safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, these rules do not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Volatile organic compounds, Reporting and recordkeeping requirements.

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

Dated: April 12, 2013.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2013–10048 Filed 4–26–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 420, 424, and 498

[CMS–6045–P]

RIN 0938–AP01

Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Incentive Reward Program provisions in § 420.405 and certain provider enrollment requirements in part 424, subpart P. The most significant of these revisions include: changing the Incentive Reward Program potential reward amount for information on individuals and entities who are or have engaged in acts or omissions which resulted in the imposition of a sanction from 10 percent of the overpayments recovered in the case or $1,000, whichever is less, to 15 percent of the final amount collected applied to the first $66,000,000 for the sanctionable conduct; expanding the instances in which a felony conviction can serve as a basis for denial or revocation of a provider or supplier's enrollment; if certain criteria are met, enabling us to deny enrollment if the enrolling provider, supplier, or owner thereof had an ownership relationship with a previously enrolled provider or supplier that had a Medicare debt; enabling us to revoke Medicare billing privileges if we determine that the provider or supplier has a pattern or practice of submitting claims for services that fail to meet Medicare requirements; and limiting the ability of ambulance suppliers to ''backbill'' for services performed prior to enrollment. We believe this proposed rule would—increase the incentive for individuals to report information on individuals and entities that have or are engaged in sanctionable conduct; improve our ability to detect new fraud schemes; and help us ensure that fraudulent entities and individuals do not enroll in or maintain their enrollment in the Medicare program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 28, 2013.

ADDRESSES: In commenting, please refer to file code CMS–6045–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By Regular Mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6045–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By Express or Overnight Mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6045–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By Hand or Courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

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

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

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

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT: Morgan Burns, (202) 690–5145, for issues related to the Incentive Reward Program. Frank Whelan, (410) 786–1302, for issues related to provider enrollment.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning

approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

a. Need for Regulatory Action

This proposed rule is necessary to make revisions to the Incentive Reward Program in 42 CFR 420.405, and to make certain changes to the provider enrollment provisions in 42 CFR part 424, subpart P. This proposed rule would: (1) increase the incentive for individuals to report information on individuals and entities that have or are engaged in sanctionable conduct; and (2) help ensure that fraudulent entities and individuals do not enroll in or maintain their enrollment in the Medicare program.

b. Legal Authority

As discussed in more detail in section I.B. of this proposed rule, there are several legal authorities for our proposed provisions as follows:

- Incentive Reward Program. Section 203(b)(1) of the Health Insurance Portability and Accountability Act of 1996, codified at 42 U.S.C. 1395b-5, instructed the Secretary to establish a program to encourage individuals to report information regarding persons and entities that have or are engaged in acts or omissions that constitute grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act or who have otherwise engaged in sanctionable fraud and abuse against the Medicare program under Title XVIII of the Social Security Act (the Act).
- Provider enrollment provisions. Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program. Also, section 1866(j) of the Act, codified at 42 U.S.C. 1395cc(j), provides specific authority with regard to the enrollment process for providers and suppliers.

2. Brief Summary of the Major Provisions

a. Incentive Reward Program

We propose to increase the potential reward structure from 10 percent of the overpayments recovered in the case or $1,000, whichever is less, to 15 percent of the final amount collected applied to the first $66,000,000 for the sanctionable conduct. We are also proposing other changes that would clarify which individuals are eligible for a reward.

b. Provider Enrollment Provisions

We are proposing the following provisions regarding provider enrollment:

- Allow denial of enrollment if the provider, supplier or current owner thereof was the owner of another provider or supplier that had a Medicare debt when the latter's enrollment was voluntarily or involuntarily terminated or revoked and—

++ The owner left the provider or supplier that had the Medicare debt within 1 year of that provider or supplier's voluntary termination, involuntary termination, or revocation;

++ The Medicare debt has not been fully repaid; and

++ We determine that the uncollected debt poses an undue risk of fraud, waste, or abuse.

- Allow denial of enrollment or revocation of Medicare billing privileges if the provider, supplier, owner or managing employee thereof was convicted of a felony within the past 10 years. (Currently, enrollment cannot be denied or revoked based on a managing employee's felony conviction.)
- Allow revocation of Medicare billing privileges if the provider or supplier has a pattern or practice of billing for services that do not meet Medicare requirements.
- With the exception noted in section II.B.5. of this proposed rule, require all revoked providers and suppliers (regardless of type) to submit their remaining claims within 60 days after their revocation.
- Limit the ability of ambulance companies to ''back bill'' for services furnished prior to enrollment. Under § 424.520(d), physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations currently cannot bill for services furnished prior to the later of the date the supplier filed an enrollment application that was subsequently approved or the date the supplier began furnishing services at a practice location. (Independent diagnostic testing facilities (IDTFs) and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) have similar restrictions.) We propose to expand this to include ambulance suppliers.
- Eliminate the ability of revoked providers and suppliers to submit a corrective action plan (CAP) unless the revocation is based on § 424.535(a)(1).

3. Summary of Costs and Benefits

The following table provides a summary of the costs and benefits associated with the principal provisions in this proposed rule.

TABLE 1—SUMMARY OF COSTS AND IMPACTS

Provision description	Impacts
Incentive Reward Program	Based upon the experience under the IRS reward program, the increase in the portion of the amount collected eligible for a reward will likely result in an increase of reporting of sanctionable conduct, which would increase the collection of improper payments by the federal government. There may also be a sentinel effect whereby fraud and errors are reduced by Medicare beneficiaries' scrutiny of their bills. For these reasons, and as further explained in the Regulatory Impact Analysis of this proposed rule, we tentatively project a net increase in recoveries of $24.5 million per year as a result of our proposed changes to the Incentive Reward Program. Estimated costs of preparing attestations $0.07 million.
Denial of Enrollment Based on Prior Medicare Debt.	Though a savings to the federal government would accrue from such a denial, the monetary amount cannot be quantified.
Expansion of Ability to Deny or Revoke Medicare Billing Privileges Based on Felony Conviction.	Though a savings to the federal government would accrue from such a denial or revocation, the monetary amount cannot be quantified.
Revocation Based on Pattern or Practice of Billing for Services that Do Not Meet Medicare Requirements.	Though a savings to the federal government would accrue from such a revocation, the monetary amount cannot be quantified.

TABLE 1—SUMMARY OF COSTS AND IMPACTS—Continued

Provision description	Impacts
Requirement for Revoked Providers and Suppliers to Submit Remaining Claims within 60 Days after Revocation.	Monetary amount cannot be quantified. We believe, however, that this requirement would (1) limit the Medicare program's vulnerability to fraudulent claims; and (2) allow more focused medical review. This would likely result in some savings to the federal government.
Inclusion of Ambulance Suppliers within § 424.520(d).	Would result in a transfer of $327.4 million per year (primary estimate) from ambulance suppliers to the federal government.
Elimination of Ability to Submit CAP if Revoked on Grounds Other Than § 424.535(a)(1).	Monetary amount cannot be quantified. However, the provision would prevent these providers and suppliers from being able to immediately begin billing Medicare again once they submit the correct information.

B. Background and General Overview

1. Incentive Reward Program

Section 203(b)(1) of HIPAA required the Secretary to establish a program to encourage individuals to report information on individuals and entities who are engaging in or who have engaged in acts or omissions that constitute grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act or who have otherwise engaged in fraud and abuse against the Medicare program under Title XVIII of the Act for which there is a sanction provided under law, otherwise referred to ''sanctionable conduct'' throughout the rule. Section 203(b)(2) of HIPAA authorized the Secretary to pay a portion of the amounts collected to individuals who report information to the Secretary under the program established by section 203(b)(1) of HIPAA which serves as the basis for collection by the Secretary or the Attorney General of the United States of at least $100 (excluding penalties under section 1128B of the Act). Section 203(b)(2) of HIPAA also requires that any reward be paid from the amounts collected, under procedures similar to those applicable under section 7623 of the Internal Revenue Code of 1986 for payments to individuals providing information on violations of such Code. The purpose of these provisions is to help protect the Medicare Trust Funds by providing incentives to Medicare beneficiaries and other parties to report suspected conduct. The intent of these provisions is not to provide rewards for ''simple mistakes'' or unintentional billing errors.

In the June 8, 1998 **Federal Register** (63 FR 31123), we published a final rule with comment period titled, ''Medicare Program; Incentive Programs-Fraud and Abuse.'' This final rule with comment period implemented section 203(b) of HIPAA by establishing a reward program to encourage individuals to report potential fraud and abuse to Medicare and by adding a new section, 42 CFR 420.405, to the regulations. Section 420.405(a) specifies a collection threshold of at least $100 (consistent with section 203(b)(2) of HIPAA). Section 420.405(b) specifies that in order for an individual to be eligible to receive a reward, the information must relate to the activities of a specific individual or entity and must specify the time period of the alleged activities. Examples of specific activities include, but are not limited to, billing for services never rendered, and billing for supplies not ordered. Other activities may include offers of money, goods or free services in exchange for the beneficiary's Medicare identification number. The rule also states that CMS does not give a reward for information relating to an individual or entity that, at the time the information is provided, is already the subject of a review or investigation by CMS or law enforcement. Section 420.405(e) states the amount of a reward represents what CMS considers to be adequate compensation in the particular case, not to exceed 10 percent of the overpayments recovered in the case or $1,000, whichever is less.

2. Provider Enrollment

In the April 21, 2006 **Federal Register** (71 FR 20754), we published a final rule titled, ''Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment.'' As its title indicates, the final rule set forth requirements in part 424, subpart P that providers and suppliers must meet in order to obtain and maintain Medicare billing privileges. Since its publication in April 2006, we have updated subpart P to address a number of enrollment issues. Such topics have included the establishment of performance standards for IDTFs, issues related to the National Provider Identifier (NPI), ordering and certifying requirements, enrollment application fees, site visits, and screening requirements.

In the April 2006 final rule, we cited sections 1102 and 1871 of the Act as general authority for our establishment of these requirements, which were designed for the efficient administration of the Medicare program. Pursuant to this general rulemaking authority and pursuant to section 1866(j) of the Act, we again propose several changes to our provider enrollment regulations to ensure that Medicare payments are only made to qualified providers and suppliers. Section 1866(j) of the Act states that, the Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers that includes certain specified statutory elements, including a process for screening providers and suppliers.

II. Provisions of the Proposed Regulations

A. Incentive Reward Program (IRP)

As demonstrated by the sustained record-breaking returns to the federal government that result from private persons filing suit on behalf of the government, fraud reporting by individuals is a proven tool for the government to detect fraud, waste and abuse in the Medicare program. In 2012, the Health Care Fraud and Abuse Control Program had record collections for health care fraud, where collections topped $4 billion.[1] Public involvement in our anti-fraud efforts is critical because alert and vigilant providers, beneficiaries, family members, and caregivers are able to detect and prevent fraud as it occurs. Information from beneficiaries and other parties helps us to quickly identify fraudulent practices, stop payment to suspect providers and suppliers for inappropriate services or items, and prevent further abuses in the program. However, many people do not report suspected fraud because they are not monitoring claims submitted to Medicare for their care, or noticed a suspicious claim but were not motivated to report. Every fraudulent claim submitted contains a beneficiary's Medicare number. Therefore, we believe

[1] *http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2012.pdf.*

that each complaint we receive may represent hundreds of other individuals that did not spot a fraudulent activity or did not report their suspicions to us.

To promote the importance of reporting fraud, we conduct national campaigns to train Medicare beneficiaries and caregivers to detect and prevent health care fraud. On March 7, 2012, we released new explanations of benefits (Medicare Summary Notices (MSNs)) that are easier to read and provide instructions on how to spot fraud available online, and starting in 2013, the new MSNs will be mailed out quarterly to beneficiaries. We believe these changes will encourage beneficiaries to routinely review their MSNs. The State Health Insurance Assistance Programs and Senior Medicare Patrol counselors also educate beneficiaries about the importance of viewing and monitoring their health care claims and of identifying and reporting any suspicious activity 1–800-Medicare or 1–800–HHS–TIPS.

We have evaluated the existing Incentive Reward Program (IRP) and believe that the proposed changes for enhanced incentives would motivate more individuals to review their MSNs and to report suspicious activity. Section 203(b)(2) of HIPAA permitted CMS to pay a portion of amounts collected under procedures similar to section 7623 of the Internal Revenue Code, which authorized reward payments to individuals providing information on violations of the IRS code by individual taxpayers. The Congress enacted the Medicare Incentive Reward Program in HIPAA on August 21, 1996, shortly after the Taxpayer Bill of Rights 2 (Pub. L. 104–168) was enacted on July 30, 1996 that amended the IRS program.

