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CMS-6045-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 424, and 498

[CMS-6045-F]

RIN 0938-AP01

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

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

ACTION: Final rule.

SUMMARY: This final rule implements various provider enrollment requirements.

These include: 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 that fail to meet Medicare requirements; and limiting the ability of ambulance suppliers to "backbill" for services performed prior to enrollment.

DATES: These regulations are effective on [INSERT DATE 60 days after the date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

a. Need for Regulatory Action

This final rule is necessary to make certain changes to the provider enrollment provisions in 42 CFR part 424, subpart P. This final rule will strengthen program integrity and help ensure that fraudulent entities and individuals do not enroll in or maintain their enrollment in the Medicare program.

b. Legal Authority

Sections 1102 and 1871 of the Social Security 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 respect to the enrollment process for providers and suppliers.

2. Brief Summary of the Major Provider Enrollment Provisions

We are finalizing the following major provisions regarding provider enrollment:

- Allowing denial of enrollment if the provider, supplier, or owner thereof was previously the owner 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--

++ 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.

A denial under this provision can be averted if the enrolling provider, supplier, or owner thereof-- (1) satisfies the criteria set forth in § 401.607 and agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt; or (2) repays the debt in full.

- Allowing denial of enrollment or revocation of Medicare billing privileges if, within the preceding 10 years, the provider or supplier, or any owner or managing employee thereof, was convicted of a federal or state felony offense that CMS determines to be detrimental to the best interests of the Medicare program and its beneficiaries. (Under the previous regulation, enrollment could not be denied or revoked based on a managing employee's felony conviction.)

- Allowing revocation of Medicare billing privileges if the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.

- With the exception noted in section II.B.5. of this final rule, requiring all revoked providers and suppliers (regardless of type) to submit all of their remaining claims within 60 days after the effective date of their revocation.

- Limiting the ability of ambulance companies to "back bill" for services furnished prior to enrollment. Under § 424.520(d), physicians, non-physician practitioners, and physician and non-physician practitioner organizations currently cannot bill for services furnished prior to the later of the date the supplier filed a Medicare enrollment application that was subsequently approved by a Medicare contractor or the

date the supplier first began furnishing services at a new practice location. (Independent diagnostic testing facilities (IDTFs) and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) have similar restrictions.) We are expanding this to include ambulance suppliers.

- Limiting the ability of revoked providers and suppliers to submit a corrective action plan (CAP) to situations where the revocation was based on § 424.535(a)(1).

3. Incentive Reward Program (IRP)

We may finalize the provisions relating to the IRP in future rulemaking.

4. Summary of Costs and Benefits

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

TABLE 1: SUMMARY OF COSTS AND IMPACTS

Provision Description	Impacts
Denial of Enrollment Based on Medicare Debt	Though a savings to the federal government will 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 will accrue from such a denial or revocation, the monetary amount cannot be quantified.
Revocation Based on Pattern or Practice of Submitting Claims that Do Not Meet Medicare Requirements	Though a savings to the federal government will accrue from such a revocation, the monetary amount cannot be quantified.
Requirement for Revoked Providers and Suppliers to Submit Remaining Claims within 60 Days after Effective Date of Revocation	Monetary amount cannot be quantified. However, we believe this requirement will-- (1) limit the Medicare program's vulnerability to fraudulent claims; and (2) allow more focused medical review. This will likely result in some savings to the federal government.
Inclusion of Ambulance Suppliers within § 424.520(d)	Will result in a transfer of \$327.4 million per year (primary estimate) from ambulance suppliers to the federal government.
Limitation of Ability to Submit CAP to Situations where Revocation based on § 424.535(a)(1)	Monetary amount cannot be quantified. However, the provision will 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

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." 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.

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 as well as to section 1866(j) of the Act, we proposed several additional changes to our provider enrollment regulations to help ensure that Medicare payments are only made to qualified providers and suppliers.

In the April 29, 2013 **Federal Register** (78 FR 25013), we published a proposed rule that would revise the IRP provisions and certain provider enrollment requirements in part 424, subpart P.

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

A. Incentive Reward Program (IRP)

We received a number of comments regarding our proposed IRP provisions. They focused largely on several issues.

First, a number of commenters stated that the significantly increased reward amount would lead to many reports containing irrelevant or erroneous information that would ultimately impose a heavy burden on CMS and its contractors. Providers would also be seriously burdened because they would constantly have to fight unwarranted complaints, perhaps leaving less time for such providers to treat Medicare beneficiaries.

Second, several commenters expressed concern regarding our proposal to limit reward eligibility to the first reporter of information about a provider's actual or potential sanctionable conduct. They contended that this could create "shoot first, ask questions later" situations; such a rush to report could also create tension between providers and patients.

Third, several commenters stated that our proposal would encourage whistleblowers to first report their concerns to CMS: (1) instead of using established internal compliance reporting methods (such as hotlines) created within Medicare provider organizations; and (2) without undertaking any initial validation of facts or discussing the matter with the provider.

Fourth, commenters questioned whether CMS has the resources in place to handle the enormous influx of tips and complaints that our proposal would generate.

Due to the complexity of the operational aspects of our proposal, we are not finalizing our proposed IRP provisions in this rule. We may finalize them in future rulemaking.

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 that rule's publication, we have revised and supplemented various provisions in part 424, subpart P to address certain payment safeguard issues. As discussed in the following section, this final rule makes additional changes to subpart P.

1. Definition of Enrollment

Most physicians and non-physician practitioners enroll in Medicare to become eligible to receive payment for covered services furnished to Medicare beneficiaries. However, some physicians and non-physician practitioners who are not enrolled in Medicare via the Form CMS-855I enrollment application may wish to enroll for the sole and exclusive purpose of ordering or certifying items or services for Medicare

beneficiaries. Consistent with § 424.507, and assuming all other applicable requirements are met, these individuals are eligible to enroll for the sole purpose of ordering or certifying Medicare items or services by completing the CMS-855O application. The CMS-855O (OMB Approval # 0938-0685), which became available for use 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 non-physician practitioners who complete the CMS-855O are not eligible to submit claims to Medicare for services they provide, for they are not granted Medicare billing privileges. Because some of our regulatory provisions did not clearly articulate the difference between enrolling in Medicare: (1) to obtain Medicare billing privileges; and (2) solely to order or certify items or services for Medicare beneficiaries, we proposed three remedial changes.

The first change involved the definition of "Enroll/Enrollment" in § 424.502, the initial sentence of which stated: "Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare-covered services and supplies." We proposed to change this to read: "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." Our purpose was to clarify that the overall enrollment process includes enrollment via the CMS-855O.

The second revision concerned paragraph (4) of the definition of "Enroll/Enrollment" in § 424.502. We proposed to change the language in this paragraph 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 was intended to emphasize that although 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 third change involved § 424.505, which states in part that a provider or supplier, once enrolled, receives Medicare billing privileges. We proposed 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, our purpose was to clarify 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 the supplier.

The following is a summary of the comments we received on these three changes and our responses:

Comment: Several commenters recommended that the CMS-855O be modified to require the applicant to provide information about his or her practice location and medical record location. The commenters contended that § 424.510(d)(2)(ii) mandates

that each submitted enrollment application include the submission of all documentation to uniquely identify a provider or supplier – including, but not limited to, proof of a practice location and medical record storage location. Such proof, the commenters stated, can help reduce identity theft and other forms of Medicare fraud, waste and abuse. A commenter recommended that CMS deactivate the billing privileges of any individual who enrolled in Medicare using the CMS-855O because the CMS-855O does not collect information on practice locations and medical record storage locations. Another commenter suggested that CMS require individuals who have enrolled using the CMS-855O to provide practice location information.

Response: These recommended changes regarding the CMS-855O are outside the scope of this rule, though we may consider adding practice location information to the CMS-855O at a later date.

Some of the enrollment requirements in § 424.510 are applicable only to providers and suppliers enrolling in Medicare to obtain billing privileges, and do not apply to providers and suppliers enrolling strictly to order or certify items or services for Medicare beneficiaries. In order to clarify those requirements that apply to all enrollments and those that only apply to enrollments to obtain billing privileges, we are revising § 424.510 as follows:

- The first two sentences of existing paragraph (a) will be designated as new paragraph (a)(1).
- The third sentence of existing paragraph (a) will be designated as new paragraph (a)(2) and is revised to read: "To be enrolled to furnish Medicare-covered items and services, a provider or supplier must meet the requirements specified in

paragraphs (d) and (e) of this section."

- New paragraph (a)(3) will state the following: "To be enrolled solely to order and certify Medicare items or services, a physician or non-physician practitioner must meet the requirements specified in paragraph (d) of this section except for paragraphs (2)(iii)(B), (2)(iv), (3)(ii), (5), (6), and (9)." These paragraphs only apply to individuals enrolling to obtain Medicare billing privileges.

With respect to the commenter's suggestion regarding deactivation, enrollment via the CMS-855O does not confer billing privileges. Hence, there are no billing privileges to deactivate.

Comment: Several commenters disagreed with the use of the CMS-855O, arguing that CMS: (1) lacks the statutory and regulatory basis to either establish a registration process for ordering and certifying physicians and non-physician practitioners or to use an enrollment application for any purpose other than to enroll a provider or supplier (including physicians and non-physician practitioners); and (2) violates 5 U.S.C. 551 et seq. in its use of the CMS-855O without having issued a proposed and final regulation. The commenters further contended that § 424.500 does not contemplate such a registration process and that CMS did not solicit comments on revising § 424.500 for such purpose. A commenter recommended that CMS: (1) discontinue use of the CMS-855O until it completes the notice and comment rulemaking process described in section 1871 of the Act; and (2) furnish the legal basis for registering physicians and non-physician practitioners for the sole purpose of ordering or certifying Medicare services or items.

Other commenters expressed concern that CMS is using the Paperwork Reduction

Act of 1995 (PRA) to circumvent the notice and comment rulemaking requirements of the Administrative Procedure Act as a means of establishing a new Medicare enrollment application – specifically, the CMS-855O. A commenter contended that CMS essentially used the PRA process to prohibit physicians from obtaining Medicare billing privileges via the CMS-855O. The commenter recommended that CMS explain its use of the CMS-855O: (1) without having utilized the notice and comment rulemaking process; and (2) in lieu of using the CMS-855I, which has a legal basis, has already been subject to rulemaking, and duplicates all of the data on the CMS-855O; the commenter argued that CMS has already established an enrollment application for physicians (that is, the CMS-855I) and that the CMS-855O is therefore duplicative of the CMS-855I. With respect to the second suggestion regarding CMS using the PRA process to prohibit physicians from enrolling to obtain billing privileges, the commenter added that CMS could modify the CMS-855I to accommodate physicians and non-physician practitioners seeking only to order or certify items or services. The commenter stated that this would ease the paperwork burden on such individuals should they later wish to obtain Medicare billing privileges; rather than having to complete two separate forms (the CMS-855I and CMS-855O), the commenter continued, the individual would only need to submit an updated CMS-855I application as part of the enrollment process.

Another commenter stated that the Privacy Act Statement for the CMS-855O includes various references to payments to providers and suppliers. Since the CMS-855O is designed for the sole purpose of ordering and certifying, the commenter requested that CMS explain its rationale for including such references in the CMS-855O Privacy Act Statement.

Response: As already indicated, comments regarding the use or content of the CMS-8550 are outside the scope of this rule. However, we note that section 6405 of the Affordable Care Act gave us the authority to require the Medicare enrollment of physicians and non-physician practitioners who order or certify certain items or services for Medicare beneficiaries. We implemented this statutory provision at § 424.507 via a May 5, 2010 interim final rule with comment period (75 FR 24437) and an April 27, 2012 final rule (77 FR 25284). These two rules, as well as the CMS-8550 itself, were subject to a notice-and-comment process. (We solicited public comments on the CMS-8550 in two **Federal Register** notices as mandated by the PRA.) Moreover, we disagree with the contention that the PRA process was used to prohibit physicians from obtaining Medicare billing privileges via the CMS-8550. The CMS-8550 was not designed as a prohibition of any kind but instead as means of permitting – consistent with section 6405 of the Affordable Care Act – certain physicians and non-physician practitioners to enroll in Medicare solely to order or certify Medicare items or services. We believe that completion of an abbreviated form such as the CMS-8550, rather than all or part of the CMS-855I, has eased the burden on the physician and non-physician practitioner communities.

Comment: A commenter questioned whether physicians who submit the CMS-8550 are required to revalidate their enrollment with the Medicare contractor every 5 years.

Response: We reserve the right to require individuals who are enrolled solely to order or certify items or services to revalidate their enrollment information every 5 years.

Comment: A commenter stated that since CMS did not discuss reassignment in

this proposed rule, it would seem that section 1871 of the Act would not preclude CMS from barring physicians and non-physician practitioners from enrolling in Medicare via the CMS-855O and reassigning their benefits to a medical group. The commenter sought clarification as to whether a physician can enroll using the CMS-855O and reassign payment/benefits to either an employer or an entity under contractual arrangement. Another commenter questioned whether a physician can simultaneously submit a CMS-855O and CMS-855R if he or she is billing for services through a group practice.

Response: The concept of reassignment (as that term is used in § 424.80) does not apply to CMS-855O situations because there is no right to payment associated with an enrollment via the CMS-855O. In other words, a physician or non-physician practitioner who enrolls via the CMS-855O does not have Medicare billing privileges, and therefore has no right to payment to reassign via the CMS-855R. If he or she wishes to enroll in Medicare, bill the program for services, and reassign his or her benefits to an eligible party, he or she must complete both the CMS-855I and CMS-855R forms. A CMS-855O form cannot be used as a means of obtaining Medicare billing privileges.

Comment: A commenter questioned whether a physician or non-physician practitioner can use the CMS-855O if he or she submits only very few claims to Medicare per year or whether he or she must use the CMS-855I.

Response: In the scenario the commenter poses, the physician or non-physician practitioner must use the CMS-855I because he or she will be billing for Medicare services. As discussed previously, the CMS-855O may only be used by physicians or other eligible practitioners who wish to enroll solely to order or certify items or services. It cannot be used to obtain Medicare billing privileges.

Comment: A commenter questioned whether a Medicare-enrolled physician or non-physician practitioner who also works part-time at (and only orders services from) a rural health clinic (RHC) must complete the CMS-8550 for his or her activities at the RHC.

Response: The individual need not complete a CMS-8550 in this scenario, for he or she is already enrolled in Medicare via the CMS-8551.

Comment: A commenter stated that if suppliers who enroll solely to order or certify Medicare items or services are not granted Medicare billing privileges, the regulatory provisions found in Part 424, subpart P do not apply and CMS does not have the authority to approve, deny, deactivate, or revoke individuals who have enrolled or seek to enroll in Medicare via the CMS-8550 solely to order and certify. The commenter recommended that CMS propose a new rule to allow CMS to approve, deny, revoke, or deactivate the enrollment of a physician or non-physician practitioner in such instances.

Response: The regulations in Part 424, subpart P apply to suppliers who are enrolled or enrolling in Medicare and are not limited to suppliers who have or seek Medicare billing privileges. In light of our changes to §§ 424.502, 424.505, and 424.510, the provisions of subpart P apply equally to suppliers who enroll in order to obtain Medicare billing privileges and those who enroll exclusively to order or certify Medicare items or services.

Comment: A commenter requested clarification as to whether a physician must have a valid enrollment record in PECOS to order infusion and nebulizer drugs or other Part B drugs.

Response: We believe this comment is outside the scope of this final rule.

Comment: Several commenters sought clarification from CMS concerning the difference between the use of the term "registration" on the CMS-855O and the proposed changes to §§ 424.502 and 424.505, which use the term "enrollment." One commenter questioned whether these two terms have the same meaning. Another commenter suggested that CMS establish a definition of "register."

Response: Our use of the term "registration" on the CMS-855O was designed to clarify the distinction between enrolling in Medicare to obtain billing privileges and enrolling in Medicare solely to order or certify items and services. In the latter situation, the process is the same irrespective of the precise term that is used to describe it. For this reason, and because the CMS-855O process will now be included within the scope of the enrollment provisions of §§ 424.502, 424.505, and 424.510, we do not believe a separate definition of "register" is warranted or needed.

Comment: Citing the current definition of "Enroll/Enrollment" in § 424.502, a commenter noted that the enrollment process includes identifying and confirming the provider's practice locations. The commenter contended that since the CMS-855O does not collect practice location information, referencing the CMS-855O in § 424.502 is inappropriate. The commenter suggested that CMS discontinue use of the CMS-855O until it proposes changes to the definition of "Enroll/Enrollment" that eliminate the reference to practice location data.

Response: As mentioned earlier, we may consider adding practice location information to the CMS-855O at a later date. Therefore, we do not believe that the definition of "Enroll/Enrollment" in § 424.502 should be revised to remove the reference

to practice locations. However, we will modify paragraph (2) of the definition of "Enroll/Enrollment" in § 424.502 to account for that paragraph's inapplicability to CMS-855O applications. The current version of paragraph (2) states that the enrollment process includes, "Validation of the provider's or supplier's eligibility to provide items or services to Medicare beneficiaries." Since suppliers who complete the CMS-855O are enrolling solely to order or certify Medicare items and services, we are modifying paragraph (2) to state: "Except for those suppliers who 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, validating the provider or supplier's eligibility to provide items or services to Medicare beneficiaries." We note that the new language in paragraph (2) is the same as that which is being added to paragraph (4).

Comment: Several commenters supported our proposed changes to §§ 424.502 and 424.505 to reflect that some physicians and non-physician practitioners may enroll solely to order or certify certain items or services for Medicare beneficiaries. However, one commenter suggested that the verbiage "or CMS-equivalent or successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services" is too wordy and confusing and should be stricken from both sections.

Response: While we appreciate the commenters' support, we do not believe the quoted language should be stricken from §§ 424.502 and 424.505. This language is necessary to account for the possibility that a different process for enabling individuals to enroll solely to order or certify Medicare items and services could be established in the

future.

Comment: A commenter believed that there remains confusion in the physician and non-physician practitioner communities regarding the difference between enrolling exclusively to order and certify Medicare services, and enrolling for the purpose of participating in and billing Medicare. The commenter urged CMS to make this distinction clear on the CMS-855O form itself and in all applicable CMS educational efforts.

Response: We have undertaken extensive educational efforts—including close collaboration with various professional associations—to clarify for the public and the provider community the distinction between the two processes. We will continue our outreach activities on this issue.

Comment: A commenter questioned whether CMS is changing its longstanding policy of requiring providers and suppliers to submit to CMS or its Medicare contractor the applicable provider enrollment application based on the type of provider or supplier enrolling. The commenter also requested that CMS propose and explain the differences between the Medicare enrollment process to convey Medicare billing privileges and this ostensibly new concept of enrolling solely to order and certify items and services in the Medicare program.

