share of State expense for the Medicaid RAC program subject to CMS' reporting requirements. The burden associated with a State reporting quarterly expenditure estimates is currently approved under OMB# 0938-0067 with an expiration date of August 31, 2011.

E. ICRs Regarding Exceptions from Medicaid RAC Programs (§455.516)

Section 455.516 would require a State that is seeking an exception from any of the requirements of the Medicaid RAC program to submit a written justification to CMS.

The burden associated with this requirement is the time and effort put forth by the State to prepare and submit a written justification for the request. We estimate it would take 1 State 20 hours to meet this requirement. We estimate approximately 15 States would request an exception; therefore, the total annual burden associated with this requirement is 300 hours.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-6034-P]

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

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 Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on

Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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). We tentatively estimate that this rulemaking may be "economically significant" as measured by the \$100 million threshold, and, therefore, may be a major rule under the Congressional Review Act.

This proposed rule applies to States' requirement to contract with Medicaid RACs to perform audits of Medicaid providers on a contingency fee basis. The majority of anticipated savings, as a result of the provisions in this rule, are related to improper payments. However, as seen in the Medicare RAC Demonstration period, we expect a limited financial impact on most providers, as significant improper payments are relatively rare. The CMS Office of the Actuary (OACT) estimated the potential impact on Federal Medicaid costs and savings. OACT used the historical experience from the Medicare program to estimate potential savings to

Medicaid. As such, these estimates are highly uncertain, as a result we offer estimates for FYs 2011 through 2015 to illustrate the potential effects of this program. As a result, OACTs estimates for FYs 2011 through 2015 are presented in Table A.

TABLE A: Potential Net Savings to Federal Medicaid Program from the Expansion of the Recovery Audit Contractor Program

Fiscal Year	Estimated Savings (in millions of dollars)
2011	\$80
2012	\$170
2013	\$250
2014	\$310
2015	\$330

We plan to refine the estimated impacts in the final rule’s analysis and we request comment on the potential underpayments and overpayments collected by States and the associated contingency fees.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most Medicaid providers are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.0 million to \$34.5 million in any 1

year). For purposes of the RFA, approximately 75 percent of Medicaid providers are considered small businesses according to the Small Business Administration's size standards with total revenues of \$35 million or less in any 1 year and 80 percent are nonprofit organizations. Individuals and States are not included in the definition of a small business entity. Medicaid providers are required, as a matter of course, to follow the guidelines and procedures as specified in State and Federal laws and regulations. As such, Medicaid providers must retain accurate billing records for the requisite period of time. Additionally, Medicaid providers must cooperate in audits conducted by the State and/or Federal governments and their agents. Therefore, the Secretary has determined that this proposed rule will 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 metropolitan statistical area and has fewer than 100 beds. For the same reason as stated above, this proposed rule would not have a significant impact on the operation of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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. In 2010, that threshold is approximately \$135 million. This proposed rule applies to the States' requirement to procure Medicaid RACs to perform audits of Medicaid providers on a contingency fee basis. State expenditure associated with this proposed rule would initially involve directing or allocating personnel resources to procurement activities. Per the terms of the contracts, States would not be expending funds over \$135 million for RACs to perform the contracts. Associated costs that may include the operation of RAC programs, collateral State personnel costs, and maintenance of records are not expected to exceed the \$135 million threshold. Therefore, this proposed rule is not anticipated to have an effect on State, local or tribal governments in the aggregate, or by the private sector of \$135 million or more.

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. We have reviewed this proposed rule under the threshold criteria of

Executive Order 13132, Federalism, and have determined that it would not have substantial direct effects on the rights, roles, and responsibilities of States, local or tribal governments.

B. Conclusion

We tentatively estimate that this rule may be "economically significant" as measured by the \$100 million threshold as set forth by Executive Order 12866, as well as the Congressional Review Act. The analysis above provides our initial Regulatory Impact Analysis. We have not prepared an analysis for section 1102(b) of the RFA, section 202 of the UFMA and Executive Order 13132 because the provisions are not impacted by this rule.

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 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 proposes to 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: Section 1102 of the Social Security Act (42 U.S.C. 1302), section 1902(a)(42)(B) (42 U.S.C. 1396a(a)(42)(B)).

2. New subpart F is added to read as follows:

Subpart F--Medicaid Recovery Audit Contractors Program

Sec.

455.500 Purpose.
 455.502 Establishment of program.
 455.504 Definitions.
 455.506 Activities to be conducted by Medicaid RACs.
 455.508 Eligibility requirements for Medicaid RACs.
 455.510 Payments to RACs.
 455.512 Medicaid RAC provider appeals.
 455.514 Federal share of State expense for the Medicaid RAC program.
 455.516 Exceptions from Medicaid RAC program.
 455.518 Applicability to the territories.

Subpart F--Medicaid Recovery Audit Contractors Program

§455.500 Purpose.

