EPA APPROVED LOUISIANA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or non-attainment area	State submittal date/effective date	EPA approval date	Explanation
*	*	*	*	*
Clean Air Interstate Rule Sulfur Dioxide Trading Program.	Statewide	09/22/06	07/20/07, [Insert *FR* page number where document begins]	Acid Rain Program Provisions NOT in SIP.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 402

[CMS–6146–F; CMS–6019–F]

RINS 0938–AM98; 0938–AN48

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

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

ACTION: Final rule.

SUMMARY: This final rule establishes the procedures for imposing exclusions for certain violations of the Medicare program and is based on the procedures that the Office of Inspector General has published for civil money penalties, assessments, and exclusions under their delegated authority. Implementation of this final rule protects beneficiaries from persons (that is, health care providers and entities) found in noncompliance with Medicare regulations, and otherwise improves the safeguard provisions under the Medicare statute. This final rule also establishes procedures that enable a person targeted for exclusion from the Medicare program to request the Centers for Medicare & Medicaid Services to act on its behalf to recommend to the Inspector General that the exclusion from Medicare be waived due to hardship that would be placed on Medicare beneficiaries as a result of the person's exclusion.

DATES: *Effective Date:* This final rule is effective on August 20, 2007.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory History

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

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

In the December 14, 1998 **Federal Register** (63 FR 68687), we published a final rule entitled ''Medicare and Medicaid Program; Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures.'' That rule set forth the procedures for pursuing civil money penalties (CMPs) and assessments, and added a new part 402 to title 42, chapter IV of the Code of Federal Regulations (CFR) to incorporate our CMP and assessment authorities. However, we did not address exclusions in that final rule. Instead, we reserved subpart C for exclusions so that we could incorporate the relevant regulations at a future date.

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

In the July 23, 2004 **Federal Register** (69 FR 43956), we published a proposed rule entitled ''Medicare Program; Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures.'' This proposed rule would amend subpart C by establishing the procedures for imposing exclusions for certain violations of the Medicare program. The proposed rule would incorporate the general requirements and procedures that are common to the imposition of an exclusion from the Medicare program.

In the August 4, 2005 **Federal Register** (70 FR 44879), we published a proposed rule entitled ''Medicare Program; Revised Civil Money Penalties, Assessments, Exclusions and Related Appeals Procedures'' that would implement section 949 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 949 of the MMA amended section 1128(c)(3)(B) of the Act to indicate that ''[s]ubject to

subparagraph (g), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than 5 years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on individuals entitled to benefits under Part A of title XVIII or enrolled under Part B of such title, or both, the Secretary may, after consulting with the Inspector General of the Department of Health and Human Services, waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in the community.'' The Conference Agreement accompanying the MMA clarifies the intent of the statutory requirement that a hardship determination be made before a waiver is approved. In short, we proposed the general requirements and procedures that would allow certain providers and entities identified for exclusion from the Medicare program to request that we act on their behalf to recommend to the OIG that their exclusion from Medicare be waived because of a hardship that would result on Medicare beneficiaries. We also stated in this proposed rule our intent to respond to the public comments we received from the July 23, 2004 proposed rule and this proposed rule in a single final rule.

B. Timelines for Publication of This Medicare Final Rule

Section 902 of the MMA amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final rules based on the previous publication of a Medicare proposed or interim final rule. Section 902 of the MMA also states that the timelines for these rules may vary, but must not exceed 3 years after publication of the preceding proposed or interim final rule, except under exceptional circumstances.

This final rule finalizes provisions set forth in the July 23, 2004 and the August 4, 2005 proposed rules. In addition, this final rule will be published within the 3-year time limit imposed by section 902 of the MMA. Therefore, this final rule will be published in accordance with the Congress' intent for ensuring timely publication of final rules.

II. Provisions of the Proposed Rules and Analysis and Responses to Public Comments

A. Provisions of the July 23, 2004 Proposed Rule

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

We proposed adding the following provisions under part 402 subpart C.

