

§ 424.350

services furnished as in-kind beneficiary engagement incentives that exceed \$25 in retail value.

(1) The documentation must be established contemporaneous with the furnishing of the in-kind items and services and must include at least the following:

(i) The date the item or service is furnished.

(ii) The identity of the MDPP beneficiary to whom the item or service is furnished.

(iii) The agent of the MDPP supplier that furnished the item or service, if applicable.

(iv) A description of the item or service.

(v) The retail value of the item or service.

(vi) Documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.

(2) Documentation regarding items or services that are furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items involving technology exceeding \$100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier.

(3) The documentation regarding items involving technology exceeding \$100 in retail value must also include contemporaneous documentation of any attempt to retrieve the item as required by paragraph (c)(3)(ii) of this section.

(4) The MDPP supplier must retain and provide access to the documentation required in this section in accordance with § 424.205(g).

[82 FR 53364, Nov. 15, 2017, as amended at 88 FR 79540, Nov. 16, 2023]

Subparts J–L [Reserved]

42 CFR Ch. IV (10–1–24 Edition)

Subpart M—Replacement and Reclamation of Medicare Payments

§ 424.350 Replacement of checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

(a) *U.S. Government checks*—(1) *Responsibility*. The Treasury Department is responsible for the investigation and settlement of claims in connection with Treasury checks issued on behalf of CMS.

(2) *Action by CMS*. CMS forwards reports of lost, stolen, defaced, mutilated, destroyed, or forged Treasury checks to the Treasury Department disbursing center responsible for issuing checks.

(3) *Action by the Treasury Department*. The Treasury Department will replace and begin reclamation of Treasury checks in accordance with Treasury Department regulations (31 CFR parts 235, 240, and 245).

(b) *Intermediary and carrier benefit checks*. Checks issued by intermediaries and carriers are drawn on commercial banks and are not subject to the Federal laws and Treasury Department regulations that govern Treasury checks. Replacement procedures are carried out in accordance with § 424.352 under applicable State law (including any Federal banking laws or regulations that may affect the relevant State proceedings).

[58 FR 65129, Dec. 13, 1993]

§ 424.352 Intermediary and carrier checks that are lost, stolen, defaced, mutilated, destroyed or paid on forged endorsements.

(a) When an intermediary or carrier is notified by a payee that a check has been lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsement, the intermediary or carrier contacts the commercial bank on whose paper the check was drawn and determines whether the check has been negotiated.

(b) If the check has been negotiated—

(1) The intermediary or carrier provides the payee with a copy of the check and other pertinent information (such as a claim form, affidavit or questionnaire to be completed by the

payee) required to pursue his or her claim in accordance with State law and commercial banking regulations.

(2) To pursue the claim, the payee must examine the check and certify (by completing the claim form, questionnaire or affidavit) that the endorsement is not the payee's.

(3) The claim form and other pertinent information is sent to the intermediary or carrier for review and processing of the claim.

(4) The intermediary or carrier reviews the payee's claim. If the intermediary or carrier determines that the claim appears to be valid, it forwards the claim and a copy of the check to the issuing bank. The intermediary or carrier takes further action to recover the proceeds of the check in accordance with the State law and regulations.

(5) Once the intermediary or carrier recovers the proceeds of the initial check, the intermediary or carrier issues a replacement check to the payee.

(6) If the bank of first deposit refuses to settle on the check for good cause, the payee must pursue the claim on his or her own and the intermediary or carrier will not reissue the check to the payee.

(c) If the check has not been negotiated—

(1) The intermediary or carrier arranges with the bank to stop payment on the check; and

(2) Except as provided in paragraph (d), the intermediary or carrier reissues the check to the payee.

(d) No check may be reissued under (c)(2) unless the claim for a replacement check is received by the intermediary or carrier no later than 1 year from the date of issuance of the original check, unless State law (including any applicable Federal banking laws or regulations that may affect the relevant State proceeding) provides a longer period which will control.

[58 FR 65130, Dec. 13, 1993]

Subparts N–O [Reserved]

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

SOURCE: 71 FR 20776, Apr. 21, 2006, unless otherwise noted.

§ 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 for Medicare covered services or supplies.

§ 424.502 Definitions.

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

Additional disclosable party means, with respect to a skilled nursing facility defined at section 1819(a) of the Act, any person or entity who does any of the following:

(1)(i) Exercises operational, financial, or managerial control over the facility or a part thereof;

(ii) Provides policies or procedures for any of the operations of the facility; or

(iii) Provides financial or cash management services to the facility.

(2)(i) Leases or subleases real property to the facility; or

(ii) Owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property.

(3) Provides—

(i) Management or administrative services;

(ii) Management or clinical consulting services; or

(iii) Accounting or financial services to the facility.

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 paragraph (3), 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.

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 be granted 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 statutes, regulations, and program instructions of the Medicare program. For purposes of this definition only, the term "organization" means the enrolling entity as identified by its legal business name and tax identification number.

Change in majority ownership occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA or hospice during the 36 months following the HHA's or hospice's initial enrollment into the Medicare program or the 36 months following the HHA's or hospice's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organi-

zation that acquires majority ownership in an HHA or hospice through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's or hospice's most recent change in majority ownership.

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

Delegated official means an individual who is 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 items or services provided to Medicare beneficiaries.

Director means a director of a corporation, regardless of whether the provider or supplier is a non-profit entity. This includes any member of the corporation's governing body irrespective of the precise title of either the board or the member.

Disclosable event means, for purposes of § 424.519, any of the following:

(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 (for example, as part of a repayment plan); 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 by the OIG 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—

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

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

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

Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services. The process includes—

(1) Identification of a provider or supplier;

(2) Except for those suppliers that complete the CMS-855O form, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services, validating the provider or supplier's eligibility to provide items or services to Medicare beneficiaries;

(3) Identification and confirmation of the provider or supplier's practice location(s) and owner(s); and

(4) Except for those suppliers that complete the CMS-855O form, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services, granting the Medicare provider or supplier Medicare billing privileges.

Enrollment application means a CMS-approved paper enrollment application or an electronic Medicare enrollment process approved by OMB.

Final adverse action means one or more of the following actions:

(1) A Medicare-imposed revocation of any Medicare billing privileges;

(2) Suspension or revocation of a license to provide health care by any State licensing authority;

(3) Revocation or suspension by an accreditation organization;

(4) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or

(5) An exclusion or debarment from participation in a Federal or State health care program.

Indirect ownership interest means as follows:

(1)(i) Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier.

(ii) Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.

(2) The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership interest in the provider or supplier and need not be reported.

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (not including physician and nonphysician practitioner organizations), CMS-855S, or an associated internet-based PECOS enrollment application.

Managing employee means—

(1) 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. For purposes of this definition, this includes, but is not limited to, a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director.

(2) With respect to the additional requirements at § 424.516(g) for a skilled nursing facility defined at section 1819(a) of the Act, an individual, including a general manager, business manager, administrator, director, or

consultant, who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility.

Managing organization means an entity that exercises operational or managerial control over, or that directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.

NPI stands for National Provider Identifier.

Officer means an officer of a corporation, regardless of whether the provider or supplier is a non-profit entity.

Operational means the provider or supplier has a qualified physical practice location, is open to the public for the purpose of providing health care related services, is prepared to submit valid Medicare claims, and is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered), to furnish these items or services.

Organizational structure means, with respect to a skilled nursing facility defined at section 1819(a) of the Act, in the case of any of the following:

(1) *A corporation.* The officers, directors, and shareholders of the corporation who have an ownership interest in the corporation which is equal to or exceeds 5 percent.

(2) *A limited liability company.* The members and managers of the limited liability company including, as applicable, what percentage each member and manager has of the ownership interest in the limited liability company.

(3) *A general partnership.* The partners of the general partnership.

(4) *A limited partnership.* The general partners and any limited partners of the limited partnership who have an ownership interest in the limited partnership which is equal to or exceeds 10 percent.

(5) *A trust.* The trustees of the trust.

(6) *An individual.* Contact information for the individual.

Owner means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of the provider or

supplier as defined in sections 1124 and 1124A(A) of the Act.

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

Physician or nonphysician practitioner organization means any physician or nonphysician practitioner entity that enrolls in the Medicare program as a sole proprietorship or organizational entity.

Private equity company means, for purposes of this subpart only, a publicly traded or non-publicly traded company that collects capital investments from individuals or entities and purchases a direct or indirect ownership share of a provider.

Real estate investment trust means, for purposes of this subpart only, a real estate investment trust as defined in 26 U.S.C. 856.

Reject/Rejected means that the provider or supplier's enrollment application was not processed due to incomplete information, or that additional information or corrected information was not received from the provider or supplier in a timely manner.

Revoke/Revocation means that the provider or supplier's billing privileges are terminated.

State oversight board means, for purposes of §§ 424.530(a)(15) and 424.535(a)(22) only, any State administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the State.

Supplier means, for purposes of this subpart, all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

Voluntary termination means that a provider or supplier, including an individual physician or nonphysician practitioner, submits written confirmation

to CMS of its decision to discontinue enrollment in the Medicare program.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 69939, Nov. 19, 2008; 75 FR 70464, Nov. 17, 2010; 75 FR 73628, Nov. 29, 2010; 76 FR 5962, Feb. 2, 2011; 79 FR 72531, Dec. 5, 2014; 82 FR 53368, Nov. 15, 2017; 84 FR 47852, Sept. 10, 2019; 84 FR 63203, Nov. 15, 2019; 86 FR 65682, Nov. 19, 2021; 87 FR 70231, Nov. 18, 2022; 88 FR 77877, Nov. 13, 2023; 88 FR 79540, Nov. 16, 2023; 88 FR 80168, Nov. 17, 2023]

§ 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 CMS-855O form or CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services; once enrolled the provider or supplier receives billing privileges and is issued a valid billing number effective for the date a claim was submitted for an item that was furnished or a service that was rendered. (See 45 CFR part 162 for information on the National Provider Identifier and its use as the Medicare billing number.)

