§ 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—

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.

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

Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare covered services and supplies. The process includes—

(1) Identification of a provider or supplier;

(2) Validation of the provider’s 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
§ 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. 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.)

§ 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.
§ 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 paragraph (b) of this section, and Part B drugs), a provider or supplier must meet all of the following requirements:

(1) 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 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)(I) 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 professional 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:
(i) As the ordering supplier.
(ii) 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—
(i) Resident, who is enrolled in Medicare in an approved status to order; or
(ii) Teaching physician, who is enrolled in Medicare in an approved status.

(b) Conditions for payment of claims for covered home health services. To receive payment for covered Part A or Part B home health services, a provider’s home health services claim must meet all of the following requirements:
(1) The ordering/certifying physician 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.

(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]
(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 provisions in part 488 of this chapter to be surveyed or certified by the State survey and certification agency, and to 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 §424.530 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” requirement 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.

§ 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.

(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(e)). 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(e) (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.

§ 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, 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:

(1) 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 in 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, 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);
(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 items of DMEPOS, clinical laboratory, imaging services, or covered ordered/certified home health services is required to—
(A) Maintain documentation (as described in paragraph (f)(2)(ii) of this section) for 7 years from the date of 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 who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered the items of DMEPOS or the clinical laboratory or imaging services) relating to written orders or certifications or requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.
§ 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 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.
§ 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, including applications for a new practice location, and any applications received in response to a revalidation request 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) Hospitals, including critical access hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.
   (viii) 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.
   (ix) Mammography screening centers.
   (x) Mass immunization roster billers.
   (xi) Pharmacies newly enrolling or revalidating via the CMS-855B application.
   (xii) Radiation therapy centers.
   (xiii) Religious non-medical health care institutions.
   (xiv) Rural health clinics.
   (xv) Skilled nursing facilities.

(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) Hospice organizations.
   (v) Independent clinical laboratories.
   (vi) Independent diagnostic testing facilities.
   (vii) Physical therapists enrolling as individuals or as group practices.
   (viii) Portable x-ray suppliers.
   (ix) Revalidating home health agencies.
   (x) Revalidating DMEPOS suppliers.

(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 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) 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.

VerDate Mar<15>2010 18:38 Nov 15, 2012 Jkt 226186 PO 00000 Frm 00704 Fmt 8010 Sfmt 8010 Q:\42\42V3.TXT ofr150 PsN: PC150
(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 home health agencies and suppliers of DMEPOS as “high” categorical risk:

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

(ii) Prospective (newly enrolling) DMEPOS suppliers.

(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 “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.

(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).
practitioner organizations. The effective date for billing privileges for physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations is the later of the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor or the date an enrolled physician or nonphysician practitioner first began furnishing services at a new practice location.


§ 424.521 Request for payment by physicians, nonphysician practitioners, physician or nonphysician organizations.

(a) Physicians, nonphysician practitioners and physician or nonphysician organizations may retroactively bill for services when a physician or nonphysician practitioner or a physician or a nonphysician organization have met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to—

(1) 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or

(2) 90 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.

(b) [Reserved]

[73 FR 69940, Nov. 19, 2008]

§ 424.525 Rejection of a provider or supplier's enrollment 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 prospective provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the contractor request for the missing information.

(2) The prospective 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 prospective 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.

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

§ 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) Compliance. The provider or supplier at any time is found not to be in compliance with the Medicare enrollment requirements described in this section or on the applicable enrollment application to the type of provider or supplier enrolling, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

(2) Provider or supplier conduct. A provider, supplier, an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel furnishing Medicare reimbursable services who is required to be reported on the enrollment application, in accordance with section 1862(e)(1) of the Act, is—

(1) Excluded from the Medicare, Medicaid and any other Federal health care programs, as defined in §1001.2 of this chapter, in accordance with section
Centers for Medicare & Medicaid Services, HHS

§ 424.530

1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) 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).

(3) Felonies. If within the 10 years preceding enrollment or revalidation of enrollment, the provider, supplier, or any owner of the provider or supplier, was convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. CMS considers the severity of the underlying offense.

(i) Offenses include—
(A) Felony crimes against persons, such as murder, rape, or 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 outlined in section 1128 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.