Response: All providers and suppliers, including those suppliers submitting the CMS-855O, will continue to submit enrollment applications based on the provider or supplier type involved. As for the second comment, we will continue our educational efforts to clarify the distinction between these two processes.

Comment: A commenter contended that §§ 424.507 and 424.510 must be revised

in order for CMS to establish a registration process for physicians and non-physician practitioners seeking only to order or certify items and services.

Response: Our use of the term "registration" on the CMS-855O was intended to articulate the distinction between enrolling in Medicare to obtain billing privileges and enrolling in Medicare strictly to order or certify items and services. In the latter situation, the process is the same regardless of the precise term that is used to describe it. The general procedures for completing the CMS-855O and the contractor's processing of the application are similar to those used for other CMS-855 forms. As such, we do not believe that §§ 424.507 and 424.510 need to be revised to establish a unique process for submitting and reviewing CMS-855O applications. Nevertheless, we have (as explained earlier) revised § 424.510 to clarify which paragraphs in that section do not apply to individuals who enroll solely to order or certify items or services.

Comment: A commenter questioned whether a physician who completes the CMS-855O can elect to be a participating physician even though he or she is ordering services in the Medicare program.

Response: A CMS-855O form cannot be used as a means of obtaining Medicare billing privileges. Medicare participation status does not apply in situations where the physician or non-physician practitioner enrolls solely for the purpose of ordering or certifying items or services. If the individual wishes to enroll in Medicare to furnish Medicare services, he or she must submit a CMS-855I application.

Comment: A commenter recommended that CMS identify whether any other federal or state health plan or any state Medicaid agency permits a physician or non-physician practitioner to obtain Medicare billing privileges for the sole purpose of

ordering or certifying services for their members. The commenter was unaware of any other health plan that permits this.

Response: One cannot obtain Medicare billing privileges through any state health plan, state Medicaid agency, or federal health plan other than Medicare.

Comment: A commenter stated that on May 20, 2011, September 30, 2011, and April 14, 2012, CMS published a summary of the information collection for the CMS-8550 in the **Federal Register**. The commenter noted that in each of these summaries, CMS stated that the CMS-8550 permits a physician to receive a Medicare identification number (without being approved for billing privileges) for the sole purpose of ordering and referring beneficiaries to approved Medicare providers and suppliers. The commenter indicated further that CMS states, in the proposed rule on which the commenter is commenting, that the CMS-8550 is exclusively designed to allow physicians and eligible professionals to enroll in Medicare solely to order or certify items or services. The commenter requested that CMS explain this apparent discrepancy. The commenter also requested CMS to outline how giving a physician or practitioner a Medicare billing number (which is already required to be the National Provider Identifier) is consistent with enrolling in the Medicare program. Another commenter questioned why the September 30, 2011 and April 14, 2012 notices refer to the registration of such individuals while our proposed rule refers to enrollment. This commenter also urged CMS to explain why it did not choose to solicit public comments on changes to regulatory provisions found in §§ 424.502 and 424.505 for almost 2 years after adopting and using the CMS-8550.

Response: If the commenter is referring to the use of the term "order or certify" in lieu of the term "order or refer," we replaced "refer" with "certify" because, as explained in the April 27, 2012 final rule: (1) a "certifying" provider generally means a person who orders/certifies home health services for a beneficiary, and (2) home health services fall within the purview of § 424.507.

The Medicare number referenced in the three notices is not a "billing number" and is not intended to grant billing privileges to the individual; it instead serves as an identifier of the physician or non-physician practitioner. Likewise, our revisions to §§ 424.502 and 424.505 do not furnish billing privileges to an individual who is enrolling solely to order or certify items or services.

As explained earlier, our use of the term "registration" was intended to clarify the difference between enrolling in Medicare to obtain billing privileges and enrolling in Medicare solely to order or certify items and services.

Comment: A commenter requested whether completion of another CMS-8550 is required if the applicable physician or non-physician practitioner moves and opens a new practice in another contractor jurisdiction.

Response: At this time, a separate CMS-8550 is required for each Medicare contractor jurisdiction in which the individual practices.

Comment: Section 1866(j) of the Act states that the Secretary shall establish by regulation a process for enrolling providers and suppliers; such process shall include, in part, a screening process. A commenter contended that CMS has violated section 1866(j) of the Act because our proposed rule does not establish a screening process for physicians and non-physician practitioners enrolling solely to order or certify items or services. The

commenter recommended that CMS propose a moderate level of risk for such physicians and non-physician practitioners because CMS cannot link an order from such individual to the billing by a DMEPOS supplier, imaging facility, or clinical laboratory.

Response: We disagree with the commenter. The screening process implemented pursuant to section 1866(j) of the Act applies to all CMS-855 applications, including the CMS-855O. Regardless of which CMS-855 enrollment application is used, physician and non-physician practitioners are designated to the limited screening level pursuant to § 424.518(a)(1)(i), unless an adjustment applies under § 424.518(c)(3).

Comment: A commenter recommended that CMS provide the number of individuals enrolled or registered in the Medicare program using the CMS-855O since July 2011.

Response: This comment is outside the scope of this rule.

Comment: A commenter stated that contrary to the information found in the CMS-855O Privacy Act Notice, CMS has not updated the PECOS System of Records document to include the CMS-855O. The commenter recommended that CMS update the System of Records document No 09-70-0532 to reflect the collection and dissemination of information from the CMS-855O.

Response: This comment is outside the scope of this rule.

Comment: A commenter stated that permitting physicians who do not bill Medicare to order services for Medicare beneficiaries will likely increase Medicare fraud and the number of improper Medicare payments. The commenter recommended that CMS: (1) explain how it will protect the Medicare Trust Funds from fraud when it cannot verify whether the physician actually conducted an exam or treated a Medicare

beneficiary; and (2) require prior authorization for any service ordered by a physician or practitioner who does not have an associated claim for medical services; using prior authorization, the commenter believed, is the only way that Medicare can verify that a physician is treating a patient and not merely signing an order for services.

Response: This comment is outside the scope of this rule.

Comment: A commenter recommended that in lieu of using the CMS-8550, CMS should exempt infrequent billers or physicians who see Medicare patients at a rural health clinic from deactivation for 3 or 5 years. This approach ensures that a physician can bill if he/she needs to, but reduces the amount of paperwork associated with an annual deactivation process. Another commenter offered several alternatives to the use of the CMS-8550: (1) a 1-year deactivation process for physicians who accept assignment and bill the Medicare program on a regular basis; (2) a 5-year deactivation process for physicians who bill Medicare as non-participating and only bill infrequently; and (3) an exception to the 1-year deactivation process for certain physicians – such as those listed on the CMS-8550 - who bill the Medicare program infrequently.

Response: These comments are outside the scope of this rule.

After consideration of the comments received, we are finalizing the three proposed changes to §§ 424.502 and 424.505. We are also further modifying the definition of "enroll/enrollment" in § 424.502 and modifying §424.510(a) as previously discussed.

2. Debts to Medicare

Under § 424.530(a)(6), an application can be denied if "[t]he current owner (as defined in § 424.502), physician or non-physician 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.

As we explained in II.B.2. of the proposed rule, such situations were discussed in a November 2008 Department of Health and Human Services Office of Inspector General (OIG) Early Alert Memorandum entitled, "Payments to Medicare Suppliers and Home Health Agencies Associated with 'Currently Not Collectible' Overpayments" (OEI-06-07-00080). The memorandum noted 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.¹ 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 2006.² 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 2007.³ The OIG also found that most of the reviewed DMEPOS suppliers were connected with their associated DMEPOS suppliers and HHAs through

¹ 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.

² Ibid. p.1.

³ Ibid. p.7.

shared owners or managers.⁴

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 our current authority to deny based on § 424.530(a)(6) enables us to stem this practice to a certain extent, it is limited to situations where an enrolling physician, non-physician 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 with which the enrolling provider, supplier, or owner was affiliated had incurred the debt. We believed that these latter situations were of particular concern to the OIG in the 2008 memorandum. Therefore, we proposed several changes to § 424.530(a)(6).

First, we proposed to incorporate the existing language of § 424.530(a)(6) into a new paragraph (a)(6)(i) that would apply to all enrolling providers, suppliers (including physicians and non-physician practitioners), and owners thereof. We stated that we did not believe (a)(6) should be limited to individual physicians and non-physician practitioners. All providers and suppliers, regardless of type, are responsible for reimbursing Medicare for any 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 Funds. If the provider or supplier cannot repay its existing Medicare debts, this raises questions about its ability to pay future debts

⁴ Ibid. p.2.

incurred as part of any additional enrollments.

We proposed that a denial of Medicare enrollment under paragraph (a)(6)(i) could be avoided if the enrolling provider, supplier, or owner thereof satisfied the criteria set forth in § 401.607 and agreed to an extended CMS-approved repayment schedule for the entire outstanding Medicare debt; agreement to such a schedule would indicate that the provider, supplier, or owner is not seeking to avoid its debts to Medicare. The provider, supplier, or owner thereof could also avoid denial by repaying the debt in full. We also solicited 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.

Second, we proposed to replace the term "overpayment," as it is currently used in § 424.530(a)(6), with "Medicare debt" in our regulatory text. We noted that "overpayment" more appropriately describes the types of debts that are subject to (a)(6). We also stated that our denial authority under proposed (a)(6) should include all forms of debt to Medicare, not just overpayments. We solicited comments on this proposed change as well as on the appropriate scope of the term "Medicare debt" for purposes of § 424.530(a)(6).

Third, we proposed to add a new paragraph (ii) to § 424.530(a)(6) permitting a denial of Medicare enrollment if the provider, supplier, or current owner (as defined in § 424.502) thereof was 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 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 proposed in § 424.530(a)(6)(iii) that the enrolling provider or supplier would be able to avoid a denial under § 424.530 (a)(6) if the enrolling provider, supplier, or owner thereof satisfies the criteria set forth in § 401.607 and agrees to an extended repayment schedule for the entire outstanding Medicare debt of the revoked provider or supplier. We noted our belief that this provision is warranted because agreement to a repayment plan evidences an intention to pay back the debt. We also proposed in § 424.530(a)(6)(iii) that no denial would occur under paragraph (a)(6)(ii) if the debt was repaid in full.

We explained that the difference between our proposed § 424.530(a)(6)(ii) and the existing language in § 424.530(a)(6) was that the latter involved situations in which the current owner, physician or non-physician practitioner had a Medicare debt. Section 424.530(a)(6)(ii), on the other hand, would focus 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. We offered 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 affiliated (Z) has the debt. However, under proposed § 424.530(a)(6)(ii), and assuming the other criteria are met, X's application could be denied because X's owner was an owner of a supplier (Z) that has a Medicare debt. We cited 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, as authority for proposed paragraph (ii).

We proposed the following as factors we would consider in determining whether an "undue risk" exists under paragraph (ii): (1) the amount of the Medicare debt; (2) the length and timeframe that the enrolling provider, supplier, or owner thereof was an owner of the prior entity; and (3) the percentage of the enrolling provider's, supplier's, or owner's ownership of the prior entity. We also noted that the scope and breadth of ownership interests would vary widely (for example, the amount of ownership; direct versus indirect ownership). For this reason, we believed it was important that CMS have the flexibility to make enrollment decisions under § 424.530(a)(6)(ii) on a case-by-case basis, using the factors previously outlined. However, we also solicited 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 proposed factors 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 solicited comments on whether paragraph (ii) should apply to the enrolling entity's managing employees (as that term is defined in § 424.502), corporate officers, corporate directors, and/or board members.

Many of the comments we received regarding our proposed changes to § 424.530(a)(6) were applicable to two or more of the proposals. Hence, we have summarized and collectively listed all of the comments we received on § 424.530(a)(6). Our responses to these comments are as follows:

Comment: Several commenters supported CMS's proposal to use the term "Medicare debt" instead of "overpayment" for the reasons specified in the proposed rule, with one commenter stating that the term "overpayment" has long seemed inaccurate and, at times, confusing to Medicare physicians. One commenter, encouraged CMS to more thoroughly define "Medicare debt." Another commenter recommended that the term "Medicare debt" be interpreted liberally.

Response: We appreciate the commenters' support for our proposed change. We did not propose a definition of "Medicare debt" and do not do so in this final rule; rather, we had sought comments on the appropriate scope of the term for purposes of applying § 424.530(a)(6).

With respect to § 424.530(a)(6)(i) and (ii), we agree that the term "Medicare debt" should be interpreted broadly. An existing Medicare liability, simply put, is an unpaid Medicare debt. As such, an existing debt to the Medicare program – regardless of its type, or how the debt was incurred or discovered – may result in the denial of Medicare

enrollment under § 424.530(a)(6). The only exceptions to this would be the situations described in proposed § 424.530(a)(6)(iii) regarding: (1) the satisfaction of the criteria set forth in § 401.607 and the agreement to an extended repayment schedule for the entire outstanding Medicare debt; or (2) the repayment of the debt in full. We are finalizing these two exceptions.

We do not believe that specific types of Medicare debt should be articulated in the text of § 424.530(a)(6). Since the particular facts of each case will differ, we must retain the flexibility to address a variety of situations. We also note that our denial authority under § 424.530(a)(6) is discretionary, and there may be instances when a denial under § 424.530(a)(6) might not be warranted. For instance, under § 424.530(a)(6)(ii), our determination as to whether the debt poses an undue risk to the Medicare program will include consideration of the three factors we proposed: (1) the amount of the Medicare debt; (2) the length and timeframe of the ownership interest; and (3) the percentage of ownership interest -- as well as two additional factors that we discuss in more detail later in this section-- specifically; (4) whether the Medicare debt is currently being appealed; and (5) whether the provider was an owner when the debt was incurred. (These factors will be added at § 424.530(a)(6)(ii)(C).) We will make all final determinations regarding § 424.530(a)(6)(i) and (ii), and may conclude after reviewing the relevant factors that a particular denial under § 424.530(a)(6)(i) is unwarranted.

Comment: A commenter suggested that CMS limit the term "Medicare debt" to those debts that have undergone and completed the CMS appeals process and final administrative adjudication; the commenter specifically requested that the phrase "after final administration adjudication" be inserted into a definition of "Medicare debt."

Otherwise, the commenter stated, honest and legitimate providers and suppliers could be prohibited from expanding or selling their practices based upon a single claim determination.

Response: We have added at § 424.530(a)(6)(ii)(C)(4) the appeal status of the debt as a factor in the determination of whether the debt poses an undue risk to Medicare. However, we are not wholly excluding debts that are being appealed from § 424.530(a)(6)'s application for two reasons. First, a provider or supplier with a Medicare debt (particularly a large debt) that poses an undue risk to the Medicare program should not be given an automatic opportunity to incur future debts with additional Medicare billing privileges simply because the debt is being appealed. Second, permitting providers and suppliers to obtain additional Medicare billing privileges if a Medicare debt is being appealed may encourage providers and suppliers to file meritless appeals simply to avoid and circumvent the application of § 424.530(a)(6)(ii).

Comment: A commenter expressed concern that an expansion of the word "overpayment" to the word "debt" could lead to inequitable results, such as denials due to debts stemming from-- (1) coordination of benefits issues with secondary payers; and (2) meaningful use audits. The commenter urged CMS to strictly narrow the scope of whatever term it finalizes to ensure that physicians do not unreasonably experience enrollment denials.

Response: As alluded to earlier, we believe that any type of Medicare debt – regardless of how it was incurred or discovered – is of concern to us. It is for this reason that we are not excluding particular types of debts (such as those to which the commenter

refers) from § 424.530(a)(6)'s scope. Nevertheless, we do not believe that our intended use of the term "Medicare debt" will lead to inequitable results, for we will only exercise our discretion under § 424.530(a)(6) in a careful and consistent manner.

Comment: Several commenters did not support expanding § 424.530(a)(6)'s purview to include the enrolling entity's current managing employees, corporate officers, directors, or board members. They contended that such an expansion would be excessively broad and unnecessarily complicated.

Response: We disagree that such an expansion would be overly broad and complex. To nonetheless ensure that we can focus on the implementation of our revisions to § 424.530(a)(6), we have decided not to include the enrolling entity's current managing employees, corporate officers, directors, or board members within the scope of § 424.530(a)(6) at this time, although we may consider doing so via future rulemaking.

Comment: A commenter expressed general support for our proposed § 424.530(a)(6)(ii) and stated that CMS identified the appropriate factors to consider in this respect. However, the commenter did: (1) suggest that CMS also adopt as a factor whether or not the person was an owner at the time the debt was incurred; and (2) urge CMS to exercise its discretion regarding § 424.530(a)(6)(ii) fairly and carefully; the commenter, citing an example, argued that a 5 percent owner for 6 months should not be penalized to the same extent as someone who has been a 50 percent owner for 5 years.

Response: We appreciate the commenter's support and, as stated, will apply § 424.530(a)(6)(ii) in a fair and careful manner. We also agree with the commenter's suggestion to include as a factor the party's ownership status at the time the debt was incurred. We have added this as a factor at § 424.530(a)(6)(C)(5), although a finding that

the party was not an owner when the debt was incurred will not in and of itself result in § 424.530(a)(6)(ii)'s non-application. All factors and particular circumstances will be considered before a denial under § 424.530(a)(6)(ii) is imposed.

Comment: A commenter expressed concern that a physician group may not be aware that an individual physician has unpaid Medicare debt related to previous affiliations. The commenter urged CMS to make such information available in an accessible database.

Response: While we understand the commenter's concern, it is ultimately the hiring provider or supplier's responsibility to perform a thorough review of the physician's background, including his or her prior affiliations. We do not believe that such a review should be dependent upon the creation of a publicly available database.

Comment: A commenter disagreed with our proposal to add § 424.530(a)(6)(ii), contending that CMS did not explain why it-- (1) needs this new authority; and (2) cannot collect a debt through the Federal Payment Levy Program. The commenter also requested CMS to explain why it did not propose revoking existing providers and suppliers that have Medicare overpayments.

Response: Our rationale for the proposed addition of § 424.530(a)(6)(ii) was contained in the preamble of the proposed rule and is restated earlier in this final rule. While we are aware of the authority furnished by the Federal Payment Levy Program, the issue is not merely the collection of existing Medicare debts; it is also the need to prevent the accumulation of additional Medicare debts. We believe that our denial authority under § 424.530(a)(6)(ii) will be an important step in this direction.

We did not propose to incorporate a new revocation reason regarding Medicare

debts that would apply to currently enrolled providers (for example, via revalidation), for this is a different situation than what is being described here. However, we may consider establishing such a revocation reason via future rulemaking.