[71 FR 20776, Apr. 21, 2006, as amended at 79 FR 72531, Dec. 5, 2014]

§ 424.506 National Provider Identifier (NPI) on all enrollment applications and claims.

(a) *Definition.* *Eligible professional* means any of the professionals specified in section 1848(k)(3)(B) of the Act.

(b) *Enrollment requirements.* (1) A provider or a supplier that is eligible for an NPI must do the following:

(i) Report its NPI on its Medicare enrollment application.

(ii) If the provider or supplier was in the Medicare program before obtaining an NPI and the provider's or the supplier's NPI is not in the provider's or supplier's Medicare enrollment record, the provider or supplier must update its Medicare enrollment record by submitting its NPI using either of the following:

(A) The applicable paper CMS-855 form.

(B) Internet-based PECOS.

(2) A physician or eligible professional who has validly opted-out of the Medicare program is not required to submit a Medicare enrollment application for any reason, including to order or certify.

(c) *Claims reporting requirements.* (1) A provider or supplier that is enrolled in Medicare and submits a paper or an electronic claim must include its NPI and the NPI(s) of any other provider(s) or supplier(s) identified on the claim.

(2) A Medicare beneficiary who submits a claim for service to Medicare—

(i) Must include the legal name of any provider or supplier who is required to be identified in that claim; and

(ii) May, if known to the beneficiary, include the National Provider Identifier (NPI) of any provider or supplier who is required to be identified in that claim.

(3) A Medicare contractor will reject a claim from a provider or a supplier if the required NPI(s) is not reported.

[75 FR 24448, May 5, 2010, as amended at 77 FR 25317, Apr. 27, 2012]

§ 424.507 Ordering covered items and services for Medicare beneficiaries.

(a) *Conditions for payment of claims for ordered covered imaging and clinical laboratory services and items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)*—(1) *Ordered covered imaging, clinical laboratory services, and DMEPOS item claims.* 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), a provider or supplier must meet all of the following requirements:

(i) 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 a physician or, when permitted, an eligible professional (as defined in § 424.506(a) of this part).

(ii) The claim from the provider or supplier must contain the legal name and the National Provider Identifier (NPI) of the physician or the eligible

§ 424.507

42 CFR Ch. IV (10–1–24 Edition)

professional (as defined in § 424.506(a) of this part) who ordered the item or service.

(iii) The physician or, when permitted, other eligible professional, as defined in § 424.506(a), who ordered the item or service 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 item or service is ordered by—

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

(1) As the ordering supplier.

(2) By his or her legal name.

(3) By his/her NPI.

(B) A licensed resident (as defined in § 413.75), 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 order such items and services, the claim must identify by legal name and NPI the—

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

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

(2) *Part B beneficiary claims.* To receive payment for ordered covered items and services listed at § 424.507(a), a beneficiary's claim must meet all of the following requirements:

(i) The physician or, when permitted, other eligible professional (as defined § 424.506(a)) who ordered the item or service 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 item or service is ordered by—

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

(1) As the ordering supplier.

(2) By his or her legal name.

(B) A licensed resident (as defined in § 413.75), 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 such items and services, the claim must identify by legal name the—

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

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

(b) *Conditions for payment of claims for covered home health and hospice services.* To receive payment for covered Part A or Part B home health services or for covered hospice services, a provider's home health or hospice services claim must meet all of the following requirements:

(1) The ordering/certifying physician for hospice or home health services, or, for home health services, the ordering/certifying physician assistant, nurse practitioner, or clinical nurse specialist working in accordance with State law, must meet all of the following requirements:

(i) Be identified by his or her legal name.

(ii) Be identified by his or her NPI.

(iii)(A) Be enrolled in Medicare in an approved status; or

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

(2) If the services were ordered/certified by—

(i) An unlicensed resident, as defined in § 413.75, or by a non-enrolled licensed resident, as defined in § 413.75, the claim must identify a teaching physician who must be enrolled in Medicare in an approved status—

(A) As the ordering/certifying supplier;

(B) By his or her legal name; and

(C) By his or her NPI.

(ii) A licensed resident (as defined in § 413.75), 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 such items and services, the claim must identify by legal name and NPI the—

(A) Resident, who is enrolled in Medicare in an approved status to order; or

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

(3) For claims for hospice services, the requirements of this paragraph (b) apply with respect to any physician described in § 418.22(c) of this chapter who made the applicable certification described in § 418.22(c) of this chapter.

(c) *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 covered items and services described in paragraph (a) or (b) of this section if the claim does not meet the requirements of paragraphs (a)(1) and (b) of this section, respectively.

(d) *Denial of beneficiary-submitted claims.* A Medicare contractor denies a claim from a Medicare beneficiary for covered items or services described in paragraphs (a) and (b) of this section if the claim does not meet the requirements of paragraph (a)(2) of this section.

[77 FR 25317, Apr. 27, 2012, as amended at 85 FR 27625, May 8, 2020; 88 FR 51199, Aug. 2, 2023]

§ 424.510 Requirements for enrolling in the Medicare program.

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

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

(3) To be enrolled solely to order and certify Medicare items or services, a

physician or non-physician practitioner must meet the requirements specified in paragraph (d) of this section except for paragraphs (d)(2)(iii)(B), (d)(2)(iv), (d)(3)(ii), and (d)(5), (6), and (9) of this section.

(b) The effective dates for reimbursement are specified in § 489.13 of this chapter for providers and suppliers requiring State survey or certification or accreditation, § 424.5 and § 424.44 for non-surveyed or certified/accredited suppliers, and § 424.57 and section 1834(j)(1)(A) of the Act for DMEPOS suppliers.

(c) The effective date for reimbursement for providers and suppliers seeking accreditation from a CMS-approved accreditation organization as specified in § 489.13.

(d) Providers and suppliers must meet the following enrollment requirements:

(1) *Submittal of the enrollment application.* A provider or supplier must submit a complete enrollment application and supporting documentation to the designated Medicare fee-for-service contractor.

(2) *Content of the enrollment application.* Each submitted enrollment application must include the following:

(i) Complete, accurate, and truthful responses to all information requested within each section as applicable to the provider or supplier type.

(ii) Submission of all documentation required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to uniquely identify the provider or supplier. This documentation may include, but is not limited to, proof of the legal business name, practice location, social security number (SSN), tax identification number (TIN), National Provider Identifier (NPI), if issued, and owners of the business.

(iii) Submission of all documentation, including—

(A) All applicable Federal and State licenses, certifications including, but not limited to Federal Aviation Administration; and

(B) Documentation associated with regulatory and statutory requirements necessary to establish a provider's or

supplier's eligibility to furnish Medicare covered items or services to beneficiaries in the Medicare program.

(iv) At the time of enrollment, an enrollment change request, revalidation or change of Medicare contractors where the provider or supplier was already receiving payments via EFT, providers and suppliers must agree to receive Medicare payments via EFT, if not already receiving payment through EFT. In order to receive Medicare payments via EFT, providers and suppliers must submit the CMS-588 form.

(3) *Signature(s) required on the enrollment application.* The certification statement found on the enrollment application must be signed by an individual who has the authority to bind the provider or supplier, both legally and financially, to the requirements set forth in this chapter. This person must also have an ownership or control interest in the provider or supplier, as that term is defined in section 1124(a)(3) of the Act, such as, the general partner, chairman of the board, chief financial officer, chief executive officer, president, or hold a position of similar status and authority within the provider or supplier organization. The signature attests that the information submitted is accurate and that the provider or supplier is aware of, and abides by, all applicable statutes, regulations, and program instructions.

(i) *Requirements.* The signature requirements specified in paragraphs (d)(3)(i)(A) through (C) of this section outline who must sign the enrollment application for an enrolling provider or supplier. In the case of—

(A) An individual practitioner, the applying practitioner.

(B) A sole proprietorship, the applying sole proprietor.

(C) A corporation, partnership, group, limited liability company, or other organization (hereafter referred to collectively in this section as an organization), an authorized official, as defined in § 424.502. When an authorized official signs the certification statement on behalf of an organization, the signed statement is considered legally binding upon the organization.

(ii) *Delegation of authority.* The original enrollment application submitted for an organization's initial enrollment

and all subsequent enrollment applications submitted for periodic revalidation of the organization's enrollment data (as required to maintain enrollment in the Medicare program) must be signed by an authorized official. Any updates or changes reported outside of the initial enrollment or periodic revalidation process may be signed by a delegated official(s) of the organization. The delegated official's signature binds the organization both legally and financially, as if the signature was that of the authorized official. Before the delegation of authority is established, the only acceptable signature on the enrollment application to report updates or changes to the enrollment information is that of the authorized official currently on file with Medicare. Once the delegation of authority is established, the only acceptable signatures on correspondence to report updates or changes to the enrollment information are those of the authorized official and the person(s) to whom this authority is delegated in accordance with the requirements described in this section. Individual practitioners and sole proprietors cannot delegate signature authority when submitting an enrollment application for any reason. All enrollment applications submitted by individual practitioners and sole proprietors must be signed by the enrolling or enrolled individual. Each delegation of authority to a delegated official must—

(A) Be assigned by the authorized official currently on file with CMS;

(B) Be submitted to CMS using the appropriate enrollment application or CMS established electronic enrollment process;

(C) Include the title and SSN of each person delegated authority to update or change the organization's enrollment information;

(D) Be an individual that has an ownership or control interest in the organization or is a W-2 managing employee as defined in section 1126(b) of the Act; and

(E) Be signed by the authorized official and the delegated official(s) of the organization.

(4) *Verification of information.* The information submitted by the provider or supplier on the applicable enrollment

application must be such that CMS can validate it for accuracy at the time of submission.

