

this reason, we are proposing that we would initiate a revalidation process for any individual or organization that has not submitted a change or update within the last three years. Routine revalidation may or may not be accompanied by site visits.

We reserve the right to perform non-routine revalidation and request the provider or supplier to re-certify as to the accuracy of the enrollment information when warranted to assess and confirm the validity of the enrollment information. Non-routine revalidation may be triggered as a result of information indicating local problems, national initiatives, fraud investigations, complaints from beneficiaries, or other reasons that cause us to question the integrity of the provider or supplier in its relationship with the Medicare program. Like routine revalidation, non-routine revalidation may or may not be accompanied by site visits.

We are proposing that the revalidation of enrollment information occur no more than once every 3 years. We reserve the right to adjust this schedule if we determine that revalidation should occur on a more frequent basis due to complaints or evidence we receive indicating non-compliance with the Medicare 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 Medicare statute and regulations by specific provider or supplier types indicates that less frequent validation is justified. If such a change were to occur, we will notify all affected providers and suppliers in writing at least 90-days in advance of implementing the change. We will continue to revalidate enrollment information for Ambulance Service Suppliers in accordance with regulations set forth at § 410.41(c)(2) (Requirements for ambulance suppliers), and DME suppliers will continue to renew enrollment in accordance with regulations set forth at § 424.57(e) (Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers). We specifically invite further comments on the initially proposed revalidation time frame.

We propose at new § 424.515(a) that during the revalidation or update process all providers and suppliers must attest by way of a signed certification statement that the requirements set forth in this regulation continue to be met. This requirement will not only ensure continued accuracy of the CMS 855 information, but will also ensure that the provider or supplier is committed to

taking the necessary steps to maintain compliance with these requirements. However, it should be noted that periodic validation of a provider or supplier's Medicare enrollment information is separate from the survey requirements for the provider or supplier as contained in 42 CFR chapter IV, subchapter E (standards and certification).

We would require the information submitted for revalidation or update to include any new or changed documentation as required by CMS under this or other statutory or regulatory authority that identifies the provider or supplier, and any documentation as required by CMS under this or other statutory or regulatory authority required to verify the provider or supplier's continued eligibility to furnish services to beneficiaries in the Medicare program. We would also require a signature on the completed CMS 855 that meets the requirements proposed in § 424.510(a)(3).

We are also requiring at proposed § 424.515(b) that a provider or supplier must submit a CMS 855 with complete information for revalidation within 60 calendar days of our revalidation notification. For those providers and suppliers who initially enrolled in the Medicare program via the CMS 855, we would furnish a copy of the information currently on file for their review, request that they make any changes, and certify via their signature that the information is accurate, complete, and truthful. We estimate that completion of the form will require on average 8 hours. Therefore, we believe 60 days is a reasonable time frame for providers and suppliers to comply.

As part of the revalidation process, we would verify the accuracy of the reported information on the applicable CMS 855. Because survey and certification are independent program requirements distinct from the revalidation of enrollment information requirements set forth in this subpart, we are stating in proposed § 424.515(c) that new surveys or certifications are not required for the revalidation process. However, providers must continue to meet the provisions of 42 CFR Part 488 concerning mandatory State survey and certification requirements. When applicable, providers must also have completed a provider agreement in accordance with 42 CFR Part 489, which specifies the requirements for provider agreements. We would also reserve the right, at proposed § 424.575(d), to perform on-site inspections, to further ensure

compliance with Medicare requirements.

We understand that the resubmission and update of enrollment information will place an obligation on providers and suppliers. We are considering a variety of ways to minimize the burden of this important information collection and verification provision (including the use of Internet technology).

To reduce the burden when reporting updates or changes in the future, we will require that all providers and suppliers currently in the Medicare program complete, in its entirety, the CMS 855 at least once if they have not done so in the past. This will ensure that we have the most current and accurate information, and will allow us to make full use of electronic data submissions via the Internet. By having a complete enrollment record, we will be able to produce and transmit or mail the CMS 855, pre-complete with previously reported information, to the provider or supplier for their review and signature certification as to the continued accuracy of the information and require them to update any information that is no longer current.

E. Additional Provider and Supplier Requirements for Enrolling and Maintaining Active Enrollment Status in the Medicare Program

In new § 424.520, we are specifying the additional requirements that providers and suppliers must meet to enroll or maintain enrollment in the Medicare program. The provider or supplier must certify that it meets, and continues to meet, the following requirements:

- Compliance with Title XVIII of the Act (Medicare Statutory Provisions) and applicable regulations.
- Compliance with all applicable Federal and State licensure and regulatory requirements that apply to the specific provider or supplier type that relate to providing health care services.
- Not employing or contracting with individuals or entities excluded from participation in Federal Health care programs for the provision of items and services reimbursable under these programs in violation of section 1128A(a)(6) of the Act.

The OIG program exclusion regulations were amended effective August 25, 1995, in accordance with the Federal Acquisition Streamlining Act of 1994 (FASA), and with the HHS Common Rule at 45 CFR part 76, to explain the scope and effect of an OIG exclusion. In accordance with the FASA, government-wide reciprocal effect will be given by all Federal