Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 420, 424, 489, and 498

[CMS–6002–P]

RIN 0938–AH73

Medicare Program; Requirements for Establishing and Maintaining Medicare Billing Privileges

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would require that all providers and suppliers (other than physicians who have elected to ''opt-out'' of the Medicare program) complete an enrollment form and submit specified information to us, and periodically update and certify to the accuracy of the enrollment information, to receive and maintain billing privileges in the Medicare program. The information must clearly identify the provider or supplier and its place of business, provide documentation that it is qualified to perform the services for which it is billing, ensure that it is not currently excluded from the Medicare program, and meets any other applicable Medicare requirements. If we determine the information submitted is incomplete, invalid, or insufficient to meet Medicare requirements, we would have the discretion to reject, deny, deactivate, or revoke billing privileges.

This proposed rule would implement provisions in the Medicare statute that require the Secretary to ensure that all Medicare providers and suppliers are qualified to provide the appropriate health care services. These statutory provisions include requirements meant to protect beneficiaries and the Medicare trust fund by preventing unqualified, fraudulent, or excluded providers and suppliers from providing services to Medicare beneficiaries or billing the Medicare program or its beneficiaries.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on June 24, 2003.

ADDRESSES: In commenting, please refer to file code CMS–6002–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6002–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for us to receive mailed comments on time in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses:

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–8013.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available if you wish to retain proof of filing by stamping in and retaining an extra copy of the comments being filed).

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Michael C. Collett, (410) 786–6121.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7197.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Background

A. General

The Medicare program, Title XVIII of the Social Security Act (the Act), is currently the principal payer for health care for 39.2 million enrolled beneficiaries. Under section 1802 of the Act, a beneficiary may obtain health services from any institution, agency, or person qualified to participate in the Medicare program. Qualifications to participate are specified in statute and in regulations. See, for example, sections 1814, 1815, 1819, 1833, 1834, 1842, 1861, 1866, and 1891 of the Act; and 42 CFR Chapter IV, Subchapter E, which concerns standards and certification requirements.

Providers and suppliers furnishing services must comply with the Medicare requirements stipulated in the Act and in our regulations. These requirements are meant to ensure compliance with applicable statutes, as well as to promote the furnishing of high quality care. We and/or State Survey and Certification Agencies inspect facilities when required, for compliance with regulatory and operational requirements before we allow them to participate in the Medicare program. Thereafter, either

as part of a scheduled re-certification survey, or as a result of a complaint or other information received that would directly affect the provider's or supplier's business relationship with the Medicare program or indicate non-compliance of this regulation, we will review and re-verify the continued adherence to our requirements. The initial certification and subsequent re-certification ensure that Medicare requirements are met and continue to be met, and promote the appropriate spending of the Medicare trust fund by helping to ensure that unqualified providers and suppliers are not granted billing privileges with the Medicare program.

Historically, a provider or supplier wishing to receive payment from Medicare or its beneficiaries would contact a fiscal intermediary (FI), State Survey Agency, or carrier. In compliance with sections 1816 or 1842 of the Act, as stipulated in 42 CFR Part 421, we contract with FIs and carriers to administer payment for services and to carry out other administrative responsibilities that the law imposes. Our Regional Offices, State Survey Agencies, carriers and FIs use statutes, regulations, and operating instructions as guidance when assigning appropriate identification numbers and determining whether to grant billing privileges in the Medicare program to providers and suppliers.

As Medicare program expenditures have grown, increasing attention has been focused on strategies to curb improper Medicare payments by implementing business processes and standards that safeguard the Medicare program and its beneficiaries, while ensuring that well qualified individuals and health care organization serve beneficiaries as promptly as possible.

B. Specific Authority to Collect Enrollment Information

1. Various sections of the Act and the Code of Federal Regulations require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities who furnish medical services to beneficiaries before payment can be made.

Sections 1102 and 1871 of the Act allow general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program. Under the above authority, this proposed regulation will require the collection of information from providers and suppliers for the purpose of enrolling in the Medicare program and granting privileges to bill the program for health care services rendered to Medicare beneficiaries.

Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due to a provider or other person.

Section 1842(r) of the Act requires us to establish a system for furnishing a unique identifier for each physician who furnishes services for which payment may be made. To do so, we need to collect information unique to that physician.

Section 1862(e)(1) of the Act states that no payment may be made when an item or service was at the medical direction of an individual or entity that has been excluded in accordance with sections 1128, 1128A, 1156, or 1842(j)(2) of the Act.

Section 1834(j) of the Act states that no payment may be made for items furnished by a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) unless that supplier obtains, and renews at such intervals as we may require, a billing number.

