

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 424, 455, and 457

[CMS-6058-P]

RIN 0938-AS84

Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement sections of the Affordable Care Act that require Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers to disclose certain current and previous affiliations with other providers and suppliers. This proposed rule would also provide CMS with additional authority to deny or revoke a provider's or supplier's Medicare enrollment. In addition, this proposed rule would require that to order, certify, refer or prescribe any Part A or B service, item or drug, a physician or, when permitted, an eligible professional must be enrolled in Medicare in an approved status or have validly opted-out of the Medicare program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 25, 2016.

ADDRESSES: In commenting, please refer to file code CMS-6058-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6058-P, P.O. Box 8013, Baltimore, MD 21244-8013.

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

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for

Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6058-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

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

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

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

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT: Frank Whelan, (410) 786-1302.

SUPPLEMENTARY INFORMATION:

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

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid

Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Need for Regulatory Action

This proposed rule would implement a provision of the Affordable Care Act that requires Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers to disclose any current or previous direct or indirect affiliation with a provider or supplier that—(1) has uncollected debt; (2) has been or is subject to a payment suspension under a federal health care program; (3) has been excluded from Medicare, Medicaid or CHIP; or (4) has had its Medicare, Medicaid or CHIP billing privileges denied or revoked. This provision permits the Secretary to deny enrollment based on affiliations that the Secretary determines pose an undue risk of fraud, waste or abuse. Also, this proposed rule would revise various provider enrollment provisions in 42 CFR part 424, subpart P.

As discussed in greater detail in section II of this rule, our proposed provisions are necessary to address various program integrity issues and vulnerabilities that require regulatory action. We believe that our proposals would help make certain that entities and individuals who pose risks to the Medicare program are removed from and kept out of Medicare for extended periods of time; in particular, the rule would crack down on providers and suppliers who attempt to circumvent Medicare requirements through name and identity changes as well as through elaborate, inter-provider relationships. In short, the rule would enable us to take action against unqualified and potentially fraudulent entities and individuals, which in turn could deter other parties from engaging in improper behavior.

The following are the five principal legal authorities for our proposed provisions:

- Sections 1102 and 1871 of the Social Security Act (the Act), which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1866(j) of the Act, which provides specific authority with respect to the enrollment process for providers and suppliers.

- Section 1866(j)(5) of the Act, as amended by section 6401(a)(3) of the Affordable Care Act, which states that a provider or supplier that submits a Medicare, Medicaid or CHIP application for enrollment or a revalidation application must disclose any current or previous affiliation (direct or indirect) with a provider or supplier that—(1) has uncollected debt; (2) has been or is subject to a payment suspension under a federal health care program; (3) has been excluded from participation in Medicare, Medicaid or CHIP; or (4) has had its billing privileges denied or revoked, and permits the Secretary to deny enrollment based on affiliations that the Secretary determines pose an undue risk of fraud, waste or abuse.

- Section 1902(kk)(3) of the Act,¹ as amended by section 6401(b) of the Affordable Care Act, which mandates that states require providers and suppliers to comply with the same disclosure requirements established by the Secretary under section 1866(j)(5) of the Act.²

- Section 2107(e)(1) of the Act, as amended by section 6401(c) of the Affordable Care Act, which makes the requirements of section 1902(kk) of the Act, including the disclosure requirements, applicable to CHIP.

2. Summary of the Major Provisions

The major provisions in this proposed rule would do the following:

- Implement a provision of the Affordable Care Act that requires certain Medicare, Medicaid, and CHIP providers and suppliers to disclose if a provider or supplier has any current or previous direct or indirect affiliation with a provider or supplier that has uncollected debt; has been or is subject to a payment suspension under a federal health care program; has been excluded from Medicare, Medicaid or CHIP; or has had its Medicare, Medicaid or CHIP billing privileges denied or revoked, and that permits the Secretary to deny enrollment based on an affiliation that

the Secretary determines pose an undue risk of fraud, waste or abuse.

- + Describe the terms “affiliation”, “disclosable event,” “uncollected debt,” and “undue risk” as they pertain to this Affordable Care Act provision.

- Provide CMS with the authority to do the following:

- ++ Deny or revoke a provider’s or supplier’s Medicare enrollment if CMS determines that the provider or supplier is currently revoked under a different name, numerical identifier or business identity, and the applicable reenrollment bar period has not expired.

- ++ Revoke a provider’s or supplier’s Medicare enrollment—including all of the provider’s or supplier’s practice locations, regardless of whether they are part of the same enrollment—if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements.

- ++ Revoke a physician’s or eligible professional’s Medicare enrollment if he or she has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries or otherwise fails to meet Medicare requirements.

- ++ Increase the maximum reenrollment bar from 3 to 10 years, with exceptions.

- ++ Prohibit a provider or supplier from enrolling in the Medicare program for up to 3 years if its enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to gain enrollment in the Medicare program.

- ++ Revoke a provider’s or supplier’s Medicare enrollment if the provider or supplier has an existing debt that CMS refers to the United States Department of Treasury.

- ++ Require that to order, certify, refer or prescribe any Part A or B service, item or drug, a physician or, when permitted under state law, an eligible professional must be enrolled in Medicare in an approved status or have validly opted-out of the Medicare program. Also, the provider or supplier furnishing the Part A or B service, item or drug, as well as the physician or eligible professional who ordered, certified, referred or prescribed the service, item or drug, would have to maintain documentation for 7 years from the date of the service and furnish access to that documentation upon a CMS or Medicare contractor request.

- ++ Deny a provider’s or supplier’s Medicare enrollment application if—(1) the provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a particular state Medicaid program or any other federal health care program; or (2) the provider’s or supplier’s license is currently revoked or suspended in a state other than that in which the provider or supplier is enrolling.

3. Summary of Costs and Benefits

As explained in greater detail in sections III. and V. of this proposed rule, we estimate an average annual cost to providers and suppliers of \$289.8 million in each of the first 3 years of this rule. This cost involves the information collection burden associated with the following proposals:

- The requirement that Medicare, Medicaid and CHIP providers and suppliers disclose certain current and prior affiliations.

- The requirement that a physician or, when permitted under state law, an eligible professional, be enrolled in Medicare in an approved status or have opted-out of the Medicare program to order, certify, refer or prescribe a Part A or B service, item or drug.

Other potential costs which we are unable to calculate are discussed in sections III. and V. of this proposed rule.

We believe there would be benefits, although unquantifiable, associated with this rule, because problematic providers would be kept out of or removed from Medicare, Medicaid, and CHIP, thus saving program dollars.

B. General Overview

1. Medicare

The Medicare program (title XVIII of the Act) is the primary payer of health care for approximately 54 million enrolled beneficiaries. Under section 1802 of the Act, a beneficiary may obtain health services from an individual or an organization qualified to participate in the Medicare program. Qualifications to participate are specified in statute and in regulations (see, for example, sections 1814, 1815, 1819, 1833, 1834, 1842, 1861, 1866, and 1891 of the Act; and 42 CFR chapter IV, subchapter G of the regulations, which concerns standards and certification requirements).

Providers and suppliers furnishing services must comply with the Medicare requirements stipulated in the Act and in our regulations. These requirements are meant to confirm compliance with applicable statutes, as well as to promote the furnishing of high quality care. As Medicare program expenditures

¹ Because section 6401(b) of the Affordable Care Act erroneously added a duplicate section 1902(ii) of the Act, the Congress enacted a technical correction in the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) to redesignate section 1902(ii) of the Act as section 1902(kk) of the Act, a designation we will use in this proposed rule.

² Section 1304 of the Health Care and Education Reconciliation Act (Pub. L. 111–152) added a new paragraph (j)(4) to section 1866 of the Act, thus redesignating the subsequent paragraphs. Accordingly, we are interpreting the reference in section 1902(kk)(3) of the Act to “disclosure requirements established by the Secretary under section 1866(j)(4)” of the Act to mean the disclosure requirements described in section 1866(j)(5) of the Act.

have grown, we have increased our efforts to make certain that only qualified individuals and organizations are allowed to enroll in and maintain their enrollment in Medicare.

2. Medicaid and CHIP

The Medicaid program (title XIX of the Act) is a joint federal and state health care program that covers nearly 70 million low-income individuals. States have considerable flexibility in how they administer their Medicaid programs within a broad federal framework, and programs vary from state to state. CHIP (title XXI of the Act) is a joint federal and state health care program that provides health care coverage to more than 7.7 million children. In operating Medicaid and CHIP, states historically have permitted the enrollment of providers who meet the state requirements for program enrollment as well as any applicable federal requirements (such as those in 42 CFR part 455).

C. General Background on the Enrollment Process

1. The 2006 Provider Enrollment Final Rule

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 certain requirements in 42 CFR part 424, subpart P that providers and suppliers must meet in order to obtain and maintain Medicare billing privileges. We cited in that rule 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.

2. The 2011 Provider Enrollment Final Rule

In the February 2, 2011 **Federal Register** (76 FR 5861), we published a final rule with comment period titled, “Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers.” This final rule implemented various Affordable Care Act provisions, including the following:

- Submission of application fees by institutional providers and suppliers as part of the Medicare, Medicaid, and CHIP provider enrollment processes.
- Establishment of Medicare, Medicaid, and CHIP provider

enrollment screening categories and corresponding screening requirements.

- Imposition of temporary moratoria on the enrollment of new Medicare, Medicaid, and CHIP providers and suppliers of a particular type (or the establishment of new practice locations of a particular type) in a geographic area.

3. Form CMS–855—Medicare Enrollment Application

Under § 424.510, a provider or supplier must complete, sign, and submit to its assigned Medicare contractor the appropriate Form CMS–855 (OMB Control No. 0938–0685) application in order to enroll in the Medicare program and obtain Medicare billing privileges. The Form CMS–855, which can be submitted via paper or electronically through the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process, captures information about the provider or supplier that is needed for CMS or its contractors to determine whether the provider or supplier meets all Medicare requirements. The enrollment process helps ensure that unqualified and potentially fraudulent individuals and entities do not bill Medicare and that the Medicare Trust Funds are accordingly protected. Data collected during the enrollment process include, but are not limited to—(1) general identifying information (for example, legal business name, tax identification number); (2) licensure data; (3) practice locations; and (4) information regarding the provider’s or supplier’s owning and managing individuals and organizations. The application is used for a variety of provider enrollment transactions, including the following:

- Initial enrollment—The provider or supplier is—(1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor’s jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled.
- Change of ownership—The provider or supplier is reporting a change in its ownership.
- Revalidation—The provider or supplier is revalidating its Medicare enrollment information in accordance with § 424.515.
- Reactivation—The provider or supplier is seeking to reactivate its Medicare billing privileges after it was deactivated in accordance with § 424.540.
- Change of information—The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

Besides the aforementioned 2006 and 2011 final rules, we have made several other regulatory changes to 42 CFR part 424, subpart P to address various payment safeguard issues that have arisen.

D. Statutory Background on Medicare Requirements for Physicians and Eligible Professionals Who Order or Certify Services or Items

The Affordable Care Act addressed the problem of certain Medicare services and items being ordered or certified by physicians or eligible professionals (as the latter term is defined in section 1848(k)(3)(B) of the Act) who may not be qualified to do so. The Affordable Care Act included the following provisions:

- Section 6405(a) of the Affordable Care Act amended section 1834(a)(11)(B) of the Act to specify, with respect to DME suppliers, that payment may be made under section 1834(a)(11)(B) of the Act only if the written order for the item has been communicated to the DMEPOS supplier by a physician or eligible professional who is enrolled under section 1866(j) of the Act before delivery of the item.
- Section 6405(b) of the Affordable Care Act, as amended by section 10604 of the Affordable Care Act, amended sections 1814(a)(2) and 1835(a)(2) of the Act and specifies, with respect to Part A home health services, that payment may be made to providers of services if they are eligible and only if a physician enrolled under section 1866(j) of the Act certifies (and recertifies, as required) that the services are or were required in accordance with section 1814(a)(1)(C) of the Act. Section 1835(a)(2) of the Act specifies, with respect to Part B home health services, that payments may be made to providers of services if they are eligible and only if a physician enrolled under section 1866(j) of the Act certifies (and recertifies, as required) that the services are or were medically required in accordance with section 1835(a)(1)(B) of the Act.
- Section 6405(c) of the Affordable Care Act gives the Secretary the authority to extend the requirements of subsections (a) and (b) to all other categories of items or services under title XVIII of the Act, including covered Part D drugs as defined in section 1860D–2(e) of the Act, that are ordered, prescribed or referred by a physician or eligible professional enrolled under section 1866(j) of the Act.

In addition, section 6406(b)(3) of the Affordable Care Act amended section 1866(a)(1) of the Act to require that providers maintain and, upon request, provide to the Secretary, access to

written or electronic documentation relating to written orders or requests for payment for DME, certifications for home health services or referrals for other items or services written or ordered by the provider as specified by the Secretary. Under section 6406(a) of the Affordable Care Act, which amended section 1842(h) of the Act, the Secretary may revoke a physician's or supplier's enrollment if the physician or supplier fails to adhere to these requirements. .

E. Background on Disclosure of Affiliations for Medicare, Medicaid, and CHIP (Section 1866(j)(5) of the Act)

As previously mentioned, providers and suppliers must complete and submit (via paper or through Internet-based PECOS) a Form CMS-855 application to their Medicare contractor in order to enroll or revalidate their enrollment in the Medicare program. The Form CMS-855 requires the provider or supplier to disclose certain information, such as general identifying data (for example, legal business name), the provider's or supplier's practice locations, and the provider's or supplier's owning and managing employees and organizations.

In operating Medicaid and CHIP, states may have somewhat different enrollment processes, although all states must comply with the federal requirements in 42 CFR part 455, subparts B and E. Under 42 CFR part 455, subpart B, providers and disclosing entities must furnish disclosures regarding ownership and control of the provider or supplier entity, certain business transactions, and criminal convictions related to federal health care programs. States must also comply with their individual medical programs and procurement laws and rules, which may include additional provider or supplier disclosures.

Section 6401(a)(3) of the Affordable Care Act, which amended section 1866(j) of the Act to add new paragraph (5), states that a provider or supplier that submits an enrollment application or a revalidation application shall disclose (in a form and manner and at such time as determined by the Secretary) any current or previous affiliation (directly or indirectly) with a provider or supplier that has uncollected debt; has been or is subject to a payment suspension under a federal health care program (as defined in section 1128B(f) of the Act); has been excluded from participation from Medicare, Medicaid or CHIP; or has had its billing privileges denied or revoked. The Secretary may deny an application under section 1866(j)(5)(B) of the Act if

the Secretary determines that the affiliation poses an undue risk of fraud, waste or abuse.

We mentioned earlier that section 6401(b) of the Affordable Care Act added a new section 1902(kk)(3) to the Act, mandating that states require providers and suppliers to comply with the same disclosure requirements established by the Secretary under section 1866(j)(5) of the Act. Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to make the requirements of section 1902(kk) of the Act, including the disclosure requirements, applicable to CHIP.

II. Provisions of the Proposed Regulations

A. Disclosure of Affiliations

We propose to carry out the legislative mandate of section 1866(j)(5) of the Act as previously discussed in section I.A. of this proposed rule.

Consistent with the text of section 1866(j)(5) of the Act, we believe that implementing these disclosure provisions would help combat fraud, waste, and abuse by enabling CMS and the states to: (1) Better track current and past relationships between and among different providers and suppliers; and (2) identify and take action on affiliations among providers and suppliers that pose an undue risk to Medicare, Medicaid, and CHIP. While the Form CMS-855 captures information on parties that have ownership or managerial interests in the enrolling or enrolled provider or supplier, it does not collect data about prior affiliations or about entities in which the provider or supplier (or its owning or managing individuals or organizations) has or had an interest. We believe that our knowledge of these affiliations and interests would greatly assist our program integrity efforts, for such data could reveal inter-provider schemes involving inappropriate behavior and lead to the denial or revocation of enrollment.

In November 2008, the Department of Health and Human Services Office of Inspector General (OIG) issued an Early Alert Memorandum titled "Payments to Medicare Suppliers and Home Health Agencies Associated with 'Currently Not Collectible' Overpayments" (OEI-06-07-00080). The memorandum stated that anecdotal information from OIG investigators and Assistant United States Attorneys indicated that DMEPOS suppliers with outstanding Medicare debts may inappropriately receive Medicare payments by, among other means, operating businesses that

are publicly fronted by business associates, family members or other individuals posing as owners. 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. The OIG found that 6 of the 10 reviewed DMEPOS suppliers were associated with 15 other DMEPOS suppliers or home health agencies (HHAs) that received Medicare payments totaling \$58 million during 2002 through 2007. Most associated DMEPOS suppliers had lost billing privileges by January 2005 and had accumulated a total of \$6.2 million of their own CNC debt to Medicare. The OIG also found that most of the reviewed DMEPOS suppliers were connected to other DMEPOS suppliers and HHAs through shared owners or managers.

On March 2, 2011, the OIG testified before the Congress that fraud schemes in South Florida often rely on the use of networks of affiliations among fraudulent owners.³ In those schemes, Medicare providers and suppliers disguise true ownership by the use of nominee owners in order to bill Medicare fraudulently on a temporary basis in order to evade detection. Providers and suppliers will—(1) hide their true ownership through the use of nominee owners; (2) bill the Medicare program for millions of dollars; and (3) close down and then take over another company, and then repeat the process in another location. In addition to OIG reports, our experience has found that networks of individuals and entities can be behind widespread fraud schemes; in some instances, shared owners were behind multiple providers and suppliers engaging in improper billings.

We have long shared these and other concerns the OIG has expressed regarding individuals and entities that enroll in Medicare (or own or operate Medicare providers or suppliers), accumulate large debts or otherwise engage in inappropriate activities, and depart the Medicare program voluntarily or involuntarily, yet continue their behavior by—(1) reentering the program in some capacity (for instance, as an owner); and/or (2) shifting their activities to another enrolled Medicare provider or supplier with which they are affiliated. To illustrate, a provider or supplier may engage in inappropriate billing, exit Medicare prior to detection, and then change its name or business identity in

³ https://oig.hhs.gov/testimony/docs/2011/perez_testimony_03022011.pdf.

order to reenroll in Medicare under this new identity. Another example involves an entity that owns or manages several Medicare providers and suppliers. One of the providers or suppliers may be involved in abusive behavior with the approval or at the instigation of that owner or managing entity. In this example, if the abusive provider's enrollment is revoked, the owning/managing entity shifts its behavior to another of its enrolled entities.

In these situations, and absent the owning or managing individual's or organization's felony conviction, exclusion from Medicare by the OIG or debarment from participating in any federal procurement or non-procurement program, CMS does not currently have a regulatory basis to prevent such individuals or entities from continuing their activities through other enrolled or newly enrolling providers and suppliers. Put another way, providers and suppliers currently can be denied, revoked or terminated from participating in Medicare, Medicaid or CHIP; but absent a felony conviction, exclusion or debarment, their owners and managers can often remain as direct or indirect participants in these programs. Consider this illustration: Individual X owns 100 percent of three enrolled DMEPOS suppliers, each of which has submitted a revalidation application to Medicare. Individual X completes each application. He submits false information on one application in order to retain that supplier's Medicare enrollment, but not on the other two applications. CMS revokes the first DMEPOS supplier's enrollment under § 424.535(a)(4). However, we cannot revoke the other two suppliers because false information was not submitted on their applications; this means that two Medicare suppliers whose owner has furnished false information to Medicare are still enrolled in the program.

We believe that we must address this and similar situations. In many cases, the owners and managers of fraudulent entities hide behind the organizational structure itself when in fact they are, for purposes of their behavior, one in the same. This proposed rule would allow CMS to take immediate action against such persons and entities to ensure that they do not continue to use the provider or supplier organization as a shield for their conduct. If finalized, the proposal would help protect the Medicare Trust Funds, the taxpayers, Medicare beneficiaries, and honest and legitimate Medicare providers and suppliers. The changes described later in this section serve these goals by implementing section 1866(j)(5) of the Act. We further

propose applying these changes to Medicaid and CHIP, such that states must require providers and suppliers to comply with the same disclosure requirements established by the Secretary.

1. Medicare

a. Definition of Affiliation

In § 424.502, we propose to define "affiliation" as meaning, for purposes of applying § 424.519, any of the following:

- A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
- A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
- An interest in which an individual or entity exercises operational or managerial control over or directly or indirectly conducts the day-to-day operations of another organization (including, for purposes of § 424.519 only, sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization.
- An interest in which an individual is acting as an officer or director of a corporation.
- Any reassignment relationship under § 424.80.