In 2006, the Tax Relief and Health Care Act of 2006 (Pub. L. 109–432) [2] was enacted, further amending section 7623 of the Internal Revenue Code to provide rewards of 15 to 30 percent of collected amounts to individuals for information on claims exceeding $2 million (and in the case of an individual taxpayer, the taxpayer had gross income exceeding $200,000), while maintaining the reward structure of 15 percent of collected amounts not to exceed $10 million applied to claims in dispute of less than $2 million (in case of an individual taxpayer, the individual's gross income was below $200,000). In June 2010, the IRS aligned the reward amounts for claims under and above the $2 million threshold, if the claim was filed after July 1, 2010.[3] Individuals may now receive rewards of 15 to 30 percent of collected amounts on claims of any value. However, rewards for claims filed before July 1, 2010 will be paid under the reward structure of 15 percent not to exceed $10 million.

The reward structure of IRS program for claims received after July 2010 is similar to the *qui tam* provisions of the False Claims Act (FCA) under 31 U.S.C. 3729 through 3733. Private individuals called ''relators'' may file a *qui tam* action on behalf of the federal government and are eligible for a share of the amounts collected as a result of the action. Many states have enacted laws similar to the FCA that permit individuals to file suit on behalf of the state. The FCA generally imposes civil liability on any person who submits, or causes the submission of, a false or fraudulent claim to the government (including federal health care programs like Medicare and Medicaid) for payment. The Department of Justice is the only government agency that can release a person's liability under the FCA. Relators generally obtain legal counsel prior to the filing of a FCA complaint and may be significantly involved in the development of a FCA case. The potential relator's share in a *qui tam* action can range between 15 and 30 percent of the total amount collected, depending on whether the government ''intervenes'' or joins the *qui tam* action.

We are proposing to revise § 420.405(e)(2) to increase the reward for information on individuals and entities that leads to the imposition of a sanction to 15 percent of the final amount collected applied to the first $66,000,000 for the sanctionable conduct; the reward would not increase if the amount collected was greater than $66,000,000.[4] This approach is similar to the IRS reward structure for claims received before July 1, 2010. We are proposing this structure because the IRS program has proved to be highly successful in generating leads that returned far greater sums than the existing Medicare IRP, which limited rewards to 10 percent of the first $10,000 of the final amount collected. Since the current IRP was put into operation in July, 1998, only 18 rewards have been paid, for a total of less than $16,000 and amounts collected of less than $3.5 million. In contrast, between 2007 and 2012, the IRS collected almost $1.6 billion, and paid approximately $193 million in rewards.[5] Based on the reported experience of the IRS, we believe our proposed improvements will provide greater incentives to beneficiaries, providers, and other parties to report sanctionable conduct. Providing potential rewards for 15 percent of the final amounts collected applied the first $66,000,000 for the sanctionable conduct sends a clear message to individuals trying to defraud Medicare—we are using all available tools to root out systematic and widespread fraud from the program.

We believe that proposing a reward structure for the IRP that is similar to the IRS program for claims under the $2 million threshold and received before July 2010 will provide additional incentives to individuals who otherwise would not have brought the information to the government's attention by filing a *qui tam* lawsuit. We believe proposing a reward program with a range of 15 to 30 percent could result in confusion about the IRP and the *qui tam* provisions of the FCA. The IRS program does not interact with the *qui tam* provisions because recoveries under Title 26 (the Internal Revenue Code) are excluded from the FCA (31 U.S.C. 3729(d)). We note that the Congress enacted the law that created the Medicare incentive reward program after the FCA had been in place for many years and had been significantly amended in 1986, thus we infer the Congress anticipated that the IRP would exist in parallel with the FCA, but not as a supplement to it. We believe the reward structure proposed here will fulfill the mandate of the Medicare statute and also create clear distinguishing features from the FCA.

We are also proposing this reward structure because it has an administrative structure similar to the existing IRP program. On that basis, we believe it will be administratively more

[2] The Internal Revenue Service Fiscal Year 2011 Report to Congress on the Use of Section 7623, available at *http://www.irs.gov/pub/irs-utl/fy2011_annual_report.pdf.*

[3] The Internal Revenue Service Fiscal Year 2011 Report to Congress on the Use of Section 7623, available at *http://www.irs.gov/pub/irs-utl/fy2011_annual_report.pdf.*

[4] Section 7623(a) of the Internal Revenue Code is implemented at 26 CFR 301.7623–1(c). Section 301.7623–1(c) states that the amount of a reward will represent what the district or service center director deems to be adequate compensation in the particular case, generally not to exceed 15 percent of the amounts (other than interest) collected by reason of the information. Payment of a reward will be made as promptly as the circumstances of the case permit, but not until the taxes, penalties, or fines involved have been collected. However, if the informant waives any claim for reward with respect to an uncollected portion of the taxes, penalties, or fines involved, the claim may be immediately processed. The reward for information that led to the collection of the first $66,000,000 will not be more than $10 million, similar to the IRS program.

[5] The Internal Revenue Service Fiscal Year 2012 Report to Congress on the Use of Section 7623, available at *http://www.irs.gov/pub/whistleblower/2012%20IRS%20Annual%20Whistleblower%20Report%20to%20Congress_mvw.pdf.*

efficient to implement. In particular, keeping the reward at a fixed percent of the amounts collected up to a set dollar amount avoids the need to establish a new administrative process to adjudicate the size of a reward that could range from 15 percent to 30 percent. This reward structure would be the simplest both to administer and, for individuals who may eligible for the IRP, to understand. Additionally, we believe the potential for a larger reward would motivate individuals to report who may otherwise have been discouraged by the length of collection, since we have estimated that the average timeframe for collection is 3 to 5 years before overpayment appeals are exhausted, Medicare funds are collected, and applicable fines and penalties are collected.

Although we believe the reward structure of 15 percent of final amounts collected applied to the first $66,000,000 for the sanctionable act is the preferred approach, we are soliciting comments on whether we should adopt the reward structure of 15 to 30 percent of amounts collected that the IRS offers for claims received after July 1, 2010 or a different reward structure, and whether the 15 percent reward should apply to final amounts collected other than $66,000,000. We anticipate that in increasing the size of the amounts collected that we would apply a reward for from $10,000 to $66,000,000, which would ensure that the vast majority of individuals would receive a portion of the collected amount that corresponds with the value of their information. Reports that have resulted in a reward under the IRP have led to an average collection of $193,069 by CMS, with the highest single collection of $998,770. In contrast, the IRS reported collecting $61,556,175 in 2003, the earliest data reported by the IRS.[6] In 2012, the IRS reported collecting a $592,498,294.[7] While there are limitations on estimating an increase in recoveries from the IRS' experience, given the significant upward trend in collections reported by the IRS following the changes to the reward amount in 2004, and again in 2006, we believe that the potential for a larger reward may encourage more individuals to report the specific information needed to begin the review or investigation of a provider or supplier for sanctionable conduct that may lead to the recoupment of an overpayment, which could result in higher amounts collected than we have experienced in the past.

We anticipate that some commenters may question the interaction of the IRP and the *qui tam* provisions of FCA described previously. We are proposing to clarify that an individual is not eligible for an IRP reward if he or she has filed a *qui tam* lawsuit under the federal or any state False Claims Act. We are also proposing that we do not give a reward for the same or substantially similar information that is the basis of a payment of a share of the amounts collected under the False Claims Act or any state False Claims Act, or if the same or substantially similar information is the subject of a pending False Claim Act case. We believe these restrictions on information eligible for a reward prevent us from paying rewards from amounts collected for the same sanctionable conduct.

Section 420.405(a) specifies that we will pay a monetary reward for information that leads to the collection of at least $100 of Medicare funds from individuals and entities that are engaging in, or have engaged in, acts or omissions that constitute grounds for the imposition of a sanction under section 1128, 1128A or section 1128B of the Act or that have otherwise engaged in sanctionable fraud and abuse against the Medicare program. Section 420.405(b) specifies that in order for an individual to be eligible to receive a reward, the information must relate to the activities of a specific individual or entity and must specify the time period of the alleged activities and states that CMS does not give a reward for information relating to an individual or entity that, at the time the information is provided, is already the subject of a review or investigation by CMS or law enforcement. The determination of whether an individual provided information eligible for a reward and whether the specific individual or entity was already the subject of a review or investigation by CMS or law enforcement are at the exclusive discretion of CMS. We pay rewards only if a reward is not otherwise provided for by law. When we apply the criteria specified in paragraphs (b), (c), and (e) of this section to determine the eligibility and the amount of the reward, the recipient is notified as specified in paragraph (d) of this section.

In § 420.405(a), we propose two revisions. First, we are proposing to redesignate the existing text in paragraph (a) to paragraph (a)(2) to emphasize that the determinations as to whether the reward criteria are met and the amount of the reward are at the exclusive discretion of CMS. Second, we are proposing to move the remaining text stating that when CMS applies the criteria specified in paragraphs (b), (c), and (e), and determines the eligibility and amount of the reward, it notifies the recipient as specified at new (a)(3).

In new paragraph (b)(3), we propose to specify that we do not give a reward for the same or substantially similar information that was the basis for a payment of a share of the amounts collected under the False Claims Act or any state False Claims Act, or if the same or substantially similar information is the subject of a pending False Claim Act case. This proposed change would prevent us from paying rewards from amounts collected for the same sanctionable conduct, or from amounts that may collected as a result of a pending False Claims Act case.

In new paragraph (c)(2)(v), we propose to clarify that an individual is not eligible for a reward under the IRP if he or she is eligible for a reward for furnishing the same or substantially similar information to the federal government under any other federal reward program or payment under federal law.

At § 420.405(e)(2), we propose to change the reward structure from an amount not to exceed 10 percent of the overpayments recovered in the case or $1,000, whichever is less for information received after the effective date of the final rule to 15 percent of the final amounts collected applied to the first $66,000,000 for the sanctionable conduct. It is important to note that the degree of specificity in the information provided is significant because a tip needs to provide sufficient information to start a review or investigation by CMS or law enforcement or otherwise lead to the collection of amounts for sanctionable conduct before an individual is eligible for a reward.

At § 420.405(e)(3), we propose to limit eligibility for a reward to the first individual who provides us with specific information on a provider or supplier that is engaging in, or has engaged in, acts or omissions that constitute grounds for the imposition of a sanction under section 1128, section 1128A or section 1128B of the Act or that has otherwise engaged in sanctionable fraud and abuse that leads to a review or investigation by CMS or law enforcement or other actions that result in the imposition of a sanction. Once we receive information on a specific provider or supplier for a specific time period of the alleged sanctionable conduct, we will consider the provider or supplier to be subject to a review or investigation by CMS, its

[6] The Internal Revenue Service First Report to Congress on the Whistleblower Program, available at *http://www.irs.gov/pub/whistleblower/whistleblower_annual_report.pdf.*

[7] See the IRS Web site at *http://www.irs.gov/pub/whistleblower/whistleblower_annual_report.pdf.*

contractors, or its law enforcement partners.

In § 420.405 (f)(1), we propose to remove the reference to the submission of information regarding sanctionable conduct to Medicare intermediaries or carriers. We refer generally to the CMS contractor that has jurisdiction.

In new paragraph (f)(3), we propose to add a requirement that upon notification of eligibility, or when otherwise required by CMS, an individual must complete an attestation stating that he or she is not participating and has not participated in the sanctionable conduct, is not otherwise ineligible to receive a reward, that the information he or she has furnished is accurate and truthful to the best of their knowledge, and that he or she acknowledges that knowingly failing to provide truthful information could subject him or her to potential civil and criminal liability. Section 203(b) of HIPAA directs us to discourage the provision of, and to not consider, information that is frivolous or irrelevant to the imposition of a sanction. An attestation may discourage individuals from furnishing baseless reports of sanctionable conduct. We are soliciting comments on whether we should adopt the proposed approach of requiring the completion of an attestation, the timing of the attestation, and on the content of any attestation.

In revised § 420.405 (h)(1), we propose to clarify that CMS reserves its right to recover a reward from the individual if CMS finds that the individual was ineligible for the reward. In new paragraph (h)(2), we propose that CMS would notify an individual in writing of our determination of ineligibility, and request a full refund within 30 days. We are soliciting comments on whether CMS should provide an appeals process, and what such an appeals process may consist of. We are also soliciting comments on whether an individual may request that CMS review and waive the request for a full refund of the reward. We note that our proposed IRP revisions would not apply to information furnished under § 420.405 before the effective date of the final rule.