Comment: A commenter supported the denial of enrollment of providers and suppliers that have existing Medicare debts that have not been fully repaid or if the provider or supplier is not current in its existing repayment schedule. Yet the commenter urged CMS to exclude from § 424.530(a)(6)'s purview debts that: (1) are currently within a CMS-approved appeals process; and (2) have not been forgiven by CMS due to financial considerations. Other commenters, too, suggested that debts that are currently being appealed or are part of an extended repayment plan should be exempt from § 424.530(a)(6)'s application. With respect to appeals, one commenter contended that the Congress' passage of section 935 of the Medicare Modernization Act (MMA) envisioned a congressional intent to permit physicians to delay repaying an overpayment pending the completion of the appeals process.

Response: As explained earlier, we will consider a debt's appeal status in our determination of whether the debt poses an undue risk to the Medicare program under § 424.530(a)(6)(ii). In addition, we will exclude from § 424.530(a)(6)(i) and (ii) those situations where the enrolling provider, supplier, or owner thereof meets the criteria of § 401.607 and agrees to an extended repayment schedule for the entire outstanding Medicare debt. While we are unclear as to the commenter's suggestion that debts that CMS has not forgiven due to financial considerations be excluded from our § 424.530(a)(6) determinations, we can assure the commenter that we will apply § 424.530(a)(6)(i) and (ii) in a careful and judicious manner.

We do not believe that our revisions to § 424.530(a)(6) are inconsistent with section 935 of the MMA. Our provisions address enrollment denials, not recoupment. Nothing in § 424.530(a)(6) requires a provider to repay an overpayment prior to the completion of the appeals process.

Comment: Several commenters opposed our proposed § 424.530(a)(6)(ii), contending that the provision would potentially punish persons and entities who: (1) were not responsible for the debt; or (2) had only a very limited association with the party that was responsible for the debt. One commenter noted that our proposed criteria for denying enrollment under § 424.530(a)(6)(ii) did not take into account whether the enrolling provider or supplier is actually responsible for the debt. Another commenter contended that our proposal is overreaching and exhibits a lack of understanding of the complexities of the new coordinated care models that are evolving pursuant to payment and delivery reform advanced by the Affordable Care Act. The commenter stated that denials under our proposed provision could be frequent because many of today's systems of health care are diverse, geographically large, and encompass numerous entities and groups.

Response: We are adopting as a factor in our § 424.530(a)(6)(ii) determinations whether or not the person was an owner at the time the debt was incurred. In addition, we will only deny a Medicare application under § 424.530(a)(6)(ii) after careful review of all the factors associated with a particular situation. We believe these actions may alleviate to some extent the commenters' concerns about § 424.530(a)(6)(ii)'s application.

Comment: A commenter requested that CMS furnish evidence that the problem of suppliers departing Medicare with large, unpaid overpayments and then re-enrolling in

Medicare exists with respect to physicians and group practices.

Response: As explained in the proposed rule and earlier in this final rule, the OIG's November 2008 Early Alert Memorandum titled "Payments to Medicare Suppliers and Home Health Agencies Associated with 'Currently Not Collectible' Overpayments" (OEI-06-07-00080) cautioned 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. We also noted our receipt of reports of providers, suppliers, and owners thereof accumulating large Medicare debts, departing Medicare, and then attempting to reenter the program through other channels.

Comment: A commenter expressed concern with CMS's publication of Transmittal 469, which operationalizes the current version of § 424.530(a)(6). The commenter contended that CMS did not abide by the Administrative Procedure Act (APA) in issuing Transmittal 469 because it did not use the prescribed notice and public comment process. Another commenter urged CMS to retract Transmittal 469, contending that certain policies in the transmittal conflict with the contents of our proposed rule, thereby causing confusion in the provider community. Another commenter sought clarification as to how Transmittal 469 would interact with our proposed revisions to § 424.530(a)(6). As an example, the commenter stated that Transmittal 469 contained a \$1,500 threshold – which the commenter believed was too low – yet the proposed rule contained no such threshold and does not define the scope of the overpayments that would be subject to our proposed provisions.

Response: The publication of Transmittal 469 – which has since been rescinded

and replaced by Transmittal 479 - did not violate the APA. The current version of § 424.530(a)(6) was subject to public notice and comment prior to its enactment.

Transmittal 479 adds guidance regarding existing § 424.530(a)(6) to chapter 15 of our Program Integrity Manual (CMS Pub. 100-08).

Upon publication of this final rule, we will revise CMS Publication 100-08, chapter 15, to ensure that the guidance to our contractors and the public is consistent with our changes to § 424.530(a)(6).

Comment: A commenter offered several suggestions regarding our proposed changes to § 424.530(a)(6). First, the commenter recommended that CMS exclude from § 424.530(a)(6)'s scope those debts resulting from contractor error or from retroactive changes made by CMS or the Congress. Second, the commenter suggested that CMS establish a debt monetary threshold below which § 424.530(a)(6) would not apply; the commenter cited the \$1,500 threshold set forth in the aforementioned Transmittal 469 as an example. Third, the commenter suggested that CMS establish an ownership percentage threshold below which § 424.530(a)(6) would not apply; the commenter recommended 20 percent. The commenter stated that such thresholds would foster consistency and assist CMS's efforts to curb fraud and abuse without unnecessarily burdening providers and suppliers that have small debts.

Response: We mentioned earlier that the amount of the debt and the percentage of ownership will be factors in our § 424.530(a)(6)(ii) determinations, although specific thresholds will not be established due to the need to maintain flexibility to address various situations. In terms of contractor errors, we will be including the debt's appeal status as another factor.

We are not adding retroactive changes as a factor because we are unclear as to the types of situations to which the commenter is referring.

Comment: A commenter requested that CMS identify the enrollment applications and types of enrollment changes that would be impacted by our proposed revisions to § 424.530(a)(6).

Response: Initial CMS-855 applications are the only applications subject to § 424.530(a)(6).

Comment: A commenter expressed support for our proposed revisions to § 424.530(a)(6), stating that this will lead to increased scrutiny of the ownership and leadership of provider and supplier organizations.

Response: We appreciate the commenter's support.

Comment: A commenter contended that our proposed § 424.530(a)(6) exceeds the statutory authority granted to the Secretary in 42 U.S.C. 1395cc(j)(5), which provides that the Secretary may deny an application based on a disclosure of a current or previous affiliation, subject to a finding of "undue risk." At a minimum, the commenter recommended, CMS should revise the proposed regulatory text to: (1) include the criteria for a finding of undue risk as described in the proposed rule's preamble; and (2) state that a denial of enrollment "may be warranted," rather than "is warranted"..

Response: We agree with the commenter's first recommendation and will revise the regulatory text accordingly. We note that the second recommendation is moot because the regulatory text does not contain the phrase "is warranted."

We disagree with the assertion that our changes to § 424.530(a)(6) exceed our statutory authority. Our expansion of § 424.530(a)(6)(i) – the existing version of which

has been in effect since 2009 – and our addition of § 424.530(a)(6)(ii) are consistent with the authority in section 1866(j)(1) and (5) of the Act (42 U.S.C. 1395cc(j)(1) and (5)). It is also consistent with our general rulemaking authority in sections 1102 and 1871 of the Act.

Comment: A commenter supported CMS's proposal to extend § 424.530(a)(6)(i) to other provider and supplier entities. The commenter stated that since physicians are in the "limited" screening level in § 424.518(a), it is sensible to include higher risk providers and suppliers in that category as well.

Response: We appreciate the commenter's support.

Comment: A commenter stated that CMS proposed § 424.530(a)(6)(ii) is based on a false premise that any uncollected debt poses an undue risk of fraud, waste or abuse and does not take into consideration the due process rights that should be afforded to providers through the appeals process.

Response: We do not believe that every uncollected debt poses an undue risk of fraud, waste or abuse. As we stated in the proposed rule, we will make an individual determination – based on the factors set forth at § 424.530(a)(6)(ii)(C) – as to whether the debt in question poses an undue risk. If the debt, after our analysis, does not present such a risk, we will not deny the enrollment application under § 424.530(a)(6)(ii).

Comment: A commenter noted that certain DMEPOS suppliers are subject to a \$50,000 bond requirement. As such, there is an existing avenue - outside of denying enrollment - to address CMS's concerns regarding uncollected debts.

Response: Though it is true that certain DMEPOS suppliers must obtain a surety bond in order to enroll in Medicare, there are at least 1.4 million other Medicare

providers and suppliers that do not. Moreover, the presence of a surety bond does not in itself guarantee that the full amount of a Medicare debt will be recovered via the bond.

Therefore, we need additional mechanisms – such as those we are finalizing with respect to § 424.530(a)(6) – to help ensure that Medicare debts are repaid and that providers and suppliers with unpaid debts do not incur additional Medicare debts through the establishment of additional enrollments.

Given the comments received and the preceding discussion, we are finalizing our proposed revisions to § 424.530(a)(6), albeit with three revisions to § 424.530(a)(6)(ii)(C) and one change to § 424.530(a)(6)(iii):

- We are revising § 424.530(a)(6)(ii)(A) to state: "The owner left the provider or supplier with the Medicare debt within 1 year before or after that provider or supplier's voluntary termination, involuntary termination or revocation." The insertion of "with" in lieu of "that had" and the insertion of "before or after" are merely intended to clarify our original intention that the 1-year period applies to separations occurring prior to or after the provider or supplier's termination or revocation.

- To § 424.530(a)(6)(ii)(C) will be added a second sentence that reads: "In making this determination, we consider the following factors:"

- New paragraphs (1) through (5) will be added to § 424.530(a)(6)(ii)(C) identifying these factors. The paragraphs state 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.

++ Whether the Medicare debt is currently being appealed.

++ Whether the enrolling provider, supplier, or owner thereof was an owner of the prior entity at the time the Medicare debt was incurred.

- To ensure consistency in application, in § 424.530(a)(6)(iii) we are combining proposed paragraphs (A) and (B)(1) into a revised paragraph (A) that will read as follows: "(1) Satisfies the criteria set forth in § 401.607; and (2) agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt." Proposed paragraph (B)(2) will be redesignated as new paragraph (B) and will read as follows: "Repays the debt in full."

3. Felony Convictions

Under § 424.530(a)(3) and § 424.535(a)(3), respectively, a provider or supplier's Medicare enrollment may be denied or revoked 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 proposed several changes to §§ 424.530(a)(3) and 424.535(a)(3).

First, we proposed to modify the list of felonies in each section such that any felony conviction that we determine to be detrimental to the best interests of the Medicare program and its beneficiaries would constitute a basis for denial or revocation. We stated that considering the very serious nature of any felony conviction, our authority in §§ 424.530(a)(3)(i) and 424.535(a)(3)(i) should not be restricted to the categories of felonies identified in (a)(3)(i); this was especially true considering that the types of felony offenses often vary from state to state.

Second, we proposed 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. Since certain managing employees of a provider or supplier may have as much (if not more) day-to-day control as an owner, we explained that managing employees should be held to the same standard as owners.

Third, we proposed to revise the language "within the 10 years preceding enrollment or revalidation of enrollment" in § 424.530(a)(3) and § 424.535(a)(3) to "within the preceding 10 years." The existing language has caused confusion as to how the 10-year period is calculated. We believe that our revised wording clarifies this timeframe.

Fourth, we proposed to clarify in §§ 424.530(a)(3) and 424.535(a)(3) that the term "convicted" – as used in these two sections – has the same definition as the one set forth in 42 CFR 1001.2. This was intended to address the numerous inquiries we have received regarding the proper interpretation of the term "convicted" as it relates to §§ 424.530(a)(3) and 424.535(a)(3).

The following is a summary of the comments received regarding these four proposed changes and our responses thereto.

Comment: A commenter urged CMS to retain the current language in §§ 424.530(a)(3) and 424.535(a)(3) that states that CMS will consider the severity of the underlying offense before denying or revoking enrollment. The commenter contended that while some felony convictions may bear directly on a provider's ability to care for patients, other convictions may be irrelevant to patient care - especially those that may be as many as 10 years old. In all instances, the commenter added, CMS should employ its denial and revocation authority under §§ 424.530(a)(3) and 424.535(a)(3) judiciously and should use a reasonableness standard in making such determinations.

Response: Regardless of whether the "severity of the underlying offense" language is present in §§ 424.530(a)(3) and 424.535(a)(3), we have always considered – and will continue to do so - the seriousness of the offense in determining whether a denial

or revocation is warranted under §§ 424.530(a)(3) and 424.535(a)(3). Therefore, we do not believe that including the "severity" verbiage in §§ 424.530(a)(3) and 424.535(a)(3) is necessary, for CMS already takes this factor into account in such determinations.

Although we did propose to expand the categories of felonies that can serve as the basis of a denial or revocation, we are not suggesting that every felony conviction will automatically result in such an action. Each case will be carefully reviewed on its own merits and, as the commenter recommends, we will act judiciously and with reasonableness in our determinations.

Comment: Several commenters disagreed with CMS's proposed expansion of §§ 424.530(a)(3) and 424.535(a)(3) to include all felonies. They contended that (1) our proposal is arbitrary and an abuse of discretion; and (2) CMS offered no facts to support its proposal. One commenter stated that some felonies – such as those related to drugs, alcohol, or traffic violations - could not reasonably be considered as detrimental to the Medicare program, yet CMS would have the discretion to deny or revoke a provider for such a felony. This could lead to unfair results, particularly if a sentence of less than 3 years (which is the maximum re-enrollment bar period) is imposed. The commenter – as well as several other commenters - requested that CMS reconsider its proposal and: (1) furnish a definition of "detrimental to the Medicare program or its beneficiaries;" and (2) exclude felonies related to drugs, alcohol, or traffic violations from the scope of §§ 424.530(a)(3) and 424.535(a)(3).

Response: We disagree that our proposal was arbitrary or an abuse of discretion. Section 4302 of the Balanced Budget Act (BBA) amended section 1866 of the Act to furnish CMS with broad authority to refuse to enter into Medicare agreements with

individuals or entities convicted of felonies that the Secretary determines to be detrimental to the best interests of the program or program beneficiaries. We identified in the proposed rule the legal grounds for all of our proposed enrollment provisions and explained the policy rationale for each of them. For instance, we indicated the need for flexibility with respect to the application of §§ 424.530(a)(3)(i) and 424.535(a)(3)(i) when considering that categories of felony offenses often vary from state to state. We do not believe that felonies relating to drugs, alcohol, or traffic violations cannot be detrimental to the best interests of Medicare beneficiaries, and thus should be automatically excluded from the purview of §§ 424.530(a)(3) and 424.535(a)(3). While certain felonies carry different, potentially more severe penalties than others, each case is distinct and state law classifications of certain criminal actions can vary widely. Therefore, we must maintain the flexibility to address all potential situations.

Comment: A commenter supported our proposed expansion of §§ 424.530(a)(3) and 424.535(a)(3), believing it was a step forward in CMS's attempts to prevent Medicare fraud on the front end.

Response: We appreciate the commenter's support.

Comment: A commenter questioned whether CMS will revoke the Medicare billing privileges of a physician who is convicted of a non-violent firearm felony.

Response: The determination of whether a particular conviction will or will not result in the revocation or denial of Medicare enrollment will depend upon the specific facts of each individual situation.

Comment: A commenter expressed concern that CMS will deny or revoke billing privileges under § 424.530(a)(3) or § 424.535(a)(3), respectively, such that a physician's

right to participate in the Medicaid program will be affected.

Response: The commenter correctly notes that under § 455.416(c), a State Medicaid agency must deny enrollment or terminate the enrollment of any provider whose Medicare enrollment is revoked for cause, although there is no corresponding requirement in cases where a provider is denied enrollment in the Medicare program. As noted previously, we will only exercise our authority under § 424.530(a)(3) or § 424.535(a)(3) after consideration of the relative seriousness of the underlying offense and all of the circumstances surrounding the conviction.

Comment: A commenter contended that our proposed expansions of §§ 424.530(a)(3) and 424.535(a)(3) violate the principles of federalism established in Executive Order 13132 3(b), 3(c) and 3(d) and diminishes the role of state licensing boards across the country. The commenter requested that CMS furnish justification for expanding the role of the federal government into matters best resolved by state licensing boards.

Response: We disagree with the commenter. As mentioned earlier, section 4302 of the BBA (which amended section 1866 of the Act) gave CMS broad authority to refuse to enter into Medicare agreements with individuals or entities convicted of felonies that the Secretary determines to be detrimental to the best interests of the program or program beneficiaries. Additionally, our changes to §§ 424.530(a)(3) and 424.535(a)(3) in no way impair or infringe upon a state licensing agency's ability to take or not take action on a provider's licensure status in the event of a criminal conviction. Such a decision will – as it should – remain within the purview of the state.

Comment: A commenter stated that CMS should not deny or revoke a supplier's

enrollment based on § 424.530(a)(3) or § 424.535(a)(3) if the supplier made a good-faith effort – using generally accepted employee screening and hiring practices – to ensure that an employee did not have a felony conviction. The commenter added, if CMS desires comprehensive screening for felony convictions, it should work with other government agencies to develop a nationwide database so that employers have one reliable source from which to screen their employees for felony convictions. The commenter further stated that recent enforcement actions by the United States Equal Employment Opportunity Commission (EEOC) have targeted companies for alleged discrimination against minority applicants based on policies to exclude people from employment based on a criminal record. CMS's revisions to §§ 424.530(a)(3) and 424.535(a)(3) should be reconciled with the EEOC's current enforcement position.

Response: We disagree with the commenter. The core issue is not whether the organization made a good-faith effort to determine whether a current or prospective owner or managing employee has a felony conviction. Rather, it is whether the owner or managing employee has such a conviction and whether the conviction poses a risk to the Medicare program or its beneficiaries. In other words, it is the felony conviction itself - not whether the organization screened for such convictions - that is the relevant matter. We note that there are many resources available to help organizations ascertain one's criminal background history; a CMS-initiated project to establish a single, all-encompassing felony database for the use of employers is not necessary. We further add that CMS is not requiring, through its expansion of § 424.530(a)(3) and § 424.535(a)(3), that providers and suppliers perform criminal background checks of their current or prospective owners or managing employees as part of the enrollment

process.

We do not believe that the EEOC's recent enforcement actions mandate that prospective employers discourage taking into account a prospective employee's criminal background history. Our principal focus in this rule is to protect the Medicare program from individuals and entities that could threaten its integrity, and we believe our expansion of §§ 424.530(a)(3) and 424.535(a)(3) is an important step towards this end.

