developing the Copyright Office's system for online preregistration, it is not entirely clear whether the system will be compatible with web browsers other than Microsoft Internet Explorer versions 5.1 and higher. Filers of preregistration applications will be able to employ these Internet Explorer browsers successfully. Support for Netscape 7.2, Firefox 1.0.3, and Mozilla 1.7.7 is planned but will not be available when preregistration goes into effect. Present users of these browsers may experience problems when filing claims.

In order to ensure that preregistration can be implemented in a smoothly functioning and timely manner, the Office now seeks comments that will assist it in determining whether any eligible parties will be prevented from preregistering a claim due to browser requirements of the preregistration system. Therefore, this notice seeks information whether any potential preregistration filers would have difficulties using Internet Explorer (version 5.1 or higher) to file preregistration claims, and if so, why. More generally, in the interest of achieving support for browsers in the Office's preregistration processing environment, this notice inquires whether (and why) an eligible party who anticipates preregistering a claim on the electronic–only form will not be able to use Internet Explorer to do so, or will choose not to preregister if it is necessary to use Internet Explorer.

The Office requests that responses to this supplemental notice of inquiry be made part of the responders' comments on the July 22nd Notice of Proposed Rulemaking. Whether or not accompanied by comments on the proposed rule, the response to this notice of inquiry should be submitted by the due dates for comment on the Notice of Proposed Rulemaking, i.e., no later than August 22, 2005, with reply comments due no later than September 7, 2005.

Dated: August 1, 2005.

Tanya Sandros,

Associate General Counsel.

[FR Doc. 05–15458 Filed 8–3–05; 8:45 am]

BILLING CODE 1410–30–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 402

[CMS–6019–P]

RIN 0938–AN48

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth the general requirements and procedures that would allow certain entities who are identified 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. This proposed rule would implement section 949 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

DATES: To be assured consideration, comments must be received at the appropriate address, as provided below, no later than 5 p.m. on October 3, 2005.

ADDRESSES: In commenting, please refer to file code CMS–6019–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6019–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

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

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

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–6019–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public website as soon as possible after they have been received. Hardcopy comments received timely will 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.

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

I. Background

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

Section 1128A of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to impose civil money penalties (CMPs), assessments, and/or exclusion from the Medicare program for certain health care facilities, practitioners, suppliers or other entities under prescribed circumstances. Exclusion, as defined in 42 CFR 402.3, provides the ultimate enforcement tool for agencies attempting to establish compliance with legal and program standards, and is used in addition to potential civil, criminal, and/or administrative proceedings.

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

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

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

On July 23, 2004, we published a proposed rule in the **Federal Register** (69 FR 43956), delineating the procedures for pursuing exclusions. It is our intent to respond to the public comments we received from the July 3, 2004 proposed rule and this rule in a single final rule.

Section 949 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended section 1128(c)(3)(B) of the Act to indicate that, ''Subject to subparagraph (g), in the case of an exclusion under subsection (a), the minimum period of exclusion shall not be 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.

II. Provisions of the Proposed Rule

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

This proposed rule would amend part 402, by adding to subpart C, a new section that establishes the general requirements and procedures concerning our authority to request a waiver of exclusion, for an excluded person, from Medicare exclusions that are imposed by the OIG.

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

- *Section 402.308, Waivers of Exclusions.*

This section provides the basis and purpose for the excluded person to make a request to us. This subpart also sets forth the requirements that must be met by the excluded person in order for us to make a request to the OIG of a waiver to the exclusion. The statute specifies the basis upon which a request of waiver for an exclusion must be based, but provides few details regarding the administrative decision-making process.

We will consider any supportive information submitted by the respondent. We will not limit nor suggest what type of information may be presented. However, while the burden to present convincing information is left to the discretion of the respondent, we will initiate our own validation of the facts presented. During this analysis, we may require the person to furnish 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 the validity of the facts provided.

It is our interpretation that unless a hardship (defined for purposes of § 402.308 as 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) is met, no requests for a waiver of Medicare exclusion will be considered or forwarded to the OIG by CMS. Our decision is not subject to administrative or judicial review. Furthermore, a request made by CMS to the OIG does not automatically grant a waiver. The final decision is that of the OIG as defined in § 1001.1801 of the OIG's regulations.

III. Collection of Information Requirements

The collection of information requirements at 5 CFR part 1320 are applicable to requirements affecting 10 or more entities. While this proposed rule contains information collection requirements, because we believe that these requirements will affect less than 10 entities, we believe that these collection requirements are exempt from OMB for review and approval, as specified at 5 CFR 1320.3(c)(4). Consequently, this proposed rule need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

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

respond to the major comments in the preamble to that document.

V. Regulatory Impact Statement

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

Executive Order 12866 directs agencies taking ''significant regulatory action'' to reflect consideration of all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule is not a significant regulatory action as defined by section 3(f) of Executive Order 12866. We believe that there are no significant costs associated with this proposed rule that would impose any mandates on State, local or tribal governments, or the private sector that would result in an expenditure of $100 million in any given year. Since most program participants comply with the statutory and regulatory requirements making unnecessary the imposition of an exclusion from Medicare, Medicaid and, where applicable, other Federal health care programs, we do not anticipate more than a *de minimis* economic impact as a result of this proposed rule. Further, any impact that may occur would only affect those limited few individuals or entities that engage in prohibited behavior. We do not anticipate any savings or costs as a result of this proposed rule.

The RFA (15 U.S.C. 603(a)), as modified by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121), requires agencies to determine whether the proposed rule would have a significant economic impact on a substantial number of small entities and, if so, to identify in the notice of proposed rulemaking any regulatory options that could mitigate the impact of the proposed regulation on small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $26 million or less annually. Individuals and States are not included in the definition of a small entity. We believe that any impact as a result of the proposed rule would be minimal, since, as mentioned above, the only individuals or entities affected would be those limited few who have engaged in prohibited conduct and were excluded from the Medicare program by the OIG. Since the vast majority of program participants comply with statutory and regulatory requirements and are not excluded from the Medicare program, any aggregate economic impact would not be significant.

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

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We believe that there are no significant costs associated with this technical rule that would impose any mandates on State, local, or tribal governments, or the private sector that would result in an expenditure of $110 million in any given year.

As was previously mentioned, since the majority of program participants comply with statutory and regulatory requirements and are not excluded from the Medicare program, any aggregate economic impact would not be significant.

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

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

List of Subjects in 42 CFR Part 402

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

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

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

Subpart C—Exclusions

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

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

2. Part 402, subpart C is amended by adding § 402.308 to read as follows:

§ 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) *Definition.* For purposes of this part:

(1) *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.

(2) *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.

(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 recommendation 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)(3) 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: April 8, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 15, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–15291 Filed 8–3–05; 8:45 am]

BILLING CODE 4120–01–P