Given the aforementioned proposed revisions, we would make the following regulatory changes to § 420.405:

- In new paragraph (a)(1), we propose to incorporate the first sentence of existing § 420.405(a).
- In new paragraph (a)(2), we propose to reemphasize that the determinations as to whether the eligibility criteria are met are at the exclusive discretion of CMS.
- In new paragraph (a)(3), we propose to incorporate the last sentence of existing § 420.405. When CMS applies the criteria specified in paragraphs (b), (c), and (e) of this section to determine the eligibility and the amount of the reward, it notifies the individual as specified in paragraph (d) of this section.
- In a new paragraph (b)(3), we propose to add that CMS does not give a reward if the same or substantially similar information was the basis of payment for a relator's share of the amounts collected under the False Claims Act or any state False Claims Act.
- In new paragraph (c)(2)(v), we propose to clarify that an individual is not eligible for the IRP if he or she is eligible for a reward for furnishing the same or substantially similar information to the federal government under any other federal reward program or payment under federal law.
- In paragraph (e)(2), we propose to change the reward structure from 10 percent of the recovered overpayments not to exceed $1,000, to 15 percent of the final amounts collected applied to the first $66,000,000 for sanctionable conduct for information received after the effective date of the final rule.
- In paragraph (e)(3), we propose to limit eligibility for a reward to the first individual who provides us with specific information, defined in paragraph (b), on a specific individual or entity that is engaging in, or has engaged in, acts or omissions that constitute grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act or that has otherwise engaged in sanctionable fraud and abuse against the Medicare program that leads to the imposition of a sanction.
- In paragraph (f)(1), we propose to remove the reference to submitting information regarding fraud and abuse to Medicare intermediaries or carriers, and propose to add new paragraphs (f)(1)(i) identifying the Office of Inspector General and (f)(1)(ii) identifying CMS or the CMS contractor that has jurisdiction of the provider.
- In new paragraph (f)(3), we propose to add a requirement that upon notification of eligibility, an individual must complete an attestation stating that he or she is not participating and has not participated in the sanctionable act, is not otherwise ineligible to receive a reward under paragraph (c)(2), that the information he or she has furnished is accurate and truthful to the best of their knowledge, and that he or she acknowledges that knowingly failing to provide truthful information could subject him or her to potential criminal and/or civil liability.
- In revised paragraph (h)(1), we propose to modify the current paragraph at (h) to clarify that CMS reserves its right to recover a reward from the individual.
- In new paragraph (h)(2), we propose that CMS would notify an individual in writing of our determination of ineligibility, and request a full refund within 30 days.

B. Provider Enrollment

As noted previously, in April 2006 we published a final rule that set forth requirements that providers and suppliers must meet in order to obtain and maintain Medicare billing privileges. Since the final rule's publication, we have revised and supplemented certain provisions in part 424, subpart P to address various payment safeguard issues. In this proposed rule, we are revising the provider enrollment regulatory provisions identified in this section.

1. Definition of Enrollment

Most physicians and nonphysician practitioners enroll in Medicare to receive payment for covered services furnished to Medicare beneficiaries. However, some physicians and nonphysician practitioners who are not enrolled in Medicare via the Form CMS–855I enrollment application may wish to enroll for the sole purpose of ordering or certifying items or services for Medicare beneficiaries. Consistent with § 424.507, these individuals can become eligible to do so, assuming all other applicable requirements are met, by completing the CMS–855O via a paper application or via the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process. The use of the CMS–855O (OMB Approval # 0938–0685), which began in July 2011, is exclusively designed to allow physicians and eligible professionals to enroll in Medicare solely to order or certify items or services.

Physicians and nonphysician practitioners who complete the CMS–855O are not eligible to send claims to Medicare for services they provide, as they are not granted Medicare billing privileges. We believe that several of our existing regulatory provisions do not, as currently written, adequately articulate the distinction between enrolling in Medicare: (1) To obtain Medicare billing privileges; and (2) solely to order or certify items or services for Medicare beneficiaries. We believe it is important to clarify that suppliers who enroll solely to order or certify cannot bill the

Medicare program and are not granted Medicare billing privileges.

Therefore, we are proposing the following regulatory changes:

• The first involves the definition of ''Enroll/enrollment'' in § 424.502. The initial sentence of the definition currently reads: ''Enroll/enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare covered services and supplies.'' We propose to revise this to state: ''Enroll/enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare covered items and services, and the process that Medicare uses to establish eligibility to order or certify for Medicare-covered items and services.'' This is to clarify that the overall enrollment process includes enrollment via the CMS–855O.

• We also propose to change paragraph (4) of § 424.502 in the definition of ''Enroll/enrollment'' from ''(g)ranting the provider or supplier Medicare billing privileges'' to the following: ''(4) Except for those suppliers that complete the CMS–855O form or CMS-identified equivalent or successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services, granting the Medicare provider or supplier Medicare billing privileges.'' This is to emphasize that while enrollment via the CMS–855O enables the supplier to order or certify Medicare-covered items and services, it does not convey Medicare billing privileges to the supplier.

• The last change involves § 424.505. This section states that a provider or supplier, once enrolled, receives Medicare billing privileges. We propose to revise the second sentence of this section to state: ''Except for those suppliers that complete the CMS–855O or CMS-identified equivalent or successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare covered items and services, once enrolled the provider or supplier receives billing privileges and is issued a valid billing number effective for the date a claim was submitted for an item that was furnished or a service that was rendered. (See 45 CFR part 162 for information on the National Provider Identifier and its use as the Medicare billing number.)'' Again, we wish to stress that enrollment via the CMS–855O enables the supplier to order or certify Medicare-covered items and services but does not grant Medicare billing privileges to a supplier.

Given the proposals noted previously, we would make the following regulatory changes to 42 CFR part 424, subpart P:

• In § 424.502, we propose to change the first sentence to state: ''Enroll/enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.''

• We also propose to revise paragraph (4) in § 424.502 to read: ''(4) Except for those suppliers that complete the CMS–855O form or CMS-identified equivalent or successor form or process for the sole purpose of ordering or certifying Medicare covered items and services, granting the Medicare provider or supplier Medicare billing privileges.''

• In § 424.505, we propose to change the second sentence to read: ''Except for those suppliers that complete the CMS–855O form or CMS-identified equivalent or successor form or process for the sole purpose of ordering or certifying Medicare covered items and services, once enrolled the provider or supplier receives billing privileges and is issued a valid billing number effective for the date a claim was submitted for an item that was furnished or a service that was rendered. (See 45 CFR part 162 for information on the National Provider Identifier and its use as the Medicare billing number.)''

2. Debts to Medicare

Section 424.530(a) lists a number of reasons for which a provider or supplier's Medicare enrollment application may be denied. Under § 424.530(a)(6), an application can be denied if ''[t]he current owner (as defined in § 424.502), physician or nonphysician practitioner has an existing overpayment at the time of filing of an enrollment application.'' This provision was established in large part to address situations in which the owner of a provider or supplier incurs a substantial debt to Medicare, exits the Medicare program or shuts down operations altogether, and attempts to re-enroll through another vehicle or under a new business identity. Indeed, such situations were discussed in a November 2008 Department of Health and Human Services Office of Inspector General (OIG) Early Alert Memorandum titled ''Payments to Medicare Suppliers and Home Health Agencies Associated with 'Currently Not Collectible' Overpayments'' (OEI–06–07–00080). The memorandum stated that anecdotal information from OIG investigators and assistant United States Attorneys indicated that DMEPOS suppliers with outstanding Medicare debts may inappropriately receive Medicare payments by, among other means, operating businesses that are publicly fronted by business associates, family members, or other individuals posing as owners.[8] In its study, the OIG selected a random sample of 10 DMEPOS suppliers in Texas that each had Medicare debt of at least $50,000 deemed currently not collectible (CNC) by CMS during 2005 and 2006.[9] The OIG found that 6 of the 10 reviewed DMEPOS suppliers were associated with 15 other DMEPOS suppliers or HHAs that received Medicare payments totaling $58 million during 2002 through 2007.[10] Most associated DMEPOS suppliers had lost billing privileges by January 2005 and had accumulated a total of $6.2 million of their own CNC debt to Medicare.[11] The OIG also found that most of the reviewed DMEPOS suppliers were connected with their associated DMEPOS suppliers and HHAs through shared owners or managers.[12]

Since this memorandum was issued, we have continued to receive reports of providers, suppliers, and owners thereof accumulating large Medicare debts, departing Medicare, and then attempting to reenter the program through other channels—often to incur additional debts. While the current version of § 424.530(a)(6) gives us the ability to stem this practice to a certain extent, it is limited to situations where an enrolling physician, nonphysician practitioner, or an owner of the enrolling provider or supplier has a current Medicare overpayment. It does not apply to instances where an enrolling provider or supplier entity has a current Medicare debt, be it an overpayment or some other type of financial obligation to the Medicare program. Furthermore, it does not address cases where an entity that the enrolling provider, supplier or owner was affiliated with had incurred the debt. We believe that these latter situations were of particular concern to the OIG in the aforementioned report. They remain of concern to us as well. Therefore, to enhance the existing authority in § 424.530(a)(6), we propose several changes.

a. New Paragraph § 424.530(a)(6)(i)

We propose to incorporate the existing language of § 424.530(a)(6) into

[8] Department of Health and Human Services, Office of Inspector General (OIG). ''Early Alert Memorandum: Payments to Medicare Suppliers and Home Health Agencies Associated with 'Currently Not Collectible' Overpayments'' (OEI–06–07–00080), November 26, 2008, p.1.

[9] Ibid. p.1.

[10] Ibid. p.7.

[11] Ibid. p.7

[12] Ibid. p.2.

a new paragraph (a)(6)(i) that would apply to all enrolling providers, suppliers (including physicians and nonphysician practitioners), and owners thereof. We do not believe that the purview of the current version of (a)(6) should be limited to individual physicians and nonphysician practitioners. All providers and suppliers, regardless of type, are responsible for reimbursing Medicare for the debts they owe to the program. Permitting them to enroll additional provider or supplier sites in Medicare when they have existing debts to Medicare potentially endangers the Trust Fund. If the provider or supplier cannot repay its existing Medicare debts, this raises questions about its ability to pay future debts incurred as part of any additional enrollments. In addition, we note that physicians and nonphysician practitioners fall within the ''limited'' level of categorical risk under § 424.518. To not include other provider and supplier types of equal or greater risk—such as hospices and IDTFs, which are classified as ''moderate'' risk under § 424.518—within the scope of proposed § 424.530(a)(6)(i) would only add to the existing threat to the Trust Fund posed by providers and suppliers that fail to repay their Medicare debts.

Notwithstanding these concerns, a denial of Medicare enrollment under paragraph (a)(6)(i) could be avoided if the enrolling provider, supplier, or owner thereof satisfies the criteria set forth in § 401.607 and agrees to an extended CMS-approved repayment schedule for the entire outstanding Medicare debt. We believe this provision is appropriate because an agreement to a CMS-approved repayment plan indicates that the provider, supplier, or owner is not seeking to avoid its debts to Medicare. The provider, supplier, or owner thereof could also, of course, avoid denial by simply repaying the debt in full. We solicit comment on whether the scope of our proposed revision to § 424.530(a)(6)(i) should be expanded to include the enrolling provider or supplier's managing employees (as that term is defined in § 424.502), corporate officers, corporate directors, and/or board members.

We note that the term ''overpayment'' as currently used in § 424.530(a)(6) would be changed to ''Medicare debt'' in our regulatory text. We believe that the latter term more appropriately describes the types of debts that are subject to (a)(6). Moreover, as indicated earlier, we believe that our denial authority under proposed (a)(6) should include all forms of debt to Medicare, not just overpayments. It is the fact that a debt exists, rather than the specific type of debt involved, that is of concern to us. We nonetheless solicit comments on: (1) our proposal to replace the term ''overpayment'' with ''Medicare debt'' and our rationale for the change; and (2) the appropriate scope of the term ''Medicare debt'' for purposes of § 424.530(a)(6) only, specifically whether there are certain types of debts that should or should not fall within the purview of § 424.530(a)(6).

b. New Paragraph § 424.530(a)(6)(ii)

We propose in new paragraph § 424.530(a)(6)(ii) that a denial of Medicare enrollment is warranted if the provider, supplier or current owner (as defined in § 424.502) thereof was the owner (as defined in § 424.502) of another provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily or involuntarily terminated or revoked, and the following criteria are met:

- The owner left the provider or supplier that had the Medicare debt within 1 year of that provider or supplier's voluntary termination, involuntary termination, or revocation.
- The Medicare debt has not been fully repaid.
- We determine that the uncollected debt poses an undue risk of fraud, waste, or abuse.

Similar to proposed § 424.530(a)(6)(i), we propose that the enrolling provider or supplier would be able to avoid a denial under § 424.530 (a)(6)(ii) if the enrolling provider, supplier or owner thereof agrees to an extended repayment schedule for the entire outstanding Medicare debt of the revoked provider or supplier. Again, we believe this provision is warranted because agreement to a repayment plan evidences an intention to pay back the debt. Also, no denial would occur under paragraph (a)(6)(ii) if the debt was repaid in full.