1. Basis and Purpose (Proposed § 402.200)

Section 402.200 provides the basis and purpose for the imposition of an exclusion from Medicare, Medicaid, and (where applicable) other Federal health care programs based on noncompliance with the respective provisions of part 402 subpart A, § 402.1(e). This subpart also sets forth the appeal rights of a person subject to exclusion, as well as the procedures for a person's reinstatement following an exclusion. (This subpart is based on § 1003.102, § 1003.105, § 1003.107, and § 1003.109 of the OIG's regulations.)

2. Length of Exclusion (Proposed § 402.205)

This section describes the duration of exclusion from Medicare, Medicaid, and (where applicable) other Federal health care programs for the applicable violation. Currently, there are four general categories for which violations may cause exclusions. These categories involve noncompliance with assignment billings, noncompliance with charge or service limits, failure to provide information, or improperly providing information.

Some exclusion provisions provide that the exclusion is imposed in accordance with section 1842(j)(2) of the Act, which provides for exclusion from participation in programs under the Act. These exclusions may not exceed 5 years. For these exclusion provisions, we propose using our discretion to set a duration for the exclusion, up to 5 years, after considering aggravating and mitigating circumstances as described in the July 23, 2004 proposed rule (69 FR 43956).

By contrast, many other exclusion provisions extend to all Federal health care programs, and do not address the minimum or maximum duration of the exclusion. Instead, they simply refer to applying the provisions of section 1128A of the Act or section 1128(c) of the Act for imposition of the exclusion. However, neither section 1128A of the Act, nor section 1128(c) of the Act, address the specific duration of an exclusion for any of the title XVIII exclusion provisions described in this proposed rule. Therefore, where the duration of an exclusion is not specifically addressed by statute for a specific exclusion provision, we proposed using our discretion to apply a time period we believed was justified, taking into account appropriate aggravating and mitigating factors that are described in the July 23, 2004 proposed rule (69 FR 43956).

While several provisions of title XVIII of the Act refer on their face only to CMPs, they also make cross-references to section 1128A of the Act, from which we assert that our exclusion authority derives. This is the case with both sections 1877 and 1882 of the Act. Each of these provisions incorporates by reference portions of section 1128A of the Act, articulating with specificity which section 1128A provisions are applicable. In each case, this includes section 1128A's exclusion authority (and, in the case of section 1877 of the Act, the exclusion authority is made even more clear with the term ''exclusion'' being found in the section heading). The applicable provision of section 1128A of the Act is the provision's last sentence, explicitly made applicable to all the foregoing, which provides that the Secretary ''may make a determination in the same [CMP] proceeding to exclude the person from participation in Federal health care programs.''

3. Factors Considered in Determining Whether To Exclude, and the Length of Exclusion (Proposed § 402.208)

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

Proposed § 402.208 would provide the specific details of the aggravating and mitigating circumstances that may be considered. (This section is based on the corresponding OIG sections of 42 CFR parts 1001 and 1003.) We note that our application of aggravating and

mitigating factors flows both as a natural result of a statutory scheme that contemplates exclusions of varying lengths, as well as the Secretary's rulemaking authority specified in section 1871 of the Act.

4. Scope and Effect of Exclusion (Proposed § 402.209)

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

5. Notice of Exclusion (Proposed § 402.210)

Proposed § 402.210 would specify the contents of respective notices and specifically, the timing for release of—(1) the written notice of intent to exclude (that is, the proposed determination); and (2) the written notice of exclusion. At a minimum, the written notice of intent to exclude provides the person with information as to the reason why it is noncompliant with the statute, the length of the proposed exclusion, and instructions for responding to the notice, including providing argument against exclusion for the agency to consider. The written notice to exclude is sent to the person in the same manner as the written notice of intent to exclude if the agency determines that the exclusion is warranted. This notice would also provide the person with information on its appeal rights regarding the exclusion. (This section is based on criteria provided by the OIG in § 1001.2001, § 1001.2002, § 1001.2004, and § 1003.109.)