(5) *Completion of any applicable State surveys, certifications, and provider agreements.* The providers or suppliers who are mandated under the provision in part 488 of this chapter to be surveyed or certified by the State survey and certification agency, and to also enter into and sign a provider agreement as outlined in part 489 of this chapter, must also meet those requirements as part of the process to obtain Medicare billing privileges.

(6) *Ability to furnish Medicare covered items or services.* The provider or supplier must be operational to furnish Medicare covered items or services before being granted Medicare billing privileges.

(7) *Additional requirements.* Providers and suppliers must meet the provisions of § 424.520 regarding additional compliance and reporting requirements.

(8) *On-site review.* CMS reserves the right, when deemed necessary, to perform on-site inspections of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation.

(i) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) *Medicare Part B suppliers.* CMS determines, upon review that the supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(9) In order to obtain enrollment and to maintain enrollment for the first three months after Medicare billing privileges are conveyed, a home health agency must satisfy the home health “initial reserve operating funds” re-

quirement as set forth in § 489.28 of this chapter.

(e) Providers and suppliers must—

(1) Agree to receive Medicare payment via electronic funds transfer (EFT) at the time of enrollment, revalidation, change of Medicare contractors where the provider or supplier was already receiving payments via EFT or submission of an enrollment change request; and

(2) Submit the CMS-588 form to receive Medicare payment via electronic funds transfer.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 36461, June 27, 2008; 75 FR 50418, Aug. 16, 2010; 75 FR 70464, Nov. 17, 2010; 75 FR 73628, Nov. 29, 2010; 77 FR 29030, July 16, 2012; 79 FR 72531, Dec. 5, 2014]

§ 424.514 Application fee.

(a) *Application fee requirements for prospective institutional providers.* Beginning on or after March 25, 2011, prospective institutional providers that are submitting an initial application or currently enrolled institutional providers that are submitting an application to establish a new practice location must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(b) *Application fee requirements for revalidating institutional providers.* Beginning March 25, 2011, institutional providers that are subject to CMS revalidation efforts must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(c) *Hardship exception for disaster areas.* CMS will assess on a case-by-case basis whether institutional providers enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) should receive an exception to the application fee.

(d) *Application fee.* The application fee and associated requirements are as follows:

(1) For 2010, \$500.00.

§ 424.514

42 CFR Ch. IV (10–1–24 Edition)

(2) For 2011 and subsequent years—

(i) Is adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year;

(ii) Is effective from January 1 to December 31 of a calendar year;

(iii) Is based on the submission of an initial application, application to establish a new practice location or the submission of an application in response to a CMS revalidation request;

(iv) Must be in the amount calculated by CMS in effect for the year during which the application for enrollment is being submitted;

(v) Is nonrefundable, except if submitted with one of the following:

(A) A request for hardship exception that is subsequently approved;

(B) An application that is rejected prior to initiation of screening processes;

(C) An application that is subsequently denied as a result of the imposition of a temporary moratorium;

(e) *Denial or revocation based on application fee.* A Medicare contractor may deny or revoke Medicare billing privileges of a provider or supplier based on noncompliance if, in the absence of a written request for a hardship exception from the application fee that accompanies a Medicare enrollment application, the bank account on which the check that is submitted with the enrollment application is drawn does not contain sufficient funds to pay the application fee.

(f) *Information needed for submission of a hardship exception request.* A provider or supplier requesting an exception from the application fee must include with its enrollment application a letter that describes the hardship and why the hardship justifies an exception.

(g) *Failure to submit application fee or hardship exception request.* A Medicare contractor may—

(1) Reject an enrollment application from a newly-enrolling institutional provider that, with the exceptions described in § 424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(2) Revoke the billing privileges of a currently enrolled institutional provider that, with the exceptions described in § 424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(3)(i) Notwithstanding the foregoing, the contractor must first inform the provider that the application fee was not submitted in accordance with this section.

(ii) Within 30 days after the date of the notification, the contractor may reject the application of the newly-enrolling institutional provider or revoke the billing privileges of the currently enrolled institutional provider that has not submitted the fee.

(h) *Consideration of hardship exception request.* CMS has 60 days in which to approve or disapprove a hardship exception request. If a provider submits a request for hardship exception to the fee and the provider or supplier has not already submitted the fee consistent with provisions in § 424.514(a) and (b), and the request for hardship exception is not approved, CMS notifies the provider or supplier that the hardship exception request was not approved and allows the provider or supplier 30 days from the date of notification to submit the application fee.

(1) A Medicare contractor does not—

(i) Begin processing an enrollment application that is accompanied by a hardship exception request until CMS has made a decision to approve or disapprove the hardship exception request; and

(ii) Deny an enrollment application that is accompanied by a hardship exception request unless the hardship exception request is denied by CMS and the provider or supplier fails to submit the required application fee within 30 days of being notified that the request for a hardship exception was denied.

(2) A hardship exception determination made by CMS is appealable using § 405.874 of this chapter.

[76 FR 5962, Feb. 2, 2011]

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

To maintain Medicare billing privileges, a provider or supplier (other than a DMEPOS supplier) must resubmit and recertify the accuracy of its enrollment information every 5 years. All providers and suppliers currently billing the Medicare program or initially enrolling in the Medicare program are required to complete the applicable enrollment application. The provider or supplier then enters a 5-year revalidation cycle once a completed enrollment application is submitted and validated. (Ambulance service providers must continue to resubmit enrollment information in accordance with § 410.41(c)(2) of this chapter and DMEPOS suppliers must continue to renew enrollment in accordance with § 424.57(g)). The requirements for the resubmission, recertification and reverification of enrollment information include the following:

(a) *Submission of the enrollment application and supporting documentation.* The provider or supplier must meet the submission, content, signature, verification, operational, inspection, and other requirements outlined in § 424.510.

(1) CMS contacts each provider or supplier directly when it is time to revalidate their enrollment information.

(2) A provider or supplier must submit to CMS the applicable enrollment application with complete and accurate information and applicable supporting documentation within 60 calendar days of our notification to resubmit and certify to the accuracy of its enrollment information.

(b) *Completion of any applicable State surveys, certifications and provider agreements.* A new certification and a new provider agreement are not required for the purpose of resubmission and certification for revalidation of enrollment information. Providers and suppliers must continue to meet the requirements of parts 488 and 489 of this chapter, or any currently established supplier agreement, if applicable.

(c) *On-site inspections.* CMS reserves the right to perform on-site inspections of a provider or supplier to verify that

the information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation.

(1) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(2) *Medicare Part B suppliers.* CMS determines, upon review that the supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(d) *Off Cycle revalidations.* (1) CMS reserves the right to perform off cycle revalidations in addition to the regular 5-year revalidations and may request that a provider or supplier recertify the accuracy of the enrollment information when warranted to assess and confirm the validity of the enrollment information maintained by CMS. Off cycle revalidations may be triggered as a result of random checks, information indicating local health care fraud problems, national initiatives, complaints, or other reasons that cause CMS to question the compliance of the provider or supplier with Medicare enrollment requirements. Off cycle revalidations may be accompanied by site visits.

(2) CMS reserve the right to adjust the routine 5-year revalidation schedule if we determine that revalidation should occur on a more frequent basis due to complaints or evidence we receive indicating noncompliance with the statute or regulations by specific provider or supplier types. The schedule may also be on a less frequent basis if we determine that the integrity of and compliance with the statute and regulations by specific provider or supplier types indicates that less frequent

validation is justified. If a change occurs, CMS notifies all affected providers and suppliers at least 90 days in advance of implementing the change.

(3) CMS revalidates enrollment information for ambulance service suppliers in accordance with § 410.41(c)(2) of this chapter (Requirements for ambulance suppliers), and DMEPOS suppliers renews enrollment in accordance with § 424.57(g) (Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers).

(e) *Additional off-cycle revalidation.* On or after March 23, 2012, Medicare providers and suppliers, including DMEPOS suppliers, may be required to revalidate their enrollment outside the routine 5-year revalidation cycle (3-year DMEPOS supplier revalidation cycle).

(1) CMS will contact providers or suppliers to revalidate their enrollment for off-cycle revalidation.

(2) As with all revalidations, revalidations described in this paragraph are conducted in accordance with the screening procedures specified at § 424.518.

[71 FR 20776, Apr. 21, 2006, as amended at 76 FR 5963, Feb. 2, 2011; 79 FR 69775, Nov. 24, 2014]

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

(a) *Certifying compliance.* CMS enrolls and maintains an active enrollment status for a provider or supplier when that provider or supplier certifies that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet, all of the following requirements:

(1) Compliance with title XVIII of the Act and applicable Medicare regulations.

(2) Compliance with Federal and State licensure, certification, and regulatory requirements, as required, based on the type of services or supplies the provider or supplier type will furnish and bill Medicare.

(3) Not employing or contracting with individuals or entities that meet either of the following conditions:

(i) Excluded from participation in any Federal health care programs, for the provision of items and services covered under the programs, in violation of section 1128A(a)(6) of the Act.

(ii) Debarred by the General Services Administration (GSA) from any other Executive Branch procurement or non-procurement programs or activities, in accordance with the Federal Acquisition and Streamlining Act of 1994, and with the HHS Common Rule at 45 CFR part 76.

(b) *Reporting requirements Independent Diagnostic Testing Facilities (IDTFs).* IDTF reporting requirements are specified in § 410.33(g)(2) of this chapter.

(c) *Reporting requirements DMEPOS suppliers.* DMEPOS reporting requirements are specified in § 424.57(c)(2).

(d) *Reporting requirements for physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations.* Physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations must report the following reportable events to their Medicare contractor within the specified timeframes:

(1) Within 30 days—

(i) A change of ownership;

(ii) Any adverse legal action; or

(iii) A change, addition, or deletion of a practice location.

(2) All other changes in enrollment must be reported within 90 days.