The first four types of interests are consistent with the definitions of—(1) "owner" and "managing employee" in § 424.502; and (2) "ownership or control interest" in section 1124(a)(3) of the Act. We also note that consistent with sections 1124 and 1124A of the Act, entities and individuals that have one or more of these four interests in an enrolling or enrolled Medicare provider or supplier must be reported on the provider's or supplier's Form CMS-855 enrollment application. Likewise, reassignment relationships must be reported to Medicare via the Form CMS-855R (OMB Control No. 0938-1179); this form facilitates the reassignment of benefits from a physician or non-physician practitioner to another Medicare provider or supplier. To make certain that there is uniformity with these other reporting requirements and that we are aware of prior and current relationships that could present risks of fraud, waste or abuse, we believe that the "affiliation" definition should include these five interests.

We believe there is a sufficiently close relationship between the reassignor (the physician or practitioner) and the

reassignee (the provider or supplier) to warrant including reassignments within the definition of "affiliation". Indeed, a W-2 employee or independent contractor may have a closer day-to-day relationship with the entity or person he or she works for and reassigns benefits to than, for instance, an indirect owner has with an entity in which he or she has a 5 percent ownership interest. We request comment on the regularity of close reassignor and reassignee relationships and whether inclusion of these relationships is likely to lead to additional information that may prevent fraud, waste and abuse.

b. Disclosable Events (§ 424.519)

In new § 424.519, we propose in paragraph (b) that a provider or supplier that is submitting an initial or revalidating Form CMS-855 application must disclose whether it or any of its owning or managing employees or organizations (consistent with the terms "owner" and "managing employee" as defined in § 424.502) has or, within the previous 5 years, has had an affiliation with a currently or formerly enrolled Medicare, Medicaid or CHIP provider or supplier that—

- Currently has an uncollected debt to Medicare, Medicaid or CHIP, regardless of—(1) the amount of the debt; (2) whether the debt is currently being repaid (for example, as part of a repayment plan); or (3) whether the debt is currently being appealed. For purposes of § 424.519 only, and as stated in proposed § 424.519(a), the term "uncollected debt" only applies to—

++ Medicare, Medicaid or CHIP overpayments for which CMS or the state has sent notice of the debt to the affiliated provider or supplier;

++ Civil money penalties (CMP) (as defined in § 424.57(a)); and

++ Assessments (as defined in § 424.57(a)).

- Has been or is subject to a payment suspension under a federal health care program (as that term is defined in section 1128B(f) of the Act), regardless of when the payment suspension occurred or was imposed;
- Has been or is excluded from participation in Medicare, Medicaid or CHIP, regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed (although section 1866(j)(5) of the Act states "has been excluded," we believe it is appropriate to clarify that a current exclusion is also a disclosable event); or

- Has had its Medicare, Medicaid or CHIP enrollment denied, revoked or terminated, regardless of—(1) the reason for the denial, revocation or

termination; (2) whether the denial, revocation or termination is currently being appealed; or (3) when the denial, revocation or termination occurred or was imposed. For purposes of § 424.519 only, and as stated in proposed paragraph (a), the terms “revoked,” “revocation,” “terminated,” and “termination” would include situations where the affiliated provider or supplier voluntarily terminated its Medicare, Medicaid or CHIP enrollment to avoid a potential revocation or termination.

Regarding proposed § 424.519(b), it is important to note that the affiliated provider or supplier need not have been enrolled in Medicare, Medicaid or CHIP when the disclosing party had its relationship with the affiliated provider or supplier. To illustrate, assume Provider A sold its 30 percent interest in an affiliated provider in January 2016. In March 2016, the affiliated provider enrolled in Medicare yet had its enrollment revoked in September 2016. In April 2017, Provider A applied for Medicare enrollment. If we limited the reporting of affiliations to periods when the affiliated provider was enrolled in Medicare, Medicaid or CHIP, Provider A would not have to report—and we would perhaps not learn of—its relationship with a provider that was revoked only 8 months after the affiliation ended. We believe that such information would be valuable in helping us determine whether the affiliation poses an undue risk of fraud, waste or abuse.

We also propose that the § 424.519(b) event (hereafter referred to as the “disclosable event”) could have occurred or been imposed either before the affiliation began or after it ended. If disclosure of an affiliation were restricted to the time period of the disclosing party’s relationship with the affiliated provider, we might remain unaware of situations where, for instance—(1) a disclosing party sold its majority interest in an affiliated provider or supplier that was terminated from Medicaid 2 months after the sale; and (2) a 40 percent owner of a Medicare-enrolled affiliated provider engages in questionable billing practices, sells its share, and seeks to separately enroll in Medicare, shortly after which the affiliated provider is notified that it has a large Medicare debt that must be repaid. We are particularly concerned about the latter scenario; as previously mentioned, we have seen instances where providers and suppliers with significant overpayments close down their businesses and attempt to enroll under other business identities.

All affiliations that meet the requirements of § 424.519(b) would

have to be reported. To illustrate, suppose a revalidating Medicare provider has three owners: A, B, and C. Owner A had an affiliation 30 months ago with a revoked Medicare provider. Owner B had an affiliation 2 years ago with a terminated Medicaid provider. Owner C currently serves as a management company for a CHIP provider with an uncollected debt. Each of these three affiliations would have to be disclosed on the revalidating provider’s Form CMS–855 application.

We believe the actions identified in § 424.519(b) should be reported regardless of whether an appeal is pending. We want to avoid situations where an initially enrolling provider or supplier would not have to disclose, for example, an affiliated provider that was revoked from Medicare 6 months ago (based on a felony conviction) because the revocation is under appeal; without this information, the provider or supplier in question might become enrolled in Medicare without CMS knowing of its relationship with a recently convicted affiliated provider or supplier. Conversely, actions that are overturned on appeal or otherwise reversed need not be reported. For purposes of this rule only, the reversal of a disclosable event would effectively nullify said event.

Section 1866(j)(5) of the Act refers to the disclosure of current or previous affiliations “directly or indirectly.” We believe this concept should apply to ownership interests. Consequently, affiliations involving a 5 percent or greater indirect ownership interest must be disclosed to the same extent as those involving direct ownership. Consider the following example: A newly-enrolling provider listed in section 2 of the Form CMS–855A (OMB Control No. 0938–0685) application is wholly (100 percent) owned by Company A. Company B wholly owns Company A. Companies C and D each own 50 percent of Company B. Here, Company A is considered a direct owner of the newly-enrolling provider because it actually owns the assets of the business. Companies B, C, and D are considered indirect owners of the provider. Unlike Company A, they do not own the provider’s assets. However, Company B directly owns Company A’s assets, while Companies C and D own Company B’s assets.

We believe that the disclosure of indirect ownership interests is important. We have seen cases where the direct owner of the provider or supplier is a mere holding company, while the actual management and control of the provider or supplier is exercised by the provider’s or supplier’s

indirect owner(s). Restricting the disclosure requirements to direct owners could deprive CMS of important information about the entities that are actually running the provider’s or supplier’s operations.

We are proposing a “look-back” period of 5 years for previous affiliations. A sufficient look-back period is necessary because a past affiliation could be an indicator of a disclosing party’s future behavior. For instance, suppose a physician who is enrolling in Medicare was a 50 percent owner of an affiliated provider from July 2013 through December 2013. In October 2013, the affiliated provider’s Medicare enrollment was revoked for falsifying information on a Form CMS–855 change of information request. Considering the physician’s degree of involvement with the affiliated provider, we believe this scenario would raise questions regarding the level of risk posed to the Medicare program. In short, a 5-year look-back period would divulge to us past situations that could present future concerns. We believe that a 5-year look-back period would be less onerous for providers and suppliers than, for instance, a 10-year period, while still providing us with enough information to make a proper decision as to whether an undue risk of fraud, waste or abuse exists. For purposes of this rule, the look-back period would be the 5-year timeframe prior to the date on which the disclosing provider or supplier submits its Form CMS–855; thus, the affiliation must have occurred within the 5-year period preceding the date on which the application is submitted. However, we note that only part of the affiliation period would have to have occurred inside the 5-year timeframe; the entire affiliation (from beginning to end) need not fall within the 5-year window. To illustrate, if an affiliation began 8 years prior to enrollment and ended 4 years before enrollment, it would have to be reported because at least part of the affiliation occurred within the previous 5 years.

While we propose to limit disclosure to affiliations that occurred within the previous 5 years, the event triggering the disclosure (for example, a revocation) could have occurred or been imposed more than 5 years previously. In other words, we are proposing a 5-year look-back period for the affiliation; but we are not proposing a specific look-back period for when the disclosable event occurred or was imposed. Consider the following examples:

- A provider is submitting an initial Form CMS–855A application in May 2017. The provider was the owner of a

Medicaid-enrolled group practice from August 2014 to January 2015. The group practice had its Medicaid enrollment terminated in January 2010. Although the disclosable event (the termination) was imposed more than 5 years ago, it must be reported because the affiliation occurred within the previous 5 years.

- A supplier is submitting a Form CMS-855B (OMB Control No. 0938-0685) revalidation application. The supplier currently has a managerial interest in an ambulance company that was subject to a Medicare payment suspension 8 years ago. The affiliation and the payment suspension must be disclosed even though the latter was imposed outside of the 5-year affiliation look-back period.

Our proposed 5-year look-back limit for affiliation disclosures, as already indicated, is partly intended to reduce the burden on providers and suppliers. Yet we believe that a similar time restriction on the underlying event that is triggering the disclosure could present program integrity concerns. To illustrate, assume Individual X purchased Medicare Provider Y in 2007. In 2009, Provider Y was revoked from Medicare for falsifying information on its Form CMS-855A revalidation application. In 2017, Provider Z submits a Form CMS-855A initial application; Individual X (which still owns revoked Provider Y) is the sole owner of Provider Z. If we restricted the look-back period for disclosable events to 5 years rather than having an unlimited period, we may not learn that the sole owner of an enrolling provider was (and remains) the owner of another provider that was revoked for furnishing false information to Medicare. Even if the action happened more than 5 years ago, it could still raise concerns about the potential risk the newly enrolling provider poses. For this reason, we must retain the flexibility to address a variety of factual scenarios, regardless of when the underlying event occurred or was imposed.

If the affiliated provider or supplier had its Medicare, Medicaid or CHIP enrollment denied, revoked or terminated, this must be reported regardless of the reason for the denial, revocation or termination. Since all denial, revocation, and termination reasons are of concern to us, we do not believe certain reasons should be excluded from disclosure. Nonetheless, we seek comment on whether disclosure should be restricted to certain denial, revocation and termination reasons and, if so, what those reasons should be.

We also propose to define the term “uncollected debt” in proposed § 424.519(b) as—

++ Medicare, Medicaid or CHIP overpayments for which CMS or the state has sent notice of the debt to the affiliated provider or supplier;

++ CMPs (as defined in § 424.57); and

++ Assessments (as defined in § 424.57).

We are proposing this definition, which is included in proposed § 424.519(a), because it is consistent with our requirements for DMEPOS surety bond coverage under § 424.57(d). Under § 424.57(d)(5), a DMEPOS supplier's surety bond must guarantee that the surety will—within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond of unpaid claims, CMPs or assessments—pay CMS a total of up to the full penal amount of the bond in the amounts described in § 424.57(d)(5)(i). We believe it is appropriate to use a concept of unpaid debt for which there is precedent in 42 CFR part 424. However, we seek comment on the following issues regarding our proposed definition of “uncollected debt”: (1) Whether there should be a threshold for the level of debt that would need to be reported; (2) whether a provider or supplier should be exempt from reporting an uncollected debt if it is complying with a repayment plan; and (3) whether the level of reporting burden is low enough to merit collection of this information without any threshold or exemption.

Section 1866(j)(5)(B) of the Act states that if an undue risk of fraud, waste or abuse is found, the Secretary shall deny the application in question. Revocation of enrollment is not mentioned. However, we believe that section 1866(j)(5)(A) of the Act's reference to a revalidation application, which can only be submitted by an enrolled provider or supplier, suggests that a provider's or supplier's Medicare enrollment may be revoked if an undue risk is found. Furthermore, we believe that having the ability to revoke the enrollment of providers or suppliers with affiliations that we have determined to pose an undue risk is necessary to protect the integrity of the Medicare program. Therefore, we are proposing to use our general rulemaking authority in sections 1102 and 1871 of the Act to—(1) require the submission of a Form CMS-855 change of information request to report a new or changed affiliation (per proposed § 424.519(h)); and (2) permit revocation (per proposed § 424.519(i)) if an undue risk is found outside of the provider's or supplier's submission of an initial, revalidating or change of information application.

We believe that the terms “revoked,” “revocation,” “terminated,” and “termination,” for purposes of disclosure under § 424.519(b), should include situations where the affiliated provider or supplier voluntarily terminated its Medicare, Medicaid or CHIP enrollment to avoid a potential revocation or termination; this is referenced in proposed § 424.519(a). As explained in more detail in section II.B.11. of this proposed rule, we have seen instances where the provider or supplier engages in inappropriate behavior, recognizes that its enrollment may soon be revoked, and then voluntarily withdraws from Medicare prior to the imposition of a revocation so as to avoid the revocation itself as well as a subsequent reenrollment bar under § 424.535(c). (See section II.B.4. of this proposed rule for more information on reenrollment bars.) Since the provider or supplier is not revoked from Medicare, it could immediately reenroll in Medicare without having to wait until the reenrollment bar expires. We believe such behavior poses a risk to the Medicare program in that the provider or supplier is seeking to avoid Medicare rules and, in the process, possibly reenter the Medicare program to continue its improper activities. We thus believe that for purposes of § 424.519(b), such actions should be included within the category of “revocations” and “terminations.”

c. Affiliation Data, “Reasonableness” Standard, and Mechanism of Disclosure

In § 424.519(c), we propose to require the disclosure of the following information about the affiliation:

- General identifying data about the affiliated provider or supplier. This would include the following:
 - ++ Legal name as reported to the Internal Revenue Service or the Social Security Administration (if the affiliated provider or supplier is an individual).
 - ++ “Doing business as” name (if applicable).
 - ++ Tax identification number.
 - ++ National Provider Identifier (NPI).
- Reason for disclosing the affiliated provider or supplier (for example, uncollected Medicare debt or Medicaid payment suspension).
- Specific data regarding the relationship between the affiliated provider or supplier and the disclosing party. Such data would include the—(1) length of the relationship; (2) type of relationship (for example, an owner of the initially enrolling provider or supplier was a managing employee of the affiliated provider or supplier); and (3) degree of affiliation (for example,

percentage of ownership; whether the ownership interest was direct or indirect; the individual's specific managerial position; the scope of the individual's or entity's managerial duties; whether the partnership interest was general or limited).

- If the affiliation has ended, the reason for the termination.

We believe the information in proposed § 424.519(c) is necessary so that we can—(1) conclusively identify the affiliated provider or supplier and the disclosing party's relationship therewith; and (2) assess the risk of fraud, waste or abuse that the affiliation poses.

However, we also believe it is appropriate to build a “reasonableness” standard into § 424.519(b) and (c), such that we would require particular information to be reported only if the disclosing provider or supplier knew or should reasonably have known of said data. For instance, while we believe a provider or supplier would typically know of a past affiliation, it may not necessarily know whether a § 424.519(b) action occurred or was imposed after the affiliation ended. We will review each situation on a case-by-case basis in determining whether the disclosing entity knew or should have known of the information.

d. Affiliation and Disclosure Examples, Methodology, and Consequences of Non-Disclosure

(1) Examples

The following are examples of when the information described in § 424.519 would or would not have to be disclosed.

Example 1: Physician Group X was a 10 percent indirect owner of a medical provider (the affiliated provider) between January 2015 and March 2015. The affiliated provider was not enrolled in Medicare during this timeframe because its Medicare enrollment had been revoked in December 2014. Physician Group X is revalidating its Medicare enrollment in January 2017. Though the affiliated provider was not enrolled in Medicare during the period of affiliation, Physician Group X would need to disclose the affiliation as part of its revalidation because—(1) it was a 5 percent or greater owner of a formerly enrolled Medicare provider; (2) the formerly enrolled Medicare provider had its Medicare enrollment revoked; and (3) the affiliation occurred within the previous 5 years.

Example 2: Ambulance Company X had a limited partnership interest in a Medicaid provider (the affiliated provider) between February 2015 and April 2015. The affiliated provider voluntarily terminated its Medicaid enrollment in May 2015. In June 2015, the state notified the affiliated provider that it had a large Medicaid overpayment that must be repaid. In September 2017, Ambulance

Company X is enrolling in Medicare for the first time. The affiliated provider's debt is still outstanding. Ambulance Company X must report the affiliation as part of its initial Medicare enrollment because—(1) it had a partnership interest in an affiliated Medicaid provider; (2) the formerly enrolled Medicaid provider has an uncollected debt; and (3) the affiliation occurred within the previous 5 years.

Example 3: In February 2017, Provider X is preparing to submit a Form CMS–855 application to enroll in Medicare. Between January 2014 and June 2014, one of its owners, Owner Y, functioned as a managing company for Home Health Agency Z (the affiliated provider). Home Health Agency Z attempted to enroll in Medicare in December 2013, but its application was denied. Provider X would have to disclose this information as part of its enrollment because—(1) one of its 5 percent or greater owners (Owner Y) was a managing employee (as that term is defined in § 424.502) of Home Health Agency Z, whose Medicare enrollment application was denied; and (2) the affiliation occurred within the previous 5 years.

Example 4: In March 2017, Physician Group X is revalidating its Medicare enrollment information. X was a 50 percent owner of a Medicaid provider (the affiliated provider) between January 2008 and December 2008. The affiliated provider's enrollment was revoked in April 2009. Physician Group X would not need to disclose this information because the affiliation ended more than 5 years ago.

Example 5: In June 2017, Provider Y is initially enrolling in Medicare. Between May 2014 and July 2014, Provider Y had a 25 percent ownership interest in a medical group (the affiliated provider) whose Medicare enrollment was revoked in August 2014. However, the revocation was reversed on appeal prior to Provider Y's application submission. Though the affiliation occurred within the previous 5 years, Provider Y need not report it because the revocation was overturned on appeal.

Considering the statute's explicit flexibility regarding disclosure methodology, we are interested in comments on proposed § 424.519(b) and (c), particularly:

- Whether the types of disclosable affiliations should include additional ownership or managerial interests or other relationships;
- Whether 5 years is an appropriate look-back period for affiliations;
- Whether exclusions, denials and revocations that are being appealed should be exempt from disclosure.
- Whether we should establish a “reasonableness” test, whereby we explain what constitutes a sufficient effort to obtain information in the context of the “should reasonably have known” standard;
- If we establish such a test, what the specific elements of this standard should be (for example, what constitutes

a reasonable inquiry; the minimum steps that the provider must undertake in researching information); and

- Whether there should be a lookback period for disclosable events and, if so, how long (for example, 15 years, 10 years, 7 years).

(2) Methodology and Non-Disclosure

In § 424.519(d), we propose that the information required under § 424.519 be furnished to CMS or its contractors via the Form CMS–855 application (paper or the Internet-based PECOS enrollment process). This is to ensure that all enrollment information continues to be reported via a single vehicle.

In § 424.519(e), we propose that the disclosing provider's or supplier's failure to fully and completely furnish the information specified in § 424.519(b) and (c) when the provider or supplier knew or should reasonably have known of this information may result in either of the following:

- The denial of the provider's or supplier's initial enrollment application under § 424.530(a)(1) and, if applicable, § 424.530(a)(4).
- The revocation of the provider's or supplier's Medicare enrollment under § 424.535(a)(1) and, if applicable, § 424.535(a)(4).

e. Undue Risk

In § 424.519(f), we propose that upon receiving the information described in § 424.519(b) and (c) (and consistent with section 1866(j)(5)(B) of the Act), we would determine whether any of the disclosed affiliations poses an undue risk of fraud, waste or abuse. The following factors would be considered:

- The duration of the disclosing party's relationship with the affiliated provider or supplier.
- Whether the affiliation still exists and, if not, how long ago it ended.
- The degree and extent of the affiliation (for example, percentage of ownership).
- If applicable, the reason for the termination of the affiliation.
- Regarding the disclosable event—
 - ++ The type of action (for example, payment suspension);
 - ++ When the action occurred or was imposed;
 - ++ Whether the affiliation existed when the action (for example, revocation) occurred or was imposed;
 - ++ If the action is an uncollected debt—(1) the amount of the debt; (2) whether the affiliated provider or supplier is repaying the debt; and (3) to whom the debt is owed (for example, Medicare); and
 - ++ If a denial, revocation, termination, exclusion or payment

suspension is involved, the reason for the action (for example, felony conviction; failure to submit complete information).

- Any other evidence that CMS deems relevant to its determination.

In summary, these factors would focus largely, though not exclusively, on—(1) the length and period of the affiliation; (2) the nature and extent of the affiliation; and (3) the type of disclosable event and when it occurred. A closer, longer, and more recent affiliation involving, for instance, an excluded provider or a large uncollected debt might pose a greater risk to the Medicare program than a brief affiliation that occurred 5 years ago. Yet it should not be assumed that the latter situation would never pose an undue risk. We are not prepared in this proposed rule to make specific conclusions as to what would constitute an undue risk. Affiliations vary widely. For this reason, we must retain the flexibility to deal with each situation on a case-by-case basis, utilizing the aforementioned factors. We do, nevertheless, solicit comment on the following issues related to these factors:

- Whether additional factors should be considered.
- Which, if any, of the proposed factors should not be considered.
- Which, if any, factors should be given greater or lesser weight than others.

In § 424.519(g), we propose that a CMS determination that a particular affiliation poses an undue risk of fraud, waste or abuse would result in, as applicable, the denial of the provider's or supplier's initial enrollment application under new § 424.530(a)(13) or the revocation of the provider's or supplier's Medicare enrollment under new § 424.535(a)(19). We stress that an actual finding of fraud, waste or abuse would not be necessary for § 424.519(g) to be invoked. Only a determination that an "undue risk" of fraud, waste or abuse exists would be required.

On December 5, 2014, we published in the **Federal Register** (79 FR 72499) a final rule titled "Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment." In that rule, we finalized new § 424.530(a)(6)(ii), which states that CMS may deny enrollment if the enrolling provider, supplier or owner (as defined in § 424.502) 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 all of the following criteria are met:

- 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 Medicare debt has not been fully repaid.
- CMS determines that the uncollected debt poses an undue risk of fraud, waste or abuse.

We are not proposing to modify this provision in this rule. Our proposed affiliation provision would supplement but not supplant § 424.530(a)(6)(ii). We would be able to deny enrollment under § 424.530(a)(6)(ii), § 424.530(a)(13) or both if the conditions for the denial reason(s) are met.

f. Additional Affiliation Provisions

In § 424.519, we propose in paragraph (h)(1) that providers and suppliers must report new or changed information regarding existing affiliations, consistent with our requirement in § 424.516 to submit changes in enrollment information; this would include the reporting of new affiliations. However, under paragraph (h)(2) providers and suppliers would not be required to report either of the following:

- New or changed information regarding past affiliations (except as part of a Form CMS-855 revalidation application).
- Affiliation data in that portion of the Form CMS-855 that collects affiliation information if the same data is being reported in the "owning or managing control" (or its successor) section of the Form CMS-855.

We believe that requiring providers and suppliers to report new or changed information regarding past affiliations would impose an unnecessarily excessive burden; providers and suppliers would have to constantly monitor and track information changes involving parties with whom they, their owners or their managers no longer have a relationship. Regarding the second exception, we believe this would limit duplicate reporting and ease the burden on providers and suppliers.

In § 424.519(i), we propose that CMS may apply proposed § 424.530(a)(13) or § 424.535(a)(19) (as applicable) to situations where a disclosable affiliation poses an undue risk of fraud, waste or abuse, but the provider or supplier has not yet disclosed or is not required at that time to disclose the affiliation to CMS. We believe that section 1866(j)(5) of the Act is aimed at protecting Medicare, Medicaid and CHIP against undue risks of fraud, waste or abuse at all times, not merely upon a provider's or supplier's initial enrollment, revalidation or reporting of new or

changed affiliation information. There may be time lapses between these events during which a particular affiliation poses an undue risk based on changed circumstances. Consider the following examples:

Example 1: An enrolled disclosing provider had an affiliation with Supplier Q that ended on January 1. On May 1, Q's Medicare enrollment was revoked. As this is a past affiliation, the provider under § 424.519(h) need not disclose the revocation as part of a Form CMS-855 change of information. However, we should have the authority to consider whether, in light of Q's revocation—(1) the recently terminated affiliation poses an undue risk of fraud, waste or abuse; and (2) the provider's enrollment should accordingly be revoked.

Example 2: Three months after § 424.519's effective date but before the Form CMS-855 is updated to capture affiliation data, we receive information that Medicare-enrolled Provider X owns 35 percent of a Medicaid supplier that—(1) was recently terminated under § 455.106(c)(2) for concealing information that must be disclosed per § 455.106(a), and (2) up until 4 months ago, owned one-half of a Medicare supplier whose enrollment was recently revoked. Although X need not report this information until the Form CMS-855 is revised, we should not have to wait to take action under § 424.519. Permitting a provider or supplier with an affiliation that we know poses an undue risk of fraud, waste or abuse to enroll or remain enrolled in Medicare would be inconsistent with section 1866(j)(5) of the Act.

As with all other Medicare denials and revocations, these providers and suppliers would be notified if their enrollment is denied or revoked per § 424.519(i).

g. Conclusion

To summarize, the process for disclosing information under § 424.519 would be as follows.

First, the provider or supplier must determine whether it or any of its owning or managing individuals or organizations has or has had an affiliation (as defined in § 424.502).

Second, if an affiliation exists or existed within the applicable 5-year timeframe, the provider or supplier must determine whether a disclosable event in § 424.519(b) has occurred. If it has, it must be disclosed.

Third, we would determine whether the affiliation poses an undue risk of fraud, waste or abuse. If it does, the provider's or supplier's application would be denied or, if applicable, the provider's or supplier's enrollment would be revoked. The provider or supplier may appeal the denial or revocation under § 405.874 or part 498, respectively.

2. Medicaid

Consistent with our discussion in section II.A.1.a. of this proposed rule and for the reasons stated therein, we propose to revise the Medicaid provisions in 42 CFR part 455.

In § 455.101, we propose to add the same definition of “affiliation” that we are proposing to add to § 424.502, with the exception of the paragraph regarding “reassignment.” Section § 424.80 only applies to Medicare. However, we propose to include payment assignments under § 447.10(g) within the definition of “affiliation” in § 455.101. Under § 447.10(g), payment for services provided by an individual practitioner may be made to—

++ The employer of the practitioner, if the practitioner is required as a condition of employment to turn over his fees to the employer;

++ The facility in which the service is provided, if the practitioner has a contract under which the facility submits the claim; or

++ A foundation, plan or similar organization operating an organized health care delivery system, if the practitioner has a contract under which the organization submits the claim.

As with Medicare reassignments, we believe that the relationships described in § 447.10(g) are sufficiently close to warrant their inclusion within the definition of “affiliation” in § 455.101; again, a W–2 employee or independent contractor may have a closer day-to-day relationship with the individual or organization he or she works for than, for instance, an indirect owner has with an entity in which he or she has a 5 percent ownership interest. We also note that these provisions are similar to those in § 424.80.

In revised § 455.103, we propose that a state plan must provide that the requirements of §§ 455.104 through 455.107 are met. Section 455.103 currently only references §§ 455.104 through 455.106. Our revision would include a reference to new § 455.107.

In new § 455.107, we propose several paragraphs.

In paragraph (b), we propose that a provider that is submitting an initial or revalidating Medicaid application must disclose whether it or any of its owning or managing employees or organizations (consistent with the definitions of “person with an ownership or control interest” and “managing employee” in § 455.101) has or, within the previous 5 years, has had an affiliation with a currently or formerly enrolled Medicare, Medicaid or CHIP provider or supplier that—

• Currently has an uncollected debt to Medicare, Medicaid or CHIP,

regardless of—(1) the amount of the debt; (2) whether the debt is currently being repaid (for example, as part of a repayment plan); or (3) whether the debt is currently being appealed. For purposes of § 455.107 only, and as stated in proposed § 455.107(a), the term “uncollected debt” only applies to—

++ Medicare, Medicaid or CHIP overpayments for which CMS or the state has sent notice of the debt to the affiliated provider or supplier;

++ CMPs (as defined in § 424.57(a)); and

++ Assessments (as defined in § 424.57(a));

• Has been or is subject to a payment suspension under a federal health care program (as that latter term is defined in section 1128B(f) of the Act), regardless of when the payment suspension occurred or was imposed;

• Has been or is excluded from participation in Medicare, Medicaid or CHIP, regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed; or

• Has had its Medicare, Medicaid or CHIP enrollment denied, revoked or terminated, regardless of—(1) the reason for the denial, revocation or termination; (2) whether the denial, revocation or termination is currently being appealed; or (3) when the denial, revocation or termination occurred or was imposed. For purposes of § 455.107 only, the terms “revoked,” “revocation,” “terminated,” and “termination” would include situations where the affiliated provider or supplier voluntarily terminated its Medicare, Medicaid or CHIP enrollment to avoid a potential revocation or termination. This clarification is included in proposed § 455.107(a).

In paragraph (c), we propose that the following information about the affiliation must be disclosed:

• General identifying data about the affiliated provider or supplier. This would include the following:

++ Legal name as reported to the Internal Revenue Service or the Social Security Administration (if the affiliated provider or supplier is an individual).

++ “Doing business as” name (if applicable).

++ Tax identification number.

++ NPI.

++ Reason for disclosing the affiliated provider or supplier (for example, uncollected CHIP debt; payment suspension).

++ Specific data regarding the affiliation relationship. Such data would include the—(1) length of the relationship; (2) type of relationship; and (3) degree of affiliation.

++ If the affiliation has ended, the reason for the termination.

In paragraph (d), we propose that the information described in § 455.107(b) and (c) must be furnished to the state in a manner prescribed by the state.

In paragraph (e), we propose that the disclosing provider’s failure to fully and completely furnish the information in § 455.107(b) and (c) when the provider knew or should reasonably have known of this information may result in—

• The denial of the provider’s initial enrollment application; or

• The revocation of the provider’s Medicaid or CHIP enrollment.

In paragraph (f), we propose that upon receiving the information described in § 455.107(b) and (c), the state, in consultation with CMS, would determine whether any of the disclosed affiliations poses an undue risk of fraud, waste or abuse. The state, in consultation with CMS, would consider the following factors in its determination:

• The duration of the disclosing party’s relationship with the affiliated provider or supplier.

• Whether the affiliation still exists and, if not, how long ago it ended.

• The degree and extent of the affiliation.

• If applicable, the reason for the termination of the affiliation.

• Regarding the affiliated provider’s or supplier’s disclosable event—

++ The type of action;

++ When the action occurred or was imposed; and

++ Whether the affiliation existed when the action occurred or was imposed.

++ If the action is an uncollected debt—(1) the amount of the debt; (2) whether the affiliated provider or supplier is repaying the debt; and (3) to whom the debt is owed (for example, Medicare);

• If a denial, revocation, termination, exclusion or payment suspension is involved, the reason for the action; and

• Any other evidence that the state, in consultation with CMS, deems relevant to its determination.

In paragraph (g), we propose that a determination that a particular affiliation poses an undue risk of fraud, waste or abuse results in, as applicable, the denial of the provider’s initial enrollment application or the termination of the provider’s Medicaid or CHIP enrollment.

In paragraph (h), we propose the following:

• Providers would be required to report new or changed information regarding existing affiliations. This would include the reporting of any new affiliations.

• Providers would not be required to report new or changed information regarding past affiliations (except as part of a revalidation application).

In paragraph (i), we propose that the state, in consultation with CMS, may apply paragraph (g) to situations where a reportable affiliation poses an undue risk of fraud, waste or abuse, but the provider has not yet disclosed or is not required at that time to disclose the affiliation to the state.

c. CHIP

Section 2107(e) of the Act states that sections 1902(a)(77) and (kk) of the Act (which relate to Medicaid provider screening, oversight, and reporting requirements) apply to CHIP to the same extent that they apply to Medicaid. Therefore, we would apply our proposed Medicaid affiliation disclosure requirements to CHIP providers for two principal reasons. First, section 1866(j)(5) of the Act specifically references the need to disclose current and prior affiliations with CHIP providers. We believe it logically follows that CHIP providers should have to disclose similar affiliation information. Second, and for reasons already explained, the disclosure of affiliation information would assist our efforts in deterring fraud, waste, and abuse in CHIP.

Section 457.990(a) states that part 455, subpart P, applies to a state under Title XXI in the same manner as it applies to a state under Title XIX. We propose to revise § 457.990(a) such that § 455.107 would also apply to Title XXI. Paragraph (a) would thus read: “(a) part 455, subpart E and § 455.107, of this chapter.”

B. Other Proposed Regulations Affecting the Medicare Program Only

Except as stated otherwise, the legal authorities for our proposals in section II.B, are as follows. First, sections 1102 and 1871 of the Act give the Secretary the authority to establish requirements for the efficient administration of the Medicare program. Second, section 1866(j) of the Act states that the Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers.

1. Revoked Under Different Name, Numerical Identifier or Business Identity

We propose in new § 424.530(a)(12) that CMS may deny a provider's or supplier's Medicare enrollment application if CMS determines that the provider or supplier is currently revoked under a different name, numerical identifier or business

identity, and the applicable reenrollment bar period has not expired. Likewise, we propose in new § 424.535(a)(18) that CMS may revoke a provider's or supplier's Medicare enrollment if CMS determines that the provider or supplier is revoked under a different name, numerical identifier or business identity.

As discussed in section II.A.1.a. of this proposed rule, we have identified instances in which a provider or supplier has its Medicare enrollment revoked but tries to evade the revocation and reenrollment bar by opening a new provider or supplier organization to effectively “replace” the revoked entity. The OIG indicated in the previously-mentioned memorandum that some providers and suppliers operate “fronts,” whereby associates, family members or other individuals pose as owners or managers of the entity on behalf of the persons who actually operate, run or profit from the business. We believe that such behavior must be stemmed, hence our proposed additions of §§ 424.530(a)(12) and 424.535(a)(18).

In determining whether a provider or supplier is in fact a currently revoked provider or supplier under a different name, numerical identifier or business identity, CMS would investigate the degree of commonality by considering the following factors:

- Owning and managing employees and organizations, regardless of whether they have been disclosed on the Form CMS-855 application (for the definitions of “owner” and “managing employee” in § 424.502 do not require the individual or organization to be listed on the Form CMS-855 in order to qualify as such).

- Geographic location (for example, same city or county).

- Provider or supplier type (for example, same provider type).

- Business structure.

- Any evidence indicating that the two parties are similar or that the provider or supplier was created to circumvent the revocation or the reenrollment bar.

It should not be assumed that having different owners, locations or business structures would automatically result in a finding that the two are not the same. CMS would consider any evidence indicating whether the entities are effectively identical or that the new entity was established to evade the revocation or reenrollment bar. Therefore, even if several factors suggest that the entities may be distinct, we would reserve the right to apply §§ 424.530(a)(12) or 424.535(a)(18) if we find evidence of evasion.

Unlike with § 424.519(f), no finding of “undue risk” would be required in a determination under §§ 424.530(a)(12) or 424.535(a)(18). We could invoke the latter two provisions even if there is no finding that the revoked entity, the newly enrolling entity or the currently enrolled entity (as applicable) poses an undue risk of fraud, waste or abuse.

This is because we are not relying upon section 1866(j)(5) of the Act as authority for these two provisions. We are instead relying upon our general rulemaking authority in sections 1102 and 1871, as well as 1866(j) of the Act, which provides specific authority with respect to the enrollment process for providers and suppliers.

2. Non-Compliant Practice Location

We propose in new § 424.535(a)(20) that we may revoke a provider's or supplier's Medicare enrollment—including all of the provider's or supplier's practice locations, regardless of whether they are part of the same enrollment—if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements.

CMS has identified examples of providers or suppliers operating from multiple practice locations (either as part of the same enrollment or, for DMEPOS suppliers and independent diagnostic testing facilities (IDTFs), through separately enrolled locations), of which one or more of the locations does not meet Medicare enrollment requirements. For instance, a particular location may not be operational, does not comply with certain DMEPOS or IDTF supplier standards or is otherwise noncompliant, yet the provider or supplier continues to perform services at or furnish items from this location (or claims to do so) when it knows or should know that the location does not meet Medicare enrollment requirements. We have seen this with providers and suppliers that operate locations that either do not exist or are false storefronts, meaning that the location appears legitimate from the outside but is in fact a vacant site or a nonmedical business.

We have conducted site visits uncovering several similar situations and revocations of providers and suppliers locations have accordingly ensued. However, we believe more must be done. Dishonest providers and suppliers must realize that if they submit claims for services or items furnished at or from non-compliant locations, they risk not only the revocation of that location but also of their other locations. As an illustration,

assume that a DMEPOS supplier has four separately enrolled locations. The supplier shifts one of its locations without notifying Medicare, and the new site is a false storefront. The supplier furnishes no items from this location, but it submits bills for DME allegedly provided from this site. Under our proposal, CMS could revoke this location as well as the three other sites. Even if the other sites had different numerical identifiers, legal business names or ownership, we could take action against them if there is evidence to suggest that they are effectively under the control of similar parties. This is to ensure that suppliers do not attempt to circumvent § 424.535(a)(20) by opening locations under different identities or with different “front men” (such as family members).

We would consider the following factors when determining whether and how many of the provider’s or supplier’s other locations should be revoked:

- The reason(s) for and facts behind the location’s non-compliance (for example, false storefront; otherwise non-operational; other violation of supplier standards).
- The number of additional locations involved.
- Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502) or Medicare or Medicaid payment suspensions.
- The degree of risk that the location’s continuance poses to the Medicare Trust Funds.
- The length of time that the non-compliant location was non-compliant.
- The amount that was billed for services performed at or items furnished from the non-compliant location.
- Any other evidence that we deem relevant to our determination.

We emphasize that our proposal is primarily designed to identify and pursue providers and suppliers that knowingly operate fictitious or otherwise non-compliant locations in order to circumvent CMS policies.

3. Improper Ordering, Certifying, Referring or Prescribing of Part A or B Services, Items or Drugs

In the previously mentioned December 5, 2014 final rule, we finalized § 424.535(a)(8)(ii), which states that we may revoke a provider’s or supplier’s Medicare billing privileges if the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements such as, but not limited to, the requirement that the service be reasonable and necessary. This provision is intended to place

providers and suppliers on notice that they have a legal obligation to always submit correct and accurate claims; the provider’s or supplier’s repeated failure to do so poses a risk to the Medicare Trust Funds.

On May 23, 2014 we published a final rule in the **Federal Register** (79 FR 29843) titled “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.” Under § 424.535(a)(14), we may revoke a physician’s or eligible professional’s Medicare billing and prescribing privileges if we determine that he or she has a pattern or practice of prescribing Part D drugs that falls into one of the following categories:

- The pattern or practice is abusive, represents a threat to the health and safety of Medicare beneficiaries or both.
- The pattern or practice of prescribing fails to meet Medicare requirements.

In the January 10, 2014 **Federal Register** proposed rule (79 FR 1917), which resulted in the aforementioned May 23, 2014 final rule, we expressed our view that the concept behind proposed § 424.535(a)(8)(ii) should extend to revoking Medicare enrollment for Part D prescribers who engage in abusive prescribing practices. We explained that if a physician or eligible professional consistently fails to exercise reasonable judgment in his or her prescribing practices, we should be able to remove such individuals from the Medicare program in order to protect beneficiaries’ safety and health, as well as the Medicare Trust Funds.

However, neither § 424.535(a)(14) nor § 424.535(a)(8)(ii) address the improper ordering or certifying of Medicare services and items or the prescribing of Part B drugs. We have received numerous reports of physicians and eligible professionals engaging in abusive or otherwise inappropriate ordering. While the particular circumstances of each case have varied, they frequently fall within one or more of the following categories: (1) The ordered service or item was not reasonable, not necessary or both; or (2) the physician or eligible professional misrepresents his or her diagnosis to justify the service or test.

Such behavior increases the risk of improper payment for inappropriate services, items or Part B drugs. It also endangers Medicare beneficiaries by unnecessarily exposing them to potentially harmful services and tests. As with the threats that abusive prescribing and billing pose, we believe that the risks of improper ordering,

certifying, referring, and prescribing of Part B drugs must be stemmed in order to protect the Medicare program.

Accordingly, we propose in new § 424.535(a)(21) that CMS may revoke a physician’s or eligible professional’s Medicare enrollment (as the term “enrollment” is defined in § 424.502) if he or she has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries or otherwise fails to meet Medicare requirements. Recognizing that not all patterns and practices involve inappropriate behavior, we would consider the following factors in determining whether a pattern or practice of improper ordering, certifying, referring or prescribing exists:

- Whether the physician’s or eligible professional’s diagnoses support the orders, certifications, referrals or prescriptions in question.
- Whether there are instances where the necessary evaluation of the patient for whom the service, item or drug was ordered, certified, referred or prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).
- The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state or states in which he or she practices, and the reason(s) for the action(s).
- Whether the physician or eligible professional has any history of final adverse actions (as that term is defined in § 424.502).
- The length of time over which the pattern or practice has continued.
- How long the physician or eligible professional has been enrolled in Medicare.
- The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to ordering, certifying, referring or prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined).
- Whether any state Medicaid program or any other public or private health insurance program has restricted, suspended, revoked or terminated the physician’s or eligible professional’s ability to practice medicine, and the reason(s) for any such restriction, suspension, revocation or termination.

- Any other information that we deem relevant to our determination.

We emphasize that we are focused on egregious patterns of ordering, certifying, referring or prescribing that fall well outside standard, acceptable practices.

4. Reenrollment Bar Period

Under § 424.535(c), if a provider, supplier, owner or managing employee has their billing privileges revoked, they are barred from participating in Medicare from the date of the revocation until the end of the reenrollment bar. The reenrollment 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.

We are proposing the following changes to § 424.535(c).

First, we propose to incorporate the existing version of § 424.535(c) into a new paragraph (1) that would increase the current maximum reenrollment bar from 3 years to 10 years (with the exception of the situations described in new paragraphs (c)(2) and (c)(3), discussed later in this section). We believe it would be reasonable in certain cases to prevent a provider or supplier from participating in Medicare for longer than 3 years. Indeed, certain behavior could prove so harmful to Medicare, its beneficiaries, and/or the Trust Funds that a very lengthy bar from Medicare is warranted. We believe that a 10-year maximum period is appropriate, both to ensure that providers and suppliers that engage in such activities are kept out of Medicare and to deter others from potentially duplicating this behavior. We chose 10 years because there is precedent for this timeframe; under § 424.535(a)(3)(iii), it constitutes the minimum revocation period for providers that have been convicted of multiple felonies. However, we do not expect to impose longer reenrollment bars for certain existing revocation reasons. For instance, revocations that currently involve only a 1-year reenrollment bar would not necessarily result in a longer period under new § 424.535(c)(1).

Second, we propose in new § 424.535 paragraph (c)(2) that CMS may add up to 3 more years to the provider's or supplier's reenrollment bar (even if such period exceeds the maximum period otherwise allowable under paragraph (c)(1)) if CMS determines that the provider or supplier is attempting to circumvent its existing reenrollment bar by enrolling in Medicare under a different name, numerical identifier or business identity. We believe that such

efforts to avoid Medicare rules warrant the provider's or supplier's prohibition from Medicare for a longer period than was originally imposed.

The affected provider or supplier could appeal CMS' imposition of additional years to the provider's or supplier's existing reenrollment bar under § 424.535(c)(2). These appeals rights would be governed by 42 CFR part 498. However, they would not extend to the imposition of the original enrollment bar under § 424.535(c)(1); they would be limited to the additional years imposed under § 424.535(c)(2).

Third, we propose in new § 424.535 paragraph (c)(3) that CMS may impose a reenrollment bar of up to 20 years if the provider or supplier is being revoked from Medicare for the second time. Multiple revocations indicate that the provider or supplier cannot be considered a reliable partner of the Medicare program. The reenrollment bar under paragraph (c)(3) would be in lieu of the reenrollment bar described in paragraph (c)(1). We would determine the bar's length by considering the following factors: (1) The reasons for the revocations; (2) the length of time between the revocations; (3) whether the provider or supplier has any history of final adverse actions (other than Medicare revocations) or Medicare or Medicaid payment suspensions; and (4) any other information that CMS deems relevant to its determination. We could apply paragraph (c)(3) even if the two revocations occurred under different names, numerical identifiers or business identities so long as we can determine that the two actions effectively involved the same provider or supplier.

Fourth, we propose in new § 424.535(c)(4) that a reenrollment bar would apply to a provider or supplier under any of its current, former or future business names, numerical identifiers or business identities. This would help ensure that revoked providers and suppliers do not attempt to circumvent a revocation and reenrollment bar by changing their name, identity, business structure, etc.

We recognize that some providers and suppliers may be concerned about our reenrollment bar proposals. Our sole objective is to ensure that unscrupulous providers and suppliers are kept out of Medicare for as long as possible. Longer bars of 10 and 20 years would be reserved for egregious cases of fraudulent, dishonest or abusive behavior.

5. Reapplication Bar

We propose in new § 424.530(f) that CMS may prohibit a prospective provider or supplier from enrolling in

Medicare for up to 3 years if its enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to gain enrollment in Medicare. This "reapplication" bar would apply to the individual or organization under any current, former or future name, numerical identifier or business identity.

The purpose of this provision is to keep untrustworthy providers and suppliers from entering the Medicare program and to forestall future efforts to enroll. We believe the submission of false information or the withholding of information relevant to the provider's or supplier's enrollment eligibility represents a significant program integrity risk. For this reason, and to provide consequences for such behavior, we believe that our proposed reapplication bar is warranted.

When determining the reapplication bar's length, we would consider the following factors: (1) The materiality of the information in question; (2) whether there is evidence to suggest that the provider or supplier purposely furnished false or misleading information or deliberately withheld information; (3) whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions; and (4) any other information that we deem relevant to our determination.

6. Referral of Debt to the United States Department of Treasury

The Debt Collection Improvement Act of 1996 requires federal agencies to refer eligible delinquent debt to the United States Department of Treasury-designated Debt Collection Center (DCC) for cross-servicing and offset. CMS must refer all eligible debt over 120 days delinquent for cross-servicing and offset. Prior to sending a debt to the Department of Treasury, CMS attempts to recoup it via the procedures outlined in CMS Publication 100-06, chapter 4. Generally speaking, we refer a debt to the Department of Treasury only if it cannot recover the debt through its existing procedures. However, in all cases, a provider or supplier is given adequate opportunity to repay the debt or make arrangements to do so (for example, via a repayment plan) before the debt is sent to the Department of Treasury.

We believe that referral to the Department of Treasury may indicate the provider's or supplier's unwillingness to repay a debt, which consequently brings into doubt whether

the provider or supplier can be a reliable partner of the Medicare program. Accordingly, we propose in new § 424.535(a)(17) that CMS may revoke a provider's or supplier's Medicare enrollment if the provider or supplier has an existing debt that CMS refers to the Department of Treasury. In determining whether a revocation is appropriate, we would consider the following factors:

- The reason(s) for the failure to fully repay the debt (to the extent this can be determined).
- Whether the provider or supplier has attempted to repay the debt.
- Whether the provider or supplier has responded to our request(s) for payment.
- Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.
- The amount of the debt.
- Any other information that we deem relevant to our determination.

7. Failure To Report

Section 424.535(a)(9) permits CMS to revoke the Medicare enrollment of a physician, non-physician practitioner, physician group or non-physician practitioner group if the provider or supplier fails to comply with § 424.516(d)(1)(ii) or (iii), which require the provider or supplier to report a change in its practice location or final adverse action status within 30 days of the change.

We propose to expand § 424.535(a)(9) in two ways. First, we propose that CMS may apply § 424.535(a)(9) to all of the reporting requirements in § 424.516(d), not merely those in § 424.516(d)(1)(ii) and (iii). Thus, we could revoke the Medicare enrollment of a physician, non-physician practitioner, physician group or non-physician practitioner group if the supplier fails to report either of the following:

- A change of ownership, final adverse action or practice location within 30 days of the change (as required under § 424.516(d)(1)(i), (ii) and (iii), respectively).
- Any other change in enrollment data within 90 days of the change (as required under § 424.516(d)(2)).

Second, we propose that CMS may apply § 424.535(a)(9) to the reporting requirements in § 410.33(g)(2) (pertaining to IDTFs), § 424.57(c)(2) (pertaining to DMEPOS suppliers), and § 424.516(e) (pertaining to all other provider and supplier types). Consequently, we could revoke a provider or supplier under § 424.535(a)(9) if any of the following occur:

- An IDTF fails to report a change in ownership, location, general supervision or final adverse action within 30 days of the change or fails to report any other change in its enrollment data within 90 days of the change.

- A DMEPOS supplier fails to submit any change in its enrollment information within 30 days of the change.

- A provider or supplier other than a physician, non-physician practitioner, physician group, non-physician practitioner group, IDTF or DMEPOS supplier fails to report any of the following:

- ++ A change in ownership or control within 30 days of the change.

- ++ A revocation or suspension of a federal or state license or certification within 30 days of the revocation or suspension.

- ++ Any other change in its enrollment data within 90 days of the change.

We do not believe our revocation authority under § 424.535(a)(9) should be restricted to certain provider and supplier types that have omitted reporting a change in practice location or final adverse action. Any failure to report changed enrollment data, regardless of the provider or supplier type involved, is of concern to us. We must have complete and accurate data on each provider and supplier to help confirm that the provider or supplier still meets all Medicare requirements and that Medicare payments are made correctly. Inaccurate or outdated information puts the Medicare Trust Funds at risk.

While we would retain the discretion to revoke a provider's or supplier's enrollment for any failure to meet the reporting requirements in § 424.516(d) or (e), § 410.33(g)(2) or § 424.57(c)(2), our proposal is focused on egregious cases of non-reporting. For instance, a provider's belated omission to report a ZIP code change until 120 days after the change does not represent the level of program integrity risk of a complete failure to report a new practice location. We would consider the following factors in determining whether a § 424.535(a)(9) revocation is appropriate: (1) Whether the data in question was reported; (2) if the data was reported, how belatedly; (3) the materiality of the data in question; and (4) any other information that we deem relevant to our determination.

8. Payment Suspensions

Section 424.530(a)(7) permits the denial of a provider's or supplier's Medicare enrollment application if the

current owner, physician or non-physician practitioner has been placed under a Medicare payment suspension in accordance with §§ 405.370 through 405.372. Under § 405.371, a Medicare payment suspension may be imposed if CMS determines that a credible allegation of fraud against a provider or supplier exists. The general purpose of a payment suspension is to temporarily halt the payment of Trust Fund dollars to a provider or supplier pending the resolution of a particular matter, such as an investigation as to whether the provider or supplier has engaged in fraudulent activity.

We propose several revisions to § 424.530(a)(7) and one revision to § 405.371.

First, we propose to expand § 424.530(a)(7)'s applicability to all provider and supplier types and to any owning or managing employee or organization of the provider or supplier. We believe the existing scope of § 424.530(a)(7), which is limited to owners, physicians, and non-physician practitioners, does not address the continuum of program vulnerabilities in this area; providers and suppliers other than physicians and non-physician practitioners are currently not prohibited from enrolling in Medicare based on a payment suspension. Furthermore, a managing individual or entity often has as much (or more) day-to-day control over a provider or supplier as an owner. In our view, permitting a provider or supplier to enroll in Medicare even though one of its managing officials or organizations is under a payment suspension poses a risk to Medicare and its beneficiaries.

Second, we propose to include Medicaid payment suspensions within the scope of § 424.530(a)(7). Under § 455.23, the state Medicaid agency must suspend all Medicaid payments to a provider or supplier after the agency determines there is a credible allegation of fraud for which a Medicaid investigation is pending (unless the agency has good cause to not suspend payments). We see no significant difference between Medicare and Medicaid payment suspensions in terms of the threat posed to federal health care program integrity; indeed, potentially fraudulent behavior in the Medicaid program could be repeated in the Medicare program. As such, we must be able to prevent such providers and suppliers from entering Medicare.

Third, we propose to incorporate these revised provisions into a new § 424.530(a)(7)(i).

Fourth, we propose to establish a new § 424.530(a)(7)(ii) that would permit

CMS to apply § 424.530(a)(7) to the following:

- Any of the provider's or supplier's or owning or managing employee's or organization's current or former names, numerical identifiers or business identities.
- Any of the provider's or supplier's existing enrollments.

This reflects our desire to ensure that questionable parties are unable to reenter the Medicare program (be it as a provider, supplier, owner or manager) by using alternate identifiers. We are also concerned about situations where the provider or supplier has multiple enrollments, including those under different business structures, tax identification numbers, etc.

We would consider the following factors in determining whether a denial is appropriate:

- The specific behavior in question.
- Whether the provider or supplier is the subject of other similar investigations.
- Any other information that we deem relevant to our determination.

Fifth, we propose to expand § 405.371 to state that a Medicare payment suspension may be imposed if a state Medicaid program suspends payment pursuant to § 455.23(a)(1). Again, we are concerned that possible fraudulent behavior in the Medicaid program might be repeated in the Medicare program.

9. Other Federal Program Termination

To further protect Medicare from inappropriate activities occurring in other programs, we propose two changes regarding denials and revocations.

(a) Denials

We propose in new § 424.530(a)(14) that CMS may deny a provider's or supplier's Medicare enrollment application if the provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a particular state Medicaid program or any other federal health care program, or the provider's or supplier's license is currently revoked or suspended in a state other than that in which the provider or supplier is enrolling. We note that under § 455.416(c), a Medicaid state agency must deny a provider's or supplier's enrollment application if the provider or supplier is presently revoked from Medicare; § 424.530(a)(14) would help ensure consistency with the framework of § 455.416(c). As mentioned previously, we are concerned that a provider's or supplier's improper behavior in another federal health care program may be duplicated in Medicare. Similarly, we believe that

a Medicare provider's or supplier's actions that led to a licensure revocation or suspension in one state could be repeated with respect to its prospective enrollment in another state.

We believe that the presence of a relevant suspension warrants additional scrutiny for providers or suppliers attempting to enroll in Medicare, for the conduct underlying the suspension could raise questions as to the prospective provider's or supplier's ability to be a dependable Medicare participant. We recognize that licensure and federal program suspensions are generally temporary rather than permanent actions. However, under certain conditions, license suspensions may be imposed for extended periods and involve serious transgressions. We believe that under conditions indicating significant risks to program integrity, we should consider such conduct and determine the risk it poses before allowing the provider or supplier to enroll.

We note that § 424.530(a)(14) could apply regardless of whether any appeals are pending. Under current § 424.535(a)(12)(ii), we may not revoke a provider's or supplier's Medicare enrollment based on a Medicaid termination unless the provider or supplier has exhausted all applicable appeal rights regarding the Medicaid termination. We do not believe a similar clause should apply to § 424.530(a)(14). Akin to what we stated in the previous paragraph, we believe it would be inappropriate to permit a Medicaid-terminated provider or supplier (or a provider or supplier terminated under any federal program) into Medicare simply because the provider or supplier has not yet exhausted its appeal rights. Indeed, such a clause might encourage the provider or supplier to file a frivolous appeal in order to enroll in Medicare prior to the exhaustion of its appeal rights.

In determining whether to invoke § 424.530(a)(14) in a particular case, we would consider the following factors:

- The reason(s) for the termination, revocation or suspension.
- Whether, as applicable, the provider or supplier is currently terminated or suspended (or otherwise barred) from more than one program (for example, more than one state's Medicaid program), has been subject to any other sanctions during its participation in other programs or by any other state licensing boards or has had any other final adverse actions imposed against it.
- Any other information that we deem relevant to our determination.

Consistent with our discussion throughout this proposed rule, we further propose that § 424.530(a)(14) would apply to the provider or supplier under any of its current or former names, numerical identifiers or business identities.

(b) Revocations

Under § 424.535(a)(12), Medicare may revoke a provider's or supplier's enrollment if a state Medicaid agency terminates the provider's or supplier's Medicaid enrollment. Similar to our discussion concerning § 424.530(a)(14), we propose to expand § 424.535(a)(12)(i) such that CMS may revoke a provider's or supplier's Medicare enrollment if the provider or supplier is terminated or revoked (or otherwise barred) from participation in any other federal health care program. In determining whether a revocation is appropriate, CMS would consider the following factors:

- The reason(s) for the termination or revocation.
- Whether the provider or supplier is currently terminated, revoked or otherwise barred from more than one program (for example, more than one state's Medicaid program) or has been subject to any other sanctions during its participation in other programs.

• Any other information that we deem relevant to our determination.

Section 424.535(a)(12)(ii) states that Medicare may not terminate a provider's or supplier's enrollment unless and until a provider or supplier has exhausted all applicable appeal rights. We are not proposing to modify this provision. We would not revoke a provider's or supplier's enrollment under paragraph (a)(12)(i) unless all applicable appeal rights have been exhausted.

Also, for reasons previously explained, we propose to add new § 424.535(a)(12)(iii) under which we may apply § 424.535(a)(12)(i) to the provider or supplier under any of its current or former names, numerical identifiers or business identities.

10. Extension of Revocation

We propose in new § 424.535(i) that CMS may revoke any and all of a provider's or supplier's Medicare enrollments—including those under different names, numerical identifiers or business identities and those under different types (for example, an entity is enrolled as a group practice via the Form CMS-855B and as a DMEPOS supplier via the Form CMS-855S (OMB Control No. 0938-1056))—if the provider or supplier is revoked under § 424.535(a).

This provision is designed to ensure that individuals and entities that are revoked for inappropriate behavior are not permitted to remain enrolled in Medicare in any capacity. Consider the following examples:

- A physician's State X enrollment is revoked because his license in X was revoked. Under § 424.535(i), we also could revoke the physician's state Y enrollment even if he is still licensed in Y.

- An entity has two enrollments: One via the Form CMS-855A as a certified supplier, another via the Form CMS-855B as a group practice. The entity's Form CMS-855A enrollment is revoked under § 424.535(a)(4). Under § 424.535(i), CMS could also revoke the organization's Form CMS-855B enrollment, even if that enrollment is in another state.

- A non-physician practitioner is enrolled via the Form CMS-855I (OMB Control No. 0938-0685) as an individual supplier and as a DMEPOS supplier via the Form CMS-855S. The individual's Form CMS-855I enrollment is revoked for abusive billing practices. Under § 424.535(i), CMS could also revoke her Form CMS-855S enrollment.

In determining whether to revoke a provider's or supplier's other enrollments under § 424.535(i), we would consider the following factors:

- The reason for the revocation and the facts of the case.
- Whether any final adverse actions have been imposed against the provider or supplier regarding its other enrollments (for example, licensure suspensions imposed by the state, prior revocations, payment suspensions).
- The number and type(s) of other enrollments (for instance, Form CMS-855B).
- Any other information that we deem relevant to our determination.

This provision would be applied in highly exceptional cases where the provider's or supplier's conduct was particularly egregious or the maintenance of the provider's or supplier's other enrollments would jeopardize the Medicare Trust Funds. Moreover, § 424.535(i) would not be an "all or nothing" provision, meaning that we would not be required to revoke all of the provider's or supplier's enrollments if we chose to invoke § 424.535(i). We would apply the previously listed factors to each enrollment in determining whether it should be revoked.

11. Voluntary Termination Pending Revocation

As mentioned in section II.A. of this proposed rule, we have seen instances

of providers and suppliers failing to meet Medicare requirements or otherwise engaging in improper behavior, and then voluntarily terminating their Medicare enrollment in order to avoid a potential revocation of their enrollment and a consequent reenrollment bar. For instance, assume that we perform a site visit of a provider's lone location. The location does not comply with our requirements. Knowing that its Medicare enrollment may soon be revoked, the provider submits a Form CMS-855 to voluntarily terminate its enrollment; the purpose, again, is to depart Medicare to avoid a formal revocation and reenrollment bar and any other consequences stemming therefrom.

We believe that such attempts to circumvent the revocation process represent a risk to the Medicare program. Not only do these actions reflect dishonesty on the provider's or supplier's part, but also that the provider or supplier may be deliberately taking advantage of program vulnerabilities because no reenrollment bar has been imposed. To this end, we propose in new § 424.535(j)(1) that we may revoke a provider's or supplier's Medicare enrollment if we determine that the provider or supplier voluntarily terminated its Medicare enrollment in order to avoid a revocation under § 424.535(a) that CMS would have imposed had the provider or supplier remained enrolled in Medicare. In making our determination, we would consider all of the following:

- If there is evidence to suggest that the provider knew or should have known that it was or would be out of compliance with Medicare requirements.
- If there is evidence to suggest that the provider knew or should have known that its Medicare enrollment would be revoked.
- If there is evidence to suggest that the provider voluntarily terminated its Medicare enrollment in order to circumvent such revocation.
- Any other evidence or information that CMS deems relevant to its determination.

In new paragraph (j)(2), we propose that a revocation under § 424.535(j)(1) would be effective the day before the Medicare contractor receives the provider's or supplier's Form CMS-855 voluntary termination application. This date is appropriate because the provider's or supplier's submission of the voluntary termination application is the basis for a revocation under paragraph (j)(1); procedurally, the voluntary termination would be reversed (if the Medicare contractor

processed the application to completion) and then the provider's or supplier's enrollment would be revoked.

12. Enrollment for Ordering/Certifying/Referring/Prescribing of All Part A and B Services, Items, and Drugs; Maintenance of Documentation.

a. Enrollment

We stated earlier that section 6405(c) of the Affordable Care Act gives the Secretary the authority to extend the requirements of section 6405(a) and (b) of the Affordable Care Act to all other categories of items or services under title XVIII of the Act (including covered Part D drugs) that are ordered, prescribed or referred by a physician or eligible professional enrolled under section 1866(j) of the Act. Under this authority, § 424.507(a) and (b) collectively state that to receive payment for ordered imaging services, clinical laboratory services, DMEPOS items or home health services, the service or item must have been ordered or certified by a physician or, when permitted, an eligible professional who—(1) is enrolled in Medicare in an approved status; or (2) has a valid opt-out affidavit on file with an A/B MAC.

Sections 424.507(a) and (b) were implemented via an April 27, 2012 final rule titled: "Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements" (77 FR 25284). Also, in the previously mentioned May 23, 2014 final rule (79 FR 29843), we finalized provisions under which the prescriptions of a physician or eligible professional who is not enrolled in Medicare and does not have a valid opt-out affidavit on file with an A/B MAC would not be covered under the Part D program.

The purpose of the provider enrollment process is to ensure that providers and suppliers that furnish services and items to Medicare beneficiaries meet all Medicare requirements. Section 424.507(a) and (b) were designed to help us confirm that individuals who order or certify certain types of Medicare services and items were qualified to do so. Indeed, without the enrollment process, we cannot determine whether these persons meet all Medicare requirements. There could be situations where an unqualified individual is ordering numerous Medicare services other than those currently listed in § 424.507 (such as tests) that are potentially dangerous to beneficiaries. Moreover, unnecessary services and items could result in

wasted Medicare expenditures. In short, we must be able to screen all physicians and eligible professionals to ensure that Medicare requirements are met, and that Medicare beneficiaries and the Trust Funds are protected.

We believe that the importance of confirming that all physicians and eligible professionals who order, certify, refer or prescribe Part A or B services, items or drugs (and not simply those services and items described in § 424.507) are qualified to do so dictates that we expand the purview of § 424.507. To this end, we propose the following changes to § 424.507(a) and (b):

The heading to paragraph (a) currently reads: “Conditions for payment of claims for ordered covered imaging and clinical laboratory services and items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).” We propose to change this to state: “Conditions for payment of claims for ordered, certified, referred or prescribed covered Part A or B services, items or drugs.”

The heading to existing paragraph (a)(1) reads: “Ordered covered imaging, clinical laboratory services, and DMEPOS item claims.” We propose to change this to state: “Ordered, certified, referred or prescribed covered Part A or B services, items or drugs.”

The opening sentence in paragraph (a)(1) currently states in part: “To receive payment for ordered imaging, clinical laboratory services, and DMEPOS items (excluding home health services described in § 424.507(b), and Part B drugs)”. We propose to change this language to read: “To receive payment for ordered, certified, referred or prescribed covered Part A or B services, items or drugs”.

Paragraph (a)(1)(i) states in part: “The ordered covered imaging, clinical laboratory services, and DMEPOS items (excluding home health services described in paragraph (b) of this section, and Part B drugs) must have been ordered by”. We propose to change this language to: “The ordered, certified, referred or prescribed covered Part A or B service, item or drug must have been ordered, certified, referred or prescribed by”.

In paragraph (a)(2), we propose to change the heading from “Part B beneficiary claims” to “Part A and B beneficiary claims.” We also propose to change the language that states “To receive payment for ordered covered items and services listed at § 424.507(a)” to “To receive payment for ordered, certified, referred or prescribed covered Part A or B services, items or drugs”.

In paragraphs (a)(1)(ii), (a)(1)(iii), and (a)(2)(i), we propose to change the language that reads “who ordered the item or service” to “who ordered, certified, referred or prescribed the Part A or B service, item or drug”.

We propose to change the existing language in paragraphs (a)(1)(iv) and (a)(2)(ii) that reads “If the item or service is ordered by” to “If the Part A or B service, item or drug is ordered, certified, referred or prescribed by”.

We propose to revise the existing language in paragraphs (a)(1)(iv)(A)(1) and (a)(2)(ii)(A)(1) from “As the ordering supplier” to “As the ordering, certifying, referring or prescribing supplier”.

We propose to change the current language in paragraphs (a)(1)(iv)(B) and (a)(2)(ii)(B) that reads “order such items and services” to “order, certify, refer or prescribe such services, items, and drugs”.

In paragraphs (a)(1)(iv)(B)(1) and (a)(2)(ii)(B)(1), we propose to replace the word “order” with “order, certify, refer or prescribe”.

We propose to delete the existing version of paragraph (b), which deals with home health services. Such services would be addressed in revised paragraph (a). We propose to redesignate current paragraph (c) as revised paragraph (b). We also propose in this paragraph to—

- Change the language that reads “covered items and services” to “ordered, certified, referred or prescribed Part A or B services, items or drugs;”
- Delete “or (b)” and “and (b)”, since the existing version of paragraph (b) would be replaced;
- Change “paragraphs (a)(1)” to “paragraph (a)(1)”; and
- Delete “respectively.”

We propose to redesignate current paragraph (d) as revised paragraph (c). We also propose in this paragraph to do the following:

- Change the language that reads “covered items or services” to “ordered, certified, referred or prescribed covered Part A or B services, items or drugs”.
- Change the language that states “paragraphs (a) and (b)” to “paragraph (a).” Delete paragraph (d).

Our proposal would include drugs that are covered under Part B. This, combined with § 423.120(c), would help confirm that all prescribers of Medicare drugs are thoroughly vetted for compliance with Medicare requirements.

We further propose that our changes to § 424.507 would become effective on January 1, 2018, in order to give sufficient time for—(1) providers and

suppliers to complete the enrollment or opt-out process; (2) stakeholders (including CMS and its contractors) to prepare for, operationalize, and implement these requirements; and (3) provider and beneficiary education. The current version of § 424.507 would remain in effect through December 31, 2017.

In the April 27, 2012 final rule (77 FR 25291), we agreed with commenters that there were a number of operational issues associated with a requirement that services of a specialist be ordered or referred, and we removed that requirement. However, with the successful implementation of the current version of § 424.507, we believe that the expansion of § 424.507 to include other services can be fully operationalized.

b. Maintenance of Documentation

In the November 19, 2008 **Federal Register**, we published a final rule with comment period titled, “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E- Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies” (73 FR 69726). In that rule, we established § 424.516(f) stating that—(1) a provider or supplier is required to maintain ordering and referring documentation, including the NPI, received from a physician or eligible non-physician practitioner for 7 years from the date of service; and (2) physicians and non-physician practitioners are required to maintain written ordering and referring documentation for 7 years from the date of service.

Section 6406(b)(3) of the Affordable Care Act amended section 1866(a)(1) of the Act to require that providers and suppliers maintain and, upon request, provide to the Secretary, access to written or electronic documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services or referrals for other items or services written or ordered by the provider as specified by the Secretary. Under section 6406(a) of the Affordable Care Act, which amended section 1842(h) of the Act, the Secretary may revoke a physician’s or supplier’s enrollment if the physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services or referrals for

other items or services written or ordered by such physician or supplier, as specified by the Secretary.

Consistent with the authority given to the Secretary in sections 6406(a) and (b)(3) of the Affordable Care Act, we revised § 424.516(f) in the previously referenced April 27, 2012 final rule to state as follows:

- Under paragraph (f)(1), a provider or supplier that furnishes covered ordered items of DMEPOS, clinical laboratory, imaging services or covered ordered/certified home health services is required to maintain documentation for 7 years from the date of service, and provide access to that documentation upon the request of CMS or a Medicare contractor.

- Under paragraph (f)(2), a physician who orders/certifies home health services and the physician or, when permitted, other eligible professional who orders items of DMEPOS or clinical laboratory or imaging services is required to maintain documentation for 7 years from the date of service, and provide access to that documentation upon the request of CMS or a Medicare contractor.

The documentation in paragraphs (f)(1) and (2) includes written and electronic documents (including the NPI of the physician who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

We propose to expand these requirements in § 424.516(f) to include all Part A and Part B services, items, and drugs that are ordered, certified, referred or prescribed by a physician or, when permitted, eligible professional. Thus, the provider or supplier furnishing the Part A or B service, item or drug, as well as the physician or, when permitted, eligible professional who ordered, certified, referred or prescribed the service, item or drug, would have to maintain documentation for 7 years from the date of the service and furnish access to that documentation upon a CMS or Medicare contractor request. The documentation would include written and electronic documents (including the NPI of the ordering/certifying/referring/prescribing physician or, when permitted, eligible professional) relating to written orders, certifications, referrals, prescriptions, and requests for payments for a Part A or B service, item or drug.

We believe it is important that our expansion of § 424.516(f) include all Part A and B services, items, and drugs be consistent with our proposed revisions to § 424.507. Both provisions are intended to help make certain that payments for Part A and B services, items, and drugs are made correctly. To require all persons who order, certify, refer, and prescribe Part A and B services, items or drugs to enroll in Medicare without requiring them (or the billing provider) to retain supporting documentation would undercut the effectiveness of § 424.507. Without being able to review this documentation, we may lack the ability to confirm that the order, certification, referral or prescription was proper and that the ordering, certifying, referring or prescribing individual was qualified.

13. Opt-Out Physicians and Practitioners

As previously mentioned, no Medicare payment (either directly or indirectly) will be made for services furnished by opt-out physicians or practitioners, except as permitted in accordance with § 405.435(c) and § 405.440. The effects of opting-out are described in § 405.425. Section 405.425(i) states that an opt-out physician or practitioner who has not been excluded under sections 1128, 1156 or 1892 of the Act may order, certify the need for or refer a beneficiary for Medicare-covered items and services, provided he or she is not paid directly or indirectly for such services (except as provided in § 405.440). Under § 405.425(j), an excluded physician or practitioner may not order, prescribe or certify the need for Medicare-covered items and services except as provided in 42 CFR 1001.1901, and must otherwise comply with the terms of the exclusion in accordance with 42 CFR 1001.1901.

We propose to revise § 405.425(i) and (j) by including opt-out physicians and practitioners who are revoked under § 424.535. Thus, a revoked opt-out physician or practitioner would be unable to order, prescribe, and certify the need for or refer a beneficiary for Medicare-covered services and items except as otherwise provided in those paragraphs.

We are concerned that revoked physicians and practitioners who have opted-out could, through inappropriate ordering and certifying practices, pose a risk to Medicare beneficiaries. Our concern is heightened because opt-out physicians and practitioners are not subject to the same stringent enrollment and verification processes that enrolled physicians and practitioners are.

Therefore, we believe that these proposed changes are necessary.

14. Moratoria

Under § 424.570(a), CMS may impose a temporary moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. Per § 424.570(a)(2)(i), a moratorium is imposed when CMS determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or a particular geographic area or both. Consistent with this authority, we have published several **Federal Register** documents announcing the imposition of a temporary moratorium on the enrollment of HHAs and ambulance suppliers. (See, for example, the July 31, 2013 (78 FR 46339) and February 4, 2014 (79 FR 6475) **Federal Register**.)

We are proposing several changes to § 424.570(a).

a. Change in Practice Location

Section 424.570(a)(1)(iii) states that a temporary moratorium does not apply to changes in practice locations, changes in provider or supplier information (such as phone numbers) or changes in ownership (except changes in ownership of HHAs that would require an initial enrollment under § 424.550).

We are proposing three revisions to § 424.570(a)(1)(iii).

The first proposal would divide the current version of § 424.570(a)(1)(iii) into paragraphs (A), (B), and (C) so that each requirement mentioned in paragraph (iii) could be addressed individually.

Secondly, we would clarify in paragraph (a)(1)(iii)(A), which would address practice locations, that a temporary moratorium applies to situations in which a provider or supplier is changing a practice location from a location outside the moratorium area to a location inside the moratorium area. We see no difference between this situation and one in which a provider or supplier is opening a brand new practice location in the moratorium area. In both cases, an additional site is being established in the moratorium area, something the moratorium is designed to prevent. Therefore, we believe this change is necessary.

Lastly, we would clarify the existing policy in paragraph (a)(1)(iii)(C) by removing the language “under § 424.550”. Under § 489.18(c), if an HHA changes ownership as specified in § 489.18(a), the existing provider agreement is automatically assigned to

the new owner. However, if the new owner declines to accept the assets and liabilities of the HHA and refuses assignment of the provider agreement, § 489.18(c) does not apply and the HHA must enroll as a new provider, that is, via an initial enrollment. The existing reference to § 424.550 in paragraph (a)(1)(iii) may have caused some confusion on this point. Accordingly, we are proposing to remove this reference in order to clarify current policy.

b. Application of Moratorium

Section 424.570(a)(1)(iv) currently states that a temporary enrollment moratorium does not apply to any enrollment application that has been approved by the enrollment contractor but not yet entered into PECOS at the time the moratorium is imposed. We propose to revise this paragraph to state that a temporary moratorium does not apply to any enrollment application that has been received by the Medicare contractor prior to the date the moratorium is imposed.

In the moratoria that have been imposed, some providers and suppliers have spent many thousands of dollars preparing for enrollment only to have their Form CMS-855 applications denied near the end of the enrollment process because of the sudden imposition of a moratorium. This has been especially problematic for HHAs—(1) whose Form CMS-855A applications have been recommended for approval by the contractor; (2) that have successfully completed a state survey; and (3) whose applications and survey results have been forwarded by the state to the CMS regional office for final review. This entire process can take a substantial amount of time, and the considerable resources the provider or supplier may have expended by this point are effectively lost when CMS imposes a moratorium.

We believe this has been an unintended consequence of the moratoria. In our view, the overall objective of the moratoria—the need to reduce the potential for fraud, waste or abuse in certain geographic areas—can be equally satisfied by applying a moratorium to applications submitted after the moratorium is imposed. Thus, we believe that our proposed “prior to the moratorium date” threshold is appropriate.

We also propose in § 424.570(a)(1)(iv) to change the term “enrollment contractor” to “Medicare contractor.” We believe the latter term is more consistent with CMS’ use of Medicare Administrative Contractors.

15. Surety Bonds

Since 2009, certain DMEPOS suppliers have been required under § 424.57(d) to obtain, submit, and maintain a surety bond in an amount of at least \$50,000 as a condition of enrollment. Paragraph (d)(5)(i) states that the surety bond must guarantee that the surety will, within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety’s liability under the bond of unpaid claims, CMPs or assessments, pay CMS a total of up to the full penal amount of the bond in the following amounts: (1) The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible; and (2) the amount of any unpaid claims, CMPs or assessments imposed by CMS or the OIG on the DMEPOS supplier, plus accrued interest. Further, paragraph (d)(5)(ii) states that the surety bond must provide that the surety is liable for unpaid claims, CMPs or assessments that occur during the term of the bond.

We have specific procedures for collecting monies from sureties in accordance with § 424.57(d)(5) and have recouped several million dollars via these procedures. However, we have encountered instances where the surety has failed to submit payment to CMS, notwithstanding its obligation to do so under both § 424.57(d)(5) and the surety bond’s terms. We do not believe we should permit a DMEPOS supplier to use that particular surety when the latter has not fulfilled its legal responsibilities to us as the obligee under the surety bond. We thus propose in new § 424.57(d)(16) that CMS may reject an enrolling or enrolled DMEPOS supplier’s new or existing surety bond if the surety that issued the bond has failed to make a required payment to CMS in accordance with § 424.57(d). This means that we could reject any and all surety bonds furnished by the surety to enrolling or enrolled DMEPOS suppliers under § 424.57(d), not just the surety bond(s) on which the surety refused to make payment. If we reject a surety bond under proposed § 424.57(d)(16), the enrolling or enrolled DMEPOS supplier would have to obtain a bond from a new surety in order to enroll in or maintain its enrollment in Medicare.

To illustrate how § 424.57(d)(16) would operate, suppose a surety has issued surety bonds for DMEPOS suppliers W, X, Y, and Z, all of which are enrolled in Medicare. CMS sought to collect from the surety on the bond issued for Supplier X, but the surety failed to make payment. We would have

the discretion to—(1) reject the bonds for W, X, Y, and Z, thus requiring the suppliers to obtain new bonds from a different surety; and (2) refuse to accept future bonds issued to DMEPOS suppliers by the non-compliant surety. In making a determination under items (1) and (2) in the previous sentence, CMS would consider the following several factors:

- The total number of Medicare-enrolled DMEPOS suppliers to which the surety has issued surety bonds.
- The total number of instances in which the surety has failed to make payment to CMS.
- The reason(s) for the surety’s failure(s) to pay.
- The percentage of instances in which the surety has failed to pay.
- The total amount of money that the surety has failed to pay.
- Any other information that CMS deems relevant to its determination.

Although CMS would reserve the right to reject all of a surety’s existing bonds with Medicare-enrolled DMEPOS suppliers if the surety failed to make even one required payment, CMS would take into account the circumstances surrounding the surety and its failure to make payment per the aforementioned factors.

16. Reactivation

Under § 424.540(a), a provider’s or supplier’s Medicare billing privileges may be deactivated if the provider or supplier fails to—(1) submit any Medicare claims for 12 consecutive calendar months; (2) report a change to its Medicare enrollment information within 90 calendar days (or, for changes in ownership or control, within 30 days); or (3) furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or to resubmit and certify the accuracy of its enrollment information. To reactivate its billing privileges, the provider or supplier must follow the requirements of § 424.540(b). Specifically—

- Section 424.540 paragraph (b)(1) states that if the provider or supplier is deactivated for any reason other than non-submission of a claim, the provider or supplier must submit a new enrollment application or, when deemed appropriate, recertify that the enrollment information currently on file with Medicare is correct; and
- Paragraph (b)(2) states that if the provider or supplier is deactivated for non-submission of a claim, it must recertify that the enrollment information currently on file with Medicare is

correct and furnish any missing information as appropriate.

We propose to revise subsection (b) in two ways. Paragraph (1) would state that in order for a deactivated provider or supplier to reactivate its Medicare billing privileges, it must recertify that its enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate. Paragraph (2) would state that notwithstanding paragraph (1), CMS may for any reason require a deactivated provider or supplier to submit a complete Form CMS-855 application as a prerequisite for reactivating its billing privileges:

There are several reasons for these proposed changes. First, the existing language in § 424.540(b)(1) has been a source of confusion to providers and suppliers because it does not articulate what the phrase “when deemed appropriate” means; there also is some repetition between paragraphs (b)(1) and (b)(2), for both indicate that a recertification is acceptable. Our proposed version of paragraph (b)(1), which combines parts of existing paragraphs (b)(1) and (b)(2), would clarify that a provider or supplier may use recertification—regardless of the deactivation reason—as a means of reactivation.

Second, we believe CMS should have the discretion to require at any time the submission of a complete Form CMS-855 reactivation application irrespective of the deactivation reason. The Form CMS-855 captures information about the provider or supplier that, in the case of a reactivation, would help us determine whether the provider or supplier is still in compliance with Medicare enrollment requirements. A recertification, meanwhile, generally only consists of a statement from the provider or supplier that the information on file is correct and, if necessary, the submission of Form CMS-855 pages containing updated information. Therefore, the Form CMS-855 collects more information than the recertification submission, and there may be situations where CMS determines that a complete application must be submitted. These could include, but are not limited to, the following:

- The provider or supplier was deactivated for failing to submit a claim for 12 consecutive months and has been deactivated for at least 6 months.
- The provider or supplier does not have access to Internet-based PECOS.
- The provider or supplier was deactivated for failing to report a change of information.

In these circumstances, respectively, the provider or supplier—(1) has not submitted a claim for at least 18 months; (2) cannot view its existing enrollment data and thus may be unable to determine the accuracy of this information; and (3) previously failed to comply with Medicare requirements by not timely reporting changed enrollment data. Such instances, in our view, raise questions as to the validity of the provider’s or supplier’s current enrollment information and possibly its compliance with existing Medicare requirements, thus warranting a complete Form CMS-855 if we deem it necessary. We stress that we could request a complete application in any reactivation situation, not simply those outlined in this proposed section. However, we solicit comments on whether we should restrict the reasons for which CMS may request a complete reactivation application and, if so, what those reasons should be.

While we propose to revise § 424.540(b)(1) and (2) as previously described, we are not proposing any changes to § 424.540(b)(3).

17. Changes to Definition of Enrollment

We propose several additional changes to 42 CFR part 424 to address the general concept of enrollment as it pertains to the Form CMS-855O (OMB Control No. 0938-1135), which is used by physicians and eligible professionals seeking to enroll in Medicare solely to order and certify certain items or services and/or prescribe Part D drugs.

a. Definition of “Enroll/Enrollment” (§ 424.502)

We propose several revisions of the existing definition of “Enroll/Enrollment” in § 424.502.

First, the opening sentence of the definition currently states: “Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.” We propose 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, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs or to prescribe Part D drugs.” There are two reasons for this change. One is to align this definition with the language in our proposed revisions to § 424.507(a) and (b). (See section II.A.12. of this proposed rule.) The second is to address in this

definition the enrollment provisions in § 423.120(c)(6) relating to Part D drugs. In both cases, we are clarifying that the enrollment process includes a physician’s or eligible professional’s completion of the Form CMS-855O in order to meet the requirements of §§ 424.507(a) and (b) and 423.120(c)(6).

Second, the current version of paragraph (2) of the definition of “Enroll/Enrollment” states: “Except for those suppliers that complete the Form 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 propose to change this to read: “Except for those suppliers that complete the Form CMS-855O, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs or to prescribe Part D drugs, validating the provider’s or supplier’s eligibility to provide items or services to Medicare beneficiaries.” This revision is to clarify that a supplier’s completion of the Form CMS-855O solely to obtain eligibility to order, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs or to prescribe Part D drugs, does not convey Medicare billing privileges to the supplier.

Third, and for reasons similar to those involving our proposed change to paragraph (2) of the definition of “Enroll/Enrollment,” we propose to revise paragraph (4) thereof. The new version of paragraph (4) would read: “Except for those suppliers that complete the Form CMS-855O, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs or to prescribe Part D drugs, granting the Medicare provider or supplier Medicare billing privileges.”

b. Revision to § 424.505

We also propose to replace the language in § 424.505 that states “to order or certify Medicare-covered items and services” with “to order, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs or to prescribe Part D drugs.” This is to clarify that completion of the Form CMS-855O does not convey Medicare billing privileges to the supplier.

c. Revision to § 424.510(a)(3)

Section 424.510(a)(3) currently reads: “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.” We propose to revise this to state: “To be enrolled solely to order, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs or to prescribe Part D drugs, 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.” This change is intended to include within the purview of § 424.510(a)(3) those suppliers who are enrolling via the Form CMS–855O pursuant to § 423.120(c)(6) or pursuant to our proposed revisions to § 424.507(a) and (b).

d. Revision to § 424.535(a)

We also propose to change the term “billing privileges” in the opening paragraph of § 424.535(a) to “enrollment.” The paragraph would thus read: “CMS may revoke a currently enrolled provider’s or supplier’s Medicare enrollment and any corresponding provider agreement or supplier agreement for the following reasons”. This is to clarify that the revocation reasons in § 424.535(a) apply to all enrolled parties, including suppliers who are enrolled solely to order, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs, or to prescribe Part D drugs; the reasons are not limited to providers and suppliers that have Medicare billing privileges. Thus, for instance, a Part D prescriber’s Medicare enrollment may be revoked if one of the revocation reasons in § 424.535(a) applies.

We note also that the opening paragraph of § 424.530(a), which deals with denials, uses the term “enrollment” as well. Our change to § 424.535(a) would achieve consistency with § 424.530(a) in this regard.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate

whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

Concerning our affiliation proposal (§§ 424.519 and 455.107), and in the following discussion, the principal burden would come from completion of the applicable enrollment application sections and the time involved in researching data. However, we do solicit public comment and feedback regarding these burdens.

There are also burdens associated with our remaining proposals as discussed later in this section.

A. ICRs Related to Affiliations (§§ 424.519 and 455.107)

Proposed §§ 424.519 and 455.107 require, respectively, that a Medicare, Medicaid or CHIP provider or supplier disclose information about present and past affiliations with certain currently or formerly enrolled Medicare, Medicaid or CHIP providers and suppliers. Medicare providers and suppliers would need to furnish this information via the paper or Internet-based version of the Form CMS–855 application. Though the specific vehicle for collecting this data from Medicaid and CHIP providers and suppliers would be left to the state’s discretion, we anticipate that the information would be provided on an existing enrollment form or through a separate form created by the state. The principal burden involved with this collection would be the time and effort needed to—(1) obtain this information; and (2) complete and submit the appropriate section of the applicable form.

1. Medicare

a. Initially Enrolling Providers and Suppliers (§ 424.519(b))

Based on CMS data, an average of approximately 70,000 providers and suppliers seek to initially enroll in the Medicare program in any given 12-month period. This includes physicians; physician groups; non-physician practitioners; non-physician practitioner groups; Part A certified providers; Part B certified suppliers; Part B non-

certified suppliers; and DMEPOS suppliers. Each of these providers and suppliers would be required to furnish the information described in § 424.519 on the appropriate Form CMS–855 enrollment application.

We estimate that it would take each provider or supplier an average of 10 hours to obtain and furnish this information. We believe this is a high-end estimate because providers and suppliers will generally know, or be able to research, their present and past affiliations and their relationship with Medicare, Medicaid, and CHIP. Also, many enrolling physicians, non-physician practitioners, and other small providers and suppliers will have few, if any, reportable affiliations due to, for example, the limited number of owners and managing employees they may have or have had. However, we do not wish to underestimate the potential burden and we acknowledge that there may be instances where the provider or supplier would need to contact the affiliated provider or supplier regarding certain information. With a 10-hour burden for 70,000 providers and suppliers, we estimate that the annual hourly burden for compliance with § 424.519 would be 700,000 hours.

Based on our experience, we believe that the reporting provider’s or supplier’s administrative staff (for example, officer managers and support staff) would be responsible for securing and listing affiliation data on the Form CMS–855. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2014, the mean hourly wage for the general category of “Office and Administrative Support Occupations” is \$17.08 per hour (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000 With fringe benefits and overhead, the per hour rate is \$34.16).

Using this per hour rate, we estimate the annual ICR cost burden for initially enrolling providers and suppliers to be \$23,912,000 (700,000 hours × \$34.16).

b. Revalidating Providers and Suppliers (§ 424.519(b))

Medicare providers and suppliers, other than DMEPOS suppliers, are required to revalidate their Medicare enrollment every 5 years. (DMEPOS suppliers must revalidate every 3 years.) There are approximately 1.5 million providers and suppliers enrolled in the Medicare program; of this figure, roughly 87,000 are DMEPOS suppliers. For purposes of this ICR statement only, we project that future revalidations will be performed in relative accordance with the previously-referenced 5-year and 3-year periods.

TABLE 1—ESTIMATED NUMBER OF NON-DMEPOS SUPPLIER REVALIDATIONS: 2017–2021

Calendar year	Number of revalidations
2017	300,000
2018	300,000
2019	300,000
2020	300,000
2021	300,000

TABLE 2—ESTIMATED NUMBER OF DMEPOS SUPPLIER REVALIDATIONS: 2017–2021

Calendar year	Number of revalidations
2017	29,000
2018	29,000
2019	29,000
2020	29,000
2021	29,000

TABLE 3—ESTIMATED NUMBER OF REVALIDATIONS: 2015–2019 *

Calendar year	Number of revalidations
2017	329,000
2018	329,000
2019	329,000
2020	329,000
2021	329,000

* Table 3 combines the figures in Tables 1 and 2.

We note that we have the authority to perform “off-cycle” revalidations under § 424.515(e), that is, revalidations occurring more frequently than the 5-year and 3-year periods. Also, certain years may see fewer revalidations than others, for example, as a result of higher levels of attrition during a previous year. Since we cannot predict the exact number of revalidations (off-cycle or otherwise) that may occur in future, the figures in Table 2 represent our best estimates.

Through the revalidation process, providers and suppliers generally need to provide the same information as initially enrolling providers and suppliers. Hence, we estimate it would take revalidating providers and suppliers 10 hours to obtain and furnish affiliation information, and the work would be performed by administrative staff.

Using our estimate of 329,000 affected providers and suppliers each year, we project an annual ICR cost burden of \$112,386,400 (329,000 × 10 hours × \$34.16).

c. New and Changed Affiliations (§ 424.519(h))

Generally speaking, the Form CMS–855 does not presently collect information regarding the provider’s or supplier’s (or the provider’s or supplier’s owning or managing individuals’ and organizations’) interests in other Medicare providers and suppliers. As such, we cannot reasonably estimate the number of providers and suppliers that would submit Form CMS–855 change of information applications reporting a new or changed affiliation based on historical data. However, we project that it would take approximately 30 minutes (or .5 hours) for a provider or supplier to report and submit new or changed affiliation information to its Medicare contractor. We request comment on how often reportable affiliations are created or are changed, therefore necessitating reporting to CMS.

We estimate a total annual ICR burden on Medicare providers and suppliers from § 424.519 of 3,990,000 hours (700,000 + 3,290,000) at a cost of \$136,298,400 (\$23,912,000 + \$112,386,400).

2. Medicaid and CHIP

a. Initially Enrolling Providers and Suppliers (§ 455.107(b))

Based on existing data, we estimate that 56,250 providers and suppliers in a given 12-month period seek to enroll in the Medicaid program or CHIP. As stated before, the mechanism for collecting the data required under § 455.107 would lie within the state’s discretion. While burden may vary depending on the specific collection vehicle, we estimate it would take each provider or supplier an average of 10 hours to obtain and furnish this information, similar to our estimate for Medicare providers and suppliers. This would result in an annual ICR hour burden of 562,500 hours. At a per hour rate of \$34.16, we estimate the annual cost burden to be \$19,215,000 (562,500 hours × \$34.16).

b. Revalidating Providers and Suppliers (§ 455.107(b))

According to State Program Integrity Assessment data, there are approximately 1.9 million Medicaid-enrolled and CHIP-enrolled providers nationwide. These providers must revalidate their enrollments every 5 years in accordance with § 455.414. For purposes of this ICR statement, we project that an average of one-fifth or 380,000 (1.9 million × 0.20), of existing Medicaid and CHIP providers would be required to revalidate their enrollment

each year and, consequently, furnish the information required under § 455.107(b). This would result in an annual ICR hour burden of 3,800,000 hours. Using an hourly rate of \$34.16, we estimate the annual ICR cost burden for revalidating Medicaid and CHIP providers suppliers to be \$129,808,000 (3,800,000 hours × \$34.16).

c. New and Changed Affiliations (§ 455.107(h))

Some states do not collect information regarding the provider’s (or the provider’s owning or managing individuals’ and organizations’) interests in other Medicaid or CHIP providers or Medicare providers or suppliers. Therefore, we cannot reasonably estimate the number of Medicaid and CHIP providers that would report data regarding new or changed affiliations. We have no past data on which to base such a projection. However, we project that it would take approximately 30 minutes (or 0.5 hours) for a provider or supplier to report and submit new or changed affiliation information. We are soliciting comments on how often reportable affiliations are created or changed therefore necessitating reporting to the states.

We estimate a total annual ICR burden on Medicaid and CHIP providers and suppliers from § 455.107 of 4,362,500 hours at a cost of \$149,023,000 (\$19,215,000 + \$129,808,000).

3. Collection of Information From States

It is possible that states may be required to report to CMS certain information regarding its processing of data submitted pursuant to § 455.107. This could include, for example, the number of applications in which an affiliation was reported and the number of cases in which the state determined that an affiliation posed an undue risk. However, we are unable to estimate the possible ICR burden because we do not know whether, to what extent, and by what vehicle data concerning § 455.107 would be reported to CMS.

4. Total Burden

We estimate a total annual ICR hour burden on Medicare, Medicaid, and CHIP providers and suppliers from our proposal of 8,352,500 hours at a cost of \$285,321,400.

B. ICRs Related to Different Name, Numerical Identifier or Business Identity (§§ 424.530(a)(12) and 424.535(a)(18))

We do not have historical data to predict the number of instances in which we would determine that a

revoked provider or supplier is attempting to enroll in Medicare or is enrolled under a different name, numerical identifier or business identity. Since evidence of these activities are confined to the results of unique investigations, we believe the examples cited in the preamble text cannot form the basis of a representative sample from which to inform projections. Consequently, we cannot estimate the ICR burden that may result from such denials and revocations, which would primarily involve the submission of Form CMS-855 applications following denials or following the expiration of reenrollment bars. To enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on—(1) whether an annual figure of 8,000 potentially affected providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate because we do not have sufficient data to provide an estimate at this time.

C. ICRs Related To Billing for Non-Compliant Location (§ 424.535(a)(20))

We do not have sufficient historical data to form an estimate of the potential ICR burden of this proposal, which would primarily involve the submission of Form CMS-855 applications following the expiration of reenrollment bars. While there is data concerning the number of locations that are terminated from Medicare for non-compliance each year, we cannot predict the number of “additional” locations that would be terminated due to § 424.535(a)(20). In other words, if a provider or supplier has five locations and one is terminated for non-compliance, we have no way to predict whether any or all of the remaining four locations would be terminated. This is because each provider’s and supplier’s circumstances are different. Consequently, we are unable to project the total number of terminated locations.

D. ICRs Related to Abusive Ordering, Certifying, Referring or Prescribing of Part A or B Services, Items or Drugs (§ 424.535(a)(21))

As this is a new provision for which there is no historical data, we cannot project the number of instances in which we would revoke enrollment under § 424.535(a)(21). Therefore, we are unable to estimate the total potential ICR burden associated with this proposal, which would primarily involve the submission of Form CMS-855 applications following the

expiration of reenrollment bars. To enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on—(1) whether an annual figure of 4,000 potentially affected physicians and eligible professionals could serve as a reasonable approximation; and (2) the potential cost burden to physicians and eligible professionals. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

E. ICRs Related to Changes in Maximum Reenrollment Bars (§ 424.535(c))

We do not anticipate any collection burden resulting from our revisions to § 424.535(c). In fact, the burden may actually decrease because certain providers and suppliers may be barred from Medicare for a longer period of time and thus would submit Form CMS-855 applications less frequently.

F. ICRs Related to Reapplication Bar (§ 424.530(f))

We do not anticipate any collection burden resulting from our addition of § 424.530(f). Additional applications would not be submitted because of our proposal.

G. ICRs Related to Revocation for Referral of Debt to the United States Department of Treasury (§ 424.535(a)(17))

Each year on average, roughly 2,000 Medicare providers and suppliers have debts that are referred to the Department of Treasury. However, we are unable to predict the number of revocations that would result from our proposal because the circumstances of each case would be different. We believe that any ICR burden associated with this proposal would principally involve the submission of Form CMS-855 applications following the expiration of reenrollment bars. We note that as with several of our other proposals, § 424.535(a)(17) is a new provision for which there is no historical data, and it cannot be assumed that all 2,000 providers and suppliers would have their Medicare enrollments revoked. Therefore, to enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on—(1) whether 2,000 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden on providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

H. ICRs Related to Reporting Requirements (§ 424.535(a)(9))

We believe there would be an increase in the number of revoked providers and suppliers resulting from our expansion of § 424.535(a)(9). However, we cannot estimate this number, for the specific facts of each case would be different. As such, we cannot project the potential collection burden associated with this proposal, which would primarily involve the submission of Form CMS-855 applications following the expiration of reenrollment bars. To enhance our ability to formulate a projection of potential collection burden associated with this proposal, we are soliciting comment on—(1) whether an annual figure of 10,000 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers.

I. ICRs Related to Payment Suspensions (§ 424.530(a)(7) and § 405.371)

We are unable to estimate the total ICR burden of these provisions, for we cannot predict the number of instances in which we would deny enrollment under § 424.530(a)(7) or suspend payment under § 405.371. Nor do we have sufficient historical data on which we can estimate the burden of payment suspensions, which would consist mostly of potential lost payments the amount of which we are unable to quantify; the principal ICR burden associated with § 424.530(a)(7) would be the submission of Form CMS-855 applications following denials. To enhance our ability to formulate an estimate of the burden associated with this provision, we are soliciting comment on—(1) whether an annual figure of 1,000 potentially affected providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

J. ICRs Related to Denials and Revocations for Other Federal Program Termination or Suspension (§ 424.530(a)(14))

The principal ICR burden associated with this provision would involve the submission of Form CMS-855 applications following denials or following the expiration of reenrollment bars. However, we cannot project the total ICR burden associated with these new provisions because we cannot predict the number of instances in which we would deny or revoke

enrollment. To enhance our ability to formulate projections of the ICR burden associated with this provision, we are soliciting comment on—(1) whether an annual figure of 2,500 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

K. ICRs Related to Extension of Revocation (§ 424.535(i))

As this is a new provision and there is no historical data on which to make an estimate, we cannot predict the number of instances in which we would revoke enrollment for this reason or the number of locations or enrollments that would be involved; thus, we are unable to estimate the total potential collection burden, which would mostly involve the submission of Form CMS–855 applications following the expiration of reenrollment bars. To enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on—(1) whether annual figures of 5,000 potentially impacted providers and suppliers and 12,000 potentially revoked enrollments and terminated practice locations could serve as reasonable approximations; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

L. Voluntary Termination Pending Revocation (§ 424.535(j))

As this is a new provision and there is no historical data on which to base a projection, we are unable to predict the number of instances in which we would revoke enrollment. Therefore, we cannot estimate the potential collection burden associated with § 424.535(j), which would principally involve the submission of Form CMS–855 applications following the expiration of reenrollment bars. Moreover, since evidence of these activities is confined to the results of unique investigations, we believe the examples cited in the preamble text cannot form the basis of a representative sample from which to inform projections. However, to enhance our ability to project of the ICR burden associated with this provision, we are soliciting comment on—(1) whether an annual figure of 2,000 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers.

However, we stress that this is not a projection since we do not have sufficient data on which to make a projection at this time.

M. ICRs Related to Part A/B Ordering, Certifying, Referring, and Prescribing (§§ 424.507 and 424.516)

1. Enrollment

The principal burden associated with this proposal would involve the completion of the applicable Form CMS–855.

Based on CMS statistics, we estimate that approximately 200,000 non-enrolled and non-opted out physicians and, when eligible under state law, non-physician practitioners, are ordering, certifying, referring or prescribing Part A or B services, items or drugs. Per revised § 424.507, these individuals would be required to enroll in or opt-out of Medicare by January 1, 2018.

We believe that these persons, assuming they do not opt-out, would complete the Form CMS–855O in lieu of the Form CMS–855I because the former application is shorter and the applicants are not seeking Medicare Part B billing privileges. As we are unable to precisely determine the percentage of the 200,000-individual universe that consists of physicians as opposed to non-physician practitioners, we will assume that 100,000 physicians and 100,000 non-physician practitioners would be affected, though we welcome comments on this estimate.

Because of the relative brevity of the Form CMS–855O, we believe that physicians and non-physician practitioners would themselves complete the application, rather than delegating this task to staff. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2014 (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000), the mean hourly wage for the general category of “Physicians and Surgeons” is \$93.74, and the mean hourly wage for the general BLS category of “Health Diagnosing and Treating Practitioners, All Other” is \$40.89. With fringe benefits and overhead, the respective per hour rates are \$187.48 and \$81.78.

On average, we project that it takes individuals approximately .5 hours to complete and submit the Form CMS–855O (OMB Control No. 0938–1135) or an opt-out affidavit. This results in an ICR burden for physicians of \$9,374,000 (50,000 hours × \$187.48). The burden for non-physician practitioners would be \$4,089,000 (50,000 hours × \$81.78). The total ICR burden would thus be 100,000 hours at a cost of \$13,463,000. We believe this burden would generally

be incurred in 2017, prior to the January 1, 2018 effective date.

2. Documentation

We are also proposing in revised § 424.516(f) that a provider or supplier furnishing a Part A or B service, item or drug, as well as the physician or, when permitted, eligible professional who ordered, certified, referred or prescribed the Part A or B service, item or drug must maintain documentation for 7 years from the date of the service and furnish access to that documentation upon a CMS or Medicare contractor request.

The burden associated with the requirements in § 424.516(f) would be the time and effort necessary to both maintain documentation on file and to furnish the information upon request to CMS or a Medicare contractor. While the requirement is subject to the PRA, we believe the associated burden is negligible. As discussed in the previously referenced November 19, 2008 final rule (73 FR 69915) and the April 27, 2012 final rule (77 FR 25313), we believe the burden associated with maintaining documentation and furnishing it upon request is a usual and customary business practice.

N. ICRs Related to Temporary Moratorium (§ 424.570)

We are unable to estimate the number of applications that would be approved or denied as a result of our changes to § 424.570, for we have insufficient data on which to base a precise projection. Consequently, we cannot estimate the ICR burden of these revisions; which would mostly involve the submission of Form CMS–855 applications by previously denied providers and suppliers following the lifting of a moratorium. To enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on—(1) whether an annual figure of 2,000 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

O. ICRs Related to Surety Bonds (§ 424.57(d))

We believe that CMS may reject some new and existing surety bonds based on surety non-payment, which would require the DMEPOS supplier to obtain a new surety bond in order to enroll in or maintain its enrollment in Medicare. This would require a supplier to do additional paperwork to obtain and

submit a new surety bond and to report this information to Medicare via the Form CMS-855S. This burden is approved under OMB Control Number 0938-1065 and is estimated to take 3 hours to complete. However, we do not have adequate data to help us estimate the number of suppliers whose bonds would be rejected, or the number that would obtain new bonds, though we welcome public feedback regarding the possible burden.

P. ICRs Related to Reactivations
(§ 424.540(b))

We are unable to project the number of certifications that would be submitted

versus the number of complete Form CMS-855 applications; therefore, we cannot predict the number of instances in which a Form CMS-855 would be requested. To enhance our ability to formulate a projection of the ICR burden associated with this provision, we are soliciting comment on—(1) whether an annual figure of 10,000 instances in which a Form CMS-855 would be requested could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

Q. Revision to Definition of Enrollment
(§§ 424.502; 424.505; 424.510; 424.535(a))

As these revisions are primarily technical in nature, we do not foresee an associated ICR burden.

R. Total ICR Overall Burden

Based on the foregoing, Table 4 estimates the total ICR hour and Table 5 estimates the total ICR cost burdens in the first 3 years of this rule. For purposes of this estimate, the burden for revised § 424.507 would be incurred in the first year (projected to be 2017).

TABLE 4—ESTIMATED ANNUAL REPORTING/RECORDKEEPING HOUR BURDEN

	Year 1	Year 2	Year 3
Affiliations	8,352,500	8,352,500	8,352,500
§ 424.507	100,000	0	0
Total	8,452,500	8,352,500	8,352,500

TABLE 5—ESTIMATED ANNUAL REPORTING/RECORDKEEPING COST BURDEN

	Year 1	Year 2	Year 3
Affiliations	\$285,321,400	\$285,321,400	\$285,321,400
§ 424.507	13,463,000	0	0
Total	298,784,400	285,321,400	285,321,400

Since 3 years is the maximum length of an OMB approval, we must average these totals over a 3-year period. This results in an annual burden of 8,385,833 hours at a cost of \$289,809,067.

We welcome comments on all aspects of and estimates in our ICR section.

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

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

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS-6058-P], Fax: (202) 395-6974; or Email: *OIRA_submission@omb.eop.gov*.

IV. Response to Comments

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

respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

As previously stated, this proposed rule is necessary to implement sections 1866(j)(5) and 1902(kk)(3) of the Act, which require providers and suppliers to disclose information related to any current or previous affiliation with a provider or supplier that has uncollected debt; has been or is subject to a payment suspension under a federal health care program; has been excluded from participation under Medicare, Medicaid or CHIP; or has had its billing privileges denied or revoked. This proposed rule is also necessary to address other program integrity issues that have arisen. We believe that all of these provisions would—(1) enable CMS and the states to better track current and past relationships involving different providers and suppliers; and (2) assist our efforts to stem fraud, waste, and abuse, hence protecting the Medicare Trust Funds.

B. Overall Impact

1. Background

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4) and Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule—(1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or

planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The costs of our proposals would exceed \$100 million in each of the first 3 years of this proposed rule. (See sections III. and V.C. of this proposed rule.) We estimate that this rulemaking is "economically significant" as measured by the \$100 million threshold, and thus also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis, which to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

2. Impact

There are several categories of costs that would be associated with this rule.

First, providers and suppliers would incur costs in completing all or part of the applicable Form CMS-855. Those costs that we are able to estimate are outlined in section III. of this proposed rule.

Second, denied and revoked suppliers could incur costs associated with potential lost billings and the filing of appeals of denials and revocations. However, no estimate is possible because—(1) we cannot project the number of providers and suppliers that would be denied or revoked, as these are new provisions for which there is no precedent upon which to base an estimate; and (2) each provider and supplier and their billing amounts are different.

Third, we believe that CMS, Medicare contractors, and the states would incur costs, in implementing and enforcing our proposed affiliation disclosure provision. These could include information technology system changes and provider education. We have no means of predicting these costs, as these are new provisions for which there is little precedent upon which to base cost estimates; moreover, each state Medicaid program varies in terms of

size, system needs, and provider outreach activities. We solicit comment, however, on the types of costs that may be incurred and the potential amount of those costs.

We believe this rule would have benefits resulting from the denial or revocation of providers and suppliers that pose program integrity risks to Medicare, Medicaid, and CHIP. However, we are unable to project the resultant potential savings to these programs.

This rule would not involve transfers from providers and suppliers to the federal government.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organization, and small governmental jurisdictions. Most entities and most other providers and suppliers are small entities, either by nonprofit status or by having revenues less than \$7.5 million to \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity.

For several reasons, we do not believe that this proposed rule would have a significant economic impact on a substantial number of small businesses. First, the furnishing of affiliation data and the completion of the Form CMS 855O would be required very infrequently, in many cases either only one time or once every several years. The cost burden per provider or supplier (only 0.5 hours for the Form CMS-855O and 10 hours for affiliation data, the latter of which is a high end estimate) would be less than \$1,000, which would not be a significant burden on a provider or supplier. (See section III. of this proposed rule.) Second, it is true that some small businesses could be denied enrollment or have their enrollments revoked under our provisions. Yet the number of denials and revocations per year is currently—and would continue to be under our new provisions—very small when compared to the total number of enrolled providers and suppliers nationwide. Therefore, we do not believe that our new denial and revocation reasons would impact a substantial number of small businesses.

D. Effects on Small Rural Hospitals

In addition, section 1102(b) of the Act requires us to prepare a regulatory

impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and therefore the Secretary has determined, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates

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 2015, that is approximately \$144 million. This rule does not mandate any requirements for state, local or tribal governments or for the private sector, although we noted earlier the possibility that states may incur costs associated with system changes, provider education, and reporting data to CMS concerning § 455.107.

F. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law or otherwise has federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

G. Accounting Statement and Table

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a0004/a-4/pdf>), in Table 6 we have prepared an accounting statement showing estimates, over the first 3 years of the rule's implementation, of the total cost burden to providers and suppliers for reporting data using, respectively, 7 percent and 3 percent annualized discount rates.

TABLE 6—ACCOUNTING STATEMENT CLASSIFICATION OF ESTIMATED COSTS
[\$ in millions]

Category Costs*	Estimates	Units		
		Year dollar	Discount rate (90%)	Period covered
Annualized Monetized (\$million/year)	289.8 289.8	2015 2015	7 3	FY 2017–FY 2019 FY 2017– FY 2019

* Cost associated with the information collection requirements.

H. Alternatives Considered

We considered and adopted several alternatives to reduce the overall burden of our provisions.

First, we contemplated a 10-year timeframe for the affiliation “look-back” period, but we propose to limit the timeframe to 5 years. We believe this would ease the burden on Medicare, Medicaid, and CHIP providers and suppliers by restricting the volume of information that must be reported. Similarly, we propose that changed data regarding past affiliations need not be reported.

Second, we proposed a “knew or should reasonably have known” standard for disclosing affiliations. We believe this would reduce the burden on providers and suppliers in terms of researching and investigating information on entities and individuals with whom they have or have had a relationship. We recognize that providers and suppliers may occasionally experience difficulty in obtaining certain affiliation data if, for instance, they must contact a previously affiliated provider or supplier for the information. We have also decided to solicit feedback from the public concerning whether we should establish a “reasonableness” test, whereby we explain what constitutes a sufficient effort to obtain information in the context of the “should reasonably have known” standard.

Third, we have established a January 1, 2018 effective date for compliance with revised § 424.507. We contemplated possible effective dates in 2017, but we believe that a January 1, 2018 date would help give providers and suppliers sufficient time to enroll in or opt-out of Medicare.

Although we considered 5-year and 10-year lookback periods for disclosable events, we are not proposing a specific lookback period. Even if a particular action occurred more than 5 or years ago, it could still raise concerns about the potential risk a newly enrolling provider poses. For this reason, we must retain the flexibility to address a variety

of factual scenarios. Nonetheless, we recognize that a definitive lookback period would be less burdensome (in terms of researching and reporting information) than an unlimited period, and have solicited public comment regarding whether a specific period should be used and, if so, the appropriate length.

I. Uncertainties

There are two principal uncertainties associated with this proposed rule.

First, we have no means of projecting the number of providers and suppliers that would be denied or revoked under our new and revised provisions. This is because we have little historical data on which we can base a precise estimate.

Second, we are uncertain as to the number of physicians or non-physician practitioners who would be required to enroll in or opt-out of Medicare pursuant to revised § 424.507. The figures we used in sections III.L. of this proposed rule are merely rough estimates, and we would appreciate comments from providers and suppliers regarding the potential number of affected parties.

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

List of Subjects

42 CFR Part 405

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

42 CFR Part 424

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

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions,

Investigations, Medicaid Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, Reporting and recordkeeping requirements.

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

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation 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. Amend § 405.371 by—
 - a. Revising paragraph (a) introductory text.
 - b. Amending paragraph (a)(1) by removing the “;” at the end of the paragraph and adding in its place “..”
 - c. Amending paragraph (a)(2) by removing “; or” at the end of paragraph and adding in its place “..”
 - d. Adding a new paragraph (a)(4).
- The revision and addition read as follows.

§ 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

(a) *General rules*—Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be one of the following:

* * * * *

(4) Suspended, in whole or in part, by CMS or a Medicare contractor if the provider or supplier has been subject to a Medicaid payment suspension under § 455.23(a)(1) of this chapter.

* * * * *

■ 3. Amend § 405.425 by revising paragraphs (i) and (j) to read as follows:

§ 405.425 Effects of opting—out of Medicare.

(i) The physician or practitioner who has not been excluded under sections 1128, 1156 or 1892 of Social Security Act or whose Medicare enrollment is not revoked under § 424.535 of this chapter may order, certify the need for, or refer a beneficiary for Medicare—covered items and services, provided the physician or practitioner is not paid, directly or indirectly, for such services (except as provided in § 405.440).

(j) The physician or practitioner who is excluded under sections 1128, 1156 or 1892 of the Social Security Act or whose Medicare enrollment is revoked under § 424.535 of this chapter may not order, prescribe or certify the need for Medicare-covered items and services except as provided in § 1001.1901 of this title, and must otherwise comply with the terms of the exclusion in accordance with § 1001.1901 effective with the date of the exclusion.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 4. The authority citation 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).

■ 5. Amend § 424.57 by adding paragraph (d)(16) to read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(d) * * * * *
 (16) *Surety non-payment.* CMS may reject an enrolling or enrolled DMEPOS supplier's new or existing surety bond if the surety that issued the bond has failed to make a required payment to CMS under paragraph (d) of this section. In making its determination, CMS considers the following factors:

- (i) The total number of Medicare-enrolled DMEPOS suppliers to which the surety has issued surety bonds.
- (ii) The total number of instances in which the surety has failed to make payment to CMS.
- (iii) The reason(s) for the surety's failure(s) to pay.
- (iv) The percentage of instances in which the surety has failed to pay.
- (v) The total amount of money that the surety has failed to pay.
- (vi) Any other information that CMS deems relevant to its determination.

* * * * *

■ 6. Amend § 424.502 by adding the definitions of "Affiliation", "NPI", and "PECOS" in alphabetical order, and by amending the definition of "Enroll/Enrollment" by revising the introductory text and paragraphs (2) and (4) to read as follows:

§ 424.502 Definitions.

* * * * *
Affiliation means, for purposes of applying § 424.519, any of the following:

- (1) A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
- (2) A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
- (3) An interest in which an individual or entity exercises operational or managerial control over or directly or indirectly conducts the day-to-day operations of another organization (including, for purposes of this provision, sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization.
- (4) An interest in which an individual is acting as an officer or director of a corporation.
- (5) Any reassignment relationship under § 424.80.

* * * * *
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, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs, or to prescribe Part D drugs.

* * * * *
 (2) Except for those suppliers that complete the Form CMS-855O, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order, certify, refer, or prescribe Medicare-covered Part A or B services, items or drugs, or to prescribe Part D drugs, validating the provider's or supplier's eligibility to provide items or services to Medicare beneficiaries.

* * * * *
 (4) Except for those suppliers that complete the Form CMS-855O, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs, or to prescribe Part D drugs, granting the Medicare

provider or supplier Medicare billing privileges.

* * * * *
NPI stands for National Provider Identifier.

* * * * *
PECOS stands for Internet-based Provider Enrollment, Chain, and Ownership System.

* * * * *

■ 7. Revise § 424.505 to read as follows:

§ 424.505 Basic enrollment requirement.

To receive payment for covered Medicare items or services from either Medicare (in the case of an assigned claim) or a Medicare beneficiary (in the case of an unassigned claim), a provider or supplier must be enrolled in the Medicare program. Except for those suppliers that complete the Form CMS-855O or CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order, certify, refer, or prescribe Medicare-covered Part A or B services, items or drugs, or to prescribe Part D drugs, 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 NPI and its use as the Medicare billing number.)

■ 8. Revise § 424.507 to read as follows:

§ 424.507 Ordering, certifying, referring and prescribing covered services, items, and drugs for Medicare beneficiaries.

(a) *Conditions for payment of claims for ordered, certified, referred, or prescribed covered Part A or B services, items or drugs—*(1) *Ordered, certified, referred, or prescribed covered Part A or B services, items or drugs.* To receive payment for ordered, certified, referred, or prescribed covered Part A or B services, items or drugs, a provider or supplier must meet all of the following requirements:

(i) The ordered, certified, referred, or prescribed covered Part A or B service, item or drug must have been ordered, certified, referred or prescribed by a physician or, when permitted, an eligible professional (as defined in § 424.506(a)).

(ii) The claim from the provider or supplier must contain the legal name and the NPI of the physician or the eligible professional (as defined in § 424.506(a)) who ordered, certified, referred or prescribed the Part A or B service, item or drug.

(iii) The physician or, when permitted, other eligible professional, as defined in § 424.506(a), who ordered,

certified, referred, or prescribed the Part A or B service, item or drug must—

(A) Be identified by his or her legal name;

(B) Be identified by his or her NPI; and

(C)(1) Be enrolled in Medicare in an approved status; or

(2) Have validly opted-out of the Medicare program.

(iv) If the Part A or B service, item or drug is ordered, certified, referred, or prescribed by—

(A) An unlicensed resident (as defined in § 413.75 of this chapter), or by a non-enrolled licensed resident (as defined in § 413.75 of this chapter), the claim must identify a teaching physician, who must be enrolled in Medicare in an approved status, as follows:

(1) As the ordering, certifying, referring or prescribing supplier.

(2) By his or her legal name.

(3) By his/her NPI.

(B) A licensed resident (as defined in § 413.75 of this chapter), he or she must have a provisional license or be otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or to order, certify, refer or prescribe such services, items, and drugs, the claim must identify by legal name and NPI either of the following:

(1) Resident, who is enrolled in Medicare in an approved status to order, certify, refer or prescribe.

(2) Teaching physician, who is enrolled in Medicare in an approved status.

(2) *Part A and B beneficiary claims.* To receive payment for ordered, certified, referred, or prescribed covered Part A or B services, items or drugs, a beneficiary's claim must meet all of the following requirements:

(i) The physician or, when permitted, other eligible professional (as defined in § 424.506(a)) who ordered, certified, referred, or prescribed the Part A or B service, item or drug must—

(A) Be identified by his or her legal name; and

(B)(1) Be enrolled in Medicare in an approved status; or

(2) Have validly opted out of the Medicare program.

(ii) If the Part A or B service, item or drug is ordered, certified, referred or prescribed by—

(A) An unlicensed resident (as defined in § 413.75 of this chapter) or a non-enrolled licensed resident, (as defined in § 413.75 of this chapter) the claim must identify a teaching physician, who must be enrolled in Medicare in an approved status as follows:

(1) As the ordering, certifying, referring or prescribing supplier.

(2) By his or her legal name.

(B) A licensed resident (as defined in § 413.75 of this chapter), he or she must have a provisional license or are otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or to order, certify, refer, or prescribe such services, items or drugs, the claim must identify by legal name the—

(1) Resident, who is enrolled in Medicare in an approved status to order, certify, refer or prescribe; or

(2) Teaching physician, who is enrolled in Medicare in an approved status.

(b) *Denial of provider or supplier submitted claims.* Notwithstanding § 424.506(c)(3), a Medicare contractor denies a claim from a provider or a supplier for ordered, certified, referred or prescribed Part A or B covered services, items or drugs described in paragraph (a) of this section if the claim does not meet the requirements of paragraph (a)(1) of this section.

(c) *Denial of beneficiary-submitted claims.* A Medicare contractor denies a claim from a Medicare beneficiary for ordered, certified, referred or prescribed covered Part A or B services, items or drugs as described in paragraph (a) of this section if the claim does not meet the requirements of paragraph (a)(2) of this section.

■ 9. Amend § 424.510 by revising paragraph (a)(3) to read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

(a) * * *

(3) To be enrolled solely to order, certify, refer or prescribe Medicare-covered Part A or B services, items or drugs, or to prescribe Part D drugs, 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.

* * * * *

■ 10. Amend § 424.516 by revising paragraphs (f)(1)(i) introductory text, (f)(1)(ii), (f)(2)(i) introductory text, and (f)(2)(ii) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(f) * * *

(1)(i) A provider or a supplier that furnishes covered ordered, certified,

referred, or prescribed Part A or B services, items or drugs is required to—

* * * * *

(ii) The documentation includes written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item or drug) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Part A or B services, items or drugs.

(2)(i) A physician or, when permitted, an eligible professional who orders, certifies, refers, or prescribes Part A or B services, items or drugs is required to—

* * * * *

(ii) The documentation includes written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item or drug) relating to written orders, certifications, referrals, prescriptions or requests for payments for Part A or B services, items, or drugs.

■ 11. Add § 424.519 to read as follows:

§ 424.519 Disclosure of affiliations.

(a) *Definitions.* For purposes of this section only, the following terms apply:

(1) “Uncollected debt” only applies to the following:

(i) Medicare, Medicaid or CHIP overpayments for which CMS or the state has sent notice of the debt to the affiliated provider or supplier.

(ii) Civil money penalties (as defined in § 424.57(a)).

(iii) Assessments (as defined in § 424.57(a)).

(2) “Revoked,” “Revocation,” “Terminated,” and “Termination” include situations where the affiliated provider or supplier voluntarily terminated its Medicare, Medicaid or CHIP enrollment to avoid a potential revocation or termination.

(b) *General.* A provider or supplier that is submitting an initial or revalidating Form CMS-855 enrollment application (via paper or Internet-based PECOS) must disclose whether it or any of its owning or managing employees or organizations (consistent with the terms “owner” and “managing employee” as defined in § 424.502) has or, within the previous 5 years, has had an affiliation with a currently or formerly enrolled Medicare, Medicaid or CHIP provider or supplier that has or had any of the following:

(1) Currently has an uncollected debt to Medicare, Medicaid or CHIP, regardless of the following:

- (i) The amount of the debt.
- (ii) Whether the debt is currently being repaid.
- (iii) Whether the debt is currently being appealed.

(2) Has been or is subject to a payment suspension under a federal health care program (as that term is defined in section 1128B(f) of the Act), regardless of when the payment suspension occurred or was imposed.

(3) Has been or is excluded from participation in Medicare, Medicaid or CHIP, regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed.

(4) Has had its Medicare, Medicaid or CHIP enrollment denied, revoked or terminated, regardless of the following:

- (i) The reason for the denial, revocation or termination.
- (ii) Whether the denial, revocation or termination is currently being appealed.
- (iii) When the denial, revocation or termination occurred or was imposed.
- (c) *Information.* The provider or supplier must disclose the following information about each reported affiliation:

(1) General identifying data about the affiliated provider or supplier. This includes:

- (i) Legal name as reported to the Internal Revenue Service or the Social Security Administration (if the affiliated provider or supplier is an individual).
- (ii) "Doing business as" name (if applicable).
- (iii) Tax identification number.
- (iv) NPI.