6. Response to Notice of Proposed Exclusion (Proposed § 402.212)

Proposed § 402.212 would state the general process and procedure for a person to follow when presenting an oral or written response to the notice of intent to exclude (that is, the proposed determination). We would accept for consideration any supportive information the person provides. We would not limit nor suggest what type of information should be presented. The burden to present convincing information is left to the person's discretion. Even though this section is based on the process and procedures delineated by the OIG in § 1003.109, to encourage timely communication between the person and the initiating agency, we have added an additional element whereby the initiating agency would contact the person within 15 days of receipt of the person's request to establish a mutually agreed upon time and place for the oral presentation and discussion.

7. Appeal of Exclusion (Proposed § 402.214)

Proposed § 402.214 would specify the general appeal process for requesting a hearing before an administrative law judge, and details the required elements of the written request for appeal. (This section is based on criteria provided by the OIG in § 1005.) Generally, the elements of the written request must include the basis for the disagreement with the exclusion, the general basis for the person's defense, and reasons why the proposed length of exclusion should be modified. (This section is based on criteria provided by the OIG in § 1001.2003 and § 1001.2007.)

8. Request for Reinstatement (Proposed § 402.300)

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

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

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

Proposed § 402.300(d) specifies that, if a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the excluded person would be permitted to request and apply for reinstatement within 120 days of the expiration of the reduced exclusion period. A written request for the reinstatement would include the same standards specified in § 402.300(b). (This section is based on criteria provided by the OIG in § 1001.3001.)

9. Basis for Reinstatement (Proposed § 402.302)

In proposed § 402.302, we would specify that the initiating agency would authorize reinstatement if the agency determines that—(1) The period of exclusion has expired; (2) there are reasonable assurances that the types of actions that formed the basis for the original exclusion will not recur; and (3) there is no additional basis under title XVIII of the Act that will justify the continuation of the exclusion.

We also stated that the initiating agency would not authorize reinstatement if the basis for denying reinstatement lies in an excluded person continuing either to submit claims (or causing claims to be submitted) or to receive and accept payments from the Medicare program for items or services it has furnished, ordered, or prescribed. This section would apply, regardless of whether the excluded person has obtained a Medicare provider number (or equivalent), either as an individual or as a member of a group, before being reinstated.

In making a determination regarding reinstatement, the initiating agency would consider—(1) The conduct of the excluded provider occurring before the date of the notice of the exclusion, if that conduct was not known to the initiating agency at the time of the exclusion; (2) the conduct of the excluded person after the date of the

exclusion; (3) whether all fines and all debts due and owing (including overpayments) to any Federal, State, or local government that relate to Medicare, Medicaid, or (where applicable) any Federal, State, or local health care program were paid in full, or alternatively that satisfactory arrangements were made to fulfill these obligations; (4) whether the excluded person complied with, or had made satisfactory arrangements to fulfill, all of the applicable conditions of participation or conditions of coverage under the Medicare statutes and regulations; and (5) whether the excluded person had, during the period of exclusion, submitted claims (or caused claims to be submitted) or payment to be made by Medicare, Medicaid, and (where applicable) any other Federal health care program for items or services furnished, ordered, or prescribed, and the conditions under which these actions occurred.

We proposed that reinstatement would not be effective until the initiating agency grants the request and provides notice under § 402.304. Reinstatement would be effective as provided in the notice. A determination for a denial of reinstatement will not be appealable or reviewable, except as provided in § 402.306.

We also proposed that an ALJ cannot require reinstatement of an excluded person according to this chapter as specified in § 402.306(d). (The content of this section is based on the criteria provided by the OIG in § 1001.3002.)

10. Approval of Request for Reinstatement (Proposed § 402.304)

With regard to approval of a request for reinstatement (§ 402.304), we would state that, if the initiating agency grants a request for reinstatement, then the initiating agency would—(1) Give written notice to the excluded person specifying the date of reinstatement; and (2) notify appropriate Federal and State agencies, and, to the extent possible, all others that were originally notified of the exclusion, that the person has been reinstated into the Medicare program.