The Balanced Budget Act of 1997 (BBA) (Public Law 105–33), section 4313, amended sections 1124(a)(1) and 1124A of the Act to require disclosure of both the Employer Identification Number (EIN) and Social Security Number (SSN) of each provider or supplier, each person with ownership or control interest in the provider or supplier, any subcontractor in which the provider or supplier directly or indirectly has a five percent or more ownership interest, and any managing employees. The Secretary of Health and Human Services (the Secretary) signed and sent to the Congress a ''Report to Congress on Steps Taken to Assure Confidentiality of Social Security Account Numbers as Required by the Balanced Budget Act'' on January 26, 1999, with mandatory collection of SSNs and EINs effective on or about April 26, 1999.

2. Section 31001(i)(1) of the Debt Collection Improvement Act of 1996 (DCIA) (Public Law 104–134) amended 31 U.S.C. section 7701 by adding paragraph (c) to require that any person or entity doing business with the Federal Government must provide their Tax Identification Number (TIN).

3. We are authorized to collect information on the Form CMS 855 (Office of Management and Budget (OMB) approval number 0938–0685) to ensure that correct payments are made to providers and suppliers under the Medicare program as established by Title XVIII of the Act.

II. Current Enrollment Initiatives

For a number of years, concern about easy entry into the Medicare program by unqualified or even fraudulent providers or suppliers has led us to step up our efforts on a number of fronts to establish more stringent controls on provider and supplier entry into the Medicare system. For example, in 1993 we established the National Supplier Clearinghouse (NSC), our contractor for enrolling suppliers of DMEPOS in Medicare. We instituted new procedures to use validation software to certify the existence of the listed business address for suppliers of DMEPOS. The NSC also checked the DMEPOS supplier telephone numbers against a national directory. This initial effort resulted in the revocation of about 1,500 supplier billing numbers and an estimated savings of $7 million per month to the Medicare trust fund.

In fiscal year 1998, we required site visits for all new DMEPOS suppliers. The DMEPOS visits resulted in:

- 156 denials of new applicants, out of 159 visits; and
- 656 revocations of existing suppliers, out of 2,091 visits.

In fiscal years 1998 and 1999, our carriers and FIs submitted proposals to conduct site visits for those provider or supplier types that they believed would yield the greatest benefit in their regions. After reviewing the submitted proposals, we funded 320 site visits to various enrolling and currently enrolled Independent Diagnostic Testing Facilities (IDTFs), skilled nursing facilities (SNFs), home health agencies (HHAs), rural health clinics, comprehensive outpatient rehabilitation facilities, physician groups, clinical psychologists, and ambulance companies. The project provided useful information for making appropriate determinations for the eligibility to bill Medicare. In the course of these reviews—

- 219 provider numbers were authorized or maintained;
- 30 provider numbers were deactivated;
- 37 provider applications were denied; and
- 34 providers were referred to contractor fraud units.

These site visits proved valuable to some providers by helping them to enroll in the Medicare program properly. The site visits were also helpful to us in ensuring that we only conduct business with legitimate providers. We believe that site visits are an important component of successful provider enrollment. As past experience has demonstrated, in many cases site

visits are the only method we have to ensure that providers and suppliers actually exist and meet the requirements to participate in the Medicare program, particularly in the absence of State licensure or regulation. Left unchecked, Medicare program resources and the health of Medicare beneficiaries may be vulnerable.

III. Provisions of the Proposed Rule

This proposed rule would build on our collective experience and set forth our standard enrollment requirements in new subpart P in Part 424 of this chapter. We are proposing that all providers and suppliers, other than the ''opt-out'' physicians and ''opt-out'' practitioners described below, must submit an enrollment application with specific information to enroll in the Medicare program, obtain a Medicare billing number, and receive Medicare billing privileges. The provisions of this proposed rule would supplement, but not replace or nullify, existing regulations concerning the establishment of provider or supplier agreements, the issuance of provider or supplier billing numbers, and payment for Medicare covered services or supplies to eligible providers or suppliers.

Specifically, we are proposing to require that providers and suppliers prove their qualifications and identity and submit specified information to us before they are granted billing privileges in the Medicare program. If the provider or supplier fails to meet the requirements or submit the required information, we would not enroll it in the Medicare program or, if it is currently in the program, we would revoke its billing privileges. We believe the documentation and associated verification methods we use to determine whether to grant a provider or supplier billing privileges are necessary to ensure compliance with Medicare requirements and to prevent abuse of the Medicare program and the inappropriate use of Medicare funds. We also believe that such requirements will not hinder qualified individuals and organizations from enrolling or maintaining enrollment in the Medicare program.