Comment: A commenter stated that providers seeking to hire physicians or managing employees must have clear rules as to the types of felonies that CMS would consider detrimental to the Medicare program. The commenter favored retaining the current versions of §§ 424.530(a)(3) and 424.535(a)(3) because CMS identifies specific felonies that fall within the scope of these two provisions. If, the commenter added, CMS seeks to include additional categories of felonies, it should use the formal rulemaking process to propose these new categories and allow the public to comment. Another commenter stated that our proposed revisions to §§ 424.530(a)(3) and 424.535(a)(3) fail to provide adequate notice of the types of felony convictions that may lead to a denial or revocation of Medicare enrollment.

Response: In light of the differences in state laws, it would be impossible to identify in our revised §§ 424.530(a)(3) and 424.535(a)(3) every felony offense that could result in a denial or revocation; indeed, if we accepted the commenter's suggestion, hundreds of crimes – perhaps even identified on a state-by-state basis – might have to be listed. Nevertheless, we agree that retaining the lists of felonies in the current versions of §§ 424.530(a)(3) and 424.535(a)(3) could prove helpful in identifying for the public some of the felonies that may serve as a basis for denial or revocation, respectively. Therefore,

we are combining our proposed revisions to §§ 424.530(a)(3) and 424.535(a)(3) with the existing language in both provisions.

Section 424.530(a)(3) will state that 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 determines is detrimental to the best interests of the Medicare program and its beneficiaries. Offenses include, but are not limited in scope or severity to –

++ 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 424.535(a)(3) will state that 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 determines is detrimental to the best interests of the Medicare program and its beneficiaries. Offenses include, but are not limited in scope or severity to –

++ 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.

(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.)

Note that the previous revisions contain two important changes. First, the current language in §§ 424.530(a)(3) and 424.535(a)(3) refers to a felony offense that CMS "*has determined*" to be detrimental to the best interests of the program and its beneficiaries."

(Emphasis added.) Consistent with our proposed revisions to §§ 424.530(a)(3) and 424.535(a)(3), we are revising this language to include any felony offense that CMS "*determines*" is detrimental to the best interests of the Medicare program and its beneficiaries." (Emphasis added.) This distinction is important. The phrase "has determined" incorrectly implies that the only felonies that may serve as a basis for denial or revocation are those specifically listed in §§ 424.530(a)(3) and 424.535(a)(3). We

believe that the term "determines" makes clearer that the lists of felonies in these two provisions are not exhaustive and include other felonies that CMS may deem as meeting the "detrimental" standard based on the particular facts of the case. Second, and to further emphasize CMS' discretion to use felonies other than those specified in §§ 424.530(a)(3) and 424.535(a)(3) as grounds for denial or revocation, we have included the phrase "but are not limited in scope or severity" within both provisions.

However, notwithstanding these changes, we again stress that we will only exercise our authority under §§ 424.530(a)(3) and 424.535(a)(3) after very careful consideration of the relative seriousness of the underlying offense and all of the circumstances surrounding the conviction. It should in no way be assumed that every felony conviction will automatically result in a denial or revocation.

Comment: A commenter stated that in proposing its expansion of §§ 424.530(a)(3) and 424.535(a)(3) to include all felonies, CMS did not comply with section 1(b)(7) of Executive Order 12866 and base its proposal on reasonably obtainable scientific, technical and other information. The commenter recommended that CMS identify the specific felony reasons in a new proposed rule.

Response: We do not agree that our proposed changes to §§ 424.530(a)(3) and 424.535(a)(3) violated section 1(b)(7) of Executive Order 12866. To the contrary, the changes were based on a careful consideration of the need to ensure that individuals and entities convicted of a felony offense that is detrimental to the best interests of the Medicare program and its beneficiaries are kept out of the Medicare program. For the reasons previously stated, we believe it is neither feasible nor practical to identify every conceivable felony offense that could result in the application of §§ 424.530(a)(3) or

424.535(a)(3).

Comment: A commenter recommended that CMS establish protections, such as a knowledge threshold, for suppliers that perform reasonable due diligence to determine if a potential employee has a felony record. The commenter stated that CMS should work with suppliers that act in good-faith to determine if a prospective employee has a felony record rather than automatically excluding a supplier. The commenter specifically suggested adding language to §§ 424.530(a)(3) and 424.535(a)(3) that, in effect, would permit a denial or revocation only if: (1) the provider or supplier knew or should have known about the conviction; (2) the provider or supplier did not have industry standard hiring practices in place; (3) the provider or supplier has not submitted a corrective action plan; (4) the disruption to beneficiaries does not outweigh the provider or supplier's termination due to one individual; and (5) CMS has already established and implemented a comprehensive state and federal database that is available to providers and suppliers.

Response: We disagree with the commenter's suggestion. As stated earlier, it is the felony conviction itself and not the extent of the organization's efforts in performing a criminal background check that is the crucial consideration.

Comment: To improve transparency – and since the OIG publicly posts information about individuals and entities excluded from federal health care programs – a commenter suggested that CMS post on its provider enrollment web page the name and NPI (if applicable) of any person who has had his or her Medicare billing privileges denied or revoked based upon a felony conviction; the date of the denial or revocation and, if applicable, the length of the re-enrollment bar should be listed as well.

Response: We appreciate this suggestion and may consider it in a future initiative

to the extent it is consistent with the Privacy Act.

Comment: A commenter was concerned that the expansion of the felonies encompassed by § 424.535(a)(3) would be applied to providers and suppliers whose recently submitted revalidation applications were approved. The commenter, in other words, opposed the retroactive application of our proposed § 424.535(a)(3).

Response: Our changes to § 424.535(a)(3) do not preclude CMS from reviewing the enrollment records of currently enrolled providers and suppliers to determine if the provider, supplier, or an owner or managing employee thereof has a felony conviction that CMS deems detrimental to the best interests of the Medicare program or its beneficiaries. However, we again stress that not every felony conviction will necessarily result in a denial or revocation.

Comment: A commenter expressed support for our proposed revisions to §§ 424.530(a)(3) and 424.535(a)(3).

Response: We appreciate the commenter's support.

Comment: A commenter agreed with CMS's proposal to clarify that the enrollment bar is for felony convictions "within the preceding 10 years" but suggested that the date be further clarified as "within the 10 years preceding the effective date of the enrollment application."

Response: While we appreciate the commenter's support, we disagree with the commenter's suggestion because it would be difficult to use a future date – that is, a date that could be well after the date the application was submitted - as the 10-year cut-off point.

After a careful consideration of the comments and in light of the previous

discussion, we are revising §§ 424.530(a)(3) and 424.535(a)(3) as follows:

Section § 424.530(a)(3) will state that 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 determines is detrimental to the best interests of the Medicare program and its beneficiaries. Offenses include, but are not limited in scope or severity to--

++ 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 424.535(a)(3) will state that 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 determines is detrimental to the best interests of the Medicare program and its beneficiaries.

Offenses include, but are not limited in scope or severity to –

++ 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.

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.

4. Abuse of Billing Privileges

Section 424.535(a)(8) currently 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 the service was provided, or when the equipment necessary for testing was not present where the testing is said to have occurred.

We proposed to expand this revocation reason by adding a new paragraph (a)(8)(ii) to § 424.535. The existing revocation reason would be incorporated into a new paragraph (a)(8)(i). 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. We explained 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 Funds. We note that the responsibility for submitting valid claims exists irrespective of whether the provider or supplier itself submits the claims or hires a billing agency to perform this function; in either case, the claims are submitted on behalf of the provider or supplier.

We solicited comment on what should qualify as a "pattern or practice" under our proposed change. We also proposed several factors we would take into account when determining whether a revocation under § 424.535(a)(8)(ii) is warranted 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 in § 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 solicited 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 further solicited comment on whether there should be a set knowledge standard associated with our proposed provision – for example, 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.

The following is summary of the comments received regarding § 424.535(a)(8)(ii) and our responses thereto:

Comment: A commenter stated that it did not dispute CMS's right to revoke billing privileges if a Medicare provider has a pattern of billing for services that do not meet Medicare requirements. However, the commenter recommended that in applying any criteria regarding the number of claim denials, CMS should take into account the number of denials that were overturned on appeal. Several other commenters also stated that they did not object to CMS's proposal, but urged that results of the administrative appeals process be considered as a significant factor before CMS concludes that a provider has engaged in a "pattern or practice" of submitting improper claims. Other

commenters stated that due process mandates that claim denials under appeal be excluded from any measurement that takes into account the number or percentage of denied claims. Another commenter questioned whether an appeal is considered to be successful when it is pursued up to and including the Administrative Law Judge (ALJ) level.

Response: A provider or supplier's claim denial that has been both-- (1) fully (rather than partially) overturned on appeal; and (2) finally and fully adjudicated will be excluded from our consideration in determining whether the provider or supplier's Medicare billing privileges should be revoked under § 424.535(a)(8)(ii). This is because, for purposes of § 424.535(a)(8)(ii), the claim denial has been effectively negated. Yet we do not believe a claim denial that fails to meet both of these requirements should be excluded from our review for two reasons. First, excluding claims that are currently being appealed could encourage providers and suppliers to file meritless appeals simply to circumvent the application of § 424.535(a)(8)(ii). Second, merely because a claim is under appeal does not necessarily mean it will be overturned.

For purposes of this claim denial exclusion, the term "finally and fully adjudicated" means that-- (1) the appeals process has been exhausted; or (2) the deadline for filing an appeal has passed.

Comment: A number of commenters opposed CMS's proposed § 424.535(a)(8)(ii). They stated that: (1) the proposal is arbitrary and subjective and grants too much discretion to CMS and its contractors; (2) CMS failed to include in its proposed rule a thorough discussion of the factors that would be used in making determinations related to § 424.535(a)(8)(ii); (3) did not define "pattern or practice"; and (4) there is nothing in the proposed rule that limits CMS's authority under

§ 424.535(a)(8)(ii). They added that despite CMS's statement in the proposed rule's preamble that it would not use this provision to revoke providers for isolated and sporadic claim denials or innocent billing errors, there are no safeguards to prohibit CMS or its multiple contractors from doing so. The commenters stated that given the complexity of Medicare's billing and coding rules and the frequency with which they change, Medicare providers would inevitably submit claims that fail to meet Medicare requirements though without any nefarious intent. They urged CMS to furnish appropriate, consistent, and clear guidelines regarding billing, coding, and payment policies before implementing § 424.535(a)(8)(ii). Other commenters stated that contractor errors, which can include a contractor's misinterpretation or misunderstanding of CMS requirements, sometimes result in claim denials.

Response: We do not believe that our proposal is arbitrary or grants CMS unlimited discretion. To the contrary, and as the commenters noted, we were very clear in the preamble of the proposed rule that sporadic billing errors would not result in revocation under § 424.535(a)(8)(ii). Although we did not define "pattern or practice" to maintain flexibility to address a variety of factual scenarios, we listed several factors that would be considered in our § 424.535(a)(8)(ii) determinations and requested feedback regarding other potential factors. Additionally, not only will CMS (rather than its contractors) make all such determinations, but also § 424.535(a)(8)(ii) will be applied only: (1) in situations where the behavior could not be considered sporadic; and (2) after the most careful and thorough consideration of the relevant factors. These points cannot be stressed enough.

We recognize that Medicare has many rules and requirements regarding billing

and coding, and that claims are occasionally submitted in error due to a provider's misunderstanding of these policies or denied incorrectly by the contractor. It is not CMS's intention to revoke billing privileges under § 424.535(a)(8)(ii) in such instances. However, Medicare billing privileges come with a responsibility for the provider to diligently seek and obtain clarification of Medicare policies should there be a misunderstanding or confusion. Constant, repeated, and systemic claim denials (as opposed to sporadic or occasional claim denials) can be indicative of the provider's failure to do so. To address such situations, we believe that the implementation of § 424.535(a)(8)(ii) should not be delayed, as some of the commenters appeared to suggest we do.

Comment: Several commenters believed that any appeals stemming from revocations initiated under § 424.535(a)(8)(ii) should be subject to an expedited appeals process.

Response: Since the impact of a revocation is the same regardless of the reason involved, we do not believe that revocations based on certain reasons should be subject to a faster appeals process than those predicated on other reasons.

Comment: A commenter contended that CMS's proposed § 424.535(a)(8)(ii) will have a chilling effect on the practice of medicine because it gives the federal government significant authority to target honest physicians. The commenter requested that CMS remove this proposed provision from the final rule or at least develop and solicit comments on a process for notifying providers of their billing issues and giving them an opportunity to correct the problem prior to revoking billing privileges.

Response: We disagree that our proposal will have a chilling effect on health

care. This rule will not affect providers that take seriously their responsibilities to submit valid claims and to seek clarification when there is confusion or disagreement involving applicable policies. No payer, public or private, should be required to continue doing business with a provider or supplier that demonstrates the type of clear pattern or practice of billing abuse that this rule addresses. Moreover, we do not believe that any additional formal notification to the provider of its billing deficiencies prior to the potential application of § 424.535(a)(8)(ii) is required. Under our current rules and practices, by the time CMS would revoke a provider or supplier under § 424.535(a)(8)(ii), the provider would have received information and education about the reasons for the claim denials on multiple occasions. From the first claim denial, when a provider or supplier is notified of the reason for the denial, providers receive information indicating compliance or non-compliance with Medicare rules and requirements. It is ultimately the provider's responsibility to review its denied claims and to take whatever remedial action is necessary.

Comment: A commenter contended that proposed § 424.535(a)(8)(ii) should have certain objective measures and standards – such as a 50 percent benchmark - to ensure that it is not applied in an arbitrary manner.

Response: We solicited and received several comments regarding whether certain numerical thresholds should be established in § 424.535(a)(8)(ii). After considering these comments, we have concluded that numerical thresholds should not be established because we need the flexibility to address a myriad of scenarios. For example, merely because a provider had over 30 percent of its claims denied does not automatically mean that a § 424.535(a)(8)(ii) revocation should be imposed; likewise, an under-30 percent

denial rate does not mean that a § 424.535(a)(8)(ii) revocation is never warranted. Each case must be judged on its own specific facts, and establishing numerical thresholds would, we believe, hinder our ability to do so.

Comment: A few commenters recommended that CMS exclude providers from the application of § 424.535(a)(8)(ii) for a period of 1 year when Medicare changes the Medicare Administrative Contractor for the provider's state, as providers in such instances must learn new local coverage determination (LCD) policies.

Response: We disagree with this recommendation. While we concede that providers in these circumstances often need to learn new LCD policies, claims can be denied for many reasons unrelated to LCDs. We thus believe it would be inappropriate to institute a blanket 1-year exemption in such cases, for we would lose the ability during that time to take action to address repeated claim denials over a period of time. Again, though, and as we have stated elsewhere in this preamble, we recognize that Medicare has many rules and requirements regarding billing and coding, and that claims are sometimes submitted in error due to a provider's honest misunderstanding of these policies. It is not our intention to revoke billing privileges under § 424.535(a)(8)(ii) for such occasional misinterpretations.

Comment: A commenter recommended that CMS delay implementation of § 424.535(a)(8)(ii) for 2 years after the implementation of the ICD-10 standard. The commenter believed that ICD-10's implementation will likely lead to the submission of incorrect claims for a period of time.

Response: We do not believe that a delay in the implementation of § 424.535(a)(8)(ii) is necessary. Again, any delay of the applicability of

§ 424.535(a)(8)(ii) would deny us the ability to address situations (unrelated to the ICD-10 implementation) involving repeated claim denials. Furthermore, as we have already noted, we recognize that Medicare has many requirements and that in isolated instances claims are submitted erroneously due to a provider's misinterpretation of these policies. Such occasional misunderstandings will generally not rise to the level of a "pattern or practice" of improper billing, and thus will not warrant revocation under § 424.535(a)(8)(ii).

Comment: A commenter stated that it would be inappropriate for CMS to revoke billing privileges under § 424.535(a)(8)(ii) when no finding of fraud is involved. The commenter recommended that CMS withdraw this proposed provision.

Response: We disagree. Revocation is an administrative remedy separate and distinct from the government's other remedies for fraudulent behavior, and is intended to protect the Medicare program and its beneficiaries from fraud, waste, and abuse. Indeed, many of our existing revocation reasons under § 424.535(a) do not require a finding of fraud. For example, § 424.535(a)(1) permits revocation of the provider or supplier's Medicare billing privileges if the provider or supplier is out of compliance with Medicare enrollment requirements. The fact that there has not been a legal finding of fraudulent conduct does not automatically mean the behavior or activity in question is compliant with Medicare requirements. We maintain that repeated claim denials over a period of time raise questions as to the provider or supplier's ability or willingness to comply with Medicare's billing and coding requirements and procedures.

Comment: A commenter opposed proposed § 424.535(a)(8)(ii), contending that: (1) CMS already has the authority and tools to revoke the billing privileges of

unscrupulous actors who defraud or abuse the Medicare program; (2) denial of payment is the appropriate remedy for the submission of an incorrect claim; (3) CMS should not assume that providers cannot correct their existing practices to ensure that accurate claims are submitted; and (4) there is no guarantee that the determination criteria CMS has outlined would not be improperly or inconsistently applied.

Response: We currently do not have the ability to revoke a provider or supplier's billing privileges based on a pattern or practice of submitting non-compliant claims, hence the need for § 424.535(a)(8)(ii). We agree that a claim denial can serve as an adequate remedy in many cases. However a repeated pattern of submitting non-compliant claims indicates that the associated claim denials are not altering the provider's behavior. More serious remedial action – specifically, the revocation of billing privileges under § 424.535(a)(8)(ii) – may thus be necessary in some cases.

We do not assume that providers cannot correct their existing practices to ensure that they submit compliant claims. We believe very strongly that they can, which is precisely why a failure to do so could warrant a revocation under § 424.535(a)(8)(ii).

CMS, rather than our contractors, will make all determinations under § 424.535(a)(8)(ii) and will consistently apply the criteria.

Comment: A commenter stated that existing procedures, including audits, are more than sufficient to detect improper billing and to educate providers in complying with Medicare's intricate rules. The commenter believes that § 424.535(a)(8)(ii) is in effect duplicative of these procedures, and would simply impose another layer of complexity and financial burden on providers.

Response: We agree with the commenter's premise: our current rules and

procedures are sufficient to bring most providers into compliance when mistakes or errors are brought to their attention. However, this final rule is focused on providers who cannot or will not come into compliance with our payment requirements after repeated claim denials. Despite our audit practices and educational activities, we continue to see situations where certain providers and suppliers regularly submit non-compliant claims. Clearly, our audit and education activities have not been enough to sufficiently stem this behavior in all instances, thus demonstrating the need for § 424.535(a)(8)(ii). Yet we reiterate that not only will we make all determinations under § 424.535(a)(8)(ii), but also that this provision will be applied in situations where the behavior was not sporadic in nature. We are focused on instances where the provider is engaged in an ongoing pattern of submitting non-compliant claims.