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

11. Denial of Request for Reinstatement (Proposed § 402.306)

In proposed § 402.306, we specified that if a request for reinstatement is denied, the initiating agency would provide written notice to the excluded person. Within 30 days of the date of this notice, the excluded person may submit to the initiating agency: (1) Documentary evidence and a written argument challenging the reinstatement denial; or (2) a written request to present written evidence or oral argument to an official of the initiating agency.

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

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

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

We received 11 comments related to the July 23, 2004 proposed rule. The following is a summary of the comments received and our responses to them.

Comment: Commenters expressed concern over the discretion that we may apply in setting the duration of exclusion when duration is not addressed by statute.

Response: The statute does not specifically set the duration of exclusion. Therefore, we will consider any and all factors, as listed in § 402.208, presented when weighing our decision on the length of the exclusion. We believe the circumstances and facts presented will provide a basis for determining the appropriate duration on a case-by-case basis.

Comment: Commenters stated that wrongful conduct that occurred at a time otherwise barred by the statute of limitations should not be considered as a factor.

Response: It is our intent to consider any and all applicable factors in making a determination of exclusion from the Medicare program, including past wrongful conduct unrelated to the specific conduct at issue. Unlike the imposition of civil monetary penalties that are only applied to the conduct at issue, we take a different position on imposing an exclusion from the Medicare program.

Comment: One commenter indicated the financial loss to the program associated as an aggravating or mitigating factor was too small. The commenter used as an example a single hospital claim whereby the value of a single claim is typically more than the loss proposed in the rule.

Response: We have drafted this final rule to be adopted as a generic template to account for all types of healthcare providers (for example, hospitals, physicians, and suppliers). The financial factors proposed for aggravating and mitigating circumstances provide us with the ability to consider a low dollar tolerance that would be applicable to both institutional and non-institutional providers.

Comment: One commenter suggested that instead of considering it a mitigating factor when the noncompliance resulted from an unintentional or unrecognized error in a request for payment, and the person took prompt corrective steps once the error was discovered, that this circumstance should mean that no exclusion was warranted.

Response: The circumstances described by the commenter would most likely result in a favorable determination. We would likely consider those particular circumstances as mitigating factors. We will look at all factors and degrees of timeliness and promptness of changing the noncompliant activity before rendering a determination on whether to exclude a person from the Medicare program and the duration of the exclusion period.

Comment: One commenter suggested adding as a mitigating circumstance the fact that the person has an effective compliance program in place.

Response: We agree that an effective compliance program could be considered a mitigating circumstance under § 402.208(b)(3). However, the compliance program would not be considered effective if a violation occurred during the time the program was in effect, and the violation was not identified and remedied by the person prior to CMS identifying the noncompliance. The remedial step of

establishing an effective compliance program may result in the period of exclusion being modified.

Comment: One commenter questioned the knowledge of furnishing services at the request of or direction of an excluded person, and whether, for example, a hospital has any obligation to check the list of excluded persons when furnishing services at the request of another entity.

Response: We believe the exceptions described in § 402.209 address how we view the knowledge factor. With regard to an obligation to check the list of excluded persons, we are not aware of any statutory requirement of this type. While it is not obligatory to check the exclusions list, a provider may wish to voluntarily add this element as part of its compliance program to ensure that all claims for services of this type will be paid.

Comment: One commenter regarded the provision that the exclusion effective date would not be delayed if an appeal was filed timely would deprive the person of economic existence. Therefore, the commenter recommended that the exclusion be stayed until the appeal process had been concluded.

Response: As specified in § 402.210(a), before written notice of the exclusion is sent, the person would receive a notice of proposed determination. The person has the opportunity at this time to present to CMS documentary evidence and a written response, or to make an oral presentation as to why the exclusion should not be imposed. In response, we may not impose the exclusion if we find that the exclusion is unwarranted. Although the commenter may feel that the appeal process is unfair because the exclusion is not delayed, we intend to remain consistent with the process that governs the other Federal agencies.