(e) *Reporting requirements for all other providers and suppliers.* Reporting requirements for all other providers and suppliers not identified in paragraphs (a) through (d) of this section, with the exception of MDPP suppliers whose reporting requirements are established at § 424.205(d), must report to CMS the following information within the specified timeframes:

(1) Within 30 days for a change of ownership or control (including changes in authorized official(s) or delegated official(s)) or a change, addition, or deletion of a practice location;

(2) All other changes to enrollment must be reported within 90 days.

(3) Within 30 days of any revocation or suspension of a Federal or State license or certification including Federal Aviation Administration certifications, an air ambulance supplier must report a revocation or suspension

of its license or certification to the applicable Medicare contractor. The following FAA certifications must be reported:

(i) Specific pilot certifications including but not limited to instrument and medical certifications.

(ii) Airworthiness certification.

(f) *Maintaining and providing access to documentation.* (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—

(A) Maintain documentation (as described in paragraph (f)(1)(ii) of this section) for 7 years from the date of service; and

(B) Upon the request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(1)(ii) of this section).

(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—

(A) Maintain documentation (as described in paragraph (f)(2)(ii) of this section) for 7 years from the date of the service; and

(B) Upon request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(2)(ii) of this section).

(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.

(g) *Skilled nursing facilities.* (1) In addition to all other applicable reporting requirements in this subpart, a skilled nursing facility (as defined in section

1819(a) of the Act) must disclose upon initial enrollment (which, for purposes of this paragraph (g), also includes a change of ownership under 42 CFR 489.18) and revalidation the following information:

(i) Each member of the governing body of the facility, including the name, title, and period of service for each such member.

(ii) Each person or entity who is an officer, director, member, partner, trustee, or managing employee (as defined in § 424.502) of the facility, including the name, title, and period of service of each such person or entity.

(iii) Each person or entity who is an additional disclosable party of the facility (as defined in § 424.502).

(iv) The organizational structure (as defined in § 424.502) of each additional disclosable party of the facility and a description of the relationship of each such additional disclosable party to the facility and to one another.

(2) The skilled nursing facility need not disclose the same information described in paragraph (g)(1) of this section more than once on the same enrollment application submission.

(3) The skilled nursing facility must report any change to any of the information described in paragraph (g)(1) of this section consistent with the applicable timeframes in paragraph (e) of this section.

[73 FR 69939, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008, as amended at 75 FR 24449, May 5, 2010; 75 FR 73628, Nov. 29, 2010; 77 FR 25318, Apr. 27, 2012; 82 FR 53368, Nov. 15, 2017; 84 FR 47852, Sept. 10, 2019; 88 FR 79541, Nov. 16, 2023; 88 FR 80168, Nov. 17, 2023]

§ 424.517 Onsite review.

(a) CMS reserves the right, when deemed necessary, to perform onsite review of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation. Based upon the results of CMS's onsite review, the provider may be subject to denial or revocation of Medicare billing privileges

§ 424.518

42 CFR Ch. IV (10–1–24 Edition)

as specified in § 424.530 or § 424.535 of this part.

(1) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider meets either of the following conditions:

(i) Is unable to furnish Medicare-covered items or services.

(ii) Has failed to satisfy any of the Medicare enrollment requirements.

(2) *Medicare Part B providers.* CMS determines, upon review, that the supplier meets any of the following conditions:

(i) Is unable to furnish Medicare-covered items or services.

(ii) Has failed to satisfy any or all of the Medicare enrollment requirements.

(iii) Has failed to furnish Medicare covered items or services as required by the statute or regulations.

(b) [Reserved]

[73 FR 66940, Nov. 19, 2008]

§ 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, revalidation applications, change of ownership applications pursuant to 42 CFR 489.18, applications to add a new practice location, and applications to report any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42, based on a CMS assessment of risk and assignment to a level of “limited,” “moderate,” or “high.”

(a) *Limited categorical risk*—(1) *Limited categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as “limited” categorical risk:

(i) Physician or nonphysician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists) and medical groups or clinics.

(ii) Ambulatory surgical centers.

(iii) Competitive Acquisition Program/Part B Vendors.

(iv) End-stage renal disease facilities.

(v) Federally qualified health centers.

(vi) Histocompatibility laboratories.

(vii) Home infusion therapy suppliers.

(viii) Hospitals, including critical access hospitals, rural emergency hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

(ix) Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act.

(x) Mammography screening centers.

(xi) Mass immunization roster billers

(xii) Opioid treatment programs (if § 424.67(b)(3)(ii) applies).

(xiii) Organ procurement organizations.

(xiv) Pharmacies newly enrolling or revalidating via the CMS–855B application.

(xv) Radiation therapy centers.

(xvi) Religious non-medical health care institutions.

(xvii) Rural health clinics.

(2) *Limited screening level: Screening requirements.* When CMS designates a provider or supplier as a “limited” categorical level of risk, the Medicare contractor does all of the following:

(i) Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination.

(ii) Conducts license verifications, including licensure verifications across State lines for physicians or nonphysician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling.

(iii) Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

(b) *Moderate categorical risk*—(1) *Moderate categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as “moderate” categorical risk:

(i) Ambulance service suppliers.

(ii) Community mental health centers.

(iii) Comprehensive outpatient rehabilitation facilities.

(iv) Independent clinical laboratories.

(v) Independent diagnostic testing facilities.

(vi) Physical therapists enrolling as individuals or as group practices.

(vii) Portable x-ray suppliers.

(viii) Prospective (newly enrolling) and revalidating opioid treatment programs that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since October 23, 2018.

(ix) Revalidating opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices to which CMS applied the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section upon the provider's or supplier's—

(A) New/initial enrollment; or

(B) Revalidation after CMS waived the fingerprinting requirements, under the circumstances described in paragraph (c)(1)(viii) of this section, when the provider or supplier initially enrolled in Medicare.

(2) *Moderate screening level: Screening requirements.* When CMS designates a provider or supplier as a “moderate” categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the “limited” screening requirements described in paragraph (a)(2) of this section.

(ii) Conducts an on-site visit.

(c) *High categorical risk—(1) High categorical risk: Provider and supplier categories.* CMS has designated the following provider and supplier types as “high” categorical risk:

(i) Prospective (newly enrolling) home health agencies.

(ii) Prospective (newly enrolling) DMEPOS suppliers.

(iii) Prospective (newly enrolling) MDPP suppliers

(iv) Prospective (newly enrolling) opioid treatment programs that have not been fully and continuously cer-

tified by SAMHSA since October 23, 2018.

(v) Prospective (newly enrolling) (SNFs).

(vi) Prospective (newly enrolling) hospices.

(vii) Enrolled opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, DMEPOS suppliers, MDPP suppliers, HHAs, SNFs, and hospices that are submitting a change of ownership application pursuant to 42 CFR 489.18 or reporting any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42.

(viii) Except as stated in paragraph (b)(1)(ix) of this section, revalidating opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices for which, upon their new/initial enrollment, CMS waived the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section in accordance with applicable legal authority due to a national, state, or local emergency declared under existing law.

(2) *High screening level: Screening requirements.* When CMS designates a provider or supplier as a “high” categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the “limited” and “moderate” screening requirements described in paragraphs (a)(2) and (b)(2) of this section.

(ii)(A) Requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier; and

(B) Conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.

(3) *Adjustment in the categorical risk.* CMS adjusts the screening level from

§ 424.519

42 CFR Ch. IV (10–1–24 Edition)

“limited” or “moderate” to “high” if any of the following occur:

(i) CMS imposes a payment suspension on a provider or supplier at any time in the last 10 years.

(ii) The provider or supplier—

(A) Has been excluded from Medicare by the OIG; or

(B) Had billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by—

(1) Enrolling as a new provider or supplier; or

(2) Billing privileges for a new practice location;

(C) Has been terminated or is otherwise precluded from billing Medicaid;

(D) Has been excluded from any Federal health care program; or

(E) Has been subject to any final adverse action, as defined at § 424.502, within the previous 10 years.

(iii) CMS lifts a temporary moratorium for a particular provider or supplier type and a provider or supplier that was prevented from enrolling based on the moratorium, applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

(4) Any screening level adjustment under paragraph (c)(3) of this section also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier for which the screening level under paragraph (c)(3) of this section was originally raised.

(d) *Fingerprinting requirements.* An individual subject to the fingerprint-based criminal history record check requirement specified in paragraph (c)(2)(ii)(B) of this section—

(1) Must submit a set of fingerprints for a national background check.

(i) Upon submission of a Medicare enrollment application; or

(ii) Within 30 days of a Medicare contractor request.

(2) In the event the individual(s) required to submit fingerprints under paragraph (c)(2) of this section fail to submit such fingerprints in accordance with paragraph (d)(1) of this section,

the provider or supplier will have its billing privileges—

(i) Denied under § 424.530(a)(1); or

(ii) Revoked under § 424.535(a)(1).

[76 FR 5963, Feb. 2, 2011, as amended at 82 FR 53368, Nov. 15, 2017; 84 FR 63203, Nov. 15, 2019; 85 FR 70355, Nov. 4, 2020; 85 FR 85038, Dec. 28, 2020; 87 FR 70231, Nov. 18, 2022; 87 FR 72293, Nov. 23, 2022; 88 FR 77877, Nov. 13, 2023]

§ 424.519 Disclosure of affiliations.

(a) *Definitions.* For purposes of this section only, the following terms apply to the definition of disclosable event in § 424.502:

(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 imposed under this title.

(iii) Assessments imposed under this title.

(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.* Upon a CMS request, an initially enrolling or revalidating provider or supplier must disclose any and all affiliations that 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, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier that has a disclosable event (as defined in § 424.502). CMS will request such disclosures when it has determined that the initially enrolling or revalidating provider or supplier may have at least one such affiliation.

(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 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) 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) of 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 disclosable event under paragraph (b) of this section:

(i) The type of disclosable event.