(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, we determine that the provider or supplier is not operational, or is not meeting Medicare enrollment requirements to furnish Medicare covered items or services. Upon on-site review, CMS determines that—

(i) A Medicare Part A 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) A Medicare Part B 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.

(6) Overpayment. The current owner (as defined in § 424.502), physician or nonphysician practitioner has an existing overpayment at the time of filing of an enrollment application.

(7) Payment suspension. The current owner (as defined in § 424.502), physician or nonphysician practitioner has been placed under a Medicare payment suspension as defined in § 405.370 through § 405.372 of this subchapter.

(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.

(b) Resubmission after denial. A provider or supplier that is denied enrollment in the Medicare program cannot submit a new enrollment application
§ 424.535 Revocation of enrollment and billing privileges 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 not to be in compliance with the enrollment requirements described in this section, 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. All providers and suppliers are granted an opportunity to correct the deficient compliance requirement before a final determination to revoke billing privileges, except for those imposed under paragraphs (a)(2), (a)(3), or (a)(5) of this section.

(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 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.

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.

(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. CMS determines, upon on-site review, that the provider or supplier is no longer operational to furnish Medicare covered items or services, or is not meeting Medicare enrollment requirements under statute or regulation to supervise treatment of, or to provide Medicare covered items or services for, Medicare patients. Upon on-site review, CMS determines that—

(i) A Medicare Part A 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) A Medicare Part B 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.

(6) Grounds related to provider and supplier screening requirements. (i)(A) An 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. 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 situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

(9) Failure to report. The provider or supplier did not comply with the reporting requirements specified in §424.516(d)(1)(i) 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.
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).

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.

(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. After a provider, supplier, delegated official, or authorizing official has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation. 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. A physician organization, physician, nonphysician practitioner or independent diagnostic testing facility must submit all claims for items and services furnished within
§ 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 12 consecutive calendar months. The 12 month period will begin the 1st day of the 1st month without a claims submission through the last day of the 12th month without a submitted claim.

(2) The provider or supplier does not report a change to the information supplied on the enrollment application within 90 calendar days of when the change occurred. Changes that must be reported include, but are not limited to, a change in practice location, a change of any managing employee, and a change in billing services. A change in ownership or control must be reported within 30 calendar days as specified in §§ 424.520(b) and 424.550(b).

(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.

(b) Reactivation of billing privileges. (1) When deactivated for any reason other than nonsubmission of a claim, the provider or supplier must complete and submit a new enrollment application to reactivate its Medicare billing privileges or, when deemed appropriate, at a minimum, recertify that the enrollment information currently on file with Medicare is correct.

(2) Providers and suppliers deactivated for nonsubmission of a claim are required to recertify that the enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate. The provider or supplier must meet all current Medicare requirements in place at the time of reactivation, and be prepared to submit a valid Medicare claim.

(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. Deactivation of Medicare billing privileges is considered an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. The deactivation of Medicare billing privileges does not have any effect on a provider or supplier’s participation agreement or any conditions of participation.

§ 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, sub-part 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
§ 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 transfer of the provider agreement.

(1) Unless an exception in (b)(2) of this section applies, if there is a change in majority ownership of a home health agency by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA’s initial enrollment in Medicare or within 36 months after the HHA’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 must instead:

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

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

(b)(2) Change of ownership. If the HHA submitted two consecutive years of full cost reports. For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports.

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

(ii) The owners of an existing HHA are changing the HHA’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.

(iii) An individual owner of an HHA 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.
§ 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. 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.

§ 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 changes in practice location, changes in provider or supplier information such as phone number, address or changes in ownership (except changes in ownership of home health agencies that would require an initial enrollment under § 424.550).

(iv) The temporary enrollment moratorium does not apply to any enrollment application that has been approved by the enrollment contractor but not yet entered into PECOS at the time the moratorium is imposed.

(2) Imposition of a temporary moratorium. 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 associated with a high risk of fraud, waste or abuse, such as—

(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 of the Public Health Service Act in the area subject to a temporary moratorium.

4. In the judgment of the Secretary, the moratorium is no longer needed.

[76 FR 5965, Feb. 2, 2011]