Comment: A commenter stated that the proposed rule does not explain how or why billing is "abusive" merely because the claim appears not to meet medical necessity criteria.

Response: There are reasons other than a failure to meet medical necessity requirements for which a claim can be denied (although the continuous submission of claims for medically unnecessary services can trigger § 424.535(a)(8)(ii)). The term "abusive," as used in the context of § 424.535(a)(8)(ii), is meant to capture a variety of situations in which a provider or supplier regularly and repeatedly submits non-compliant claims over a period of time.

Comment: Several commenters stated that whatever criteria CMS plans to use in determining whether a revocation under § 424.535(a)(8)(ii) is appropriate should be included in the final rule's regulatory text or, as one commenter suggested, be

accompanied by a binding administrative document (such as an administrator's ruling) as part of its implementation.

Response: We have included in the regulatory text the factors that CMS will consider prior to imposing a revocation under § 424.535(a)(8)(ii).

Comment: A commenter recommended that before CMS finalizes § 424.535(a)(8)(ii), it should: (1) instruct its contractors not to repeatedly audit the same beneficiary's claims once the claims have been upheld on appeal or in medical review; (2) instruct its contractors not to audit a provider for a 1-year period if the provider has been audited and found to have an acceptable error rate; (3) restore contractors' ability to use clinical judgment when performing complex medical reviews; (4) develop a comprehensive education program for practitioners who prescribe DMEPOS items; (5) exercise better supervision of its contractors; and (6) establish clear guidelines for calculating provider-specific error rates used to place providers on prepayment review. The commenter believed these changes are necessary to better ensure that providers – who are often confused by CMS policy changes, which the commenter stated are sometimes applied retroactively – are able to submit correct claims and that CMS's policies are consistent, clear, and appropriately announced to providers with adequate notice.

Response: While we appreciate the commenter's suggestions, they are outside the scope of this rule.

Comment: A commenter expressed concern that CMS will use audits performed by its contractors (for example, RACs) as a legitimate, ultimate indicator of either fraudulent behavior or noncompliance with Medicare payment policies. The commenter

recommended, as did a number of other commenters, that CMS eliminate pre-payment audits as a basis for detrimental action under § 424.535(a)(8)(ii). These commenters stated that some providers undergo pre-payment review merely as a preventative or precautionary measure to make sure that the claims submitted are appropriate and well-documented or because of the amount of the claim. They added that certain providers are subjected to pre-payment review for reasons beyond their control, and that losing billing privileges for being placed on pre-payment review is a draconian and inappropriate penalty. Several other commenters stated that there is no evidence to suggest that placing certain categories of suppliers or product categories under pre-payment review is resulting in lower error rates.

Response: While we do not intend to use the results of audits performed by our contractors as the sole and absolute criterion of fraudulent behavior or noncompliance with Medicare payment policies, such results will be considered in our review of all of the factors in § 424.535(a)(8)(ii).

We will not consider the provider's pre-payment review status in and of itself as a factor in § 424.535(a)(8)(ii) determinations. Our concern is with actual claim denials, rather than the means through which such denials were issued.

Comment: Several commenters stated that the claim denials of some individual practitioners and other suppliers sometimes stem from deficiencies in the physician's documentation. The commenters believed that CMS's inclusion of such claim denials – that is, claim denials based on the insufficient documentation of another provider – in its § 424.535(a)(8)(ii) determinations would be arbitrary and capricious.

Response: We disagree. We believe it is the responsibility of the provider

submitting the claim to ensure that all requirements – including, as necessary, proper and compliant supporting documentation – have been met prior to the claim's submission.

Repeated denials due to improper documentation are an indication to a provider or supplier that its billing behavior must change in order to become compliant with Medicare requirements—including documentation requirements.

Comment: A commenter stated that proposed § 424.535(a)(8)(ii) should contain a knowledge standard that the provider knew that the claims did not meet Medicare requirements. Several other commenters contended that CMS should only revoke billing privileges under § 424.535(a)(8)(ii) if the supplier has specific or actual knowledge of the erroneous nature of a particular claim or set of claims. This would preclude revocations based on honest mistakes; one commenter noted the challenges associated with EHR systems and the possibility that erroneous claims could be submitted as a result. One commenter stated that the proposed provision lacks any standards concerning the state of mind of the entity. Another commenter stated that between the two intent standards that are under CMS consideration—"reckless disregard" and "knew or should have known" – the former would be more appropriate. Another commenter urged CMS to apply § 424.535(a)(8)(ii) only when there is clear evidence that a provider acted knowingly and willfully in submitting non-compliant claims. This commenter stated that under Medicare's complex billing rules, it would be too easy for CMS or a contractor to assert that a provider "should have known" about a billing rule; as such, CMS should delete the phrase "should have known" in the final rule. The commenter believed that CMS should focus more on educating providers about changes to Medicare billing rules than on the punitive remedies outlined in § 424.535(a)(8)(ii).

Response: Although we solicited comments on whether a knowledge standard should be applied to § 424.535(a)(8)(ii), we have decided not to implement such a standard for two principal reasons. First, the burden on CMS of determining the provider or supplier's intent for each claim it submitted (especially when there could be hundreds of claims at issue) would be excessive. Second, if a provider submits a claim with specific or actual knowledge that it does not meet Medicare requirements or with reckless disregard of said compliance, the federal government already has various means to address these situations, such as the False Claims Act. Associating a knowledge standard with § 424.535(a)(8)(ii) would simply duplicate existing authorities.

Comment: A commenter stated that CMS appears to be attempting to keep providers and suppliers from being able to effectively provide care for beneficiaries and to limit the overall number of providers and suppliers. The commenter believed that: (1) § 424.535(a)(8)(ii) is based on a rationale that all providers and suppliers are a risk to the Medicare Trust Funds; and (2) CMS has not fully gauged the proposed provision's impact on many honest providers and suppliers that furnish services to Medicare beneficiaries.

Response: We are neither attempting to impede patient care nor reduce the number of providers and suppliers. We believe most Medicare suppliers and providers are conscientious about submitting claims that meet Medicare requirements, and this rule will not affect that majority. Once again, we are merely attempting to address the problem of providers and suppliers with patterns of non-compliant claim submissions. Providers and suppliers that are not engaged in a pattern or practice of non-compliant billing will not be adversely affected by § 424.535(a)(8)(ii).

Comment: Several commenters stated that a mere difference of opinion about

what is medically necessary – a term that is not "black and white" - should not be the basis for a revocation of billing privileges, particularly considering that LCDs and views on medical necessity will differ among MACs.

Response: We understand the commenter's concern and believe that sporadic claim denials based on a lack of medical necessity generally should not result in revocation under § 424.535(a)(8)(ii). However, we do not believe that medical necessity-based denials should be excluded from the scope of § 424.535(a)(8)(ii). It is of concern to us when a provider consistently submits claims for services that are not medically necessary, for this raises quality of care issues as well as the possibility that the provider is seeking to defraud the Medicare program.

Comment: A commenter noted that while CMS states that § 424.535(a)(8)(ii) is not designed to revoke enrollment for isolated and sporadic claim denials or for innocent errors in billing, the provision itself (as proposed) does not make that intent clear.

Response: The regulatory text of § 424.535(a)(8)(ii) states that CMS may revoke billing privileges if a provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. It also identified five factors that we will use to make such a determination, including: (1) the percentage of claims denied; (2) the reasons for the claim denials; (3) a history of final adverse actions; (4) the length of time the pattern has continued; and (5) the length of time the provider or supplier has been enrolled in Medicare.

Comment: Several commenters stated that some providers submit many claims each year electronically, meaning that a single inadvertent error could easily be repeated on numerous claims. The commenters expressed concern that such errors when repeated

could constitute a pattern or practice of submitting erroneous claims under § 424.535(a)(8)(ii). One of these commenters added that in light of the great complexity of Medicare billing and coding requirements, a provider could inadvertently submit a claim that failed to meet at least one Medicare requirement, even though the provider in good-faith believed that the claim was correct.

Response: We recognize the possibility that a single inadvertent error on similar electronic claim submissions could result in multiple claim denials. As we stated earlier, we recognize that Medicare has many rules and requirements regarding billing and coding, and that claims are sometimes submitted in error due to a provider's honest misunderstanding of these policies. It is not our intention to revoke billing privileges under § 424.535(a)(8)(ii) for such sporadic misinterpretations.

Comment: A commenter suggested that the following factors – in order of importance - be used in determining whether a "pattern or practice" exists under § 424.535(a)(8)(ii) and that such factors be included in the regulatory text: (1) the reason(s) for the claim denials; (2) the percentage of submitted claims that were denied (for which there should be a minimum threshold); (3) how long the provider has been enrolled in Medicare; (4) whether the provider has had any final adverse actions; and (5) the length of time of the pattern or practice. Another commenter requested that CMS not use the "total number of claims denied" as a criterion, for this could disproportionately and unfairly impact larger providers that submit many claims. The commenter also requested CMS to clarify whether the percentage of submitted claims that were denied would be determined using individual, subpart, or organizational NPIs.

Response: We have decided not to give certain factors greater weight in our

§ 424.535(a)(8)(ii) determinations than other, for the importance of each factor may vary based on the particular situation. We have also decided not to establish a minimum percentage threshold for claim denials; as stated earlier, we need flexibility to address a variety of scenarios. However, we included the five factors that the first commenter identified – all of which we proposed - in the regulatory text as criteria that CMS will consider, as appropriate or applicable, in its § 424.535(a)(8)(ii) determinations.

We agree with the second commenter that the "total number of claims denied" factor could present a distorted view of the provider or supplier's billing practices for purposes of § 424.535(a)(8)(ii). Therefore, we will not be finalizing this as criterion.

The "percentage of claims denied" criterion will be based on the NPI listed on the claim.

Comment: A commenter suggested that: (1) the provider should have an opportunity to show that it has remedied any error that occurred; and (2) proposed § 424.535(a)(8)(ii) should be limited to situations that are within the provider's control. With respect to this second suggestion, the commenter stated that providers sometimes rely upon physicians to provide information that must be included on the claim; if such information is incorrect, CMS should not use this as a basis for revocation under § 424.535(a)(8)(ii). Other commenters shared this view.

Response: We disagree with both of the commenter's suggestions. We believe that the provider already has an opportunity to remedy an error once it receives a claim denial notice. Repeated errors over a period of time indicate that the provider is not taking necessary corrective steps. Also, while we recognize that providers sometimes rely on physicians for certain information, the provider remains ultimately responsible for

ensuring that the claim and the supporting documentation meet Medicare requirements.

Comment: A commenter stated that inconsistent claim determinations, policies, and interpretations of policies among MACs would lead to inequitable results under § 424.535(a)(8)(ii). As written, they provide far too much latitude for administrative folly, which is nearly guaranteed to occur. At a minimum, the commenter stated, the proposed rule must not be finalized without: (1) substantial clarifying text written into the regulation itself; or (2) being accompanied by a binding administrative document (such as an administrator's ruling) for its implementation.

Response: As stated earlier, CMS, rather than its contractors, will make all § 424.535(a)(8)(ii) determinations.

Comment: Several commenters recommended that CMS include in the regulatory text of § 424.535(a)(8)(ii) a statement that the authority to make determinations that a "pattern or practice" does not rest with CMS's contractors. The commenters also suggested that CMS incorporate into the regulatory text the following criteria that CMS should use in making § 424.535(a)(8)(ii) determinations: (1) whether the provider has any history of "final adverse actions" and the nature of those actions; (2) the length of time over which the pattern or practice has continued; (3) how long the provider has been enrolled in Medicare; (4) whether the pattern or practice occurs throughout the provider or supplier's industry; (5) whether the provider had a specific intent to submit a false or fraudulent claim; (6) whether the provider has a corrective action plan in place; (7) the number of claims overturned on appeal; and (8) the reasons for the claim denials. With respect to the fourth criterion, the commenters stated that consistently high industry-wide error rates among suppliers are the result of constant changes to billing requirements,

uncertain and inconsistent interpretation of requirements by regulating and enforcing entities (including Medicare contractors), inadequately written LCDs, and CMS's expectation that suppliers can enforce physician documentation requirements. They recommended that CMS consider addressing high industry-wide error rates through billing requirement reform rather than implementing another instrument of supplier punishment via § 424.535(a)(8)(ii).

Response: As we have stated elsewhere in this final rule, we will make all determinations for revocations under § 424.535(a)(8)(ii). We do not believe this needs to be restated in the regulatory text.

Insofar as the commenters' suggested factors for consideration, we agree with the first, second, third, and eighth factors and have included them in the regulatory text. We do not agree with the fourth suggested factor. Each provider or supplier must be reviewed individually, rather than as part of a larger class of providers and suppliers. We do not agree with the fifth suggested factor, either; for reasons already stated, we will not be applying a knowledge standard to § 424.535(a)(8)(ii). We disagree with the sixth factor as well. If a provider is repeatedly and consistently submitting non-compliant claims, this indicates that the provider's corrective action plan – assuming it has one – is either being partially or wholly disregarded or is inadequate. As for the seventh factor, and as stated earlier, a provider or supplier's claim denial that has been both: (1) fully (rather than partially) overturned on appeal; and (2) finally and fully adjudicated will be excluded from our § 424.535(a)(8)(ii) determinations.

Finally, we recognize that there may be special circumstances surrounding the provider or supplier's non-compliant billing that are beyond the scope of the five factors

we are finalizing. The particular facts of each case will vary widely, and the scenarios the commenters have presented underscore this point. To effectively address these situations, we believe that a sixth criterion should be established that enables CMS to consider any other applicable and available information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination of a pattern or practice of non-compliant billing. However, information considered under this criterion will not alone be decisive in our determinations under § 424.535(a)(8)(ii); the five other factors will, of course, be considered as well. Regardless, we believe that such information, to the extent it exists, should be considered in our § 424.535(a)(8)(ii) determinations to help ensure that the Medicare Trust Funds are protected and, by the same token, that providers and suppliers are treated fairly.

Comment: Several commenters recommended that CMS give low consideration to claim volume and percentage of claims denied as factors under § 424.535(a)(8)(ii) and that thresholds not be established for these criteria. The commenters believed that these factors may lead CMS to focus on the largest suppliers that rely on automated claims administration systems, while missing smaller suppliers that do not attract attention because their data does not exceed certain thresholds.

Response: The number of denied claims will not be a factor in our § 424.535(a)(8)(ii) determinations, though the "percentage of denied claims" will remain as a factor and one that is no less important than the others. Also, and as explained earlier, we are not establishing thresholds for any of our criteria.

Comment: Several commenters expressed concern that § 424.535(a)(8)(ii) could be easily misapplied or misused because the provision is very vague and without clear

standards.

Response: As previously explained, we are finalizing all but one of the factors we proposed and are adopting an additional factor in response to the comments we received. We believe this will furnish sufficient clarity as to the scope of § 424.535(a)(8)(ii).

Comment: Several commenters expressed concern about the potential application of § 424.535(a)(8)(ii) considering that RACs have a financial incentive to deny claims.

Response: RACs review claim decisions on a post-payment basis, and are only paid for a claim denial if a Medicare Administrative Contractor (MAC) denial of a claim is upheld on appeal; this, we believe, reduces the incentive for RACs to make inappropriate determinations regarding claims. We also reiterate that claim denials that are reversed on appeal will be excluded from the application of § 424.535(a)(8)(ii) if they meet certain criteria.

Comment: Several commenters urged CMS to reconsider revocations based on billing patterns because it does not appear that there is – nor does CMS cite any - statutory authority to support such a remedy.

Response: We cited our statutory authority for § 424.535(a)(8)(ii) and all of our other provider enrollment provisions in both this rule and the proposed rule. Specifically, 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.

Comment: A commenter stated that: (1) there are often good-faith differences between providers and contractors over appropriate coding; and (2) different payers may

have different rules, which can cause confusion over the appropriate way to bill. The commenter contended that if there is no evidence that the provider intended to defraud Medicare, the provider should be given a chance to remedy the error. Medicare, the commenter added, should engage in education, counseling, and guidance that leads to correct coding before taking draconian measures.

Response: We believe that frequent claim denials should alert the provider that there may be an issue with its claim submissions and that remedial action may be required. We do not believe that an interim notification from CMS (for example, a "warning letter") should be a prerequisite for taking action under § 424.535(a)(8)(ii). Further, if the provider has questions regarding CMS's billing and coding requirements, it should review CMS's manuals, educational articles, and other informational documents at CMS's website (www.cms.hhs.gov); the provider may also contact its local MAC if it has additional questions.

Comment: A commenter stated that it fully supported proposed § 424.535(a)(8)(ii).

Response: We appreciate the commenter's support.

Comment: Several commenters stated that Medicare providers are already well aware of their legal obligation to submit correct and accurate claims for services that were reasonable and necessary. They noted that: (1) the current claim submission forms require the physician to certify that the services "were medically indicated and necessary for the health of the patient"; and (2) enforcement agencies already have ample authority under several statutory schemes to penalize providers found to have inaccurate claims, including the False Claims Act. Therefore, the commenters questioned the benefit of or

need for § 424.535(a)(8)(ii), especially in light of the danger of CMS overreach in its application of this provision.

Response: We acknowledge these authorities as well as the certification language on the current claim submission forms. However, we continue to see instances where, despite these obligations, providers and suppliers repeatedly submit non-compliant claims. The other federal authorities provide remedies different from what we have proposed. We thus believe that the authority to revoke billing privileges under § 424.535(a)(8)(ii) can be part of a comprehensive strategy to address these situations.

Comment: A commenter stated that there do not appear to be any administrative appeal rights if a provider is revoked under § 424.535(a)(8)(ii).

Response: Under § 424.545, a provider or supplier may appeal any revocation of Medicare billing privileges under 42 CFR part 498.

Comment: A commenter stated that CMS should exclude physicians from the purview of § 424.535(a)(8)(ii) because they fall within the "limited" screening category under § 424.518(a).

Response: We do not agree. The issue is the correct submission of claims, rather than the level of screening to which the provider or supplier is normally subject under § 424.518(a).

Comment: A commenter stated that revocations under proposed § 424.535(a)(8)(ii) should be limited to instances where CMS has data indicating that the provider is engaging in extreme outlier billing and has an established and ongoing pattern of abusive practices.

Response: As stated, we will consider, as appropriate or applicable, the six

factors discussed previously (and contained in § 424.535(a)(8)(ii)(A) through (F)) in determining whether a revocation under § 424.535(a)(8)(ii) is warranted. A provider or supplier could be an "outlier biller" for any number of reasons. Hence, a provider or supplier that is an "outlier biller" should not automatically be subject to revocation based on § 424.535(a)(8)(ii). We have noted previously that we will only take revocation action under § 424.535(a)(8)(ii) after careful review of factors surrounding the provider or supplier's billing behavior.