(ii) When the disclosable event occurred or was imposed.

(iii) Whether the affiliation existed when the disclosable event occurred or was imposed.

(iv) If the disclosable event 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 disclosable event.

(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) *Duplicate data*. A provider or supplier is not required to 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.

[84 FR 47853, Sept. 10, 2019]

§ 424.520 Effective date of Medicare billing privileges.

(a) *Surveyed, certified or accredited providers and suppliers*. The effective date for billing privileges for providers and suppliers requiring State survey, certification or accreditation is specified in § 489.13 of this chapter. If a provider or supplier is seeking accreditation from a CMS-approved accreditation organization, the effective date is specified in § 489.13.

§ 424.521

42 CFR Ch. IV (10–1–24 Edition)

(b) *Independent Diagnostic Testing Facilities*. The effective date for billing privileges for IDTFs is specified in § 410.33(i) of this chapter.

(c) *DMEPOS suppliers*. The effective date for billing privileges for DMEPOS suppliers is specified in § 424.57(b) of this subpart and section 1834(j)(1)(A) of the Act.

(d) *Additional provider and supplier types*. (1) The effective date of billing privileges for the provider and supplier types identified in paragraph (d)(2) of this section is the later of—

(i) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or

(ii) The date that the provider or supplier first began furnishing services at a new practice location.

(2) The provider and supplier types to which paragraph (d)(1) of this section applies are as follows:

- (i) Physicians.
- (ii) Non-physician practitioners.
- (iii) Physician organizations.
- (iv) Non-physician practitioner organizations.
- (v) Ambulance suppliers.
- (vi) Opioid treatment programs.
- (vii) Part B hospital departments.
- (viii) Clinical Laboratory Improvement Amendment labs.
- (ix) Intensive cardiac rehabilitation facilities.
- (x) Mammography centers.
- (xi) Mass immunizers/pharmacies.
- (xii) Radiation therapy centers.
- (xiii) Home infusion therapy suppliers.
- (xiv) Physical therapists.
- (xv) Occupational therapists.
- (xvi) Speech language pathologists.

[73 FR 69940, Nov. 19, 2008, as amended at 75 FR 50418, Aug. 16, 2010; 79 FR 72531, Dec. 5, 2014; 84 FR 63203, Nov. 15, 2019; 85 FR 70355, Nov. 4, 2020; 86 FR 62419, Nov. 9, 2021]

§ 424.521 Request for payment by certain provider and supplier types.

(a) *Request for payment by certain provider and supplier types*. (1) The providers and suppliers identified in paragraph (a)(2) of this section may retrospectively bill for services when the provider or supplier has met all program requirements (including State licensure requirements), and services

were provided at the enrolled practice location for up to—

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

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

(2) The provider and supplier types to which paragraph (a)(1) of this section applies are as follows:

- (i) Physicians.
- (ii) Non-physician practitioners.
- (iii) Physician organizations.
- (iv) Non-physician practitioner organizations.
- (v) Ambulance suppliers.
- (vi) Opioid treatment programs.
- (vii) Part B hospital departments.
- (viii) Clinical Laboratory Improvement Amendment labs.
- (ix) Intensive cardiac rehabilitation facilities.
- (x) Mammography centers.
- (xi) Mass immunizers/pharmacies.
- (xii) Radiation therapy centers.
- (xiii) Home infusion therapy suppliers.
- (xiv) Physical therapists.
- (xv) Occupational therapists.
- (xvi) Speech language pathologists.
- (b) [Reserved]

[79 FR 72531, Dec. 5, 2014, as amended at 84 FR 63203, Nov. 15, 2019; 85 FR 70355, Nov. 4, 2020; 86 FR 62419, Nov. 9, 2021]

§ 424.522 Additional effective dates.

(a) *Reassignments*. A reassignment of benefits under § 424.80 is effective beginning 30 days before the Form CMS–855R is submitted if all applicable requirements during that period were otherwise met.

(b) *Form CMS–855O enrollment*. The effective date of a Form CMS–855O enrollment is the date on which the Medicare contractor received the Form CMS–855O application if all other requirements are met.

[86 FR 62419, Nov. 9, 2021]

§ 424.525 Rejection of a provider's or supplier's application for Medicare enrollment.

(a) *Reasons for rejection.* CMS may reject a provider's or supplier's enrollment application for any of the following reasons:

(1) The provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the Medicare contractor's request for the missing information. This includes the following situations:

(i) The application is missing data required by CMS or the Medicare contractor to process the application (such as, but not limited to, names, Social Security Number, contact information, and practice location information).

(ii) The application is unsigned or undated.

(iii) The application contains a copied or stamped signature.

(iv) The application is signed more than 120 days prior to the date on which the Medicare contractor received the application.

(v) The application is signed by a person unauthorized to do so under this subpart.

(vi) For paper applications, the required certification statement is missing.

(vii) The paper application is completed in pencil.

(viii) The application is submitted via fax or e-mail when the provider or supplier was not otherwise permitted to do so.

(ix) The provider or supplier failed to submit all of the forms needed to process a Form CMS-855 reassignment package within 30 days of receipt.

(x) The provider or supplier submitted the incorrect Form CMS-855 application.

(2) The provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.

(3) The Prospective institutional provider or supplier does not submit the application fee in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.

(b) *Extension of 30-day period.* CMS, at its discretion, may choose to extend

the 30 day period if CMS determines that the provider or supplier is actively working with CMS to resolve any outstanding issues.

(c) *Resubmission after rejection.* To enroll in Medicare and obtain Medicare billing privileges after notification of a rejected enrollment application, the provider or supplier must complete and submit a new enrollment application and submit all supporting documentation for CMS review and approval.

(d) *Additional review.* Enrollment applications that are rejected are not afforded appeal rights.

(e) *Applicability.* Except as otherwise specified in the applicable reason for rejection under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions, including, but not limited to, the following:

(1) Form CMS-855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS-588 (Electronic Funds Transfer (EFT) Authorization Agreement) submissions.

(3) Form CMS-20134 (Medicare Enrollment Application; Medicare Diabetes Prevention Program (MDPP) Suppliers) submissions.

(4) Any electronic or successor versions of the forms identified in paragraphs (e)(1) through (3) of this section.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 36461, June 27, 2008; 76 FR 5964, Feb. 2, 2011; 86 FR 62419, Nov. 9, 2021]

EDITOR'S NOTE: At 86 FR 62419, Nov. 9, 2021, paragraph (a)(3) was amended by removing the phrase "prospective provider" and adding the word "provider" in its place; however, the phrase does not exist.

§ 424.526 Return of a provider's or supplier's enrollment application.

(a) *Reasons for return.* CMS may return a provider's or supplier's enrollment application for any of the following reasons:

(1) The provider or supplier sent its paper Form CMS-855, Form CMS-588, or Form CMS-20134 application to the incorrect Medicare contractor for processing.

(2) The Medicare contractor received the application more than 60 days prior

to the effective date listed on the application. (This paragraph (a)(2) does not apply to providers and suppliers submitting a Form CMS–855A application, ambulatory surgical centers, or portable x-ray suppliers.)

(3) The seller or buyer in a change of ownership submitted its Form CMS–855A or Form CMS–855B application more than 90 days prior to the anticipated date of the sale.

(4) The Medicare contractor received an initial application more than 180 days prior to the effective date listed on the application from a provider or supplier submitting a Form CMS–855A application, an ambulatory surgical center, or a portable x-ray supplier.

(5) The Medicare contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.

(6) The provider or supplier submitted an initial enrollment application prior to the expiration of their existing re-enrollment bar under § 424.535 or reapplication bar under § 424.530(f).

(7) The application is not needed for (or is inapplicable to) the transaction in question.

(8) The provider or supplier submitted a revalidation application more than 7 months prior to the provider's or supplier's revalidation due date.

(9) A Medicare Diabetes Prevention Program supplier submitted an application with a coach start date more than 30 days in the future.

(10) The provider or supplier requests that their application be withdrawn prior to or during the Medicare contractor's processing thereof.

(11) The provider or supplier submits an application that is an exact duplicate of an application that has already been processed or is currently being processed or is pending processing.

(12) The provider or supplier submits a paper Form CMS–855 or Form CMS–20134 enrollment application that is outdated or has been superseded by a revised version.

(13) The provider or supplier submits a Form CMS–855A or Form CMS–855B initial application followed by a Form CMS–855A or Form CMS–855B change of

ownership application. If the Medicare contractor—

(i) Has not yet made a recommendation for approval concerning the initial application, both applications may be returned.

(ii) Has made a recommendation for approval concerning the initial application, the Medicare contractor may return the change of ownership application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS–855A or Form CMS–855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS–855A or Form CMS–855B application.

(b) *Appeals.* A provider or supplier is not afforded appeal rights if their application is returned under this section.

(c) *Applicability.* Except as otherwise specified in the applicable return reason under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions including, but not limited to, the following:

(1) Form CMS–855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS–588 submissions.

(3) Form CMS–20134 submissions.

(4) Any electronic or successor versions of the forms identified in paragraphs (c)(1) through (3) of this section.

[86 FR 62420, Nov. 9, 2021]

§ 424.527 Provisional period of enhanced oversight.

(a) *New provider or supplier.* Exclusively for purposes of both section 1866(j)(3) of the Act and this § 424.527, the term “new provider or supplier” is defined as any of the following:

(1) A newly enrolling Medicare provider or supplier. (This includes providers that are required to enroll as a new provider in accordance with the change in majority ownership provisions in § 424.550(b).)

(2) A certified provider or certified supplier undergoing a change of ownership consistent with the principles of 42

CFR 489.18. (This includes providers that qualify under § 424.550(b)(2) for an exception from the change in majority ownership requirements in § 424.550(b)(1) but which are undergoing a change of ownership under 42 CFR 489.18).