This subpart implements section 1902(a)(42)(B) of the Social Security Act that establishes the Medicaid Recovery Audit Contractor (RAC) program.

§455.502 Establishment of program.

(a) The Medicaid Recovery Audit Contractor program (Medicaid RAC program) is established as a measure for States to promote the integrity of the Medicaid program.

(b) States shall enter into contracts, consistent with State law and in accordance with this section, with eligible Medicaid RACs to carry out the activities described in §455.506 of this subpart.

(c) States will be required to report to CMS certain elements describing the effectiveness of their Medicaid RAC program.

§455.504 Definitions.

As used in this subpart --

Medicaid RAC program means a recovery audit contractor program administered by a State to identify overpayments and underpayments and recoup overpayments.

Medicare RAC program means a recovery audit contractor program administered by CMS to identify underpayments and overpayments and recoup overpayments, established under the authority of section 1893(h) of the Act.

§455.506 Activities to be conducted by Medicaid RACs.

(a) Medicaid RACs will review claims submitted by providers of items and services or other individuals furnishing items and services for which payment has been made under section 1902(a) of the Act or under any waiver of the

State plan to identify underpayments and overpayments and recoup overpayments for the States.

(b) States shall have the discretion to coordinate with Medicaid RACs regarding the recoupment of overpayments.

§455.508 Eligibility requirements for Medicaid RACs.

An entity that wishes to perform the functions of a Medicaid RAC may enter into a contract with a State to carry out any of the activities described in §455.506 under the following conditions:

(a) The entity shall demonstrate to a State that it has the technical capability to carry out the activities described in §455.506 of this subpart. Evaluation of technical capability must include the employment of trained medical professionals to review Medicaid claims.

(b) In carrying out such activities, the entity agrees to coordinate its efforts with the State as well as the Office of Inspector General of the U.S. Department of Health and Human Services, the U.S. Department of Justice, including the Federal Bureau of Investigation, State Medicaid Fraud Control Units, other Federal and State law enforcement agencies as appropriate and CMS. Whenever the entity has reasonable grounds to believe that fraud or criminal activity has occurred, the entity must report it immediately to appropriate law enforcement officials.

(c) The Medicaid RAC meets such other requirements as the State may require.

§455.510 Payments to RACs.

(a) General. Fees paid to RACs shall be made only from amounts recovered.

(b) Overpayments. A State shall determine the contingency fee rate to be paid to a Medicaid RAC for the identification and recovery of Medicaid provider overpayments.

(1) The contingency fee paid to a Medicaid RAC shall be based on a percentage of the overpayment recovered.

(2) States shall determine at what stage in the Medicaid RAC process, post-recovery, Medicaid RACs will receive contingency fee payments.

(3) Except as provided in paragraph (4) of this section, the contingency fee may not exceed that of the highest Medicare RAC, as specified by CMS in the **Federal Register**, unless the State submits, and CMS approves, a waiver of the specified maximum rate. If a State does not obtain a waiver of the specified maximum rate, any amount exceeding the specified maximum rate is not eligible for Federal financial participation (FFP), either from the collected overpayment amounts, or in the form of any other administrative or medical assistance claimed expenditure.

(4) CMS will review and consider, on a case-by-case basis, a State's well-justified request that CMS provide FFP

in paying a Medicaid RAC(s) a contingency fee in excess of the then-highest contingency fee paid to a Medicare RAC.

(c) Underpayments. States shall determine the fee paid to a Medicaid RAC to identify underpayments.

§455.512 Medicaid RAC provider appeals.

States shall provide appeal rights available under State law or administrative procedures to Medicaid providers that seek review of an adverse Medicaid RAC determination.

§455.514 Federal share of State expense of the Medicaid RAC program.

(a) Funds expended by the State for the operation and maintenance of a Medicaid RAC program, not including fees paid to RACs, shall be considered necessary for the proper and efficient administration of the State plan or a waiver of the plan.

(b) FFP is available to States for administrative costs of operation and maintenance of Medicaid RACs subject to CMS' reporting requirements.

§455.516 Exceptions from Medicaid RAC programs.

A State may seek to be excepted from some or all Medicaid RAC contracting requirements by submitting to CMS a written justification for the request and getting CMS approval.

§455.518 Applicability to the territories.

The aforementioned provisions in §455.500 through §455.516 of this subpart are applicable to Guam, Puerto Rico,

U.S. Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands.

CMS-6034-P

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

Dated: August 19, 2010.

Donald M. Berwick,
Administrator,
Centers for Medicare & Medicaid
Services.

Approved: October 29, 2010

Kathleen Sebelius,
Secretary,
Health and Human Services

BILLING CODE 4120-01-P

CMS-6034-P

47

[FR Doc. 2010-28390 Filed 11/05/2010 at 4:15 pm;

Publication Date: 11/10/2010]