Comment: A commenter stated that while the proposed rule's preamble indicated that "claims for services that fail to meet Medicare requirements" meant claims denied for failing to satisfy Medicare's medical necessity requirements, the regulatory text did not explicitly state as such. The commenter recommended that CMS either: (1) delete its proposed § 424.535(a)(8)(ii); or (2) revise the provision to clearly limit "claims for services that fail to meet Medicare requirements" to claims that do not meet medical necessity requirements. The lack of a specific reference to "reasonable and necessary" requirements, the commenter believed, would enable CMS to unreasonably apply § 424.535(a)(8)(ii) to a failure to meet any Medicare requirement.

Response: We do not believe that revocations under § 424.535(a)(8)(ii) should be limited to claim denials based on medical necessity. Indeed, proposed § 424.535(a)(8)(ii) was not meant to apply only to certain claim denial reasons. Repeated claim denials over a period of time are of concern to us irrespective of the particular reason(s) involved. To alleviate any confusion about the scope of § 424.535(a)(8)(ii), we are deleting the language "for services" from this provision. This will clarify that § 424.535(a)(8)(ii) applies to claims that are denied for failing to meet Medicare requirements and is not

limited to cases where the claim is denied because the *services* did not mean Medicare requirements.

Comment: A commenter stated that CMS should establish a dispute resolution process prior to revoking a provider's privileges related to claims denials for not meeting Medicare requirements. Several other commenters stated that CMS should afford appeal rights under § 424.535(a)(8)(ii) prior to revoking a provider's billing privileges.

Response: We disagree with the commenters. No other revocation reason under § 424.535(a) currently has an interim appeals or dispute resolution process, and we do not see any basis or rationale for permitting such processes in the case of § 424.535(a)(8)(ii). As with all other revocation reasons, the provider or supplier may appeal the revocation.

Comment: A commenter stated that revocations under § 424.535(a)(8)(ii) should be reserved for only the most serious of abuses.

Response: We agree. As we have stated, § 424.535(a)(8)(ii) will only be applied when it is clearly appropriate. For instance, a § 424.535(a)(8)(ii) revocation could be proper, once all of the appropriate factors have been considered, if--

- There is a demonstrable pattern or practice;
- The pattern is long-term or has otherwise continued over a period of time;
- Education regarding appropriate billing is or has been made available to the provider in the form of claim denial notices, CMS instructional materials (such as manuals and articles) on CMS' website, etc., yet the provider or supplier continues to submit non-compliant claims, and
- A significant percentage of the provider's or supplier's claims have been denied.

(We stress that this is merely an example and should be not be interpreted as the formal establishment of minimum criteria.)

We again state that § 424.535(a)(8)(ii) is not targeted toward honest providers and suppliers that make occasional billing mistakes. Our sole focus is on providers and suppliers that engage in a systemic, ongoing, and repetitive practice of improper billing notwithstanding the public availability of CMS educational materials or guidance and CMS' issuance of claim denial notices to the provider. While we hope that this helps to reassure the provider and supplier communities of CMS' intentions, we recognize that concerns may linger. To that end, we plan to issue written guidance to and communicate with the public once this final rule is implemented, whereby we will once again reiterate the objective behind § 424.535(a)(8)(ii) and, as necessary, discuss certain operational aspects of this provision.

Comment: A commenter stated that CMS did not-- (1) explain how determinations under § 424.535(a)(8)(ii) would be made; (2) explain how errors in a revocation determination can be remedied short of a reapplication after the enrollment bar expires; and (3) furnish rationale as to the specific standards - such as the establishment of a percentage threshold for claim denials – that CMS will use in its determinations.

Response: We will make all § 424.535(a)(8)(ii) determinations after a careful and thorough consideration of the factors outlined in § 424.535(a)(8)(ii)(A) through (F). As we explained in the proposed rule, any revocation under § 424.535(a)(8)(ii) may be appealed if the provider or supplier chooses to do so.

We stated earlier that each case will be judged on its own specific facts, and that establishing specific thresholds would, we believe, hinder our ability to do so. We

believe that the factors outlined in § 424.535(a)(8)(ii)(A) through (F) sufficiently indicate to providers and suppliers the rationale we will use in our § 424.535(a)(8)(ii) determinations.

Comment: A commenter questioned whether a system would be established to ensure that § 424.535(a)(8)(ii) would be implemented and enforced uniformly across jurisdictions. The commenter also requested which entities (for example, RACs) would be tasked with enforcing these provisions as well as any financial incentives for identifying wrongdoing.

Response: Once again, we (not our contractors) will make all determinations regarding whether a § 424.535(a)(8)(ii) revocation should be imposed. We will apply the criteria consistently.

Comment: A commenter suggested that in light of the seriousness of a revocation under § 424.535(a)(8)(ii), CMS should provide direct notice to a provider that its billing privileges may be revoked if its continues to bill for services that do not meet Medicare requirements. The commenter believed that such a preliminary "warning" could encourage the provider to improve its claim submission accuracy. The commenter also suggested that CMS consider a sliding scale that includes a lower-level consequence - such as a suspension - for less severe occurrences.

Response: We do not believe that an interim alert to the provider is necessary. The provider's receipt of a substantial number of claim denials, in our view, furnishes adequate notice to the provider that corrective action is necessary.

While we appreciate the commenter's suggestion regarding lower-level consequences for less severe cases, we note again that § 424.535(a)(8)(ii) is only

intended to address the most severe of situations. Still, we will closely monitor our application of this provision and the scenarios that come before us. Should we determine that other sanctions may be appropriate, we may, as needed, undertake future rulemaking.

Comment: A commenter stated that CMS should not finalize § 424.535(a)(8)(ii) until the public has had an opportunity to comment on the specific policy CMS will use in defining "pattern or practice."

Response: As stated, we are not formally defining "pattern or practice" in this rule. We will instead consider a number of factors in our determinations as to whether a § 424.535(a)(8)(ii) revocation is warranted.

Comment: A commenter stated that although CMS sought feedback from the provider community regarding § 424.535(a)(8)(ii), it did not believe that engaging in this type of review and analysis during a 60-day public comment period was appropriate. The commenter believed that discussions and collaboration with the provider community via a stakeholder group should occur beforehand.

Response: We disagree with the commenter. While we recognize the provider community's concerns regarding § 424.535(a)(8)(ii), we do not believe that formal discussions with a stakeholder group resulting in an agreement as to what § 424.535(a)(8)(ii) should consist of are necessary prior to the provision's implementation. This is especially true considering that we received valuable comments from providers and suppliers regarding § 424.535(a)(8)(ii) and have incorporated them into our final provisions as needed. We believe that the notice-and-comment process under the APA is the most appropriate means of soliciting feedback from the public.

Comment: A commenter, expressing concern about CMS's potential use of

statistical analysis in determining patterns under § 424.535(a)(8)(ii), cited several instances in which a claim is denied but cannot automatically or necessarily be considered an abusive billing situation: (1) a patient dies prior to the interpretation of an applicable test; (2) claims for services deemed not medically necessary; (3) the beneficiary needs a Medicare denial to file secondary insurance; and (4) the beneficiary has exceeded a benefit category unbeknownst to the provider. The commenter believed CMS has the capability to distinguish between (a) abusive billing patterns and (b) claim denials that occur in the normal course of business and are not based on any nefarious intent. The commenter added that in providing examples of what may constitute a pattern of abusive billing behavior, CMS must account for certain specialty-specific situations that can occur due to the nature of the provider-patient encounter; diagnostic services, for example, should not be subject to the same standard as other providers due to the remote nature of the physician-patient relationship.

Response: We agree with the commenter's apparent rationale that certain claim denials may be for purely innocuous reasons and that CMS has the ability to distinguish between these situations and extreme instances of non-compliant billing. We note once more that the reason(s) for the claim denials will be a factor in our § 424.535(a)(8)(ii) determinations.

Comment: A commenter stated that a provider often will not be aware of a pattern of alleged improper billing under § 424.535(a)(8)(ii) until after a contractor performs an audit. Under such circumstances, the commenter believed, the provider should be given an opportunity to correct the allegedly improper billing via a plan of correction.

Response: As already stated, we acknowledge that in sporadic instances providers and suppliers may submit claims in error due to a misunderstanding of Medicare policies. It is not our intention to revoke billing privileges under § 424.535(a)(8)(ii) for such isolated misinterpretations.

Comment: A commenter stated that in situations where coordination of benefits is involved, a provider must exhaust all efforts to receive payment from a primary payer - such as Medicare - before billing a secondary payer. The commenter urged CMS to exclude coordination of benefit situations from the category of claim denials that can be considered under § 424.535(a)(8)(ii).

Response: While we do not believe that such situations should be automatically excluded from the purview of § 424.535(a)(8)(ii), we note that the reasons for the claim denials will be a factor in our § 424.535(a)(8)(ii) determinations. Consequently, the situation the commenter describes will be considered in such determinations.

Comment: A commenter stated that "length of time" should only be considered as a factor if the provider acted in reckless disregard of whether its claims did not meet Medicare requirements. The commenter added that: (1) the reckless disregard standard should be used in all cases involving § 424.535(a)(8)(ii); and (2) CMS should not use "the total number of claims denied" and "percentage of claims denied" categories in applying § 424.535(a)(8)(ii) because there are many instances in which claims are denied - such as in coordination of benefit situations - for innocuous purposes.

Response: As stated, we will neither be applying a knowledge standard to § 424.535(a)(8)(ii) nor eliminating the "percentage of claims denied" or "length of time" criteria from our analysis. However, we are removing "the total number of claims

denied" criterion.

Comment: A commenter stated that CMS must furnish the provider community with guidance regarding CMS's requirements for proper medical record documentation, including the frequency of documentation to support medical necessity for each product category. The commenter also recommended the inclusion of these documents within an electronic health record template.

Response: We believe these comments are outside the scope of this rule.

Comment: A commenter stated that a provider's claims are sometimes denied because of insufficient physician medical record documentation; such instances should not be included within the purview of § 424.535(a)(8)(ii) because the provider had no control over the physician's documentation.

Response: We do not believe that denials based on insufficient medical record documentation should be automatically excluded from the scope of § 424.535(a)(8)(ii). Again it is ultimately the provider's responsibility to ensure that the documentation it furnishes in support of a claim meets Medicare requirements, though the reason(s) for the claim denial will be a factor in our § 424.535(a)(8)(ii) determinations.

Comment: A commenter stated that claims are occasionally denied because information on the certificate of medical necessity is inconsistent with CMS's national coverage criteria. The commenter suggested that the two decisional documents be streamlined to coordinate coverage criteria effectively and uniformly.

Response: We believe this comment is outside the scope of this rule.

Comment: A commenter expressed concern about what the commenter believed was a lack of definition of "directing physician" as that term is used in § 424.535(a)(8)(i).

The commenter stated that the professional component of diagnostic testing services is often not performed in the same physical location or contractor jurisdiction as the technical component, and that the date of service may be different if the interpretation is not done on the same date done as the technical component. Such normal, compliant practices could be misinterpreted under § 424.535(a)(8)(i).

Response: As we did not propose any changes to the content of existing § 424.535(a)(8), which is merely renumbered in this final rule as § 424.535(a)(8)(i), this comment is outside the scope of this rule.

Comment: A commenter contended that although § 424.535(a)(8)(i) suggests that an abuse of billing privileges includes billing for a service when it would have been impossible to actually provide the service - such as when the physician performing the service was not available to furnish the service, or the patient was not available to receive the service because he or she was out of the state or country - the regulation does not clearly state as such. The commenter expressed particular concern regarding the situation where a laboratory is not in the same state in which the physician who ordered the service is located, meaning that the service could not have been furnished to that beneficiary on that date of service. The commenter requested that CMS clarify that this situation is outside the scope of scenarios to which this rule is meant to apply.

Response: As we did not propose any changes to the content of existing § 424.535(a)(8), which is merely renumbered in this final rule as § 424.535(a)(8)(i), we believe this comment is outside the scope of this rule.

Given the comments received and the foregoing discussion, we are finalizing proposed § 424.535(a)(8)(ii) with a modification. We are adding new paragraphs (A)

through (F) to identify the factors for consideration.

5. Post-Revocation Submission of Claims

Section § 424.535(h) currently states that a revoked physician organization, physician, non-physician practitioner or IDTF must submit all claims for furnished items and services within 60 calendar days of the effective date of the revocation. As we explained in the proposed rule, the reason for such a relatively short post-revocation claim submission period is to limit Medicare's exposure to future vulnerabilities and potentially fraudulent claims from such revoked individuals and organizations.

With this in mind, we proposed to expand § 424.535(h) to require all revoked providers and suppliers to 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.

A summary of the comments received and our responses thereto are as follows:

Comment: A commenter questioned why CMS is proposing to grant DMEPOS suppliers an additional 45 days after revocation to submit claims, for § 424.57(d) currently grants DMEPOS suppliers only 15 days to submit claims after revocation.

Response: We believe that the commenter is misreading § 424.57(d), in that § 424.57(d) does not address the timeframe in which post-revocation claims must be submitted.

Comment: A commenter expressed support for our proposed change, stating that all providers and suppliers would now be treated equally with respect to the post-revocation claim submission requirement.

Response: We appreciate the commenter's support.

Given the very few comments received and the foregoing discussion, we are finalizing our proposed changes to § 424.535(h).

6. Effective Date of Billing Privileges

Under the current version of § 424.520(d), the effective date of billing privileges for physicians, non-physician practitioners, and physician and non-physician 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 non-physician practitioner first began furnishing services at a new practice location. This policy is meant to address our concerns about providers and suppliers being able to bill for Medicare services rendered well before enrollment, for it is not always possible to verify whether a supplier has met all Medicare enrollment requirements prior to the date it submits an enrollment application. Thus, the Medicare program should not be billed for services performed before the later of the two aforementioned dates. In light of this concern, we proposed to expand the scope of § 424.520(d) to include ambulance suppliers, based in part on the elevated risk they pose to the Medicare program as stated in § 424.518. Indeed, 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.

As explained in the proposed rule, we did not include certified providers and certified suppliers in our proposed revision to § 424.520(d) because of: (1) existing limitations posed by § 489.13 on their ability to "backbill" for services; and (2) the extensive, multilayered review process they must undergo prior to enrolling in Medicare. Yet we did solicit comments on whether any other non-certified provider or non-certified supplier types that are not currently subject to a backbilling restriction similar to the one we proposed should be included.

The following is a summary of the comments received regarding this proposed change and our responses thereto.

Comment: A commenter stated that CMS should treat ambulance services in a manner consistent with physicians and non-physician practitioners when it comes to enrollment and the filing of Medicare claims. Retroactive billing for ambulance services, the commenter continued, should be similar to the 30-day retroactive billing authority that exists for these individuals; the supplier could seek a longer retroactive billing period if it can demonstrate that exigent circumstances led to a situation that forced it to provide transport services prior to the normal billing requirements.

Response: We agree that the 30-day and 90-day retroactive billing provisions in § 424.521(a), to which the commenter is referring, should apply to ambulance suppliers to the same extent that they do to physicians, physician groups, non-physician practitioners, and non-physician practitioner groups. This approach would ensure: (1) consistent treatment between ambulance suppliers and the other supplier types covered under § 424.520(d); and (2) that ambulance suppliers can avail themselves of a brief retroactive billing period if they are able to show that urgent circumstances precluded the

supplier from submitting its enrollment application earlier than it did. Therefore, we have revised the regulatory text in § 424.521(a) to include ambulance suppliers.

Comment: Several commenters stated that proposed § 424.520(d) should have a mechanism by which ambulance suppliers can obtain retroactive billing privileges in situations where the failure to file the enrollment application prior to commencing operations resulted from circumstances beyond the supplier's control; one commenter cited the example of a county-owned ambulance supplier that needs approval from the county's governing board before expanding its service area, a process that could delay the submission of the supplier's application. The commenters had two suggestions in this regard. First, the supplier could file a preliminary CMS-855 application when it anticipates expanding into a new service area; the supplier could supplement the application with additional information at a later date. Second, the supplier could appeal for retroactive billing privileges.

Response: As we explained earlier, we have incorporated a revised § 424.521(a) into this final rule. It will permit limited retrospective billing in exceptional circumstances. We believe this will alleviate some of the commenters' concerns.

Comment: Several commenters requested CMS to clarify that the "date of filing" of a CMS-855 application is the date on which the contractor initially received the application, not the date on which the contractor deemed the application "complete."

Response: The "date of filing" is the date on which the provider or supplier submitted its CMS-855 application via mail or Internet-based PECOS.

Comment: Several commenters stated that a more definitive distinction must be made as to what is meant by the date of an application that is subsequently approved.

One commenter stated that it is not uncommon for contractors to return applications with a request for supporting documentation. Another commenter requested an explicit statement that the date the application is entered into PECOS or a paper CMS-855B is mailed is the effective date of billing privileges, assuming the application is eventually accepted; this would make it clear that a request for additional documentation is part of the original process and does not begin an entirely new cycle.

Response: We indicated earlier that the effective date of billing privileges under § 424.520(d) will be the later of: (1) the "date of filing" of an enrollment application that is subsequently approved; or (2) the date the supplier began furnishing services at a practice location. The "date of filing" is considered to be the date on which the supplier submitted its CMS-855 application via mail or Internet-based PECOS.

The term "subsequently approved" includes application submissions for which the contractor requested additional information from the supplier (or otherwise undertook developmental activities with respect to the application) and the application was ultimately approved. It does not include applications that were rejected under § 424.525 or returned pursuant to CMS Publication 100-08, chapter 15, and were later resubmitted. A contractor's request for additional information does not constitute a final disposition regarding the application; that is, the application is still in process. However, a rejection or return indicates that the contractor was unable to process the application to completion, meaning that the application processing cycle has ended and the supplier must submit a new application.

Comment: A commenter stated that municipalities are sometimes required to temporarily curtail their ambulance services and must contract with another ambulance

supplier on an emergency, short-term basis; in such emergency situations, it may not be possible for the municipality to quickly secure all of the necessary paperwork to permit Medicare billing for transport services. The commenter stated that the municipality should not be held financially responsible for providing appropriate transport services for such emergency patients.

Response: In response to the comments received, we have revised § 424.521(a) to allow ambulance suppliers limited retrospective billing in exceptional circumstances.

Comment: A commenter requested that CMS clarify how the 2006 OIG report supports CMS's proposed § 424.520(d). The OIG report, the commenter contended, did not indicate whether the ambulance transports discussed therein occurred prior to the date the ambulance supplier submitted its enrollment application; citing the OIG report is misleading and creates an unfair and negative view of all ambulance suppliers.

