

visits are the only method we have to ensure that providers and suppliers actually exist and meet the requirements to participate in the Medicare program, particularly in the absence of State licensure or regulation. Left unchecked, Medicare program resources and the health of Medicare beneficiaries may be vulnerable.

III. Provisions of the Proposed Rule

This proposed rule would build on our collective experience and set forth our standard enrollment requirements in new subpart P in Part 424 of this chapter. We are proposing that all providers and suppliers, other than the “opt-out” physicians and “opt-out” practitioners described below, must submit an enrollment application with specific information to enroll in the Medicare program, obtain a Medicare billing number, and receive Medicare billing privileges. The provisions of this proposed rule would supplement, but not replace or nullify, existing regulations concerning the establishment of provider or supplier agreements, the issuance of provider or supplier billing numbers, and payment for Medicare covered services or supplies to eligible providers or suppliers.

Specifically, we are proposing to require that providers and suppliers prove their qualifications and identity and submit specified information to us before they are granted billing privileges in the Medicare program. If the provider or supplier fails to meet the requirements or submit the required information, we would not enroll it in the Medicare program or, if it is currently in the program, we would revoke its billing privileges. We believe the documentation and associated verification methods we use to determine whether to grant a provider or supplier billing privileges are necessary to ensure compliance with Medicare requirements and to prevent abuse of the Medicare program and the inappropriate use of Medicare funds. We also believe that such requirements will not hinder qualified individuals and organizations from enrolling or maintaining enrollment in the Medicare program.

A. Scope and Definitions

We are proposing to establish our standard enrollment requirements in Part 424, new subpart P. In proposed § 424.500 (Scope) we are stating that these requirements apply to all providers and suppliers except those physicians and other eligible practitioners who have elected to “opt-

out” of Medicare as described in Part 405, subpart D of our regulations.

In proposed § 400.502 (Definitions) we are establishing the definitions for several key terms used throughout subpart P. The terms “provider” and “supplier” are not defined in this subpart because their definitions have already been established throughout 42 CFR. The term “provider” is defined in both § 488.1 and § 400.202. Together these sections define a provider as including a hospital, a critical access hospital, a skilled nursing facility, a nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice, that has in effect an agreement to participate in Medicare; or a provider of outpatient physical therapy or speech pathology services; or a community mental health center. The term “supplier,” as defined in § 400.202, is a physician or other practitioner, or an entity other than a provider (as defined in §§ 400.202 and 488.1) that furnishes health care services under Medicare. Section 488.1 also defines “supplier” to mean independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; or chiropractor. The term “supplier” also includes “indirect suppliers,” as indicated in 45 CFR 61.3.

We define “managing employee” to be “a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts the day-to-day operations of, the institution, organization, or agency, either under contract or through some other arrangement, regardless of whether the individual is a W–2 employee.”

Section 1124A of the Act and 42 CFR 420.204 authorize the Secretary to collect information about “managing employees.” Section 1124A incorporates by reference the following definition of “managing employee,” contained in 1126(b) of the Act: “An individual, including a general manager, business manager, administrator, and director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity.” We have found that a number of providers and suppliers are managed by individuals that have control over the day-to-day operations of the entity and are not “employees.” Some of these individuals have been known to bill Medicare fraudulently, and are on the Office of Inspector General (OIG) “List of Excluded Individuals and Entities

and/or the General Services Administration” (GSA) “List of Parties Excluded from Federal Procurement and Nonprocurement Programs”. These lists are commonly referred to as the “OIG Sanction List” for those parties excluded by the QIG from participation in any Federal health care programs (as defined in section 1128B(f) of the Act), and the “GSA Debarment List” for those parties debarred, suspended or otherwise excluded by other Federal agencies from participation in Federal procurement and non-procurement programs and activities, in accordance with the Federal Acquisition and Streamlining Act of 1994, and with the HHS Common Rule at 455 CFR Part 76.

Extending the term “managing employee” to include individuals performing managerial duties who are not technically employees would be consistent with the legislative intent to require information on those individuals that have effective control over a provider’s or supplier’s day-to-day operations.

B. Basic Enrollment Requirement

Proposed § 424.505 requires a provider or supplier to have a valid Medicare billing number for the date a service was rendered in order to receive payment for covered Medicare services from either Medicare (in the case of assigned claims) or the Medicare beneficiary (in the case of unassigned claims).

Under longstanding policy and operating procedures, any claim submitted without an active billing number is incomplete and cannot be processed for payment. Providers and suppliers who are not enrolled in the Medicare program must adhere to the mandatory claims submission rules found at § 424.32(a)(1) (Basic requirements for all claims) and section 1848(g)(1)(B) of the Act. In addition, a claim submitted without a valid Medicare billing number would not be considered a valid claim and would be rejected. If the mandatory claims submission requirements are not met the provider or supplier could have sanctions imposed as outlined in section 1848(g)(4) of the Act for failure to file a claim as required.

C. Requirements for Obtaining a Billing Number and Medicare Billing Privileges

To obtain a Medicare billing number and be eligible to receive payment for Medicare covered services, providers and suppliers must enroll in the Medicare program and meet other applicable Federal requirements. The Medicare program, through its contractors, requires specific identifying