Comment: One commenter suggested removing or revising the requirement of providing additional information when applying for reinstatement, because that requirement is too onerous, or the additional information requested may include protected information.

Response: If we request additional information, it is the excluded person's decision whether to provide the information. A person who seeks reinstatement should be prepared to provide evidence it deems appropriate to support the reinstatement as defined in § 402.302. However, we would base our determinations on the information that we have been provided.

Comment: One commenter requested that the provision regarding our upholding the initial appeal determination to deny reinstatement should have appeal rights.

Response: In reviewing the provision, the excluded person has two opportunities to present evidence to CMS that may meet the conditions for reinstatement as set forth in § 402.302. These two opportunities to present evidence are detailed in § 402.300(a) and § 402.306(a). Failing to present convincing evidence, the excluded person is again afforded the opportunity 1 year later, as detailed in § 402.306(c). We believe these situations provide an excluded person with adequate opportunity to be heard, and decline to add additional appeal rights.

Comment: One commenter expressed that there was conflict between § 402.210(a) and § 402.212(b) regarding the time period for submitting a request for oral argument.

Response: We reviewed the provisions and have revised the time period in § 402.212(b) to be consistent with the 30-day period in § 402.210(a) for submitting a request to present oral arguments.

Comment: One commenter suggested that the exclusions related to the provisions of section 1882 of the Act are not intended for issuers of Medigap insurance or Medigap insurance policies. The commenter suggested that the Congress did clearly apply civil monetary penalties to the provisions, but made no explicit application or reference to exclusions.

Response: As we discussed previously, section 1882 of the Act cross references section 1128A of the Act, articulating with specificity the applicable portions of the latter statute, which in each case includes section 1128A's exclusion authority. We believe that we have the legal authority to impose exclusions associated with violations of section 1882 of the Act.

B. Provisions of the August 4, 2005 Proposed Rule

This proposed rule would amend part 402, subpart C, (Exclusions) to set forth the general requirements and procedures that would allow persons targeted for exclusion from the Medicare program to request that CMS act on their behalf to recommend to the Inspector General that their exclusion from Medicare be waived because of a hardship that would result on Medicare beneficiaries. These requirements and procedures implement section 949 of the MMA.

We proposed adding the following provisions under subpart C:

1. Waiver of Exclusions (Proposed § 402.308)

In § 402.308, we stated that persons who have been excluded by the Inspector General may request that CMS act on their behalf to recommend to the Inspector General that their exclusion from the Medicare program be waived. We would recommend waiver if we determine that the person's exclusion from the Medicare program would place a hardship on Medicare beneficiaries. Our decision to make the recommendation of a waiver to the Inspector General is not subject to administrative or judicial review. Additionally, our recommendation of waiver is not tantamount to the automatic granting of a waiver, because it is the Inspector General who will make the final decision on whether a waiver should be granted to the excluded person.

We received 2 comments related to the August 4, 2005 proposed rule (CMS–6019–P). Below is a summary of the comments received and our responses to them.

Comment: One commenter indicated it was unable to identify the delegation of section 949 of the MMA waiver authority from the Secretary to the OIG; therefore, the commenter is opposed to the delegation.

Response: Our authority to request a waiver under section 949 of the MMA is specified in § 402.209 of this final rule. The authority of the OIG to grant or deny a request for a waiver is outside the scope of this final rule.

Comment: One commenter requested that we provide a definition with greater clarity for the terms used to describe persons eligible for the exclusion waiver.

Response: We have revised § 402.308(a) to refer to § 1001.2 of the OIG regulations, which define ''sole community physician'' and ''sole source of essential specialized services'' in the Medicare community.

III. Provisions of the Final Regulations

We are adopting all of the provisions of the proposed rules as final with the following changes.