Response: Our citation of the report was not intended to disparage all ambulance suppliers but to present examples of instances where certain ambulance suppliers were not in compliance with Medicare requirements. Our concern about non-compliance is the precise reason for our revision to § 424.520(d). We explained earlier that allowing an extensive period of backbilling makes it difficult to verify whether an ambulance supplier was in compliance with Medicare requirements well before it submitted an enrollment application.

Comment: A commenter requested that CMS: (1) furnish the information it used to single-out ambulance suppliers in § 424.520(d); and (2) explain why it did not propose a similar backbilling limitation for other supplier types such as clinical laboratories and mass immunization roster billers.

Response: As we discussed in the proposed rule, we elected to include ambulance suppliers within § 424.520(d) based on: (1) their status as moderate-risk category suppliers under § 424.514; (2) the OIG report cited in the preamble; and (3) other program integrity issues we have detected regarding ambulance suppliers. Indeed, these issues were outlined in a July 31, 2013 notice (78 FR 46339) in which we imposed a temporary moratorium on the enrollment of new ground ambulance suppliers in several Texas counties; a similar moratorium was imposed effective January 30, 2014 against ambulance suppliers in the Philadelphia, Pennsylvania area (79 FR 6475).

Comment: A commenter stated that the loss of revenue to ambulance suppliers resulting from § 424.520(d) could preclude them from expanding into new areas.

Response: We understand the commenter's concern. Yet as we have stated, it is not always possible for us to verify that the supplier met all enrollment requirements many months prior to the application submission. To ensure that Medicare payments are made to suppliers that we have confirmed met enrollment requirements at the time the service was provided, we believe it is necessary to restrict the period of backbilling.

Given these comments and in accordance with the previous discussion, we are finalizing our proposed change to § 424.520(d). We have also revised the regulatory text of § 424.521(a) to include ambulance suppliers.

7. Effective Date of Re-enrollment Bar

Currently 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 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 if the practice location is determined by CMS or its contractor not to be operational, the date of the 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 constitutes the effective date of the revocation and, hence, the date on which the re-enrollment bar commences.

We proposed 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 rationale for this change was 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 potential 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. By starting the re-enrollment bar period after the revocation letter is sent, the full period can be imposed.

A summary of the comments we received as well as our responses follow:

Comment: A commenter requested that CMS identify the reason for its statement

in the preamble discussion for proposed § 424.535(a)(3) regarding months of potential delay in updating databases with criminal conviction and licensure information. The commenter further requested CMS to indicate: (1) whether the requirement under § 424.516 for physicians, non-physician practitioners, and owners to report a felony conviction within 30 days is being waived; and (2) if § 424.516 is being waived, whether CMS is also waiving the requirement in § 424.565 that CMS assess an overpayment back to the date of the adverse action.

Response: We indicated in the proposed rule that there could be instances where a delay exists in updating a state website with felony or licensure data. With respect to the commenter's two requests, this rule does not waive the aforementioned requirement to report felony convictions or the overpayment assessment mandate in § 424.565.

Comment: A commenter disagreed with CMS's proposed revision to § 424.535(c) because this would effectively limit overpayment collections from the date of the felony conviction or guilty plea, or would expose physicians and non-physician practitioners to higher Medicare overpayment amounts. The commenter stated that CMS should retain the current policies in these two provisions until it explains: (1) their impact on the overpayment provision found in § 424.565; and (2) CMS's intent to impose overpayments based on an OIG exclusion or felony conviction from the date of the felony conviction or exclusion, the date of the revocation letter, or the actual revocation date.

Response: Our revision to § 424.535(c) neither addresses nor impacts overpayment determinations or collections. It simply specifies when the enrollment bar begins. For example, if a provider is revoked with a retroactive effective date, the enrollment bar—whatever the length—will commence as specified in § 424.535(c). Yet

the effective date of the revocation (and from which date overpayments can be collected) will be the same as that which currently exists under our regulations.

Comment: A commenter stated that our proposal that all re-enrollment bars would begin 30 days after CMS mails the revocation notice to the provider appears prudent, for it would streamline and simplify current policy. The commenter also expressed support for our additional proposals to eliminate redundancies and make technical corrections to the regulatory text.

Response: We appreciate the commenter's support.

Given this, we are finalizing our proposal to revise § 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.

8. Corrective Action Plans

Consistent with § 405.809, a provider or supplier whose Medicare billing privileges are revoked may currently 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, compliant with Medicare requirements, the provider or supplier's billing privileges can be reinstated.

We proposed to revise § 405.809 to state in new paragraph (a)(1) that a provider or supplier may only submit a CAP when 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. We stated that providers and suppliers generally should not be exonerated

from failing to fully comply with Medicare enrollment requirements simply by furnishing a CAP, for it is the duty of providers and suppliers to always maintain such compliance. The proposed exception for § 424.535(a)(1) was based on our experiences 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. 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 grounds, though, the provider would not be able to use the CAP process; the provider would instead have to use the appeals process under Part 498.

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

We further proposed to delete the last sentence of § 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 was inconsistent with our proposed change to § 405.809(a)(1).

Lastly, we proposed to incorporate the existing language of § 405.809 into a new paragraph § 405.809(b).

A summary of the comments we received on these proposed changes and our responses follow:

Comment: Several commenters noted that under CMS's proposal to restrict the availability of CAPs, a CAP could not be used in cases where a revocation occurred due to the provider's failure to report a practice location under § 424.535(a)(9). Although these commenters generally supported the proposed change, they urged CMS to clarify the definition of a "practice location" for ambulance services because Medicare contractors may be interpreting this term differently; for instance, some may define it as the location of the supplier's management, billing, or administrative staff, while others consider it to be where the supplier garages and/or maintains its vehicles.

Response: We clarified the meaning of the term "practice location" as it pertains to ambulance suppliers in CMS Transmittal 499, dated December 27, 2013.

Comment: Several commenters opposed our proposed change to § 405.809 and urged CMS to allow CAPs to be available for additional scenarios beyond those encompassed by § 424.535(a)(1). One commenter stated that many enrollment violations can be cured. The commenter stated that CAPs should be permitted except in cases where a CAP clearly jeopardizes program integrity or beneficiary health and safety. Another commenter expressed concern about CMS's statement in the preamble concerning the revocation of billing privileges for failing to report a practice location change; to have the provider in such an instance go through the appeals process without the availability of a CAP, the commenter believed, would be unjust. Another commenter stated that CMS should never be unwilling to receive correct information and that, in the commenter's opinion, Medicare contractors furnish misleading and inaccurate

information to providers and suppliers during the enrollment process.

Response: As we explained in the proposed rule, we believe that CAPs are inappropriate in a number of revocation situations and should accordingly be unavailable; to illustrate, revocations based on a failure to timely report a practice location change should not be retroactively corrected via a CAP. Indeed, we must be promptly notified of all practice location changes so we can ensure that services are only performed at valid locations and, consequently, that payments are made correctly. More basically, it is the provider or supplier's responsibility—as indicated on the CMS-855 forms that the provider or supplier completes and signs as part of the enrollment process—to report changes to CMS on a timely basis.

Comment: A commenter recommended that CMS eliminate the provider enrollment CAP process and work with Medicare contractors to eliminate revocations based on a trivial matter.

Response: We believe that CAPs are appropriate for revocations based on § 424.535(a)(1), and they will remain available. Moreover, we stress that revocations are not imposed for trivial reasons. Each prospective revocation is carefully reviewed to ensure that there are legitimate grounds for taking such action and that the integrity of the Medicare program warrants it.

Comment: A commenter stated that there generally is not enough time for a provider to submit both a corrective action plan and appeal, for the latter is frequently not filed until the results of the former are known. The commenter thus recommended that CMS either discontinue the CAP process or require its contractors to decide upon and respond to a CAP within 10 days of receipt.

Response: We do not agree that the CAP process should be entirely discontinued or that a provider must wait until the CAP determination has been made before filing an appeal. In fact, many providers and suppliers file a CAP and an appeal as part of the same package. Requiring a 10-day period is unnecessary and could hinder the reviewer's ability to conduct a thorough, careful analysis of the merits of the CAP.

Comment: A commenter urged the continued use of CAPs in situations where the provider misinterpreted a requirement or failed to comply with an administrative or record-keeping requirement but otherwise acted in good-faith.

Response: CAPs will remain available for revocations based on § 424.535(a)(1). With respect to other revocation reasons that we suspect the commenter may classify as "record-keeping" in nature – specifically, § 424.535(a)(9) and (a)(10) – we do not view these as mere administrative requirements. The reporting mandates referred to in paragraph (a)(9) – and which are codified in § 424.516(d)(1)(ii) – help ensure that CMS has correct, up-to-date information on the provider so CMS can determine if a provider or supplier is still in compliance with Medicare requirements. The maintenance of documentation requirements referred to in paragraph (a)(10) and codified in § 424.516(f) assist CMS in confirming that the physician or other eligible professional was qualified to order or certify the item or service that the provider or supplier furnished.

Comment: Another commenter stated that unless DHHS can provide suppliers with accurate and routine visibility to statistics (such as the supplier's error rates, enrollment file, and beneficiary complaints) that furnish an opportunity for suppliers to investigate, respond to, and correct potential deficiencies, CMS should not finalize its proposed change to § 405.809.

Response: Much of the data the commenter refers to is either currently available to individual providers and suppliers (for example, by reviewing the provider or supplier's PECOS record) or can be made available to them upon request. However, it is ultimately the provider or supplier's responsibility to ensure that it has sufficient internal controls to detect deficiencies on its own. Providers and suppliers must be proactive in their efforts to comply with Medicare requirements. Thus, we do not believe that the commenter's contention constitutes grounds for withdrawing our proposed change to § 405.809.

Given these comments and the aforementioned discussion, we are finalizing our proposed CAP provisions without modification..

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

We also proposed to revise §§ 424.530(a)(5) and 424.535(a)(5). We stated in the proposed rule that the language in these two 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 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).

Accordingly, we proposed to revise § 424.530(a)(5) 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: (1) not operational to furnish Medicare-covered items or services; or (2) otherwise fails to satisfy

any Medicare enrollment requirements. Likewise, we proposed to revise § 424.535(a)(5) 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: (1) no longer operational to furnish Medicare-covered items or services; or (2) otherwise fails to satisfy any Medicare enrollment requirements.

We also proposed to add the phrase "or other reliable evidence" to § 424.535(a)(5) for two reasons. First, §424.530(a)(5) currently contains the "or other reliable evidence" standard, and we believe these two paragraphs (§424.530(a)(5) and §424.535(a)(5)) should have 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.

We received one comment regarding these proposed changes:

Comment: A commenter requested clarification of the term "other reliable evidence" as it is used in § 424.530(a)(5) and § 424.535(a)(5).

Response: The term means any credible evidence that demonstrates that the provider is not in compliance with Medicare requirements.

Given the foregoing, we are finalizing the proposed changes discussed in section II.B.9 of this final rule albeit with one very minor technical edit. The term "enrollment requirements" will be changed to "enrollment requirement" to clarify our original intention that the provider or supplier's non-compliance with any enrollment requirement can constitute grounds for revocation.

10. Technical Changes

We also proposed certain technical changes related to our provider and supplier

enrollment regulations.

In § 424.530(a)(1), we proposed 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 was 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 proposed 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 proposed to change the term "denials" to "revocations," as § 424.535 does not address denials.

Finally, § 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. Yet § 424.530(a)(10), rather than § 424.530(a)(9), applies to temporary moratoria. We proposed to correct § 498.5(l)(4) by changing the reference to § 424.530(a)(9) therein to § 424.530(a)(10).

We received no comments on these proposed technical changes. Therefore, we are finalizing these revisions without modification.

C. General and Other Comments

We also received a number of general comments regarding the proposed rule. A summary of these comments and our responses are as follows:

Comment: A commenter indicated general support for the changes in this rule that expand CMS's enrollment denial authority, for this would improve CMS's ability to detect new fraud schemes. However, the commenter expressed concern that CMS's anti-fraud efforts could inadvertently harm law-abiding physicians who unintentionally make a mistake during the enrollment process – a process, the commenter believed, that has become increasingly complicated. The commenter recommended that CMS continually evaluate PECOS and remove and identify unnecessary and outdated requirements.

Response: Although we are unclear as to the specific anti-fraud effort(s) or regulatory provision(s) of concern to the commenter, we are committed to ensuring that the enrollment process poses as minimal a burden as possible on those providers and suppliers that are conscientious about complying with Medicare requirements. We have taken steps in this direction, including – but not limited to – allowing providers and suppliers to complete CMS-855 applications via the Internet as opposed to requiring a paper application. We also, as the commenter suggested, regularly evaluate PECOS, our Program Integrity Manual instructions, and our regulations to determine whether improvements or revisions are necessary. We believe it is important and indeed necessary to strive to achieve an appropriate balance between ensuring the integrity of the Medicare Trust Funds and easing the burden on the provider and supplier communities.

Comment: A commenter recommended that CMS develop the systems and resources necessary to effectively implement our new provider enrollment requirements.

Response: We will ensure that the resources are available and the necessary systems changes are made to implement the provider enrollment requirements outlined in this rule.

Comment: A commenter suggested that CMS consider sharing with other payers (both public and private) information regarding actions taken against providers pursuant to our proposed provisions (for example, revocations under § 424.535(a)(8)(ii)). The commenter stated that such dissemination of data is critical to the prevention of fraud and abuse in our nation's health care system.

Response: We agree with the commenter that the exchange of information between medical payers is important to the prevention of health care fraud and abuse. CMS, is working to expand the exchange of information with other payers payers as evidenced by its initiative, the Healthcare Fraud Prevention Partnership.

Comment: A commenter stated that any final decision regarding the revocation of a provider's Medicare billing privileges should come from CMS Central Office rather than from the Medicare contractor.

Response: For reasons mentioned earlier, we agree.

Comment: A commenter expressed support for CMS's clarification that the re-enrollment bar does not apply if a revocation is based on the provider's failure to respond timely to a revalidation request or other request for information.

Response: We appreciate the commenter's support.

Comment: Several commenters stated that physicians need more information and education on common billing and coding mistakes and better guidance on how to avoid audits. The commenters recommended that CMS: (1) publicly release information on

frequent billing and coding errors, including aggregate statistics on such errors at a local (MAC level) and national level, as well as by specialty; (2) educate providers on these errors through existing educational channels (for instance, Open Door Forum calls and MedLearn Matters articles); (3) develop a dedicated web presence for publishing the aforementioned information and an associated CMS email list-serve to disseminate new data as it becomes public; (4) provide technical assistance for physician practices - primarily those with a high volume of coding and billing errors - on how to avoid these errors, perhaps through an expanded scope of work for Medicare's quality improvement organizations (QIOs); and (5) furnish additional guidance on the myriad of Medicare rules and regulations, which the commenter believes are often burdensome and confusing.

Response: We appreciate these suggestions and will continue, as necessary, to expand our outreach efforts to providers and suppliers regarding important coding and billing issues.

Comment: With respect to §§ 424.530(a)(1) and 424.535(a)(1), a commenter stated that CMS should make available to providers various information (for example, the supplier's error rates, enrollment file, and beneficiary complaints) that would enable providers to investigate and address potential deficiencies. Only through this vehicle can a provider confirm that it is in compliance with enrollment requirements and, if necessary, take corrective action.

Response: As we stated earlier in response to a similar comment, much of this information is either currently available to the provider or can be made available upon request. Still, providers must be proactive in establishing adequate internal controls to

ensure compliance with Medicare requirements; such compliance should not be contingent upon the provider first receiving substantial quantities of information from CMS.

Comment: A commenter stated that program integrity is best ensured when providers fully understand how to comply with complex Medicare requirements. The commenter thus urged CMS to issue final rules regarding the requirements of mandatory compliance programs (as outlined in the Affordable Care Act) as soon as possible. The commenter added that CMS should work with the OIG to update the current compliance guidance by working with industry stakeholders.

Response: We appreciate the commenter's concerns. However, the compliance plan provisions outlined in section 6401 of the Affordable Care Act are outside the scope of this rule.

Comment: A commenter stated that if CMS sees any provider or Medicare debt as a risk and plans to do everything possible to prevent unnecessary threats to Medicare beneficiaries and the Medicare Trust Funds, this gives CMS unrestrained discretion to deny enrollment or revoke billing privileges. The proposed rule, the commenter continued, does not focus on narrowly tailoring the approach to target fraud and abuse but instead seems geared towards reducing the total number of providers (including those not engaged in fraudulent or abusive actions) based on CMS's apparent belief that doing so will concomitantly reduce fraud and abuse.

Response: We have repeatedly stated in numerous forums and throughout this rule that the overwhelming majority of Medicare providers and suppliers submit claims that meet Medicare requirements. It is not CMS's overriding objective to reduce the total

number of Medicare providers and suppliers. Nonetheless, a small percentage of providers and suppliers are engaging in fraudulent, wasteful, inappropriate, or abusive activities. Our provider enrollment revisions are directed at such providers and suppliers, and we believe that removing them, as necessary, from the Medicare program will only serve to benefit Medicare beneficiaries, the Trust Funds, the taxpayers, and the hundreds of thousands of legitimate Medicare providers and suppliers that have proven to be reliable partners of the program.

Comment: A commenter expressed concern that the proposed rule would give CMS's contractors unprecedented discretion to revoke Medicare billing privileges. The commenter also stated that CMS must clearly articulate the appeal rights that providers have in revocation cases.

Response: As stated previously, a MAC must receive prior CMS approval before revoking a provider's Medicare billing privileges. With respect to appeal rights in revocation cases, these are outlined in 42 CFR part 498 and in CMS Publication 100-08, chapter 15.

Comment: A commenter supported the proposed rule's intent to reduce the time necessary to institute a recovery of Medicare funds for a provider who has submitted bad or faulty billings.

Response: We appreciate the commenter's support for our anti-fraud efforts.

Comment: A commenter urged CMS to amend its opt-out policy to allow physicians to opt-out of the Medicare program without a requirement to reaffirm the opt-out. After the 2-year minimum required by law, the commenter explained, the opt-out period should be effective indefinitely unless and until the physician chooses to

terminate his or her opt-out status and private contracts with patients in order to rejoin Medicare as a participating or non-participating physician.

Response: This comment is outside the scope of this rule.

Comment: A commenter questioned why Medicaid was excluded from the scope of our proposed rule.

Response: We have chosen to address only Medicare enrollment in this rule, though Medicaid enrollment may be addressed in the future.

