

(c) *Reversal of denial.* If the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an 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.

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**§ 424.535 Revocation of enrollment in the Medicare program.**

(a) *Reasons for revocation.* CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges 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 subpart P 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.* The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is—

(i) 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.

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

(3) *Felonies.* (i) The provider, supplier, or any owner or managing employee 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

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than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(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.

(B) The reason(s) for the claim denials.

(C) Whether the provider or supplier has any history of final adverse actions (as that term is defined under § 424.502) and the nature of any such actions.

(D) The length of time over which the pattern has continued.

(E) How long the provider or supplier has been enrolled in Medicare.

(F) Any other information regarding the provider or supplier’s specific circumstances that CMS deems relevant to its determination as to whether the provider or supplier has or has not engaged in the pattern or practice described in this paragraph.

(9) *Failure to report.* The provider or supplier did not comply with the reporting requirements specified in § 424.516(d)(1)(ii) and (iii) of this subpart.

(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) *Medicaid termination.* (i) Medicaid billing privileges are terminated or revoked by a State Medicaid Agency.

(ii) Medicare may not terminate unless and until a provider or supplier has exhausted all applicable appeal rights.

(13) *Prescribing authority.* (i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or

(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 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.

(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.* If a provider, supplier, owner, or managing

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employee has their billing privileges revoked, they are barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar.

(1) The re-enrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation.

(2) The re-enrollment bar does not apply in the event a revocation of Medicare billing privileges is imposed under paragraph (a)(1) of this section based upon a provider or supplier's failure to respond timely to a revalidation request or other request for information.

(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 an owner, managing employee, or an authorized or delegated official; or a medical director, supervising physician, or other personnel of the provider or supplier furnishing Medicare reimbursable services, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 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.* Revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, except if the revocation is based on Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational. When a revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational.

(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.

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**§ 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: