

MEMORANDUM

Date: February 26, 2016

Subject: Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process (CMS-6058-P)

OVERVIEW

On February 25, 2016, CMS filed the proposed rule to [Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process \(CMS-6058-P\)](#). 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; provide CMS with additional authority to deny or revoke a provider's or supplier's Medicare enrollment; and 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.

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 to Medicare, Medicaid, or CHIP;
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.

The proposed provisions are necessary to address various program integrity issues and vulnerabilities that require regulatory action. In short, the rule would enable CMS 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 the 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.
- 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.

MAJOR PROVISIONS

1. 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.
 - a. Affiliation means, for purposes of applying § 424.519, any of the following:
 - i. A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
 - ii. A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
 - iii. 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.
- iv. An interest in which an individual is acting as an officer or director of a corporation.
 - v. Any reassignment relationship under § 424.80.
- b. Disclosable event means 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.
- c. 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)).
- d. 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).
2. Provide CMS with the authority to do the following:
- a. 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.
 - b. 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.
 - c. 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.
 - d. Increase the maximum reenrollment bar from 3 to 10 years, with exceptions.
 - e. 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.
- f. 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.
 - g. 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.
 - h. 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.

SUMMARY OF COSTS AND BENEFITS

CMS estimates 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.

CMS believes 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.