As discussed earlier, the difference between our proposed addition and the existing language in § 424.530(a)(6) is that the latter involves situations in which the current owner, physician or nonphysician practitioner had a Medicare debt. However, our proposed addition focuses on the entity with which the enrolling provider, supplier, or owner thereof had a prior relationship. That is, the ''prior entity'' had a debt to Medicare rather than the enrolling provider, supplier, or owner thereof. Consider the following illustration: Provider X is applying for enrollment in Medicare. Y owns 50 percent of X. Y was also a 20 percent owner of Supplier Entity Z, which was revoked from Medicare 12 months ago and currently has a large outstanding Medicare debt. The current version of § 424.530(a)(6) could not be used to deny X's application because X's current owner (Y) does not have a Medicare debt. Rather, the entity with which Y was associated (Z) has the debt. Under proposed § 424.530(a)(6)(ii), however, and assuming the criteria identified therein are met, X's application could be denied because X's owner was an owner of a supplier (Z) that has a Medicare debt.

Again, we believe that our proposed provision is necessary to further address cases in which individuals and entities depart Medicare with substantial Medicare debts and attempt to re-enter the program via other vehicles in order to avoid these financial obligations. We further believe that, as with proposed § 424.530(a)(6)(i), proposed paragraph (ii): (1) may enhance our debt recovery efforts by spurring individuals and entities seeking to enroll in Medicare to facilitate the repayment of the debts of the organizations with which they were associated; and (2) would protect the Medicare Trust Fund by preventing individuals and entities intent on reentering Medicare and falsely billing the program and incurring additional Medicare debts.

The authority for our proposed change is section 1866(j)(5) of the Act, codified at 42 U.S.C. 1395cc(j)(5) and which was established by section 6401(a)(3) of the Affordable Care Act. Section 1866(j)(5) states the following:

- A provider of medical or other items or services or supplier who submits an application for enrollment or revalidation of enrollment in the program under this title, title XIX, or title XXI on or after the date that is 1 year after the date of enactment of this paragraph shall disclose (in a form and manner and at such time as determined by the Secretary) any current or previous affiliation (directly or indirectly) with a provider of medical or other items or services or supplier that has uncollected debt, has been or is subject to a payment suspension under a federal health care program (as defined in section 1128B(f) of the Act), has been excluded from participation under the program under this title, the Medicaid program under title XIX, or the CHIP program under title XXI, or has had its billing privileges denied or revoked.
- If the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny such application. Such a denial shall be subject to appeal in accordance with paragraph [(8)].

Under section 1866(j)(5) of the Act, therefore, providers and suppliers seeking to enroll in or revalidate their enrollment in Medicare must disclose any current or previous direct or indirect affiliation with a provider or supplier that has uncollected debt. The disclosing provider or supplier's application can be denied if we believe that the affiliation poses an undue risk of fraud, waste, or abuse. We believe that our proposed addition is entirely consistent with section 1866(j)(5) of the Act, in that the application would be denied only if the ''undue risk'' threshold is met. We would determine whether such a risk exists by considering various factors, including, but not limited to the following:

- The amount of the Medicare debt.
- The length and timeframe that the enrolling provider, supplier, or owner thereof was an owner of the prior entity.
- The percentage of the enrolling provider's, supplier's, or owner's ownership of the prior entity.

The scope and breadth of ownership interests will vary widely (for example, the amount of ownership; direct versus indirect ownership). For this reason, we must reserve for ourselves the flexibility to deal with each situation on a case-by-case basis, utilizing the factors previously outlined. However, we are soliciting comment on the following issues related to these factors:

- Whether additional factors should be considered and, if so, what those factors should be.
- Which, if any, of the factors previously identified should not be considered.
- Which, if any, factors should be given greater or lesser weight than others.
- Whether a minimum or maximum threshold for consideration should be established for the ''amount of Medicare debt'' and ''percentage of ownership'' factors.

We also solicit comment on whether the purview of our proposed revision to § 424.530(a)(6) should be expanded to include the enrolling entity's current managing employees (as that term is defined in § 424.502), corporate officers, corporate directors, and/or board members.

We note that while we are only proposing to implement the overarching rationale of section 1866(j)(5) of the Act with respect to Medicare debts, we are continuing to consider implementation options regarding the previously cited provisions of section 1866(j)(5) of the Act that address exclusions, payment suspensions, denials, and revocations.

Given this, we propose to revise § 424.530(a)(6) as follows:

- In paragraph (a)(6)(i), we propose that a denial of Medicare enrollment is warranted if the enrolling provider, supplier, or owner thereof has an existing Medicare debt. A denial of Medicare enrollment under this paragraph can be avoided if the enrolling provider, supplier, or owner thereof satisfies the criteria set forth in § 401.607 and agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt or pays the debt in full.
- In paragraph (a)(6)(ii), we propose that a denial of Medicare enrollment is warranted if the enrolling provider, supplier, or owner thereof was the owner of another Medicare provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily or involuntarily terminated or revoked, and the following criteria are met:

++ The owner left the provider or supplier that had the Medicare debt within 1 year of that provider or supplier's voluntary termination, involuntary termination, or revocation.

++ The Medicare debt has not been fully repaid.

++ We determine that the uncollected debt poses an undue risk of fraud, waste, or abuse.

A denial of Medicare enrollment under this paragraph can be avoided if the enrolling provider, supplier, or owner thereof satisfies the criteria set forth in § 401.607 and agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt.

3. Felony Convictions

Under § 424.530(a)(3) and § 424.535(a)(3), respectively, we may deny or revoke a provider or supplier's Medicare billing privileges if the provider or supplier—or any owner of the provider or supplier—has, within the 10 years preceding enrollment or revalidation of enrollment, been convicted of a federal or state felony offense that CMS has determined to be detrimental to the best interests of the Medicare program and its beneficiaries. Under § 424.535(a)(3)(i), as currently codified, such offenses include the following:

- Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
- Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
- Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.
- Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(Section 424.530(a)(3)(i) mirrors § 424.535(a)(3)(i) with the exception of paragraph (D), which uses the phrase: ''Any felonies outlined in section 1128 of the Act.'')

We propose to make the following changes to § 424.530(a)(3) and § 424.535(a)(3):

- To modify the list of felonies in each section such that any felony conviction—including guilty pleas and adjudicated pretrial diversions—that we have determined to be detrimental to the best interests of the Medicare program and its beneficiaries would constitute a basis for denial or revocation. This would give us the discretion to deny or revoke enrollment based on any felony conviction that we believe to be detrimental to the best interests of Medicare and its beneficiaries. There are several reasons for this change:

++ In light of the very serious nature of any felony conviction, we believe it is unwise to restrict our authority in § 424.530(a)(3)(i) and § 424.535(a)(3)(i) to the categories of felonies identified in (a)(3)(i); this is especially true considering that the types of felony offenses often vary from state to state. Any felony conviction, regardless of the type, raises real questions as to whether the provider or supplier can be relied upon to be a trustworthy partner in the Medicare program, and it is important to do everything possible to prevent unnecessary risks to Medicare beneficiaries and the Medicare Trust Fund. That stated, we are aware that certain felony convictions may raise more concerns than others, and we will continue to carefully assess the types of felony convictions that pose greater risk to Medicare beneficiaries and the Medicare Trust Fund.

We note that in the April 2006 final rule (77 FR 20760), in which we finalized the provisions in § 424.530(a)(3) and § 424.535(a)(3), we stated that we were relying upon the authority afforded to us in many of the HIPAA fraud and abuse provisions and section 4302 of the BBA. We are relying upon this same authority with respect to our proposed change.

++ The current list of felonies in § 424.530(a)(3) and § 424.535(a)(3) includes many felonies but does not encompass all felonies. In order to allow us discretion to deny or revoke

enrollment based on any felony conviction that we believe is detrimental to the Medicare program or its beneficiaries, we propose to eliminate the enumerated list of felonies and instead provide that enrollment may be denied or revoked based upon any such felony conviction.

• We propose to expand § 424.530(a)(3) and § 424.535(a)(3) to include felony convictions against a provider or supplier's ''managing employee,'' as that term is defined in § 424.502. We have found numerous instances in which a particular managing employee of a provider or supplier has as much, if not more, control of and involvement with the entity as does the owner. We believe that managing employees should be held to the same standard as owners in this regard. Clearly, having a managing employee with a felony conviction raises questions about whether the provider or supplier can be a responsible participant in the Medicare program.

• In § 424.530(a)(3) and § 424.535(a)(3), we propose to change the language ''within the 10 years preceding enrollment or revalidation of enrollment'' to ''within the preceding 10 years.'' The existing language has caused confusion as to how far back the 10-year period actually goes. We believe that our proposed wording is clearer and more straightforward.

• In § 424.530(a)(3) and § 424.535(a)(3), we propose to state that the term ''convicted''—as used in these two sections—has the same definition as the one set forth in 42 CFR 1001.2. We have received inquiries over the years regarding the proper interpretation of the term ''convicted'' as it is used in the context of § 424.530(a)(3) and § 424.535(a)(3). We believe that utilizing a well-established regulatory definition of the term would clarify for the public the types and scopes of convictions that fall within the purview of these two sections. We note that this regulatory definition is based on the definition of ''convicted'' in section 1128(i) of the Act.

In light of the foregoing discussion, § 424.530(a)(3) and § 424.535(a)(3) would be revised as follows:

• In § 424.530(a)(3)—

++ We propose to combine the opening paragraph and existing paragraph (a)(3)(i) into a revised paragraph (a)(3)(i) that would state: ''The provider, supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a federal or state felony offense that CMS has determined to be detrimental to the best interests of the Medicare program and its beneficiaries.''

++ We also propose to delete paragraphs (a)(3)(i)(A) through (D).

++ Existing paragraph (a)(3)(ii) would remain intact.

• In § 424.535—

++ We propose to combine the introductory text and existing paragraph (a)(3)(i) into a revised paragraph (a)(3)(i) that would read: ''The provider, supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR § 1001.2) of a federal or state felony offense that CMS has determined to be detrimental to the best interests of the Medicare program and its beneficiaries.''

++ We propose to make changes to paragraph (c). See section II.G. of this proposed rule for more information about our proposed change to paragraph (c).

4. Abuse of Billing Privileges

Section 424.535(a)(8) states that a provider or supplier's Medicare billing privileges may be revoked if the provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include, but are not limited to, situations where the beneficiary is deceased, the directing physician or beneficiary is not in the state or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

We propose to expand this revocation reason by adding a new paragraph (a)(8)(ii) to § 424.535. (The existing revocation reason will be incorporated into a new paragraph (a)(8)(i).) Our proposed new paragraph (a)(8)(ii) would permit revocation if we determine that the provider or supplier has a pattern or practice of billing for services that do not meet Medicare requirements such as, but not limited to, the requirement that the service be reasonable and necessary. This revocation reason would differ from that in paragraph (a)(8)(i) in two ways. First, while the former deals with individual claims, paragraph (a)(8)(ii) addresses overall billing patterns. Second, paragraph (a)(8)(i) addresses situations involving claims for services that could not have been furnished. Paragraph (a)(8)(ii) would deal with cases where the services were furnished but the claims do not meet Medicare requirements.

We believe that our proposed revocation reason is important because it would place providers and suppliers on notice that they are under a legal obligation to always submit correct and accurate claims. Providers and suppliers would know that a failure to do so may result in the revocation of their Medicare billing privileges if such failures establish a pattern of incorrect or inaccurate claims. Because the current revocation reason at § 424.535 (a)(8), again, focuses on individual claims and not on the submission of numerous claims over an extended period of time, we are proposing this authority so we may have the discretion to also revoke based on a pattern of inaccurate or erroneous claim submissions. We believe that a provider or supplier should be responsible for submitting valid claims at all times and that the provider or supplier's repeated failure to do so poses a risk to the Medicare Trust Fund.

While we solicit comment on what should qualify as a ''pattern or practice'' under our proposed change, we envision that a common—though by no means the only—scenario in which proposed § 424.535(a)(8)(ii) could apply would be one where a provider or supplier is placed on prepayment review and a significant number of its claims are denied for failing to meet medical necessity requirements over time. Indeed, any situation in which an unusually or abnormally high volume of claims are denied over time because they do not meet Medicare requirements could potentially trigger § 424.535(a)(8)(ii), though much would depend, of course, on the particular facts of the situation. In each case, we would take into account several factors, including, but not limited to the following:

• The percentage of submitted claims that were denied.

• The total number of claims that were denied.

• The reason(s) for the claim denials.

• Whether the provider or supplier has any history of ''final adverse actions'' (as that term is defined under § 424.502).

• The length of time over which the pattern has continued.

• How long the provider or supplier has been enrolled in Medicare.

