§ 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).

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

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

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

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

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

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

(ii) Debarred by the General Services Administration (GSA) from any other Executive Branch procurement or nonprocurement 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.

(f) Maintaining and providing access to documentation. (1) A provider or a supplier who furnishes covered ordered DMEPOS or referred home health, laboratory, imaging, or specialist services is required to maintain documentation for 7 years from the date of service and, upon the request of CMS or a Medicare contractor, to provide access to that documentation. The documentation includes written and electronic documents (including the NPI of the physician who ordered the home health services and the NPI of the physician or the eligible professional who ordered or referred the DMEPOS, laboratory, imaging, or specialist services) relating to written orders and requests for payments for items of DMEPOS and home health, laboratory, imaging, and specialist services.

(2) A physician who ordered home health services and a physician and an eligible professional who ordered or referred items of DMEPOS or laboratory, imaging, and specialist services is required to maintain documentation for 7 years from the date of the order, certification, or referral and, upon request of CMS or a Medicare contractor, to provide access to that documentation.