Due to a typographical error, we are replacing § 402.105(d)(2)(xix) with § 402.105(d)(2)(ix).

In § 402.308, we are adding the terms ''sole community physician'' and ''sole source of essential specialized services in the community'' to the list of definitions. For each term, we are referencing those terms as they are defined by the OIG regulations at § 1001.2. In addition, in § 402.308(b), we are revising the text, ''For purposes of

this part'' to read as ''For purposes of this subpart''.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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.

Scope and Effect of Exclusion (§ 402.209)

Section 402.209(c)(2) states that payment may be made for certain emergency items or services furnished by an excluded person, or under the medical direction or on the request of an excluded person during the period of exclusion. In order to be paid, a claim for the emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services, specifying the nature of the emergency and the reason that the items or services were not furnished by a person eligible to furnish or order the items or services.

The burden associated with this requirement is the time and effort associated with drafting and submitting a document containing a sworn statement that explains the circumstances under which services were furnished by an excluded individual. While this requirement does impose a burden, we believe it is exempt from the PRA as defined in 5 CFR 1320.4; information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

Response to Notice of Proposed Determination to Exclude (§ 402.212).

Section 412.212 outlines the procedures an individual must follow to submit a response to the notice of intent to exclude. Specifically, § 402.212(a) states that within 60 days of the receipt of the notice, a person may present to the initiating agency a written response to dispute whether the proposed exclusion is appropriate. In addition, the person submitting the written response to the notice may provide additional supportive documentation. The burden associated with this requirement is the time and effort associated with drafting and submitting a written response to the notice.

Section 402.212(b) states that recipient of a notice of intent to exclude is also afforded an opportunity to be heard by the initiating agency in order to make an oral presentation concerning whether the proposed exclusion is warranted. The person must submit the request for an oral presentation within 60 days of the receipt of the notice. The burden associated with this requirement is the time and effort associated with submitting a request for an oral presentation.

While the requirements listed in § 402.212(a) and (b) do impose burdens, we believe they are exempt from the PRA as defined in 5 CFR 1320.4; information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

Appeal of Exclusion (§ 402.214)

Section 402.214(b) lists the conditions under which an excluded person may file a request for a hearing before an administrative law judge (ALJ). Section 402.214(d) states that an excluded person must file a request for a hearing within 60 days from the receipt of the notice of exclusion. Section 402.214(e) lists the required content of the written request for a hearing.

The burden associated with these requirements is the time and effort necessary to draft and submit a request for a hearing with an ALJ as stated in § 402.214(d). In addition, the person must ensure that the request contains all of the information outlined in § 402.214(e). While these requirements do impose burdens, we believe they are exempt from the PRA as defined in 5 CFR 1320.4; information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

Request for Reinstatement (§ 402.300)

Section 402.300(a) explains that an excluded person may submit a request for reinstatement to the agency initiating the exclusion. An excluded person must submit a written request no sooner than 120 days prior to the terminal date of exclusion as specified in the notice of exclusion. Section 402.300(d) explains the request for reinstatement process for an excluded person that had the period of exclusion reduced on appeal. The excluded person must submit a written request and apply for reinstatement within 120 days of the expiration date of the reduced exclusion period.

The burden associated with these requirements is the time and effort necessary to draft and submit the request for reinstatement and to apply for reinstatement. While these requirements do impose burdens, we believe they are exempt from the PRA as defined in 5 CFR 1320.4; information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

Denial of Request for Reinstatement (§ 402.306)

Section 402.306(a) explains that if a request for reinstatement is denied, the initiating agency must notify the excluded person in writing. This section also states that within 30 days of the date of the notice of denial, the excluded person may submit to the initiating agency—documentary evidence and a written argument challenging the reinstatement denial; or a written request to present written evidence or oral argument to an official of the initiating agency.