With respect to these factors, we solicit comment on the following:

• Whether additional factors should be considered and, if so, what those factors should be.

• Which, if any, of these factors should not be considered.

• Which, if any, of these factors should be given greater or lesser weight than others.

• Whether a minimum or maximum threshold for consideration should be established for the ''percentage of claims denied'' and ''total number of claims denied'' factors.

We also solicit comment on whether there should be a set knowledge standard associated with our proposed provision—specifically, whether revocation is warranted only if the provider or supplier submitted the claims in question with ''reckless disregard'' as to their accuracy or the provider ''knew or should have known'' that the claims did not meet Medicare requirements.

We wish to emphasize and to reassure the provider and supplier communities that proposed § 424.535(a)(8)(ii) is not meant to be used to revoke providers and suppliers for isolated and sporadic claim denials or for innocent errors in billing. Our focus is instead on situations where a provider or supplier regularly fails to submit accurate claims in such a way as to—when considering the factors previously mentioned—pose a risk to the Medicare Trust Fund. We further note that as with any revocation of Medicare billing privileges, the provider or supplier may appeal a revocation based on § 424.535(a)(8)(ii).

Given this, § 424.535(a)(8) would be revised to—

• Add a new paragraph (a)(8)(ii) that states: ''CMS determines that the provider or supplier has a pattern or practice of submitting claims for services that fail to meet Medicare requirements.''

• Incorporate the existing language in § 424.535(a)(8) into a new paragraph (i).

5. Post-Revocation Submission of Claims

In the November 19, 2008 **Federal Register** (73 FR 69726), we published a final rule with comment period titled, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions,'' (hereinafter referred to as the CY 2009 PFS final rule). In that rule, we finalized a provision in § 424.535(h) stating that a revoked physician organization, physician, nonphysician practitioner or IDTF must submit all claims for items and services furnished within 60 calendar days of the effective date of the revocation.

Our rationale for this policy was outlined in the CY 2009 PFS proposed rule, published in the July 7, 2008 **Federal Register** (73 FR 38539). We noted that we had historically allowed revoked providers and suppliers to continue billing for services furnished prior to revocation for up to 27 months after the revocation effective date. We stated that this extensive post-revocation period posed a significant risk to the Medicare program and that the change to 60 days was necessary to limit Medicare's exposure to future vulnerabilities from revoked physician and nonphysician practitioner organizations and individual practitioners. We further noted that some physician and nonphysician practitioner organizations and individual practitioners were able to create false documentation to support claims payment and that our proposed change would allow Medicare to conduct focused medical review on the submitted claims to ensure that they are supported by verifiable medical documentation.

Indeed, our rationale for our expansion of § 424.535(h) is the same as that which we expressed in the CY 2009 PFS proposed rule. It is important that we limit the Medicare program's exposure to fraudulent claims. We believe that the longer a post-revocation timeframe a revoked provider or supplier has, the more opportunity the provider or supplier would have to submit false claims. Under § 424.518(c)(3)(ii), in fact, a revoked provider or supplier falls within the ''high'' categorical risk level. This heightened risk posed by revoked providers and suppliers, combined with the lengthy 12-month period they currently have for submitting claims, threatens the Medicare Trust Fund. Therefore, we believe that an expansion of § 424.535(h) to include all revoked providers and suppliers is warranted.

We propose to expand the purview of § 424.535(h) to include all revoked Medicare providers and suppliers, regardless of type (for example, DMEPOS suppliers, rural health clinics, skilled nursing facilities). All providers and suppliers, with the exception of home health agencies (HHAs), would have 60 days after the effective date of their revocation to submit their remaining claims for services furnished prior to the date of the revocation letter; for HHAs, the date would be 60 days after the later of: (1) The effective date of their revocation; or (2) the date that the HHA's last payable episode ends. The reason for the modification for HHAs is that under current CMS policy, an HHA can bill for episodes that began before it was terminated and be paid for up to 30 days following the termination date. The HHA would need to wait to bill those episodes until they were complete, which could be day 59 after the termination, giving the HHA 1 day to bill. Thus, we believe that 60 days after the later of: (1) the effective date of their revocation; or (2) the date that the HHA's last payable episode ends would be reasonable.

We note that nothing in our proposed revision to § 424.535(h) would impact the requirements of § 424.44 regarding the timely filing of claims.

Given this, and as stated previously, we propose in § 424.535(h) to require that a revoked provider or supplier (excluding HHAs) submit, within 60 days after the effective date of the revocation, all claims for items and services furnished prior to the date of the revocation letter. For HHAs, the date would be 60 days after the later of: (1) The effective date of the revocation; or (2) the date that the HHA's last payable episode ends.

6. Effective Date of Billing Privileges

Under § 424.520(d), the effective date of billing privileges for physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations is the later of: (1) the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date an enrolled physician or nonphysician practitioner first began furnishing services at a new practice location. This policy was proposed in the CY 2009 PFS proposed rule. It was meant to address our concerns about providers and suppliers being able to bill for Medicare services rendered well prior to enrollment. We explained in that proposed rule that our proposed approach was not only consistent with our requirements found at § 410.33(i) that limit the retrospective billing for IDTFs, but also that it was not possible to verify that a supplier has met all of Medicare's enrollment requirements prior to submitting an enrollment application. Thus, the Medicare program should not be billed for services before the later of the two aforementioned dates.

We propose to expand the scope of § 424.520(d) to include ambulance suppliers. Ambulance suppliers as a class pose an elevated risk to the Medicare program—higher, in fact, than the physician and nonphysician practitioner categories already identified in § 424.520(d). In a January 2006 OIG report entitled, ''Medicare Payments for Ambulance Transports'' (OEI–05–02–000590), the OIG found that 25 percent of ambulance transports did not meet Medicare's program requirements; this resulted in an estimated $402 million in improper payments. We have also seen an overabundance of ambulance

suppliers and an overutilization of ambulance services in particular regions of the country, which has raised questions as to the qualifications and integrity of some ambulance suppliers. In certain areas of ambulance supplier fraudulent activity, for instance, we have received claims for ambulance transports to hospitals with no associated hospital claims. These program integrity issues involving ambulance suppliers heighten our concerns about our inability to conclusively verify that a supplier was in compliance with Medicare's enrollment requirements during the months prior to submitting an enrollment application. It is this concern that leads us to the conclusion that allowing an ambulance supplier to ''back bill'' for services furnished well before enrollment dramatically increases the risk of improper payments and endangers the Medicare Trust Fund. Therefore, we believe that expanding § 424.520(d) to include these elevated risk suppliers is justified.

While we are not including other categories of providers and suppliers in the ''moderate'' or ''high'' screening level under § 424.518 (such as newly enrolling HHAs, community mental health centers and comprehensive outpatient rehabilitation centers), we note that the enrollment process for most of these other providers and suppliers is more extensive than that for ambulance suppliers because it involves certification. An enrolling ambulance supplier submits a CMS–855B application to its Medicare contractor, which reviews the application, performs all necessary verifications, and renders a final decision. However, for certified providers and certified suppliers, the applicant provider or supplier makes a request to its state Survey Agency (SA) for Medicare participation and submits a Medicare enrollment application to its Medicare contractor, which reviews the application, performs the required validations and, if a recommendation for approval is made, typically refers its recommendation to the SA. Thereafter, a survey that determines the applicant provider's or supplier's compliance with the applicable Medicare conditions or requirements will be conducted by the SA or a CMS-approved accrediting organization. If the applicant provider or supplier is determined to be in compliance with its Medicare conditions or requirements for Medicare participation, the SA will make its recommendation to the CMS regional office (RO) for review. If the RO determines that the applicant provider or supplier has met all federal requirements for Medicare participation, including all enrollment requirements, the RO issues an effective date for Medicare participation in accordance with § 489.13, and Medicare billing privileges would be conveyed. However, under § 489.13 the effective date of a Medicare provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met; such requirements include the Medicare contractor's review and verification of the provider/supplier's CMS–855 application. A certified provider or supplier is not eligible for Medicare payment of any services provided prior to the effective date of its Medicare provider agreement or supplier approval.

Because of the exhaustive and extensive review process involved with certified providers and certified suppliers and the existing limitations posed by § 489.13 on the ability of certified providers and certified suppliers to ''backbill'' for services, we have decided not to include these providers and suppliers in our proposal at this time. Ambulance suppliers, on the other hand, do not have this multilayered review process, which makes it more difficult to determine whether they met enrollment requirements 12 months previously. It is for these reasons that we are limiting our expansion of § 424.520(d) to ambulance companies. We solicit comment on whether any other non-certified provider or non-certified supplier type that is not currently subject to a backbilling restriction similar to the one we are proposing should be included within the purview of our proposal.

Given these factors, we would revise § 424.520(d) to include ambulance suppliers.

7. Effective Date of Re-Enrollment Bar

Under § 424.535(c), a revoked provider, supplier, delegated official, or authorizing official is barred from participating in Medicare from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar, as mentioned previously, is a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation. In accordance with § 424.535(g), the effective date of a revocation is either of the following:—

- Thirty days after CMS or the CMS contractor mails notice of its determination to the provider or supplier.
- If the revocation is based on a federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the date of exclusion, debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational.

We propose to revise § 424.535(c) to specify that all re-enrollment bars begin 30 days after CMS or the CMS contractor mails notice of the revocation determination to the provider or supplier. The reason for this change is to address situations where the revocation is based on a federal exclusion or debarment, felony conviction, license revocation or suspension, or non-operational status. Due to possible delays in the updating of databases with criminal conviction and licensure information, the revocation effective dates for these actions can be months prior to the date the contractor mails the revocation letter, and it is from these retroactive effective dates that the re-enrollment bar runs. This can eliminate several months from the re-enrollment bar period; for instance, rather than a full 3-year re-enrollment bar for a felony conviction, the re-enrollment bar might only be 2 years and 10 months—or even less. By starting the re-enrollment bar period after the revocation letter is sent, the full period can be imposed; we do not believe that a revoked provider or supplier should be benefited by a shorter reenrollment bar simply because of a gap between the effective date of the revocation and the date on which the revocation letter is mailed. As an illustration, suppose an enrolled nonphysician practitioner was convicted of a felony on January 15, 2014. On February 15, the contractor mailed notice to the practitioner that his Medicare billing privileges were revoked effective January 15, 2014. Under the current version of § 424.535(c), the re-enrollment bar would run until January 15, 2017, or 2 years and 11 months after the date the revocation notice was sent. However, under our proposed revision, the reenrollment bar would run until February 15, 2017, or 3 years after the revocation notice was mailed.

Given this, we would revise the first sentence of § 424.535(c) to state that the re-enrollment bar is effective 30 days after CMS or its contractor mails notice of its revocation determination to the provider or supplier until the end of the re-enrollment bar.

8. Corrective Action Plans

Consistent with § 405.809, a provider or supplier whose Medicare billing privileges are revoked may submit a corrective action plan (CAP). The CAP must provide evidence that the provider or supplier is in compliance with Medicare requirements. If CMS or the Medicare contractor determines that the provider or supplier is, in fact, in compliance with Medicare requirements, the provider or supplier's billing privileges can be reinstated.

We propose to revise § 405.809 to state in new paragraph (a)(1) that a provider or supplier may not submit a CAP unless the revocation was based on § 424.535(a)(1), which states in part that a provider or supplier's billing privileges may be revoked if the provider or supplier is determined not to be in compliance with our enrollment requirements. Generally, we do not believe that providers and suppliers should be exonerated from failing to fully comply with Medicare enrollment requirements simply by furnishing a CAP. It is the duty of providers and suppliers to always maintain such compliance. However, we do believe that a CAP may be appropriate for revocations based on § 424.535(a)(1). We have seen numerous instances where a provider or supplier revoked under § 424.535(a)(1) had only minimally failed to comply with our enrollment requirements. To revoke its billing privileges when the problem can be quickly and easily corrected via a CAP could in some instances lead to unfair results.

With other revocation reasons, though, we believe that a CAP either should not be available or would be impractical. For instance, if a provider is revoked based on an OIG exclusion or felony conviction, no amount of corrective action would be able to change this. If a supplier is revoked under § 424.535(a)(4) for furnishing false or misleading information or under § 424.535(a)(9) for failing to report a change in practice location, the provider should not be able escape revocation merely by furnishing the truthful or updated information through a CAP, as it was the provider's responsibility to provide this information earlier.

We note that in cases where § 424.535(a)(1) is one of several reasons for a particular revocation, the provider would be able to submit a CAP with respect to the § 424.535(a)(1) revocation reason. For the other revocation bases, however, the provider would not be able to use the CAP process; the provider would instead have to utilize the appeals process under Part 498.