(2) Reason for disclosing the affiliated provider or supplier.

(3) Specific data regarding the affiliation relationship, including the following:

- (i) Length of the relationship.
- (ii) Type of relationship.
- (iii) Degree of affiliation.
- (4) If the affiliation has ended, the reason for the termination.

(d) *Mechanism.* The information required to be disclosed under paragraphs (b) and (c) this section must be furnished to CMS or its contractors via the Form CMS-855 application (paper or the Internet-based PECOS enrollment process).

(e) *Denial or revocation.* The failure of the provider or supplier to fully and completely disclose the information specified in paragraphs (b) and (c) of this section when the provider or supplier knew or should reasonably have known of this information may result in either of the following:

(1) The denial of the provider's or supplier's initial enrollment application under § 424.530(a)(1) and, if applicable, § 424.530(a)(4).

(2) The revocation of the provider's or supplier's Medicare enrollment under § 424.535(a)(1) and, if applicable, § 424.535(a)(4).

(f) *Undue risk.* Upon receiving the information described in paragraphs (b) and (c) of this section, CMS determines whether any of the disclosed affiliations poses an undue risk of fraud, waste or abuse by considering the following factors:

- (1) The duration of the affiliation.
- (2) Whether the affiliation still exists and, if not, how long ago it ended.
- (3) The degree and extent of the affiliation.

(4) If applicable, the reason for the termination of the affiliation.

(5) Regarding the affiliated provider's or supplier's action under paragraph (b) of this section:

- (i) The type of action.
- (ii) When the action occurred or was imposed.
- (iii) Whether the affiliation existed when the action occurred or was imposed.
- (iv) If the action is an uncollected debt:

- (A) The amount of the debt.
- (B) Whether the affiliated provider or supplier is repaying the debt.
- (C) To whom the debt is owed.
- (v) If a denial, revocation, termination, exclusion or payment suspension is involved, the reason for the action.

(6) Any other evidence that CMS deems relevant to its determination.

(g) *Determination of undue risk.* A determination by CMS that a particular affiliation poses an undue risk of fraud, waste or abuse will result in, as applicable, the denial of the provider's or supplier's initial enrollment application under § 424.530(a)(13) or the revocation of the provider's or supplier's Medicare enrollment under § 424.535(a)(19).

(h) *New or changed information.* (1) A provider or supplier must report the following:

(i) New or changed information regarding existing affiliations.

(ii) Information regarding new affiliations.

(2) A provider or supplier is not required to do either of the following:

(i) Report new or changed information regarding past affiliations (except as part of a Form CMS-855 revalidation application).

(ii) Report affiliation data in that portion of the Form CMS-855 application that collects affiliation information if the same data is being reported in the "owning or managing control" (or its successor) section of the Form CMS-855 application.

(i) *Undisclosed affiliations.* CMS may apply § 424.530(a)(13) or § 424.535(a)(19) to situations where a disclosable affiliation (as described in § 424.519(b) and (c)) poses an undue risk of fraud, waste or abuse, but the provider or supplier has not yet reported or is not required at that time to report the affiliation to CMS.

■ 12. Amend § 424.530 by revising paragraph (a)(7) and adding paragraphs (a)(12), (13), (14), and (f) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(7) *Payment suspension.* (i) The provider or supplier, or any owning or managing employee or organization of the provider or supplier, is currently under a Medicare or Medicaid payment suspension as defined in §§ 405.370 through 405.372 or in § 455.23, of this chapter.

(ii) CMS may apply this provision to the provider or supplier under any of the provider's, supplier's, or owning or managing employee's or organization's current or former names, numerical identifiers, or business identities or to any of its existing enrollments.

(iii) In determining whether a denial is appropriate, CMS considers the following factors:

(A) The specific behavior in question.

(B) Whether the provider or supplier is the subject of other similar investigations.

(C) Any other information that CMS deems relevant to its determination.

* * * * *

(12) *Revoked under different name, numerical identifier or business identity.* The provider or supplier is currently revoked under a different name, numerical identifier or business identity, and the applicable reenrollment bar period has not expired. In determining whether a provider or supplier is a currently revoked provider or supplier under a different name, numerical identifier or business identity, CMS investigates the degree of commonality by considering the following factors:

(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 application).

(ii) Geographic location.

(iii) Provider or supplier type.

(iv) Business structure.

(v) Any evidence indicating that the two parties are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar.

(13) *Affiliation that poses undue risk of fraud.* CMS determines that the

provider or supplier has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste or abuse to the Medicare program.

(14) *Other program termination or suspension.* (i) The provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a particular State Medicaid program or any other federal health care program, or the provider's or supplier's license is currently revoked or suspended in a State other than that in which the provider or supplier is enrolling. In determining whether a denial under this paragraph is appropriate, CMS considers the following factors:

- (A) The reason(s) for the termination, suspension or revocation.
- (B) Whether, as applicable, the provider or supplier is currently terminated or suspended (or otherwise barred) from more than one program (for example, more than one State's Medicaid program), has been subject to any other sanctions during its participation in other programs or by any other State licensing boards or has had any other final adverse actions imposed against it.
- (C) Any other information that CMS deems relevant to its determination.
 - (ii) CMS may apply paragraph (a)(14)(i) of this section to the provider or supplier under any of its current or former names, numerical identifiers or business identities, and regardless of whether any appeals are pending.
- (f) *Reapplication bar.* CMS may prohibit a prospective provider or supplier from enrolling in Medicare for up to 3 years if its enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to gain enrollment in the Medicare program.
 - (1) The reapplication bar applies to the prospective provider or supplier under any of its current, former, or future names, numerical identifiers or business identities.
 - (2) CMS determines the bar's length by considering the following factors:
 - (i) The materiality of the information in question.
 - (ii) Whether there is evidence to suggest that the provider or supplier purposely furnished false or misleading information or deliberately withheld information.
 - (iii) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.
 - (iv) Any other information that CMS deems relevant to its determination.

- 13. Amend § 424.535 by—
 - a. In paragraph (a) introductory text by removing the term "billing privileges" and adding in its place the phrase "enrollment".
 - b. Revising paragraphs (a)(9) and (12).
 - c. Adding and reserving paragraphs (a)(15) and (16).
 - d. Adding paragraphs (a)(17) through (21).
 - e. Revising paragraph (c).
 - f. Adding paragraphs (i) and (j).

The additions and revisions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

- * * * * *
- (a) * * *
- (9) *Failure to report.* The provider or supplier did not comply with the reporting requirements specified in § 424.516(d) or (e), § 410.33(g)(2) of this chapter or § 424.57(c)(2). In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:
 - (i) Whether the data in question was reported.
 - (ii) If the data was reported, how belatedly.
 - (iii) The materiality of the data in question.
 - (iv) Any other information that CMS deems relevant to its determination.
- * * * * *
- (12) *Other program termination.* (i) The provider or supplier is terminated, revoked or otherwise barred from participation in a particular Medicaid program or any other federal health care program. In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:
 - (A) The reason(s) for the termination or revocation.
 - (B) Whether the provider or supplier is currently terminated, revoked or otherwise barred from more than one program (for example, more than one State's Medicaid program) or has been subject to any other sanctions during its participation in other programs.
 - (C) Any other information that CMS deems relevant to its determination.
 - (ii) Medicare may not terminate unless and until a provider or supplier has exhausted all applicable appeal rights.
 - (iii) CMS may apply paragraph (a)(12)(i) of this section to the provider or supplier under any of its current or former names, numerical identifiers or business identities.
- * * * * *
- (15)–(16) [Reserved]
- (17) *Debt referred to the United States Department of Treasury.* The provider

- or supplier has an existing debt that CMS refers to the United States Department of Treasury. In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:
 - (i) The reason(s) for the failure to fully repay the debt (to the extent this can be determined).
 - (ii) Whether the provider or supplier has attempted to repay the debt.
 - (iii) Whether the provider or supplier has responded to CMS' requests for payment.
 - (iv) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.
 - (v) The amount of the debt.
 - (vi) Any other evidence that CMS deems relevant to its determination.
- (18) *Revoked under different name, numerical identifier or business identity.* The provider or supplier is currently revoked under a different name, numerical identifier or business identity, and the applicable reenrollment bar period has not expired. In determining whether a provider or supplier is a currently revoked provider or supplier under a different name, numerical identifier or business identity, CMS investigates the degree of commonality by considering the following factors:
 - (i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 application).
 - (ii) Geographic location.
 - (iii) Provider or supplier type.
 - (iv) Business structure.
 - (v) Any evidence indicating that the two parties are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar.
- (19) *Affiliation that poses an undue risk.* CMS determines that the provider or supplier has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste or abuse to the Medicare program.
- (20) *Billing from non-compliant location.* CMS may revoke a provider's or supplier's Medicare enrollment, including all of the provider's or supplier's practice locations regardless of whether they are part of the same enrollment, if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements. In determining whether and how many of the provider's or supplier's other locations should be revoked, CMS considers the following factors:

(i) The reason(s) for and the specific facts behind the location's non-compliance.

(ii) The number of additional locations involved.

(iii) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.

(iv) The degree of risk that the location's continuance poses to the Medicare Trust Funds.

(v) The length of time that the non-compliant location was non-compliant.

(vi) The amount that was billed for services performed at or items furnished from the non-compliant location.

(vii) Any other evidence that CMS deems relevant to its determination.

(21) *Abusive ordering, certifying, referring, or prescribing of Part A or B services, items or drugs.* The physician or eligible professional has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries or otherwise fails to meet Medicare requirements. In making its determination as to whether such a pattern or practice exists, CMS considers the following factors:

(i) Whether the physician's or eligible professional's diagnoses support the orders, certifications, referrals or prescriptions in question.

(ii) Whether there are instances where the necessary evaluation of the patient for whom the service, item or drug was ordered, certified, referred or prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).

(iii) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state or states in which he or she practices, and the reason(s) for the action(s).

(iv) Whether the physician or eligible professional has any history of final adverse actions (as that term is defined in § 424.502).

(v) The length of time over which the pattern or practice has continued.

(vi) How long the physician or eligible professional has been enrolled in Medicare.

(vii) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to ordering, certifying, referring or prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the

plaintiff(s) (to the extent this can be determined).

(viii) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked or terminated the physician's or eligible professional's ability to practice medicine, and the reason(s) for any such restriction, suspension, revocation or termination.

(ix) Any other information that CMS deems relevant to its determination.

* * * * *

(c) *Reapplying after revocation.* (1) After a provider or supplier has had their enrollment revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar—

(i) Begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10 years (except for the situations described in paragraphs (c)(2) and (3) of this section), depending on the severity of the basis for revocation.

(ii) Does not apply in the event a revocation of Medicare enrollment is imposed under paragraph (a)(1) of this section based upon a provider's or supplier's failure to respond timely to a revalidation request or other request for information.

(2)(i) CMS may add up to 3 more years to the provider's or supplier's reenrollment bar (even if such period exceeds the 10-year period identified in paragraph (c)(1) of this section) if it determines that the provider or supplier is attempting to circumvent its existing reenrollment bar by enrolling in Medicare under a different name, numerical identifier or business identity.

(ii) A provider's or supplier's appeal rights regarding paragraph (c)(2)(i) of this section—

(A) Are governed by part 498 of this chapter; and

(B) Do not extend to the imposition of the original reenrollment bar under paragraph (c)(1) of this section; and

(C) Are limited to any additional years imposed under paragraph (c)(2)(i) of this section.

(3) CMS may impose a reenrollment bar of up to 20 years on a provider or supplier if the provider or supplier is being revoked from Medicare for the second time. In determining the length of the reenrollment bar under this paragraph (c)(3), CMS considers the following factors:

(i) The reasons for the revocations.

(ii) The length of time between the revocations.

(iii) Whether the provider or supplier has any history of final adverse actions (other than Medicare revocations) or Medicare or Medicaid payment suspensions.

(iv) Any other information that CMS deems relevant to its determination.

(4) A reenrollment bar applies to a provider or supplier under any of its current, former or future names, numerical identifiers or business identities.

* * * * *

(i) *Extension of revocation.* (1) If a provider's or supplier's Medicare enrollment is revoked under paragraph (a) of this section, CMS may revoke any and all of the provider's or supplier's Medicare enrollments, including those under different names, numerical identifiers or business identities and those under different types.

(2) In determining whether to revoke a provider's or supplier's other enrollments under this paragraph (i), CMS considers the following factors:

(i) The reason for the revocation and the facts of the case.

(ii) Whether any final adverse actions have been imposed against the provider or supplier regarding its other enrollments.

(iii) The number and type(s) of other enrollments.

(iv) Any other information that CMS deems relevant to its determination.

(j) *Voluntary termination.* (1) CMS may revoke a provider's or supplier's Medicare enrollment if CMS determines that the provider or supplier voluntarily terminated its Medicare enrollment in order to avoid a revocation under paragraph (a) of this section that CMS would have imposed had the provider or supplier remained enrolled in Medicare. In making its determination, CMS considers the following factors:

(i) Whether there is evidence to suggest that the provider knew or should have known that it was or would be out of compliance with Medicare requirements.

(ii) Whether there is evidence to suggest that the provider knew or should have known that its Medicare enrollment would be revoked.

(iii) Whether there is evidence to suggest that the provider voluntarily terminated its Medicare enrollment in order to circumvent such revocation.

(iv) Any other evidence or information that CMS deems relevant to its determination.

(2) A revocation under paragraph (j)(1) of this section is effective the day before the Medicare contractor receives the provider's or supplier's Form CMS-855 voluntary termination application.

■ 14. Amend § 424.540 by revising paragraphs (b)(1) and (2) to read as follows:

§ 424.540 Deactivation of Medicare billing privileges.

* * * * *

(b) * * *

(1) In order for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate.

(2) Notwithstanding paragraph (b)(1) of this section, CMS may, for any reason, require a deactivated provider or supplier to, as a prerequisite for reactivating its billing privileges, submit a complete Form CMS-855 application.

* * * * *

■ 15. Amend § 424.570 by revising paragraphs (a)(1)(iii) and (iv) to read as follows:

§ 424.570 Moratoria on newly enrolling Medicare providers and suppliers.

(a) * * *

(1) * * *

(iii) The temporary moratorium does not apply to any of the following:

(A) Changes in practice location (except if the location is changing from a location outside the moratorium area to a location inside the moratorium area).

(B) Changes in provider or supplier information, such as phone numbers.

(C) Changes in ownership (except changes in ownership of home health agencies that would require an initial enrollment).

(iv) A temporary moratorium does not apply to any enrollment application that has been received by the Medicare contractor prior to the date the moratorium is imposed.

* * * * *

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 16. The authority citation for part 455 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 17. Amend § 455.101 by adding the definition of “Affiliation” in alphabetical order to read as follows:

§ 455.101 Definitions.

Affiliation means, for purposes of applying § 455.107, any of the following:

(1) A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.

(2) A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.

(3) An interest in which an individual or entity exercises operational or managerial control over or directly or indirectly conducts the day-to-day operations of another organization (including, for purposes of this provision, sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization.

(4) An interest in which an individual is acting as an officer or director of a corporation.

(5) Any payment assignment relationship under § 447.10(g) of this chapter.

* * * * *

■ 18. Revise § 455.103 to read as follows:

§ 455.103 State plan requirement.

A State plan must provide that the requirements of §§ 455.104 through 455.107 are met.

■ 19. Add § 455.107 to subpart B to read as follows:

§ 455.107 Disclosure of affiliations.

(a) *Definitions.* For purposes of this section only, the following terms apply:

(1) “Uncollected debt” only applies to the following:

(i) Medicare, Medicaid or CHIP overpayments for which CMS or the State has sent notice of the debt to the affiliated provider or supplier.

(ii) Civil money penalties (as defined in § 424.57(a) of this chapter).

(iii) Assessments (as defined in § 424.57(a) of this chapter).

(2) “Revoked,” “Revocation,” “Terminated,” and “Termination” include situations where the affiliated provider or supplier voluntarily terminated its Medicare, Medicaid or CHIP enrollment to avoid a potential revocation or termination.

(b) *General.* A provider that is initially enrolling in the Medicaid program or is revalidating its Medicaid enrollment information must disclose whether it or any of its owning or managing employees or organizations (consistent with the terms “person with an ownership or control interest” and “managing employee” as defined in § 455.101) has or, within the previous 5 years, has had an affiliation with a currently or formerly enrolled Medicare, Medicaid or CHIP provider or supplier that—

(1) Currently has an uncollected debt to Medicare, Medicaid or CHIP, regardless of—

(i) The amount of the debt;

(ii) Whether the debt is currently being repaid; or

(iii) Whether the debt is currently being appealed.

(2) Has been or is subject to a payment suspension under a federal health care program (as that latter term is defined in section 1128B(f) of the Act), regardless of when the payment suspension occurred or was imposed;

(3) Has been or is excluded from participation in Medicare, Medicaid or CHIP, regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed; or

(4) Has had its Medicare, Medicaid or CHIP enrollment denied, revoked or terminated, regardless of any of the following:

(i) The reason for the denial, revocation or termination.

(ii) Whether the denial, revocation or termination is currently being appealed.

(iii) When the denial, revocation or termination occurred or was imposed.

(c) *Information.* The initially enrolling or revalidating provider must disclose the following information about each affiliation:

(1) General identifying information about the affiliated provider or supplier, which includes the following:

(i) Legal name as reported to the Internal Revenue Service or the Social Security Administration (if the affiliated provider or supplier is an individual).

(ii) “Doing business as” name (if applicable).

(iii) Tax identification number.

(iv) National Provider Identifier (NPI).

(2) Reason for disclosing the affiliated provider or supplier.

(3) Specific data regarding the affiliation relationship, including the following:

(i) Length of the relationship.

(ii) Type of relationship.

(iii) Degree of affiliation.

(4) If the affiliation has ended, the reason for the termination.

(d) *Mechanism.* The information described in paragraphs (b) and (c) of this section must be furnished to the State in a manner prescribed by the State.

(e) *Denial or revocation.* The failure of the provider to fully and completely report the information required in this section when the provider knew or should reasonably have known of this information may result in, as applicable, the denial of the provider’s initial enrollment application or the termination of the provider’s enrollment in Medicaid or CHIP.

(f) *Undue risk.* Upon receipt of the information described in paragraphs (b)

and (c) of this section, the State, in consultation with CMS, determines whether any of the disclosed affiliations poses an undue risk of fraud, waste or abuse by considering the following factors:

- (1) The duration of the affiliation.
- (2) Whether the affiliation still exists and, if not, how long ago the affiliation ended.
- (3) The degree and extent of the affiliation.
- (4) If applicable, the reason for the termination of the affiliation.
- (5) Regarding the affiliated provider's or supplier's action under paragraph (b) of this section, all of the following:
 - (i) The type of action.
 - (ii) When the action occurred or was imposed.
 - (iii) Whether the affiliation existed when the action occurred or was imposed.
 - (iv) If the action is an uncollected debt—
 - (A) The amount of the debt;
 - (B) Whether the affiliated provider or supplier is repaying the debt; and
 - (C) To whom the debt is owed.
 - (v) If a denial, revocation, termination, exclusion or payment suspension is involved, the reason for the action.

(6) Any other evidence that the state, in consultation with CMS, deems relevant to its determination.

(g) *Determination of undue risk.* A determination by the state, in consultation with CMS, that a particular affiliation poses an undue risk of fraud, waste or abuse will result in, as applicable, the denial of the provider's initial enrollment in Medicaid or CHIP or the termination of the provider's enrollment in Medicaid or CHIP.

(h) *New or changed information.* (1) A provider must report the following:

(i) New or changed information regarding existing affiliations.

(ii) Information regarding new affiliations.

(2) A provider is not required to report new or changed information regarding past affiliations (except as part of a revalidation application).

(i) *Undisclosed affiliations.* The State, in consultation with CMS, may apply paragraph (g) of this section to situations where a reportable affiliation (as described in paragraphs (b) and (c) of this section) poses an undue risk of fraud, waste or abuse, but the provider has not yet disclosed or is not required at that time to disclose the affiliation to the State.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 20. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

■ 21. Amend § 457.990 by:

■ a. Redesignating paragraphs (a) and (b) as paragraphs (b) and (c), respectively.

■ b. Adding a new paragraph (a).

The addition reads as follows:

§ 457.990 Provider and supplier screening, oversight, and reporting requirements.

* * * * *

(a) Section 455.107.

* * * * *

Dated: November 25, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: December 8, 2015.

Sylvia Burwell,

Secretary, Department of Health and Human Services.

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