The burden associated with this requirement is the time and effort necessary for the excluded person to provide the aforementioned information. While this requirement imposes burden, we believe it is exempt from the PRA as defined in 5 CFR 1320.4; information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

Waivers of Exclusions (§ 402.308)

Section 402.308 discusses the process involved in obtaining a waiver of exclusions. Section 402.308(a) states that persons may request of CMS to present, on their behalf, a request to the Office of the Inspector General (OIG) for

a waiver of the exclusion. The request must be in writing and will only be considered if it meets the criteria listed in this section. If the individual or entity meet the criteria, the written request for a waiver of exclusion must provide, at a minimum, the information listed under § 402.308(b).

The burden associated with this requirement is the time and effort necessary to prepare and submit to CMS the written document requesting a waiver of exclusion. While this requirement imposes burden, we believe it is exempt from the PRA as defined in 5 CFR 1320.4; information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

V. Regulatory Impact Statement

We have examined the impacts of this final 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 in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule. Any impact that may occur would only affect those limited few persons that engage in prohibited behavior. We do not anticipate any savings or costs as a result of this final 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 government 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 will not have a significant economic impact on a substantial number of small entities. We believe that any impact as a result of the final rule will be minimal, since the only persons affected would be those limited few who engage in prohibited conduct. Since the vast majority of program participants comply with statutory and regulatory requirements, any aggregate economic impact would not be significant.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will 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 is currently approximately $120 million. This rule will have no consequential effect on State, local, or tribal governments, or by the private sector since the majority of program participants comply with statutory and regulatory requirements.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does 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, the Office of Management and Budget reviewed this regulation.

List of Subjects in 42 CFR Part 402

Administrative practice and procedure, Medicaid, Medicare, Penalties.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV part 402 as set forth below:

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

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

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

Subpart A—General Provisions

§ 402.1 [Amended]

■ 2. In § 402.3, add the definition of ''initiating agency'' in alphabetical order to read:

§ 402.3 Definitions.

* * * * *

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

* * * * *

Subpart B—Civil Money Penalties and Assessments

■ 3. In § 402.105, redesignate paragraph (d)(1)(xix) as paragraph (d)(1)(ix).

■ 4. In part 402, add a new subpart C to read as follows:

Subpart C—Exclusions

Sec.

Subpart C—Exclusions

§ 402.200 Basis and purpose.

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

(b) *Purpose.* This subpart—

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

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

§ 402.205 Length of exclusion.

The length of exclusion from participation in Medicare, Medicaid,

and, where applicable, other Federal health care programs, is contingent upon the specific violation of the Medicare statute. A full description of the specific violations identified in the sections of the Act are cross-referenced in the regulatory sections listed in the table in paragraph (a) of this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) Any other matters that justice may require.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(vi) The person had a documented mental, emotional, or physical condition before or during the

commission of the noncompliant act(s) and that condition reduces the person's culpability for the acts in question.

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

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

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

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

§ 402.209 Scope and effect of exclusion.

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

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

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

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

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

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

§ 402.210 Notices.

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

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

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

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

(4) The length of the proposed exclusion.

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

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

(i) The person has the right to request an opportunity to meet with an official of the initiating agency to make an oral presentation; and

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

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

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

(1) The basis for the exclusion.

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

(3) The effect of exclusion.

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

(5) The requirements and procedures for reinstatement.

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

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

§ 402.212 Response to notice of proposed determination to exclude.

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

(b) The person is also afforded an opportunity to make an oral presentation to the initiating agency concerning whether the proposed

exclusion is warranted and any related matters. The person must submit this request within 30 days of the receipt of notice. Within 15 days of receipt of the person's request, the initiating agency initiates communication with the person to establish a mutually agreed upon time and place for the oral presentation and discussion.

§ 402.214 Appeal of exclusion.

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

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

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

(2) The duration of the exclusion is unreasonable.

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

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

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

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

(2) Basis for the disagreement.

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

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

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

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

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

§ 402.300 Request for reinstatement.

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

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

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

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

§ 402.302 Basis for reinstatement.