We further propose in new paragraph (a)(2) that providers and suppliers have only one opportunity to correct all of the deficiencies that served as the basis of the revocation through a CAP. We do not believe that providers should be given multiple opportunities to become compliant when it is crucial that such compliance always be maintained.

Notwithstanding these proposed changes, we note that providers and suppliers may still avail themselves of the appeals process under Part 498. Nothing in this proposed rule alters the provider or supplier's rights in this regard.

We also propose to delete the last sentence in § 424.535(a)(1), which reads: ''All providers and suppliers are granted an opportunity to correct the deficient compliance requirement before a final determination to revoke billing privileges, except for those imposed under paragraphs (a)(2), (a)(3), or (a)(5) of this section.'' This sentence is inconsistent with our proposed change in § 405.809(a)(1).

Finally, we propose to incorporate the existing language in § 405.809 into a new subparagraph (b).

Given this, we would make the following regulatory changes:

- Add a new paragraph to § 405.809(a)(1) stating the following:

++ The provider or supplier may not submit a CAP unless the revocation was for noncompliance under § 424.535(a)(1).

- Add a new paragraph (2) to § 405.809(a) stating the following: Subject to paragraph (a)(1), providers and suppliers have only one opportunity to correct all deficiencies that served as the basis of the revocation through a CAP.
- Add a new subsection (b) to § 405.809 that includes the existing language in § 405.809.
- Delete the last sentence in § 424.535(a)(1), which reads: ''All providers and suppliers are granted an opportunity to correct the deficient compliance requirement before a final determination to revoke billing privileges, except for those imposed under paragraphs (a)(2), (a)(3), or (a)(5) of this section.''

9. Revisions to § 424.530(a)(5) and § 424.535(a)(5)

We also propose to revise § 424.530(a)(5) and § 424.535(a)(5). We believe that the language in each of these subsections is redundant. To illustrate, the first sentence of § 424.530(a)(5) states that a provider or supplier's Medicare enrollment may be denied if, upon on-site review or other reliable evidence, CMS determines that the provider or supplier is not operational or is not meeting Medicare enrollment requirements. Later, paragraphs § 424.530(a)(5)(i) and (a)(5)(ii) essentially—and, in our view, needlessly—repeat this language. The same repetition is evident in § 424.535(a)(5), wherein paragraphs (a)(5)(i) and (a)(5)(ii) effectively duplicate the language in the first sentence of § 424.535(a)(5).

Therefore, § 424.530(a)(5) would be revised to state that the provider or supplier's enrollment can be denied if ''(u)pon on-site review or other reliable evidence, CMS determines that the provider or supplier is either of the following: (i) not operational to furnish Medicare covered items or services, or (ii) otherwise fails to satisfy any Medicare enrollment requirements.'' Likewise, § 424.535(a)(5) would be revised to state that a provider or supplier's Medicare billing privileges would be revoked if ''(u)pon on-site review or other reliable evidence, CMS determines that the provider or supplier is either of the following: (i) no longer operational to furnish Medicare covered items or services, or (ii) otherwise fails to satisfy any Medicare enrollment requirements.''

We note that our proposed revision to § 424.535(a)(5) would also add the phrase ''or other reliable evidence'' to this subsection. There are two reasons for this change. First, § 424.530(a)(5) currently contains the ''or other reliable evidence'' standard. We believe that these two paragraphs, § 424.530(a)(5) and § 424.535(a)(5), should contain consistent standards. Second, we believe it is important to be able to ascertain and take action under § 424.535(a)(5) against a non-operational or non-compliant provider or supplier through means other than a site review.

10. Technical Changes

We further propose certain technical changes related to the provider and supplier enrollment regulations.

In § 424.530(a)(1), we propose to change the word ''section'' to ''subpart P'' in the first sentence so that the sentence would read—''[t]he provider or supplier is determined not to be in compliance with the enrollment requirements described in this subpart P, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.'' The purpose of this change is to clarify that the provider or supplier must comply with all of the provider enrollment provisions in 42 CFR subpart P, not merely those in § 424.530.

For the same reason, we propose to revise § 424.535(a)(1) to state as follows: ''The provider or supplier is determined not to be in compliance with the enrollment requirements described in this subpart P, or in the enrollment application applicable for its provider or supplier type and has not submitted a plan of corrective action as outlined in part 488 of this chapter.''

Also, in § 424.535(a)(3)(ii), we propose to change the term ''denials'' to ''revocations'', as § 424.535 does not address denials.

Lastly, § 498.5(l)(4) states that for appeals of denials based on § 424.530(a)(9) related to temporary moratoria, the scope of the review is limited to whether the temporary moratorium applies to the provider or supplier. However, § 424.530(a)(10), rather than § 424.530(a)(9), applies to temporary moratoria. We therefore propose to correct § 498.5(l)(4) by changing the reference to § 424.530(a)(9) therein to § 424.530(a)(10).

III. Collection of Information Requirements

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

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

A. ICRs Regarding Rewards for Information Relating to Medicare Fraud and Abuse (§ 420.405)

Attestation

Our proposed revisions to the IRP at § 420.405(f)(3) would require the reporting individual complete and submit an attestation, which would result in an increase in ICR burden. Between the years of 2000 and 2012, 18 rewards were paid by us under the IRP. Although we believe that the number of paid rewards would rise because of the increased monetary incentive, it is very difficult to estimate this figure. Yet we note that since the 2006 reward amount changes to the IRS program, the IRS has paid an average of 149 rewards per year, from a low of 97 to a high of 227. While there are limitations with using this data to estimate that similar ranges of rewards would be paid under the proposed IRP changes, we believe it indicates that the number of rewards made under IRP would very likely increase from an average of 1.5 a year. For purposes of this ICR section only, we will therefore propose to use the average of 149 attestations in our ICR calculations.

Persons likely to submit an attestation would include beneficiaries, medical providers, and health care administrative personnel that have been notified that they are eligible for a reward under the IRP. We believe that most individuals would prepare the attestation themselves. It is possible, however, that in light of the legal nature of the attestation, some may elect to have legal counsel draft the document. For purposes of estimating the potential cost of this activity only and so as not to underestimate the possible burden, we will utilize the hourly wage for lawyers in our cost calculations.

According to the most recent wage data provided by the Bureau of Labor Statistics for May 2012, the mean hourly wage for the category of ''lawyers'' is $62.93 (see *http://www.bls.gov/oes/current/oes231011.htm*). With fringe benefits and overhead, the per hour rate would be $95. We further project that the attestation preparation and submission process would take the attesting individual approximately 5 hours to complete. Applying our figure of 149 attestations, this results in an average annual burden of 745 hours at a cost of $70,775 (or $95 × 5 hours × 149).

We are soliciting comments on (1) our estimate of the number of attestations per year, (2) our estimate of 5 hours for an individual to complete and submit the attestation; and (3) the per hour rate of $95.

B. ICRs Regarding Our Proposed Provider Enrollment Provisions (§ 424.530 and § 424.535)

1. Definition of Enrollment

Our proposed revisions to § 424.502 and § 424.505 reflect the existing usage of the CMS–855O (OMB Approval #number 0938–0685) and, as such, would not impose any additional ICR burden. Consistent with § 424.507, an individual who wishes to enroll in Medicare for the sole purpose of ordering or certifying items or services for Medicare beneficiaries can become eligible to do so by completing the CMS–855O. Use of the CMS–855O commenced in July 2011, and the ICR burden associated with its use was approved by OMB at that time.

2. Debts to Medicare

Our proposed revisions to § 424.530 would likely result in an increase in application denials. While these revisions would not directly impose an information collection burden, the increase in denials could lead to more appeals from denied providers and suppliers. However, we are unable to estimate the number of potential denials because we do not have data available that can support such an estimate. Therefore, we cannot project the potential ICR burden that could arise from an increased number of: (1) Appeals of denials, or (2) resubmitted enrollment applications from the denied providers and suppliers.

3. Felony Convictions

Our proposed revisions to § 424.530(a)(3) and § 424.535(a)(3), while not paperwork burdens directly imposed by the rule, would likely result in an increase in application denials and revocations, respectively. We believe this would stem mostly from the expansion of these two paragraphs to include managing employees. We believe the changes involving the elimination of the detailed list of felonies would not result in a significant increase in denials or revocations because the ''detrimental to the best interests of Medicare'' standard is currently in these two provisions. However, we cannot estimate the potential increase in denials and revocations based on these proposed changes, as we do not have data available that can support such an estimate. Therefore, we cannot project the potential ICR burden that could arise from an increased number of appeals of denials and revocations.

4. Abuse of Billing Privileges

Our proposed addition of § 424.535(a)(8)(ii) would likely result in an increase in the ICR burden because there would likely be a concomitant increase in revocations and associated appeals. However, we are unable to estimate the number of potential revocations. We do not have data available that can support such an estimate as each situation would have to be very carefully reviewed and addressed on a case-by-case basis.

5. Post-Revocation Submission of Claims

Our proposed change to § 424.535(h) would likely not result in a change in the ICR burden. While the claims in question would need to be submitted within a shorter timeframe (60 days), they would likely be submitted regardless of the applicable submission period. The shorter timeframe would, in general, neither increase nor decrease the number of claims submitted.

6. Effective Date of Billing Privileges

Our proposed change to § 424.520(d) would likely result in a decrease in the ICR burden because fewer claims would be eligible for submission under this change. However, we are unable to project the decrease in the number of claims because we do not have data available to support such an estimate.

7. Effective Date of Re-Enrollment Bar

Our proposed change to § 424.535(c) would neither increase nor decrease the ICR burden. With or without this revision, the provider would still need to submit a CMS–855 application after the expiration of the re-enrollment bar in order to enroll again in Medicare.

8. Corrective Action Plans

Our proposed change to § 405.809 would result in a decrease in the ICR burden because there would be a reduction in the number of CAPs submitted. However, we are unable to estimate the decrease in the number of CAPs submitted because we do not have sufficient data to support such an estimate.

9. Revisions to § 424.530(a)(5) and § 424.530(a)(5)

Our proposed changes to § 424.530(a)(5) and § 424.535(a)(5) would not result in a change to the ICR burden because we do not believe there would be any change in the number of denials or revocations. We note that § 424.530(a)(5) already permits revocation based upon a site review ''or other reliable evidence.'' Thus, there would be no change in the number of (1) appeals of denials, or (2) resubmitted enrollment applications from denied providers and suppliers. As for § 424.535(a)(5), it is true that the ''or other reliable evidence'' standard is not in the current version of that paragraph. But we note that § 424.535(a)(1) permits revocation if the provider or supplier is determined not to be in compliance with the enrollment requirements in this section, or in the enrollment application that is applicable to its provider or supplier type. The authority to revoke based on reliable evidence of non-compliance, therefore, is largely similar to the reasons for revocation stated in § 424.535(a)(1). Hence, we do not believe there would be any change in the number of: (1) Appeals of revocations, or (2) resubmitted enrollment applications from revoked providers and suppliers.

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

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

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–6045–P], Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

IV. Response to Comments

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

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to: (1) Increase the incentive for individuals to report information on individuals and entities that have or are engaged in sanctionable conduct; and (2) make important revisions to certain Medicare provider enrollment requirements to help ensure that fraudulent actors neither enroll in nor maintain their enrollment in the Medicare program.

B. Background

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4) and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

As we explain in more detail later in this section, we encountered several uncertainties in estimating the economic impact of many of our proposed provisions. We could not estimate the number of denials and revocations that might stem from the proposed enrollment changes. We were also unable to estimate the potential monetary savings to the federal government or the costs to providers and suppliers resulting from the remaining proposed revisions. However, we estimate that our proposed changes to § 424.520(d) and § 420.405(e) would result in an annual transfer of more than $100 million from providers and suppliers to the federal government. Therefore, we have prepared an RIA because this is a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organization, and small governmental jurisdictions. Most entities and most other providers and suppliers are small entities, either by nonprofit status or by having revenues between $7 million and $34.5 million in any 1 year. Individuals and states are not included in the definition of a small entity.

Several provisions could have at least some effect on certain small entities. These include: (1) The proposed change at § 424.520(d) to the effective date of billing privileges for ambulance suppliers; (2) the proposed change at § 424.530(a)(6) to Medicare debt; (3) the proposed revision at § 424.535(a)(8) to the abuse of billing privileges; (4) the proposed change at § 424.535(h) to the submission of claims after revocation; and (5) the proposed revision at § 405.809 to the reinstatement of provider or supplier billing privileges following corrective action. However, as explained below we do not believe that this proposed rule would have a significant economic impact on a substantial number of small entities.

Our proposal at § 424.520(d) which would change the effective date of billing privileges for ambulance suppliers would only impact newly-enrolling ambulance suppliers. Each year, new ambulance providers constitute only a very small addition to the overall universe of the roughly 1.4

million Medicare-enrolled providers and suppliers an average of 1,127 ambulance suppliers enrolled in Medicare each year between 2006 and 2011. We further note that this provision would not in any way affect their ability to bill for services furnished after the later of the two events specified in § 424.520(d)(1) and (2).