(3) A provider or supplier (including an HHA or hospice) undergoing a 100 percent change of ownership via a change of information request under § 424.516.

(b) *Effective date.* The effective date of a provisional period of enhanced oversight that is commenced under section 1866(j)(3) of the Act is the date on which the new provider or supplier submits its first claim.

[88 FR 77877, Nov. 13, 2023]

§ 424.530 Denial of enrollment in the Medicare program.

(a) *Reasons for denial.* CMS may deny a provider's or supplier's enrollment in the Medicare program for the following reasons:

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

(2) *Provider or supplier conduct.* (i) The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, of the provider or supplier is—

(A) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this

section include, but are not limited to, W-2 employees and contracted individuals and organizations of the provider or supplier.

(3) *Felonies.* The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

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

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

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

(ii) Denials based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(iii) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W-2 employees and contracted individuals and organizations of the provider or supplier.

(4) *False or misleading information.* The provider or supplier has submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program. (Offenders may be referred to the Office of Inspector General for investigation and possible criminal, civil, or administrative sanctions.)

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

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

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

(6) *Medicare debt.* (i) The enrolling provider, supplier, or owner thereof (as defined in § 424.502), has an existing Medicare debt.

(ii) The enrolling provider, supplier, or owner (as defined in § 424.502) thereof was previously the owner (as defined in § 424.502) of a provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily terminated, involuntarily terminated, or revoked, and all of the following criteria are met:

(A) The owner left the provider or supplier with the Medicare debt within 1 year before or after that provider or supplier's voluntary termination, involuntary termination or revocation.

(B) The Medicare debt has not been fully repaid.

(C) CMS determines that the uncollected debt poses an undue risk of fraud, waste, or abuse. In making this determination, CMS considers the following factors:

(1) The amount of the Medicare debt.

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

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

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

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

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

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

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

(B) Repays the debt in full.

(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 the provision in this paragraph (a)(7) 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.

(8) *Initial Reserve Operating Funds.* (i) CMS or its designated Medicare contractor may deny Medicare billing privileges if, within 30 days of a CMS or Medicare contractor request, a home health agency (HHA) cannot furnish supporting documentation which verifies that the HHA meets the initial reserve operating funds requirement found in § 489.28(a) of this title.

(ii) CMS may deny Medicare billing privileges upon an HHA applicant's failure to satisfy the initial reserve operating funds requirement found in 42 CFR 489.28(a).

(9) *Application fee/hardship exception.* An institutional provider's or supplier's hardship exception request is not granted, and the provider or supplier does not submit the application fee within 30 days of notification that the hardship exception request was not approved.

(10) *Temporary moratorium.* A provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium.

(11) *Prescribing authority.* (i) A physician or other eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause;

(ii) The applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date the physician or eligible professional submits his or her enrollment application to the Medicare contractor.

(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.* 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 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 (a)(14) 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 termi-

nated 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 (as that term is defined in § 424.502) 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.

(15) *Patient harm.* (i) The physician or other eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a denial is appropriate, CMS considers the following factors:

(A) The nature of the patient harm.

(B) The nature of the physician's or other eligible professional's conduct.

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a State oversight board, IRO, Federal or State health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(1) License restriction(s) pertaining to certain procedures or practices.

(2) Required compliance appearances before State oversight board members.

(3) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(4) Administrative/monetary penalties.

(5) Formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.

(ii) Paragraph (a)(15)(i) of this section does not apply to actions or orders pertaining exclusively to either of the following:

(A) Required participation in rehabilitation or mental/behavioral health programs; or

(B) Required abstinence from drugs or alcohol and random drug testing.

(16) [Reserved]

(17) *False Claims Act (FCA)*. (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a denial under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502 of this chapter).

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

(18) *Supplier standard or condition violation*. (i) The independent diagnostic testing facility is non-compliant with any provision in § 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

(b) *Resubmission after denial*. A provider or supplier that is denied enrollment in the Medicare program cannot submit a new enrollment application until the following has occurred if the denial:

(1) Was not appealed, the provider or supplier may reapply after its appeal rights have lapsed.

(2) Was appealed, the provider or supplier may reapply after notification that the determination was upheld.

(c) *Reversal of denial*. If the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare reimbursable services, the denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

(d) *Additional review*. When a provider or supplier is denied enrollment in Medicare, CMS automatically reviews all other related Medicare enrollment files that the denied provider or supplier has an association with (for example, as an owner or managing employee) to determine if the denial warrants an adverse action of the associated Medicare provider or supplier.

(e) *Effective date of denial*. Denial becomes effective within 30 days of the initial denial notification.

(f) *Reapplication bar*. CMS may prohibit a prospective provider or supplier from enrolling in Medicare for up to 10 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.

(3)(i) A provider or supplier that is currently subject to a reapplication bar under paragraph (f) of this section may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs.

(ii) Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a provider or supplier that is currently under a reapplication bar.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 69940, Nov. 19, 2008; 75 FR 70464, Nov. 17, 2010; 76 FR 5964, Feb. 2, 2011; 79 FR 29968, May 23, 2014; 79 FR 72531, Dec. 5, 2014; 84 FR 47853, Sept. 10, 2019; 84 FR 63203, Nov. 15, 2019; 86 FR 65682, Nov. 19, 2021; 87 FR 70231, Nov. 18, 2022; 88 FR 77878, Nov. 13, 2023; 88 FR 79541, Nov. 16, 2023]

§ 424.535 Revocation of enrollment in the Medicare program.

(a) *Reasons for revocation.* CMS may revoke a currently enrolled provider or supplier's Medicare enrollment and any corresponding provider agreement or supplier agreement for the following reasons:

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter.

(i) CMS may request additional documentation from the provider or supplier to determine compliance if adverse information is received or otherwise found concerning the provider or supplier.

(ii) Requested additional documentation must be submitted within 60 calendar days of request.

(2) *Provider or supplier conduct.* (i) The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or supplier is—

(A) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with the FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W-2 employees and contracted individuals and organizations of the provider or supplier.

(3) *Felonies.*

(i) The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

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

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

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

(iii) Revocations based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(iv) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(4) *False or misleading information.* The provider or supplier certified as “true” misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current law and regulations.)

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

(i) No longer operational to furnish Medicare-covered items or services.

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

(6) *Grounds related to provider and supplier screening requirements.* (i)(A) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application; or

(B) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(ii)(A) Either of the following occurs:

(1) CMS is not able to deposit the full application amount into a government-owned account.

(2) The funds are not able to be credited to the U.S. Treasury.

(B) The provider or supplier lacks sufficient funds in the account at the

banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(C) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

(7) *Misuse of billing number.* The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers who enter into a valid reassignment of benefits as specified in § 424.80 or a change of ownership as outlined in § 489.18 of this chapter.

(8) *Abuse of billing privileges.* Abuse of billing privileges includes either of the following:

(i) The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to the following situations:

(A) Where the beneficiary is deceased.

(B) The directing physician or beneficiary is not in the state or country when services were furnished.

(C) When the equipment necessary for testing is not present where the testing is said to have occurred.

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following:

(A) The percentage of submitted claims that were denied during the period under consideration.

(B) Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.

(C) The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).

(D) Any other information regarding the provider or supplier’s specific circumstances that CMS deems relevant to its determination.

(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 (a)(9) 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.

(10) *Failure to document or provide CMS access to documentation.* (i) The provider or supplier did not comply with the documentation or CMS access requirements specified in § 424.516(f) of this subpart.

(ii) A provider or supplier that meets the revocation criteria specified in paragraph (a)(10)(i) of this section, is subject to revocation for a period of not more than 1 year for each act of noncompliance.

(11) *Initial reserve operating funds.* CMS or its designated Medicare contractor may revoke the Medicare billing privileges of an HHA and the corresponding provider agreement if, within 30 days of a CMS or Medicare contractor request, the HHA cannot furnish supporting documentation verifying that the HHA meets the initial reserve operating funds requirement found in 42 CFR 489.28(a).

(12) *Other program termination.* (i) The provider or supplier is terminated, revoked or otherwise barred from participation in a State Medicaid program or any other federal health care program. In determining whether a revocation under this paragraph (a)(12) 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 revoke unless and until a provider or supplier has exhausted all applicable appeal rights or the timeframe for filing an appeal has

expired without the provider or supplier filing an appeal.

(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.

(13) *Prescribing authority.* (i) A physician or other eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause;

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs.

(14) *Improper prescribing practices.* CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part B or D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both. In making this determination, CMS considers the following factors:

(A) Whether there are diagnoses to support the indications for which the drugs were prescribed.

(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).

(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses.

(D) 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).

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

(F) The number and type(s) of malpractice suits that have been filed

against the physician or eligible professional related to 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).

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

(H) Any other relevant information provided to CMS.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors:

(A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority.

(B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration.

(C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the FDA nor medically accepted under section 1860D-2(e)(4) of the Act—and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

(15) *False Claims Act (FCA)*. (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502).

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

(16) [Reserved]

(17) *Debt referred to the United States Department of Treasury*. (i) The provider or supplier failed to repay a debt that CMS appropriately referred to the United States Department of Treasury. In determining whether a revocation under this paragraph (a)(17) is appropriate, CMS considers the following factors:

(A) The reason(s) for the failure to fully repay the debt (to the extent this can be determined).

(B) Whether the provider or supplier has attempted to repay the debt (to the extent this can be determined).

(C) Whether the provider or supplier has responded to CMS' requests for payment (to the extent this can be determined).

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

(E) The amount of the debt.

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

(ii) Paragraph (17)(i) of this paragraph does not apply to the following situations:

(A) The provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or

(B) The administrative appeals process concerning the debt has not been exhausted or the timeframe for filing such an appeal (at the appropriate level of appeal) has not expired.