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

(1) The period of exclusion has expired;

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

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

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

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

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

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

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

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

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

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

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

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

§ 402.304 Approval of request for reinstatement.

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

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

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

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

health care program has imposed a longer period of exclusion under its own authorities.

§ 402.306 Denial of request for reinstatement.

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

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

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

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

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

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

§ 402.308 Waivers of exclusions.

(a) *Basis.* Section 1128(c)(3)(B) of the Act specifies that in the case of an exclusion from participation in the Medicare program based upon section 1128(a)(1), (a)(3), or (a)(4) of the Act, the individual may request that CMS present, on his or her behalf, a request to the OIG for a waiver of the exclusion.

(b) *Definitions.* For purposes of this section:

Excluded person has the same meaning as a ''person'' as defined in § 402.3 who meets for the purposes of this subpart, the definition of the term ''exclusion'' in § 402.3.

Hardship for purposes of this section means something that negatively affects Medicare beneficiaries and results from the imposition of an exclusion because the excluded person is the sole community physician or sole source of essential specialized services in the Medicare community.

Sole community physician has the same meaning as that term is defined § 1001.2 of this title.

Sole source of essential specialized services in the community has the same meaning as that term defined by the § 1001.2 of this title.

(c) *General rule.* If CMS determines that a hardship as defined in paragraph (b)(2) of this section results from exclusion of an affected person from the Medicare program, CMS may consider and may make a request to the Inspector General for waiver of the Medicare exclusion.

(d) *Submission and content of a waiver of exclusion request.* An excluded person must submit a request for waiver of exclusion in writing to CMS that includes the following:

(1) A copy of the exclusion notice from the OIG.

(2) A statement requesting that CMS present a waiver of exclusion request to the OIG on his or her behalf.

(3) A statement that he or she is the sole community physician or sole source of essential specialized services in the community.

(4) Documentation to support the statement in paragraph (d)(3) of this section.

(e) *Processing of waiver of exclusion requests.* CMS processes a request for a waiver of exclusion as follows:

(1) Notifies the submitter that the waiver of exclusion request has been received.

(2) Reviews and validates all submitted documents.

(3) During its analysis, CMS may require additional, specific information, and authorization to obtain information from private health insurers, peer review organizations (including, but not limited to, Quality Improvement Organizations), and others as necessary to determine validity.

(4) Makes a determination regarding whether or not to submit the waiver of exclusion request to the OIG based on review and validation of the submitted documents.

(5) If CMS elects to submit the waiver of exclusion request to the OIG, CMS copies the excluded person on the request.

(6) If CMS denies the request, then CMS notifies the excluded person of the decision and specifies the reason(s) for the decision.

(f) *Administrative or judicial review.* A determination rendered under paragraph (e)(4) of this section is not subject to administrative or judicial review.

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

Dated: December 14, 2006.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 26 2007.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on July 9, 2007.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0 and 90

[WT Docket No. 02–55, ET Docket No. 00–258; ET Docket No. 95–18; RM–9498; RM–10024—FCC 07–102]

Improving Public Safety Communications in the 800 MHz Band, et al.

AGENCY: Federal Communications Commission.

ACTION: Final rule, clarification.

SUMMARY: In the Second Memorandum Opinion and Order, the Commission affirms and clarifies various rules governing the 800 MHz band reconfiguration process designed to improve public safety communications. The Second Memorandum Opinion and Order addresses various petitions for reconsideration and clarification asking the Commission to revisit certain decisions in the 800 MHz band reconfiguration proceeding.

DATES: Effective August 20, 2007.

FOR FURTHER INFORMATION CONTACT: John Evanoff, Public Safety and Homeland Security Bureau, (202) 418–0848, or via the Internet at *John.Evanoff@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document summarizes the Second Memorandum Opinion and Order in WT Docket No. 02–55, adopted on May 24, 2007, and released on May 30, 2007. The full text of this document is available for public inspection on the Commission's Internet site at *http://www.fcc.gov.* It is also available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The full text of this document also may be purchased from the Commission's