Denials and revocations under, respectively, § 424.530(a)(6) and § 424.535(a)(8), would not occur prior to an extremely careful examination by CMS of: (1) The level of undue risk that the unpaid debt poses; or (2) the criteria for determining whether the provider or supplier has a pattern or practice of submitting non-compliant claims. As such, while we do anticipate an increase in some denials and revocations under these two provisions, we do not believe they would impact a substantial number of small entities.

Our proposed change to § 424.535(h) would not have a significant impact on small businesses because: (1) Only a small number of Medicare providers and suppliers have their billing privileges revoked, and (2) the revoked provider's claims would likely be submitted regardless of the shorter submission period.

Our proposed change to § 405.809 would impact some small entities' ability to submit CAPs in response to a revocation. However, these small entities would still able to file a request for reconsideration. Consequently, the overall effect of this proposed change would not impact a substantial number of small entities.

In short, we believe that the vast majority of providers and suppliers—both small and large—do not commit fraud, have not been convicted of a felony, and are otherwise compliant with Medicare enrollment requirements. Consequently, they would not be affected by most of the provisions in this proposed rule.

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 that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined and the Secretary certified that 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 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, this is approximately $141 million. We believe that this proposed rule would have no consequential effect on state, local or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirements or 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 Executive Order 13132 are not applicable.

C. Anticipated Effects

1. Incentive Reward Program

Our proposed change at § 420.405(e)(5) would likely result in an increase in savings to the federal government. As stated earlier in the ICR section of this proposed rule, the IRS paid an average of 149 rewards per year following the 2006 reward structure changes to its program. We proposed to estimate that CMS may make a similar number of rewards as the IRS under our proposed reward structure. We are soliciting comments on using the IRS' experience of paying an average of 149 rewards since 2006 to estimate the potential increase in amounts collected and associated rewards. However, as the IRS experience demonstrates, the amount of collections and the number of rewards paid can vary significantly each year. There are limitations with using this estimated based on IRS experience, however we believe that creating an incentive program similar to the IRS' long-standing reward program could reasonably result in a similar number of rewards made under such a program.

In the past decade, we have had an average collection of $193,069 as a result of information provided by individuals who qualified for a reward under the IRP. We anticipate that the amount of the collections may increase under the proposed modifications; but we do not have any internal data on which to base an estimate. We propose to project the impact of the IRP changes on amounts collected by multiplying the proposed estimated increase in the number of rewards requiring attestations —149—by the average amount collected by CMS of $193,069. We solicit comments on this proposed estimate of $28,767,281 (149 × $193,069) of future amounts collected. We also solicit comment on using a range of estimates for the increase in the number of rewards, and also solicit comment on using the increase in amounts collected experienced by the IRS to estimate the potential future increases in collections to us. We also propose to estimate the impact of the IRP changes on reward payments by multiplying the proposed estimate of amounts collected, $28,767,281, by the proposed reward structure, 15 percent. We solicit comments on this proposed estimate of $4,315,092 in future reward payments ($28,767,281 × .15)—which would result in a net amount collected of $24,452,189 by us. We also solicit comments on: (1) using a range of estimates for the increase in the amount reward payments; and (2) the increase in amounts collected experienced by the IRS to estimate the potential future increases in reward payments made by CMS. While there may be an increase in costs to the federal government to administer the program due to the proposed changes, we do not have sufficient data to estimate the magnitude of such an increase at this time and believe that any increased costs would be offset by an accompanying increase in returns to the federal government.

2. Provider Enrollment Provisions

We indicated in the ICR section that there could be an ICR burden associated with several of our provider enrollment provisions but that said burden could not be estimated. The following subsections discuss other potential costs—as well as savings—associated with our proposed enrollment changes.

a. Definition of Enrollment

As stated earlier, use of the CMS–855O commenced in July 2011. Our proposed revisions to § 424.502 or § 424.505 are merely intended to reflect the usage of the CMS–855O and, as such, would not result in any additional costs or savings.

b. Debts to Medicare

Our proposed revisions to § 424.530(a)(6) would likely result in additional application denials. However, we are unable to estimate the number of potential denials because we do not have data available that could support such an estimate. Therefore, we cannot project any costs in potential lost billings to providers and suppliers or any concomitant potential savings to the government. There may be an increase

in costs to the federal government towards identifying and making available to enrollment contractors information about individuals that were associated with a revoked entity with an unpaid Medicare debt, however, we are unable to estimate the magnitude of any potential increase at this time, and we also anticipate that an increase in costs would be offset by savings to the government by preventing billing by such providers or suppliers, or by the repayment of debt by such providers or suppliers.

c. Felony Convictions

As stated in the ICR section, our proposed revisions to § 424.530(a)(3) and § 424.535(a)(3) would likely result in additional application denials and revocations, respectively. Yet we cannot estimate the potential increase in denials and revocations and associated appeals based on these proposed changes, because we do not have data available that could support such an estimate. Thus, we cannot project the potential costs to providers and suppliers in lost potential billings or the potential costs or savings to the government arising from these proposed revisions.

d. Abuse of Billing Privileges

Our proposed addition of § 424.535(a)(8)(ii) would likely result in an increase in revocations. However, we are unable to project the number of providers and suppliers that might be revoked based on this proposed change because we do not have data available that could support such an estimate. Thus, we cannot project the potential costs to providers and suppliers in lost potential billings or the potential costs or savings to the government arising from these proposed revisions.

e. Post-Revocation Submission of Claims

Our proposed change to § 424.535(h) is unlikely to increase or decrease the number of claims submitted. While the revoked provider or supplier's claims would need to be submitted within a shorter timeframe, we believe that the vast majority of claims would still be submitted. Thus, we project negligible change in costs to providers and suppliers in their claim submissions.

f. Effective Date of Billing Privileges

Our proposed change to § 424.520(d) will likely result in a decrease in claims submitted to Medicare. Rather than being able to bill for Medicare services furnished up to 12 months prior to enrollment, newly enrolling ambulance suppliers would be unable to bill for services furnished prior to the later of: (1) The date of filing a Medicare enrollment application that was subsequently approved; or (2) the date the supplier first began furnishing services at a new practice location.

According to our statistics, and as stated earlier, an average of 1,127 ambulance suppliers enrolled in Medicare each year between 2006 and 2011. We will use this figure in our calculations. As a result of our proposed change, these suppliers could lose up to 10 months in potential Medicare billings for services furnished prior to the later of (1) or (2) in the previous paragraph.

Based on our data, the average ambulance supplier receives approximately $581,000 in Medicare payments per year, though this, of course, varies by individual supplier. Ten-twelfths of this amount (that is, 10 months divided by 12 months) is $484,167. Thus, we estimate that up to $545.7 million each year (or $484,167 × 1,127) in savings to the federal government could accrue as a result of this proposed change.

We emphasize that our $545.7 million estimate is a high-end estimate. There may be new ambulance suppliers that, absent our proposed change, would have met our requirements less than 10 months prior to enrollment. For instance, if the average newly enrolling ambulance supplier would have met our requirements 3 months prior to enrollment, the potential savings would be roughly $163.7 million (or $581,000 × 3/12 × 1,127). If the average figure is 6 months, our estimate would be approximately $327.4 million. We have no way of predicting the ratio of ambulance suppliers that would have met our requirements 10 months, 6 months or 3 months (or any other point, for that matter) prior to enrollment. Therefore, we will use these three timeframes as, respectively, high-end, primary, and low-end estimates in the Accounting Statement.

g. Effective Date of Re-Enrollment Bar

Our proposed revision to § 424.535(c) would result in a longer re-enrollment bar than currently exists in cases where the date of the offenses that is the basis of the revocation occurs months before the issuance of the revocation letter. The longer period during which a provider or supplier is unable to enroll in Medicare could result in lost billings to the provider or supplier. This could also result in a savings to the government because a provider or supplier that may have been billing Medicare would not be eligible to do so as soon as would otherwise be the case. However, we are unable to estimate the costs to providers and suppliers or the savings to the federal government because we do not have data available to support to support such an estimate. We also cannot estimate (1) how many providers and suppliers would be affected by this proposed change, or (2) the specific types of providers and suppliers that would be affected.

h. Corrective Action Plans

Our proposed change to § 405.809 would result in a reduction in the number of CAPs submitted, as noted in the ICR. This could result in lost billings to the provider or supplier in cases where a CAP resulted in a favorable decision more quickly than a reversal of the revocation at the appeals level, as the CAP review process often takes place sooner than the reconsideration process. The reduction in the submission of CAPs would also result in a savings to the federal government due to a decrease in the resources needed to review the CAPs. However, we cannot estimate the potential lost billings of providers or suppliers resulting from this proposed provision, or the savings to the federal government. We do not have data that can assist us in predicting: (1) the number of provider and suppliers that our proposed change would impact; or (2) the specific types of providers and suppliers that would be affected.

i. Revisions to § 424.530(a)(5) and § 424.530(a)(5)

We stated earlier, that we do not believe there would be any change in the total number of denials or revocations based on our proposed changes to § 424.530(a)(5) and § 424.530(a)(5). Therefore, we do not anticipate any resultant change in overall costs or savings.

j. Technical Changes

As these are simply technical revisions, there are no costs or savings associated therewith.

3. Conclusion

While we are unable to furnish detailed cost and savings estimates at this point regarding many of our proposed provisions, we are soliciting comments from the public regarding their views as to the potential burdens and costs of our proposals as well as the possible savings.

D. Accounting Statement and Table

As required by OMB Circular A–4 (available at link *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-*

4.pdf), we have prepared an accounting statement.

The ''transfer'' category in Table 2 reflects the application of a 7 percent and 3 percent annualized rate to:

- The high-end, primary, and low-end estimates referred to in section V.C.2.f. of this proposed rule and involving our proposed change to § 424.520(d).
- Our estimate of the net amount that could be recovered under our proposed IRP changes. Specifically, the annualized rates are applied to a figure of $24,452,189 or the difference between the previously estimated total recovery amount ($28,767,281) and the previously estimated total reward payments ($4,315,092). Note that we solicited comment on the advisability of establishing $72,675 estimate of the potential ICR burden of IRP attestation submissions.

The 7 and 3 percent figures were applied over a 10-year period beginning in 2013, with the figures in the accounting statement reflecting the average annualized costs over this period.

The accounting statement does not address the potential financial benefits of this proposed rule from the standpoint of its effectiveness in preventing or deterring certain providers and suppliers from enrolling in Medicare or maintaining their enrollment in Medicare. It is not possible for us to quantify these benefits in monetary terms. In addition, the statement does not include those provisions above that we believe would or could result in a cost or savings that nevertheless could not be estimated.

TABLE 2—ACCOUNTING STATEMENT AND TABLE

[In millions]

Category	Primary estimates	Low estimates	High estimates	Year dollars	Discount rate (percent)	Period covered
Transfers						
Resulting from the change in the effective date of billing privileges for ambulance suppliers	327.4	163.7	545.7	2013	7	2014–2023
	327.4	163.7	545.7	2013	3	2014–2023
From Whom to Whom	Transfers from Ambulance Suppliers to Federal Government					
Transfers						
Potential net recoveries under the IRP	24.5	N/A	N/A	2013	7	2014–2023
	24.5	N/A	N/A	2013	3	2014–2023
From Whom to Whom	Transfers from Providers and Suppliers to Federal Government					
Transfers						
Potential total reward payment	4.3	4.3	N/A	2013	7	2014–2023
	4.3	4.3	N/A	2013	3	2014–2023
From Whom to Whom	Transfers from Providers and Suppliers to Individuals that received an IRP reward					
Costs						
Submission of Attestations	*0.1	N/A	N/A	2013	7	2014–2023
	*0.1	N/A	N/A	2013	3	2014–2023
Who is Affected?	Individuals that received an IRP reward					

*Rounded to the nearest hundred-thousandth.

E. Alternatives Considered

1. Incentive Reward Program

We considered a potential reward structure of a different portion and for a different amount collected than that which we have proposed. First, we considered increasing the amount of the collection we would pay a reward for, but keeping the portion of the reward at 10 percent. We also considered mirroring the current IRS program of offering a range of 15 to 30 percent with no limit on the amounts collected we would pay a reward for. However, we have proposed ''15 percent of the final amount collections applied to first $66,000,000 for sanctionable conduct'' for two principal reasons. First, this reward structure is largely consistent with that used in the highly successful IRS reward program without creating the appearance of an overlap between CMS' IRP and the *qui tam provisions* of the False Claims Act. This is important because rewards are potentially available to individuals under both the CMS IRP and the False Claims Act but the requirements under each are distinct. Second, the proposed structure of a fixed percent that pays up to a certain dollar amount of collections is identical to the current IRP reward structure. We believe that this will make a new reward structure administratively easier to implement, as well as more transparent to individuals that may receive a reward under the IRP.

