

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(10) The provider or supplier requests that their application be withdrawn prior to or during the Medicare contractor's processing thereof.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(12) The provider or supplier submits a paper Form CMS–855 or Form CMS–20134 enrollment application that is outdated or has been superseded by a revised version.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.