(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 or enrollments, even if all of the practice locations associated with a particular enrollment comply with Medicare enrollment requirements, 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 enrollments, involving the non-compliant location or 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 serv-*

ices, 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,

§ 424.535

42 CFR Ch. IV (10–1–24 Edition)

and the reason(s) for any such restriction, suspension, revocation, or termination.

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

(22) *Patient harm.* (i) The physician or other eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation is appropriate, CMS considers the following factors:

(A) The nature of the patient harm.

(B) The nature of the physician's or other eligible professional's conduct.

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by the State oversight board, IRO, Federal or State health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(1) License restriction(s) pertaining to certain procedures or practices.

(2) Required compliance appearances before State medical board members.

(3) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(4) Administrative or monetary penalties.

(5) Formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.

(ii) Paragraph (a)(22)(i) of this section does not apply to actions or orders pertaining exclusively to either of the following:

(A) Required participation in rehabilitation or mental/behavioral health programs; or

(B) Required abstinence from drugs or alcohol and random drug testing.

(23) *Supplier standard or condition violation.* (i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

(b) *Effect of revocation on provider agreements.* When a provider's or supplier's billing privilege is revoked, any provider agreement in effect at the time of revocation is terminated effective with the date of revocation.

(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.

(d) *Re-enrollment after revocation.* If a provider or supplier seeks to re-establish enrollment in the Medicare program after notification that its billing privileges is revoked (either after the appeals process is exhausted or in place of the appeals process), the following conditions apply:

(1) The provider or supplier must re-enroll in the Medicare program through the completion and submission of a new applicable enrollment application and applicable documentation, as a new provider or supplier, for validation by CMS.

(2) Providers must be resurveyed and recertified by the State survey agency as a new provider and must establish a new provider agreement with CMS's Regional Office.

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against the provider's or supplier's owner, managing employee, managing organi-

zation, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 15 days of the revocation notification.

(f) *Additional review.* When a provider or supplier is revoked from the Medicare program, CMS automatically reviews all other related Medicare enrollment files that the revoked provider or supplier has an association with (for example, as an owner or managing employee) to determine if the revocation warrants an adverse action of the associated Medicare provider or supplier.

(g) *Effective date of revocation.* (1) Except as described in paragraphs (g)(2) and (g)(3) of this section, a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier.

(2) Except as described in paragraph (g)(3) of this section, the revocation effective dates in the situations identified in this paragraph (g)(2) are as follows:

(i) For revocations based on a Federal exclusion or debarment, the date of the exclusion or debarment.

(ii) For revocations based on a felony conviction, the date of the felony conviction.

(iii) For revocations based on a State license suspension or revocation, the date of the license suspension or revocation.

(iv) For revocations based on a CMS determination that the provider's or supplier's practice location is non-operational, the date on which the provider's or supplier's practice location was no longer operational (per CMS' or the CMS contractor's determination).

(v) For revocations based on a State license surrender in lieu of further disciplinary action, the date of the license surrender.

(vi) For revocations based on termination from a Federal health care program other than Medicare (for example, Medicaid), the date of the termination.

(vii) For revocations based on termination of a provider agreement under part 489 of this chapter, and as applicable to the type of provider involved, the later of the following:

(A) The date of the provider agreement termination; or

(B) The date that CMS establishes under § 489.55.

(viii) For revocations based on § 424.535(a)(23), the effective dates are as follows:

(A) If the standard or condition violation involves the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the effective date is the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

(B) If the standard or condition violation involves a non-operational practice location, the effective date is the date the non-operational status began.

(C) If the standard violation involves a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the effective date is the date of the felony conviction.

(D) For all standard violations not addressed in paragraphs (A) through (C), the effective date in paragraph (g)(1) applies if the effective date in paragraph (g)(3) does not.

(3) If the action that resulted in the revocation occurred prior to the effective date of the provider's or supplier's enrollment, the effective date of the revocation is the same as the effective date of enrollment.

(h) *Submission of claims for services furnished before revocation.* (1)(i) Except for HHAs as described in paragraph (h)(1)(ii) of this section, a revoked provider or supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

(ii) A revoked HHA must submit all claims for items and services within 60 days after the later of the following:

(A) The effective date of the revocation.

(B) The date that the HHA's last payable episode ends.

(2) Nothing in this paragraph (h) impacts the requirements of § 424.44 regarding the timely filing of claims.

(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.

[71 FR 20776, Apr. 21, 2006, as amended at 72 FR 53648, Sept. 19, 2007; 73 FR 36461, June 27, 2008; 73 FR 69940, Nov. 19, 2008; 75 FR 24449, May 5, 2010; 75 FR 70465, Nov. 17, 2010; 76 FR 5964, Feb. 2, 2011; 77 FR 25318, Apr. 27, 2012; 77 FR 29030, May 16, 2012; 79 FR 29968, May 23, 2014; 79 FR 72532, Dec. 5, 2014; 84 FR 47854, Sept. 10, 2019; 84 FR 63204, Nov. 15, 2019; 86 FR 65682, Nov. 19, 2021; 87 FR 70232, Nov. 18, 2022; 88 FR 79541, Nov. 16, 2023]

§ 424.540 Deactivation of Medicare billing privileges.

(a) *Reasons for deactivation.* CMS may deactivate the Medicare billing privileges of a provider or supplier for any of the following reasons:

(1) The provider or supplier does not submit any Medicare claims for 6 consecutive calendar months. The 6 month period will begin the 1st day of the 1st month without a claims submission through the last day of the 6th month without a submitted claim.

(2) The provider or supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under this title.

(3) The provider or supplier does not 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 resubmit and certify to the accuracy of its enrollment information.

(4) The provider or supplier is not in compliance with all enrollment requirements in this title.

(5) The provider's or supplier's practice location is non-operational or otherwise invalid.

(6) The provider or supplier is deceased.

(7) The provider or supplier is voluntarily withdrawing from Medicare.

(8) The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

(b) *Reactivation of billing privileges.*

(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, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title.

(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.

(3) Except as provided in paragraph (b)(3)(i) of this section, reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement.

(i) An HHA whose Medicare billing privileges are deactivated under the provisions found at paragraph (a) of this section must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated.

(ii) [Reserved]

(c) *Effect of deactivation.* The deactivation of Medicare billing privileges does not have any effect on a provider's or supplier's participation agreement or any conditions of participation.

(d) *Effective dates.* (1)(i) Except as provided in paragraph (d)(1)(ii) of this section, the effective date of a deactivation is the date on which the deactivation is imposed under this section.

(ii) A retroactive deactivation effective date (based on the date that the provider's or supplier's action or non-compliance occurred or commenced (as applicable)) may be imposed in the following instances:

(A) For the deactivation reasons in paragraphs (a)(2) through (4) of this section, the effective date is the date on which the provider or supplier became non-compliant.

(B) For the deactivation reason in paragraph (a)(5) of this section, the effective date is the date on which the provider's or supplier's practice location became non-operational or otherwise invalid.

§ 424.541

42 CFR Ch. IV (10–1–24 Edition)

(C) For the deactivation reason in paragraph (a)(6) of this section, the effective date is the date of death of the provider or supplier.

(D) For the deactivation reason in paragraph (a)(7) of this section, the effective date is the date on which the provider or supplier voluntarily withdrew from Medicare.

(E) For the deactivation reason in paragraph (a)(8) of this section, the effective date is the date of the sale.

(2) The effective date of a reactivation of billing privileges under this section is the date on which the Medicare contractor received the provider's or supplier's reactivation submission that was processed to approval by the Medicare contractor.

(e) *Payment prohibition.* A provider or supplier may not receive payment for services or items furnished while deactivated under this section.

[71 FR 20776, Apr. 21, 2006, as amended at 74 FR 58134, Nov. 10, 2009; 77 FR 29030, May 16, 2012; 84 FR 47856, Sept. 10, 2019; 86 FR 62420, Nov. 9, 2021; 88 FR 77878, Nov. 13, 2023]

§ 424.541 Stay of enrollment.

(a)(1) CMS may stay an enrolled provider's or supplier's enrollment if the provider or supplier:

(i) Is non-compliant with at least one enrollment requirement in Title 42; and

(ii) Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS-855, Form CMS-20134, or Form CMS-588 change of information or revalidation application.

(2) During the period of any stay imposed under this section, the following apply:

(i) The provider or supplier remains enrolled in Medicare;

(ii)(A) Except as stated in paragraph (a)(2)(ii)(B) of this section, claims submitted by the provider or supplier with dates of service within the stay period will be rejected.

(B) Notwithstanding paragraph (a)(2)(ii)(A), claims submitted by the provider or supplier with dates of service within the stay period are eligible for payment (and may be resubmitted by the provider or supplier within applicable timeframes specified in Title 42) if:

(1) CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42; and

(2) The stay ends (as described in subsection (a)(5) of this section) on or before the 60th day of the stay period.

(3) A stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter, which is the effective date of the stay.

(4) CMS notifies the affected provider or supplier in writing of the imposition of the stay.

(5) A stay of enrollment ends on the date on which CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42 or the day after the 60-day stay period expires, whichever occurs first.

(b)(1) If a provider or supplier receives written notice from CMS or its contractor that the provider or supplier is subject to a stay under this section, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to the stay as described in paragraph (b) of this section.

(2) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (b)(1) of this section.

(3) Any rebuttal submitted pursuant to paragraph (b) of this section must:

(i) Be in writing.

(ii) Specify the facts or issues about which the provider or supplier disagrees with the stay's imposition and/or the effective date, and the reasons for disagreement.

(iii) Submit all documentation the provider or supplier wants CMS to consider in its review of the stay.

(iv) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in § 424.502), or a legal representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal

representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

(4) The provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (b)(1) of this section and fully compliant with all of the requirements of paragraph (b)(3) of this section constitutes a waiver of all rebuttal rights under this section.

(5) Upon receipt of a timely and compliant stay rebuttal, CMS reviews the rebuttal to determine whether the imposition of the stay and/or the effective date thereof are correct.