2. Provider Enrollment

As stated, our proposed provider enrollment provisions are needed to help ensure that fraudulent actors neither enroll in nor maintain their enrollment in the Medicare program. Nonetheless, we did consider four alternatives when preparing our enrollment provisions.

First, with respect to § 424.530(a)(6)(i) and (ii), we considered—and elected to propose—an exception to these denial

reasons for providers, suppliers, and owners thereof that have agreed to an extended repayment schedule. We believe that such an agreement indicates a willingness to satisfy the debt.

Second, we considered expanding the purview of proposed § 424.520(d) to include all certified providers and certified suppliers, such as hospitals, skilled nursing facilities, and ambulatory surgical centers. Yet as stated earlier in this proposed rule, we concluded that this approach would be unnecessary and even impractical. There is already an exhaustive and extensive review process involved with certified providers and certified suppliers, and there already are limitations posed by § 489.13 on the ability of such providers and suppliers to ''backbill'' for services.

Third, we contemplated eliminating CAPs altogether, as the existing appeals process already affords providers and suppliers adequate due process rights. In the interests of fairness and efficiency, however, we elected to retain the CAP process for revocations based on § 424.535(a)(1). We believe that our decision would continue to give certain providers and suppliers an additional opportunity to try to remedy inadvertent or minor errors without subjecting all parties to the lengthier appeals process. However, for reasons outlined in this proposed rule we believe that eliminating the CAP process for all other revocation reasons is warranted.

Finally, the possibility of expanding the purview of § 424.530(a)(3) and § 424.535(a)(3) to include not only managing employees but also corporate officers, corporate directors, and board members was considered. We determined that the better approach would be to simply solicit comment on the prospect of applying these sections to these individuals.

F. Impact on Beneficiary Access

We do not believe that our proposed provisions would impact beneficiary access. While it is possible that some providers and suppliers may have their Medicare enrollment applications denied or their Medicare billing privileges revoked as a result of our proposed enrollment provisions, we believe this number would be small.

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

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions. Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 420

Fraud, Health facilities, Health professions, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.809 is revised to read as follows:

§ 405.809 Reinstatement of provider or supplier billing privileges following corrective action.

(a) *General rule.* A provider or supplier—

(1) May not submit a corrective action plan unless the revocation was for noncompliance under § 424.535(a)(1) of this chapter; and

(2) Subject to paragraph (a)(1) of this section, has only one opportunity to correct all deficiencies that served as the basis of its revocation through a corrective action plan.

(b) *Review of a corrective action plan.* Subject to paragraph (a)(1) of this section, CMS or its contractor reviews a submitted corrective action plan and does either of the following:

(1) Reinstates the provider or supplier's billing privileges if the provider or supplier provides sufficient evidence to CMS or its contractor that it has complied fully with the Medicare requirements, in which case—

(i) The effective date of the reinstatement is based on the date the provider or supplier is in compliance with all Medicare requirements; and

(ii) CMS or its contractor may pay for services furnished on or after the effective date of the reinstatement.

(2) Refuses to reinstate a provider or supplier's billing privileges. The refusal of CMS or its contractor to reinstate a provider or supplier's billing privileges based on a corrective action plan is not an initial determination under part 498 of this chapter.

PART 420—PROGRAM INTEGRITY: MEDICARE

■ 3. The authority for part 420 continues to read as follows:

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

■ 4. Section 420.405 is amended by—
■ A. Revising paragraph (a).
■ B. In paragraph (b)(2), removing the phrase ''or the OIG,'' and adding in its place the phrase ''the OIG,''.
■ C. Adding new paragraphs (b)(3) and (c)(2)(v).
■ D. Revising paragraph (d)(1).
■ E. Revising paragraphs (e)(2), (e)(3), and (f)(1).
■ F. Adding paragraph (f)(3).
■ G. Revising paragraph (h).

The revisions and additions read as follows:

§ 420.405 Rewards for information relating to Medicare fraud and abuse.

(a) *General rules.* (1) CMS pays a monetary reward for information that leads to the collection of at least $100 of Medicare funds from individuals and entities that are engaging in, or have engaged in, acts or omissions that constitute grounds for the imposition of a sanction under sections 1128, 1128A, or 1128B of the Act or that have otherwise engaged in sanctionable fraud and abuse against the Medicare program, otherwise referred to as ''sanctionable conduct.''

(2) The determination of whether an individual meets the criteria for a reward is at the exclusive discretion of CMS.

(3) When CMS applies the criteria specified in paragraphs (b), (c), and (e) of this section to determine the eligibility and the amount of the reward, it notifies the individual as specified in paragraph (d) of this section.

* * * * *

(b) * * *

(3) CMS does not give a reward if the same or substantially similar information was the basis for payment of a relator's share of the amounts collected under the False Claims Act, or if the same or substantially similar information is the subject of a pending False Claim Act case.

(c) * * *

(2) * * *

(v) An individual who is eligible for a reward for furnishing the same or substantially similar information to the Federal government under any other federal reward program or payment under Federal law is excluded from receiving a reward under this section.

(d) * * *

(1) *General rule.* After all Medicare funds have been collected and CMS has determined an individual eligible to receive a reward under the provisions of this section, CMS notifies the informant of his or her eligibility, in writing, at the most recent address supplied by the individual. It is the individual's responsibility to ensure that CMS has been notified of any change in his or her address or other relevant personal information (for example, change of name, phone number).

* * * * *

(e) * * *

(2) The amount of a reward represents what CMS considers to be adequate compensation in the particular case as follows:

(i) For information received before [the effective date of the final rule], 10 percent of the final amounts collected applied to the first $10,000 for the sanctionable conduct.

(ii) For information received on or after [the effective date of the final rule], 15 percent of the final amounts collected applied to the first $66,000,000 for the sanctionable conduct.

(3) CMS allocates the total reward amount to the first individual who provides CMS with specific information, as defined in paragraph (b) of this section, on a specific individual or entity that is engaging in, or has engaged in, acts or omissions that constitute grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act or that has otherwise engaged in sanctionable fraud and abuse against the Medicare program that leads to the imposition of a sanction.

* * * * *

(f) * * *

(1) An individual may submit information on persons or entities engaging in, or that have engaged in, fraud and abuse against the Medicare program to either of the following:

(i) The Office of Inspector General.

(ii) CMS or the CMS contractor that has jurisdiction over the suspected fraudulent provider or supplier.

* * * * *

(3) *Attestation requirements:* Upon notification of reward eligibility, an individual must complete an attestation that specifies that the individual has or will do all of the following:

(i) Is not participating and has not participated in the sanctionable conduct.

(ii) Is not otherwise ineligible to receive a reward under paragraph (c)(2) of this section.

(iii) Has furnished information that is accurate and truthful to the best of his or her knowledge.

(iv) Acknowledges that knowingly failing to provide truthful information could subject him or her to potential criminal and civil liability.

* * * * *

(h)(1) *Finding of ineligibility after reward is accepted.* If CMS finds an individual ineligible after payment of a reward, CMS reserves the right to recover such reward from the individual.

(2) *Notification of ineligibility.* CMS notifies an individual in writing upon the determination of ineligibility, and requests a full refund within 30 days.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 5. The authority for part 424 continues to read as follows:

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

■ 6. Section 424.502 is amended in the definition of ''Enroll/Enrollment'' by revising the introductory text and paragraph (4) to read as follows:

§ 424.502 Definitions

* * * * *

Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services. The process includes—

* * * * *

(4) Except for those suppliers that complete the CMS–855O form, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare covered items and services, granting the Medicare provider or supplier Medicare billing privileges.

* * * * *

§ 424.505 [Amended]

■ 7. Section 424.505 is amended by removing the phrase ''Once enrolled, the provider or supplier receives'' and adding in its place the phrase ''Except for those suppliers that complete the CMS–855O form or CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare covered items and services; once enrolled the provider or supplier receives,''.

■ 8. Section 424.520 is amended by revising paragraph (d) to read as follows:

§ 424.520 Effective date of Medicare billing privileges.

* * * * *

(d) *Physicians, nonphysician practitioners, physician and nonphysician practitioner organizations, and ambulance suppliers.* The effective date for billing privileges for physicians, nonphysician practitioners, physician and nonphysician practitioner organizations, and ambulance suppliers is the later of—

(1) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or

(2) The date that the supplier first began furnishing services at a new practice location.

■ 9. Section 424.530 is amended by revising paragraphs (a)(1), (3), (5), and (6) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program

(a) * * *

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements in this subpart P or in the enrollment application applicable for its provider or supplier type and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

* * * * *

(3) *Felonies.* The provider, supplier or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the Medicare program and its beneficiaries.

* * * * *

(5) *On-site review.* Upon on-site review or other reliable evidence, CMS determines that the provider or supplier is either of the following:

(i) Not operational to furnish Medicare covered items or services.

(ii) Otherwise fails to satisfy any Medicare enrollment requirements.

(6) *Medicare debt.* (i) The enrolling provider, supplier, or owner (as defined in § 424.502), has an existing Medicare debt.

(ii) The enrolling provider, supplier, or owner (as defined in § 424.502)

thereof was previously the owner (as defined in § 424.502) of a provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily terminated, involuntarily terminated, or revoked and all of the following criteria are met:

(A) The owner left the provider or supplier that had the Medicare debt within 1 year of that provider or supplier's voluntary termination, involuntary termination or revocation.

(B) The Medicare debt has not been fully repaid.

(C) CMS determines that the uncollected debt poses an undue risk of fraud, waste or abuse.

(iii) A denial of Medicare enrollment under this paragraph (a)(6) can be avoided if the enrolling provider, supplier or owner thereof does both of the following:

(A) Satisfies the criteria set forth in § 401.607.

(B)(*1*) Agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt; or

(*2*) Repays the debt in full.

* * * * *

■ 10. Section 424.535 is amended by revising paragraphs (a)(1) introductory text and (a)(3), (a)(5), (a)(8), (c), and (h) to read as follows:

§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.

* * * * *

(a) * * *

(1) *Noncompliance.* The provider or supplier is determined not to be in compliance with the enrollment requirements described in this subpart P, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter.

* * * * *

(3) *Felonies.* (i) The provider, supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a federal or state felony offense that CMS has determined to be detrimental to the best interests of the Medicare program and its beneficiaries.

(ii) Revocations based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

* * * * *

(5) *On-site review.* Upon on-site review or other reliable evidence, CMS determines that the provider or supplier is either of the following:

(i) No longer operational to furnish Medicare covered items or services.

(ii) Otherwise fails to satisfy any Medicare enrollment requirements.

* * * * *

(8) *Abuse of billing privileges.* Abuse of billing privileges includes either of the following:

(i) The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to the following situations:

(A) Where the beneficiary is deceased.

(B) The directing physician or beneficiary is not in the state or country when services were furnished.

(C) When the equipment necessary for testing is not present where the testing is said to have occurred.

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims for services that fail to meet Medicare requirements.

* * * * *

(c) *Reapplying after revocation.* If a provider, supplier, owner, or managing employee has their billing privileges revoked, they are barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar.

(1) The re-enrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation.

(2) The re-enrollment bar does not apply in the event a revocation of Medicare billing privileges is imposed under paragraph (a)(1) of this section based upon a provider or supplier's failure to respond timely to a revalidation request or other request for information.

* * * * *

(h) *Submission of claims for services furnished before revocation.* (1)(i) Except for HHAs as described in paragraph (h)(1)(ii) of this section, a revoked provider or supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

(ii) A revoked HHA must submit all claims for items and services within 60 days after the later of the following:

(A) The effective date of the revocation.

(B) The date that the HHA's last payable episode ends.

(2) Nothing in this paragraph (h) impacts the requirements of § 424.44 regarding the timely filing of claims.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 10. The authority citation for part 498 continues to read as follows:

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

§ 498.5 [Amended]

■ 11. In § 498.5, paragraph (l)(4) is amended by removing the cross-reference ''§ 424.530(a)(9)'' and adding the cross-reference ''§ 424.530(a)(10)'' in its place.

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

Dated: August 23, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 17, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–09991 Filed 4–24–13; 11:15 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket Nos. FWS–R4–ES–2012–0068; FWS–R4–ES–2013–0010; 4500030114]

RIN 1018–AY19; 1018–AZ42

Endangered and Threatened Wildlife and Plants; Threatened Status for the Spring Pygmy Sunfish and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on our October 2, 2012, proposed listing and designation of critical habitat for the spring pygmy sunfish (*Elassoma alabamae*) under the Endangered