III. Provisions of the Final Rule

A. Incentive Reward Program

In light of the complexity of the operational aspects of our proposal, we are not finalizing our proposed IRP provisions in this rule. We may finalize them in future rulemaking.

B. Enrollment Provisions

Based on public comments, we are finalizing our proposed provider enrollment provisions with the following revisions:

- In § 424.502, we are modifying paragraph (2) of the definition of "Enroll/Enrollment" to read as follows: Except for those suppliers who complete the CMS-8550 form, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services, validating the provider or supplier's eligibility to provide items or services to Medicare beneficiaries.
- In § 424.510, we are redesignating the first two sentences of existing paragraph (a) as new paragraph (a)(1).

++Revising the third sentence of existing paragraph (a) and redesignating as new paragraph (a)(2). The new paragraph (a)(2) will state the following: To be enrolled to furnish Medicare-covered items and services, a provider or supplier must meet the requirements specified in paragraphs (d) and (e) of this section.

++ Adding a new paragraph (a)(3) that states the following: To be enrolled solely to order and certify Medicare items or services, a physician or non-physician practitioner must meet the requirements specified in paragraph (d) of this section except for paragraphs (2)(iii)(B), (2)(iv), (3)(ii), (5), (6), and (9).

- In § 424.521, we are revising paragraph (a) to include ambulance suppliers.

- In § 424.530 we are making the following revisions:

- ++ Revising § 424.530(a)(3).

- ++ In § 424.530(a)(5), we are changing "requirements" to "requirement."

- Paragraph (a)(6)(ii)(A) we are revising the sentence to state that the owner left the provider or supplier with the Medicare debt within 1 year before or after that provider or supplier's voluntary termination, involuntary termination or revocation.

- In paragraph (a)(6)(ii)(C)--

- Adding additional language to the introductory text, a second sentence that reads: In making this determination, we consider the following factors.

- Adding new paragraphs (a)(6)(ii)(C)(1) through (5)

- In § 424.530(a)(6)(iii), we are making the following changes:

- Combining proposed paragraphs (A) and (B)(1)

- Redesignating proposed paragraph (a)(6)(iii) as new paragraph (B)(2).

- In § 424.535 we are making the following revisions:

++ Revising paragraph (a)(3).

++ In § 424.535(a)(5), we are changing "requirements" to "requirement."

++ Adding paragraphs A through F to paragraph (a)(8)(ii).

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding the Definition of Enrollment (§ 424.502, § 424.505, and § 424.510)

Our revisions to § 424.502, § 424.505, and § 424.510 reflect the existing usage of the CMS-8550 (OMB Approval number 0938-0685) and, as such, will not impose any additional information collection 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 OMB at that time approved the information collection burden associated with its use. The CMS-855O is approved under OMB control number 0938-1135 and expires August 31, 2015.

B. ICRs Regarding the Debts to Medicare (§ 424.530(a)(6))

Our revisions to § 424.530(a)(6) will likely result in an increase in application denials. While these revisions will 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 possible denials because we do not have data available that can support such an estimate. Accordingly, we cannot project the potential information collection burden that could arise from an increased number of: (1) appeals of denials; or (2) resubmitted enrollment applications from the denied providers and suppliers.

C. ICRs Regarding the Felony Convictions (§§ 424.530(a)(3) and 424.535(a)(3))

Although our revisions to §§ 424.530(a)(3) and 424.535(a)(3) do not directly impose paperwork burdens, they will likely result in an increase in application denials and revocations, respectively. Yet we cannot estimate the potential increase in denials and revocations based on these changes, for we do not have data available that can support such an estimate. Therefore, we are unable to project the potential information collection burden that may result from an increased number of appeals of denials and revocations.

D. ICRs Regarding the Abuse of Billing Privileges (§ 424.535(a)(8)(ii))

Our addition of § 424.535(a)(8)(ii) will likely lead to an increase in the

information collection burden because there will 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 help us make such an estimate, for each situation will have to be reviewed and addressed on a case-by-case basis.

E. ICRs Regarding the Post-Revocation Submission of Claims (§ 424.535(h))

We do not believe that our revisions to § 424.535(h) will result in a change in the information collection burden. While the claims in question will need to be submitted within a shorter timeframe (60 days), they will likely be submitted regardless of the applicable submission period. The shorter timeframe will, in general, neither increase nor decrease the number of claims submitted.

F. ICRs Regarding the Effective Date of Billing Privileges (§ 424.520(d))

Our revisions to § 424.520(d) will most likely result in a decrease in the information collection burden because fewer claims will be eligible for submission under this change. Yet we are unable to project the extent of the decrease in the number of claims because we do not have data available to support such an estimate. Therefore, we cannot estimate the decrease in the information collection burden.

G. ICRs Regarding the Effective Date of Re-enrollment Bar (§ 424.535(c))

We believe that our revisions to § 424.535(c) will neither increase nor decrease the information collection burden. With or without this revision, the provider will still need to submit the applicable CMS-855 application (based on the provider or supplier type involved) after the expiration of the re-enrollment bar in order to enroll again in Medicare.

H. ICRs Regarding the Corrective Action Plans (§ 405.809)

Our revisions to § 405.809 will result in a decrease in the information collection burden because there will be a reduction in the number of CAPs submitted. However, we are unable to project the extent of the decrease in submitted CAPs because we do not have sufficient data to support such an estimate.

I. ICRs Regarding the Revisions to § 424.530(a)(5) and § 424.535(a)(5)

Our revisions to §§ 424.530(a)(5) and 424.535(a)(5) will not result in a change to the information collection burden, for we do not believe there will be any change in the number of denials or revocations, respectively. We note that § 424.530(a)(5) already permits revocation based upon a site review "or other reliable evidence." Thus, we do not foresee any 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), 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. Therefore, the authority to revoke based on reliable evidence of non-compliance is largely similar to the reasons for revocation stated in § 424.535(a)(1). Hence, we do not believe there will be any change in the number of: (1) appeals of revocations; or (2) resubmitted enrollment applications from revoked providers and suppliers.

The aforementioned burden projections for our provider enrollment revisions are identical to those we proposed and on which we solicited comments. We received no comments on these estimates.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to make important revisions to certain Medicare provider enrollment requirements in order to strengthen our program integrity efforts and to help ensure that fraudulent parties neither enroll in nor maintain their enrollment in the Medicare program.

B. Overview

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 explained in more detail later in this section, we encountered several uncertainties in estimating the economic impact of many of our final provisions. We could not estimate the number of denials and revocations that might stem from the

finalized 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 finalized revisions. However, we estimate that our change to § 424.520(d) will 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 for 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 below Small Business Administration thresholds that range from \$7 million and \$35.5 million per year. Individuals and states are not included in the definition of a small entity.

As we stated in the proposed rule, several provisions will have at least some effect on certain small entities. These include: (1) the changes at § 424.520(d) to the effective date of billing privileges for ambulance suppliers; (2) the changes at § 424.530(a)(6) regarding Medicare debt; (3) the addition of § 424.535(a)(8)(ii) concerning patterns or practices of non-compliant claim submissions; (4) the revision of § 424.535(h) regarding the submission of claims after revocation; and (5) the revision of § 405.809 concerning the reinstatement of provider or supplier billing privileges following corrective action. Yet as discussed later in this section, we do not believe that this final rule will have a significant economic impact on a substantial number of small entities.

Section 424.520(d), which changes the effective date of billing privileges for

ambulance suppliers, will 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 will not 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), will not occur until after a 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 anticipate an increase in some denials and revocations under these two provisions, we do not believe they will impact a substantial number of small entities.

Our revisions to § 424.535(h) will 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 will likely be submitted regardless of the shorter submission period.

Our revisions to § 405.809 will impact the ability of some small entities to submit CAPs in response to a revocation. However, these entities will still be able to file a request for reconsideration. The overall effect of this change will thus 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 will not be

affected by most of the provisions in this 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 604 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 final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (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 2014, this is approximately \$141 million. We believe that this final rule will 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

We indicated in section IV. of this final rule that there may be an ICR burden associated with several of our provider enrollment provisions but that the burden cannot be estimated. The following sections discuss other potential costs – as well as savings – associated with our enrollment changes.

1. Definition of Enrollment

As stated earlier, use of the CMS-855O commenced in July 2011. Our revisions to §§ 424.502, 424.505, and 424.510 are intended to clarify that the CMS-855O does not convey billing privileges. As such, these changes will not result in any additional costs or savings.

2. Debts to Medicare

Our revisions to § 424.530(a)(6) will likely result in additional application denials. Yet we are unable to estimate the number of potential denials because we do not have data available to support such an estimate. Therefore, we cannot project any costs in possible lost billings to providers and suppliers or any associated potential savings to the government.

While there may be an increase in costs to the federal government from identifying and making available to enrollment contractors information about individuals that were associated with a revoked entity with an unpaid Medicare debt, we are unable to estimate the magnitude of any such increase. We also anticipate that an increase in costs will be offset by savings to the government -- (1) in preventing billing by such providers and suppliers, and (2) the repayment of debt by these providers and suppliers.

3. Felony Convictions

As stated in section IV.B. of this final rule, our revisions to § 424.530(a)(3) and

§ 424.535(a)(3) will likely result in additional application denials and revocations, respectively. However, we are unable to estimate the potential increase in denials and revocations and associated appeals, for we do not have sufficient information to support such a projection. Thus, we cannot project the potential costs to providers and suppliers in lost billings or the potential costs or savings to the government arising from these revisions.

4. Abuse of Billing Privileges

Our addition of § 424.535(a)(8)(ii) will likely result in an increase in revocations. Yet we are unable to project the number of providers and suppliers that might be revoked based on this change because we do not have data available to help us make such an estimate. Thus, we cannot forecast the potential costs to providers and suppliers in lost billings or the possible costs or savings to the government arising from this provision. .

5. Post-Revocation Submission of Claims

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

6. Effective Date of Billing Privileges

The revisions 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 will 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 revisions, these suppliers could lose up to 10 months in potential Medicare billings for services furnished prior to the later of the two events cited in § 424.520(d).

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 x 1,127) in savings to the federal government could accrue as a result of this change.

We emphasize that our \$545.7 million estimate is a high-end estimate. There may be new ambulance suppliers that, absent our change to § 424.520(d), 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 x 3/12 x 1,127). If the average figure is 6 months, our projection 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) prior to enrollment. Therefore, we will use these three timeframes as, respectively, high-end, primary, and low-end estimates in the accounting statement.

7. Effective Date of Re-enrollment Bar

Our revisions to § 424.535(c) will result in a longer re-enrollment bar than that which currently exists in cases where 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 re-enroll in Medicare may result in lost billings to the provider or supplier. This may also lead to savings to the government because a provider or supplier that may have been billing Medicare will not be eligible to do so as soon as would otherwise be the case. However, we are unable to project the possible costs to providers and suppliers or the savings to the federal government because we do not have data available to support such estimates. We also cannot estimate: (1) how many providers and suppliers will be affected by this proposed change; or (2) the specific types of providers and suppliers that will be affected.

8. Corrective Action Plans

Our revisions to § 405.809 will result in a reduction in the number of CAPs submitted, as noted in the ICR. This may result in lost billings to the provider or supplier in cases where CMS' acceptance of a CAP has occurred 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 will probably 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 will impact; or (2) the specific types of providers and suppliers that will be affected.

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

We stated earlier that we do not believe there will be any change in the total number of denials or revocations based on our revisions to §§ 424.530(a)(5) and 424.535(a)(5). Therefore, we do not anticipate any resultant change in overall costs or savings.

10. Technical Changes

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

D. Comments Received and Conclusion

While we were unable – and remain unable - to furnish detailed cost and savings estimates for many of our enrollment revisions, we solicited comments from the public regarding their views as to the potential burdens and costs of our proposals as well as the possible savings. We received several comments, which are summarized and accompanied by our responses as follows:

Comment: With respect to our savings estimates for the proposed change to § 424.520(d), a few commenters believed that our projections were inflated and that actual data (as opposed to estimates) should be used. One of the commenters suggested that CMS use data regarding Medicare payments made for services furnished prior to the submission of the CMS-855B. The other commenter recommended that CMS calculate the actual payments made to new ambulance suppliers after January 1, 2011, for this is the date on which CMS began limiting payments to suppliers to 12 months from the date of service per § 424.520(d).

Response: We indeed based our estimates on actual data – specifically, the actual

average amount of payments a Medicare-enrolled ambulance supplier receives per year. As we indicated in the proposed rule, we cannot predict the number of ambulance suppliers that would have met CMS's requirements at various points (for example, 3 months; 10 months) prior to enrollment. Therefore, we can only furnish high-end, primary, and low-end estimates. Despite the commenters' request for greater monetary specificity, we believe that our estimates are reasonable.

Comment: A commenter expressed concern that CMS did not furnish more detailed monetary estimates of the rule's potential impact on providers and beneficiaries.

Response: As we explained in both sections III. and IV. of the proposed rule, we were unable to formulate detailed workload, cost, or savings projections for many of our provisions because-- (1) the necessary background data were not available; and (2) future behavior often cannot be predicted. Thus, we solicited feedback from the public that could perhaps assist us in developing quantifiable, numerical estimates, though we received very few comments in response to our request. Therefore, we are finalizing our proposed projections while reiterating our inability to develop estimates with respect to other provisions.

In light of these comments, we are finalizing the estimates as previously outlined.

E. 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 IV.C.2.f. of this final rule and involving our change to § 424.520(d).

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 previously discussed that may result in a cost or savings that nevertheless cannot be estimated.

**TABLE 2: ACCOUNTING STATEMENT AND TABLE
(IN MILLIONS)**

Category	Primary Estimates	Low Estimates	High Estimates	Year Dollars	Discount Rate	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					

* Rounded to the nearest hundred-thousandth.

F. Alternatives Considered

As stated, our provider enrollment provisions are needed to help ensure that fraudulent parties do not enroll in or 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 and finalize 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 scope of § 424.520(d) to include all certified providers and certified suppliers. Yet as we explained previously, there already: (1) is an exhaustive and extensive review process for certified providers and certified suppliers, and (2) 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 affords providers and suppliers adequate due process rights. In the interests of fairness and efficiency, we elected to retain the CAP process for revocations based on § 424.535(a)(1). We believe this will continue to give certain providers and suppliers an additional opportunity to remedy inadvertent or minor errors without subjecting all parties to the lengthier appeals process, although we continue to believe that eliminating the CAP process for all other revocation reasons is warranted.

G. Impact on Beneficiary Access

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

In accordance with the provisions of Executive Order 12866, this final 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 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 of this final rule, the Centers for Medicare & Medicaid Services amends 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 only submit a corrective action plan for a revocation 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 424—CONDITIONS FOR MEDICARE PAYMENT

3. 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).

4. In § 424.502, the definition of "Enroll/Enrollment" is amended by revising the

introductory text and paragraphs (2) and (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--

* * * * *

(2) Except for those suppliers that complete the CMS-8550 form, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services, validating the provider or supplier's eligibility to provide items or services to Medicare beneficiaries;

* * * * *

(4) Except for those suppliers that complete the CMS-8550 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]

5. 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-8550 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".

6. Section 424.510 is amended by revising paragraph (a) to read as follows:

§424.510 Requirements for enrolling in the Medicare program.

(a)(1) Providers and suppliers must submit enrollment information on the applicable enrollment application. Once the provider or supplier successfully completes the enrollment process, including, if applicable, a State survey and certification or accreditation process, CMS enrolls the provider or supplier into the Medicare program.

(2) To be enrolled to furnish Medicare-covered items and services, a provider or supplier must meet the requirements specified in paragraphs (d) and (e) of this section.

(3) To be enrolled solely to order and certify Medicare items or services, a physician or non-physician practitioner must meet the requirements specified in paragraph (d) of this section except for paragraphs (d)(2)(iii)(B), (d)(2)(iv), (d)(3)(ii), and (d)(5), (6), and (9) of this section.

* * * * *

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

§ 424.520 Effective date of Medicare billing privileges.

* * * * *

(d) Physicians, non-physician practitioners, physician and non-physician practitioner organizations, and ambulance suppliers. The effective date for billing privileges for physicians, non-physician practitioners, physician and non-physician 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.

8. Section 424.521 is revised to read as follows:

§ 424.521 Request for payment by physicians, non-physician practitioners, physician and non-physician organizations, and ambulance suppliers.

(a) Physicians, non-physician practitioners, physician and non-physician practitioner organizations, and ambulance suppliers may retrospectively bill for services when the physician, non-physician practitioner, physician or non-physician organization, and ambulance supplier has met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to--

(1) Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or

(2) Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

(b) [Reserved]

9. Section 424.530 is amended by revising paragraphs (a)(1), (a)(3) introductory text and (a)(3)(i), and (a)(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 determines is detrimental to the best interests of the Medicare program and its beneficiaries.

(i) Offenses include, but are not limited in scope or severity to--

(A) 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.

(B) 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.

(C) 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.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

* * * * *

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

(i) Is not operational to furnish Medicare-covered items or services; or

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

(6) Medicare debt. (i) The enrolling provider, supplier, or owner thereof (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 with the Medicare debt within 1 year before or after 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. In making this determination, CMS considers the following factors:

(1) The amount of the Medicare debt.

(2) The length and timeframe that the enrolling provider, supplier, or owner thereof was an owner of the prior entity.

(3) The percentage of the enrolling provider, supplier, or owner's ownership of the prior entity.

(4) Whether the Medicare debt is currently being appealed.

(5) Whether the enrolling provider, supplier, or owner thereof was an owner of the prior entity at the time the Medicare debt was incurred.

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

(A)(1) Satisfies the criteria set forth in § 401.607; and

(2) Agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt.

(B) Repays the debt in full.

* * * * *

10. Section 424.535 is amended by revising paragraphs (a)(1) introductory text, (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 to not 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 determines is detrimental to the best interests of the Medicare program and its beneficiaries.

(ii) Offenses include, but are not limited in scope or severity to—

(A) 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.

(B) 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.

(C) 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.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(iii) 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 requirement.

* * * * *

(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 that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following:

(A) The percentage of submitted claims that were denied.

(B) The reason(s) for the claim denials.

(C) Whether the provider or supplier has any history of final adverse actions (as that term is defined under § 424.502) and the nature of any such actions.

(D) The length of time over which the pattern has continued.

(E) How long the provider or supplier has been enrolled in Medicare.

(F) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination as to whether the provider or supplier has or has not engaged in the pattern or practice described in this paragraph.

* * * * *

(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**

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

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7j, and 1395hh).

§ 498.5 [Amended]

12. 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 8, 2014

Marilyn Tavenner,

Administrator,
Centers for Medicare & Medicaid Services.

Approved: November 20, 2014

Sylvia M. Burwell,

Secretary,
Department of Health and Human Services

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