(6) A determination made under paragraph (b) of this section is not an initial determination under 42 CFR 498.3(b) and therefore not appealable.

(7) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a stay pending the completion of the review described in paragraph (b)(5) of this section.

(8)(i) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a deactivation or revocation, pending the completion of the review described in paragraph (b)(5) of this section.

(ii)(A) If CMS deactivates the provider or supplier during the stay, any rebuttal to the stay that the provider or supplier submits that meets the requirements of paragraph (b) of this section is combined and considered with the provider's or supplier's rebuttal to the deactivation under § 424.546 if CMS has not yet made a determination on the stay rebuttal pursuant to this section.

(B) In all cases other than that described in paragraph (b)(8)(ii)(A) of this section, a stay rebuttal that was submitted in compliance with the requirements of paragraph (b) of this section is considered separately and independently of any review of any other rebuttal or, for revocations, appeal under 42 CFR part 498.

[88 FR 79542, Nov. 16, 2023, as amended at 89 FR 9784, Feb. 12, 2024]

§ 424.542 Prohibition on ordering, certifying, referring, or prescribing based on felony conviction.

(a) *General prohibition.* A physician or other eligible professional (regardless of whether he or she is or was enrolled in Medicare) who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs.

(b) *Payment.* Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a physician or other eligible professional (as that term is defined in section 1848(k)(3)(B) of the Act) who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

[88 FR 77878, Nov. 13, 2023]

§ 424.545 Provider and supplier appeal rights.

(a) *General.* A prospective provider or supplier that is denied enrollment in the Medicare program, or a provider or supplier whose Medicare enrollment has been revoked may appeal CMS' decision in accordance with part 498, subpart A of this chapter.

(1) *Appeals resulting in the termination of a provider agreement.* (i) When revocation of billing privileges also results in the termination of a corresponding provider agreement, the provider may appeal CMS' decision in accordance with part 498 of this chapter with the final decision of the appeal applying to both the billing privileges and the provider agreement.

(ii) When a provider appeals the revocation of billing privileges and the termination of its provider agreement, there will be one appeals process which will address both matters. The appeal procedures for revocation of Medicare billing privileges will apply.

(2) *Payment of unpaid claims.* Payment is not made during the appeals process. If the provider or supplier is successful in overturning a denial or revocation, unpaid claims for services furnished during the overturned period may be resubmitted.

§ 424.546

42 CFR Ch. IV (10–1–24 Edition)

(b) A provider or supplier whose billing privileges are deactivated may file a rebuttal in accordance with § 424.546 of this chapter.

(c) The provider or supplier must be able to demonstrate that it meets the enrollment requirements and it must be able to make available any documents and records that support the provisions of this regulation and the Medicare enrollment application if requested by CMS or its agents.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 36461, June 27, 2008; 86 FR 65683, Nov. 19, 2021]

§ 424.546 Deactivation rebuttals.

(a) *Rebuttal submittal period.* (1) If a provider or supplier receives written notice from CMS or its contractor that the provider's or supplier's billing privileges are to be or have been deactivated under § 424.540, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS as permitted under § 424.545(b).

(2) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (a)(1) of this section.

(b) *Rebuttal requirements.* A rebuttal submitted pursuant to this section and § 424.545(b) must:

(1) Be in writing.

(2) Specify the facts or issues about which the provider or supplier disagrees with the deactivation's imposition and/or the effective date, and the reasons for disagreement.

(3) Submit all documentation the provider or supplier wants CMS to consider in its review of the deactivation.

(4) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in 42 CFR 424.502), or a legal representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the ap-

pointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

(c) *Waiver of rebuttal rights.* The provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (a) of this section and fully compliant with all of the requirements of paragraph (b) of this section constitutes a waiver of all rebuttal rights under this section and § 424.545(b).

(d) *CMS review.* Upon receipt of a timely and compliant deactivation rebuttal, CMS reviews the rebuttal to determine whether the imposition of the deactivation and/or the designated effective date are correct.

(e) *Imposition.* Nothing in this section or in § 424.545(b) requires CMS to delay the imposition of a deactivation pending the completion of the review described in paragraph (d) of this section.

(f) *Initial determination.* A determination made under this section is not an initial determination under § 498.3(b) of this chapter and therefore not appealable.

[86 FR 65683, Nov. 19, 2021]

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

(a) *General rule.* A provider or supplier is prohibited from selling its Medicare billing number or privileges to any individual or entity, or allowing another individual or entity to use its Medicare billing number.

(b) *Change of ownership.* In the case of a provider undergoing a change of ownership in accordance with part 489, subpart A of this chapter, the current owner and the prospective new owner must complete and submit enrollment applications before completion of the change of ownership. If the current owner fails to complete and submit an enrollment application to report the change, the current owner may be sanctioned or penalized, even after the date of ownership change, in accordance with §§ 424.520, 424.540, and 489.53 of this chapter. If the prospective new owner fails to submit a new enrollment application containing information concerning the new owner within 30 days of the change of ownership, CMS

may deactivate the Medicare billing number. If an incomplete enrollment application is submitted, CMS may also deactivate the Medicare billing number based upon material omissions on the submitted enrollment application, or based on preliminary information received or determined by CMS that makes CMS question whether the new owner is ultimately granted a final transference of the provider agreement.

(1) Unless an exception in paragraph (b)(2) of this section applies, if there is a change in majority ownership of a home health agency (HHA) or hospice by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's or hospice's initial enrollment in Medicare or within 36 months after the HHA's or hospice's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA or hospice must instead do both of the following:

(i) Enroll in the Medicare program as a new (initial) HHA or hospice under the provisions of § 424.510 of this subpart.

(ii) Obtain a State survey or an accreditation from an approved accreditation organization.

(2)(i) The HHA or hospice submitted 2 consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. For purposes of the exception in this paragraph (b)(2)(i), low utilization or no utilization cost reports do not qualify as full cost reports.

(ii) An HHA's or hospice's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

(iii) The owners of an existing HHA or hospice are changing the HHA's or hospice's existing business structure (for example, from a corporation to a partnership (general or limited); from an LLC to a corporation; from a partnership (general or limited) to an LLC) and the owners remain the same.

(iv) An individual owner of an HHA or hospice dies.

(c) *Suppliers not covered by part 489 of this chapter.* For those suppliers not covered by part 489 of this chapter, any

change in the ownership or control of that supplier must be reported on the enrollment application within 30 days of the change as noted in § 424.540(a)(2). Generally, a change of ownership that also changes the tax identification number requires the completion and submission of a new enrollment application from the new owner.

[71 FR 20776, Apr. 21, 2006, as amended at 74 FR 58134, Nov. 10, 2009; 75 FR 70465, Nov. 17, 2010; 75 FR 76293, Dec. 8, 2010; 86 FR 62421, Nov. 9, 2021; 88 FR 77878, Nov. 13, 2023]

§ 424.555 Payment liability.

(a) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by suppliers of durable medical equipment, prosthetics, orthotics, and other supplies unless the supplier obtains (and renews, as set forth in section 1834(j) of the Act) Medicare billing privileges.

(b) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier are deactivated, denied, or revoked, or if the provider or supplier is currently under a stay of enrollment (except as stated in § 424.541(a)(2)(ii)(B)). The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

(c) If any provider or supplier furnishes an otherwise Medicare covered item or service for which payment may not be made by reason of paragraph (b) of this section, any expense incurred for such otherwise Medicare covered item or service shall be the responsibility of the provider or supplier. The provider or supplier may also be criminally liable for pursuing payments that may not be made by reason of paragraph (b) of this section, in accordance with section 1128B(a)(3) of the Act.

[71 FR 20776, Apr. 21, 2006, as amended at 88 FR 79543, Nov. 16, 2023]

§ 424.565 Overpayment.

A physician or nonphysician practitioner organization, physician or nonphysician practitioner that does not comply with the reporting requirements specified in § 424.516(d)(1)(ii) and (iii) of this subpart is assessed an overpayment back to the date of the final adverse action or change in practice location. Overpayments are processed in accordance with part 405 subpart C of this chapter.

[73 FR 69941, Nov. 19, 2008]

§ 424.570 Moratoria on newly enrolling Medicare providers and suppliers.

(a) *Temporary moratoria*—(1) *General rules.* (i) CMS may impose a 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.

(ii) CMS will announce the temporary enrollment moratorium in a FEDERAL REGISTER document that includes the rationale for imposition of the temporary enrollment moratorium.

(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.

(2) *Imposition of a temporary moratoria.* CMS may impose the temporary moratorium if—

(i) CMS determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both. CMS's determination is based on its review of existing data, and without limitation, identifies a trend that appears to be as-

sociated with a high risk of fraud, waste or abuse, such as a—

(A) Highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries; or

(B) Rapid increase in enrollment applications within a category;

(ii) A State Medicaid program has imposed a moratorium on a group of Medicaid providers or suppliers that are also eligible to enroll in the Medicare program;

(iii) A State has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type or both; or

(iv) CMS, in consultation the HHS OIG or the Department of Justice or both and with the approval of the CMS Administrator identifies either or both of the following as having a significant potential for fraud, waste or abuse in the Medicare program:

(A) A particular provider or supplier type.

(B) Any particular geographic area.

(b) *Duration of moratoria.* A moratorium under this section may be imposed for a period of 6 months and, if deemed necessary by CMS, may be extended in 6-month increments. CMS will publish a document in the FEDERAL REGISTER when it extends a moratorium.

(c) *Denial of enrollment: Moratoria.* A Medicare contractor denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium as specified in paragraph (a) of this section.

(d) *Lifting moratoria.* CMS will publish a document in the FEDERAL REGISTER when a moratorium is lifted. CMS may lift a temporary moratorium at any time after imposition of the moratorium if one of the following occur:

(1) The President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act).

(2) Circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address the program vulnerability.

(3) The Secretary has declared a public health emergency under section 319