

respond to the major comments in the preamble to that document.

List of Subjects

42 CFR Part 420

Fraud, Health facilities, Health professions, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

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

For the reasons set forth in this preamble, 42 CFR chapter IV is proposed to be amended as set forth below:

PART 420—PROGRAM INTEGRITY: MEDICARE

1. The authority citation for part 420 continues to read as follows:

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

2. In § 420.201, the definition for managing employee is revised to read as follows:

* * * * *

Managing employee means 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 operation of the institution, organization, or agency, either under contract or through some other arrangement, whether or not the individual is a W-2 employee.

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PART 424—CONDITIONS FOR MEDICARE PAYMENT

1. 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).

2. In § 424.1, the introductory text to paragraph (a)(1) is republished, and the following statutory reference is added to paragraph (a)(1) in numerical order to read as follows:

§ 424.1 Basis and scope.

(a) *Statutory basis.* (1) This part is based on the indicated provisions of the following sections of the Act:

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1833(e)—Requirement to furnish information to determine payment.

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3. Subparts N and O are added and reserved.

4. Subpart P is added to read as follows:

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

Sec.

424.500 Scope.

424.502 Definitions.

424.505 Basic enrollment requirement.

424.510 Requirements for obtaining a billing number and Medicare billing privileges.

424.515 Requirements for reporting changes and updates to, and the periodic revalidation of, Medicare enrollment information.

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

424.525 Rejection of a provider or supplier's CMS 855 for Medicare enrollment.

424.530 Denial of enrollment.

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

424.540 Deactivation of Medicare billing privileges.

424.545 Provider and supplier appeal rights.

424.550 Prohibitions on the sale or transfer of billing privileges.

424.555 Payment liability.

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

§ 424.500 Scope.

The provisions of this subpart contain the requirements for enrollment, periodic resubmission and certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers except for physicians and practitioners who have entered into a private contract with a beneficiary as described in part 405, subpart D of this chapter. Providers and suppliers must meet and maintain these enrollment requirements to bill either the Medicare program or its beneficiaries.

Note to § 424.500: Throughout subpart P, references to “supplier” or “suppliers” do not include those physicians or practitioners who have elected to “opt-out” of Medicare as

described in part 405, subpart D of this chapter.

§ 424.502 Definitions.

As used in this subpart, unless the context indicates otherwise—

Approve/Approval means the enrolling provider or supplier has been determined to be eligible under Medicare rules and regulations to receive a Medicare billing number and Medicare billing privileges.

Authorized official means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the laws, regulations, and program instruction of the Medicare program.

Deactivate means that the provider or supplier's billing privileges have been temporarily stopped, but can be restored upon the submission of updated information.

Delegated official means an individual who has been delegated by the “Authorized official”, the authority to report changes and updates to the enrollment record. The delegated official must be an individual with ownership or control interest in, or be a W-2 managing employee of the provider or supplier.

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges for Medicare covered services provided to Medicare beneficiaries. Providers and suppliers who have been denied Medicare enrollment cannot bill for Medicare covered services.

Enroll/Enrollment means the process that Medicare uses to—

- (1) Identify a provider or supplier;
- (2) Validate its eligibility to provide services to Medicare beneficiaries;
- (3) Identify and confirm the provider or supplier's practice location(s) and owner(s); and
- (4) Grant the provider or supplier Medicare billing privileges.

Managing employee means 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 operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W-2 employee of the provider or supplier.