A. Scope and Definitions

We are proposing to establish our standard enrollment requirements in Part 424, new subpart P. In proposed § 424.500 (Scope) we are stating that these requirements apply to all providers and suppliers except those physicians and other eligible practitioners who have elected to ''opt-out'' of Medicare as described in Part 405, subpart D of our regulations.

In proposed § 400.502 (Definitions) we are establishing the definitions for several key terms used throughout subpart P. The terms ''provider'' and ''supplier'' are not defined in this subpart because their definitions have already been established throughout 42 CFR. The term ''provider'' is defined in both § 488.1 and § 400.202. Together these sections define a provider as including a hospital, a critical access hospital, a skilled nursing facility, a nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice, that has in effect an agreement to participate in Medicare; or a provider of outpatient physical therapy or speech pathology services; or a community mental health center. The term ''supplier,'' as defined in § 400.202, is a physician or other practitioner, or an entity other than a provider (as defined in §§ 400.202 and 488.1) that furnishes health care services under Medicare. Section 488.1 also defines ''supplier'' to mean independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; or chiropractor. The term ''supplier'' also includes ''indirect suppliers,'' as indicated in 45 CFR 61.3.

We define ''managing employee'' to be ''a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts the day-to-day operations of, the institution, organization, or agency, either under contract or through some other arrangement, regardless of whether the individual is a W–2 employee.''

Section 1124A of the Act and 42 CFR 420.204 authorize the Secretary to collect information about ''managing employees.'' Section 1124A incorporates by reference the following definition of ''managing employee,'' contained in 1126(b) of the Act: ''An individual, including a general manager, business manager, administrator, and director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity.'' We have found that a number of providers and suppliers are managed by individuals that have control over the day-to-day operations of the entity and are not ''employees.'' Some of these individuals have been known to bill Medicare fraudulently, and are on the Office of Inspector General (OIG) ''List of Excluded Individuals and Entities and/or the General Services Administration'' (GSA) ''List of Parties Excluded from Federal Procurement and Nonprocurement Programs''. These lists are commonly referred to as the ''OIG Sanction List'' for those parties excluded by the QIG from participation in any Federal health care programs (as defined in section 1128B(f) of the Act), and the ''GSA Debarment List'' for those parties debarred, suspended or otherwise excluded by other Federal agencies from participation in Federal procurement and non-procurement programs and activities, in accordance with the Federal Acquisition and Streamlining Act of 1994, and with the HHS Common Rule at 455 CFR Part 76.

Extending the term ''managing employee'' to include individuals performing managerial duties who are not technically employees would be consistent with the legislative intent to require information on those individuals that have effective control over a provider's or supplier's day-to-day operations.

B. Basic Enrollment Requirement

Proposed § 424.505 requires a provider or supplier to have a valid Medicare billing number for the date a service was rendered in order to receive payment for covered Medicare services from either Medicare (in the case of assigned claims) or the Medicare beneficiary (in the case of unassigned claims).

Under longstanding policy and operating procedures, any claim submitted without an active billing number is incomplete and cannot be processed for payment. Providers and suppliers who are not enrolled in the Medicare program must adhere to the mandatory claims submission rules found at § 424.32(a)(1) (Basic requirements for all claims) and section 1848(g)(1)(B) of the Act. In addition, a claim submitted without a valid Medicare billing number would not be considered a valid claim and would be rejected. If the mandatory claims submission requirements are not met the provider or supplier could have sanctions imposed as outlined in section 1848(g)(4) of the Act for failure to file a claim as required.

C. Requirements for Obtaining a Billing Number and Medicare Billing Privileges

To obtain a Medicare billing number and be eligible to receive payment for Medicare covered services, providers and suppliers must enroll in the Medicare program and meet other applicable Federal requirements. The Medicare program, through its contractors, requires specific identifying

information from a provider or supplier before payment is authorized. Our issuance of an identification number to a provider or supplier does not automatically convey the privilege to bill Medicare. There must be a corresponding approval of the provider or supplier as meeting all Federal requirements to bill Medicare for the number to be an approved and active Medicare billing number.

In new § 424.510 (Form CMS 855), we propose that a provider or supplier must submit to us the appropriate completed form CMS 855—Provider/Supplier Enrollment Application based on the type of provider or supplier enrolling. As part of our continuing efforts to improve the enrollment process, the series of CMS 855 enrollment forms with proposed revisions are being submitted with this proposed rule, to be published in the **Federal Register** concurrently for review and public comment. Some of the proposed revisions are the removal of certain data collections from all forms in the series such as information on clearinghouses used in claims submission, practice locations from the CMS 855R, and a shortened attachment for ambulance companies in the CMS 855B. We have also simplified the sections for reporting owners and managers and added instructional clarifications. The forms are identified as follows:

- Form CMS 855A—For providers billing fiscal intermediaries.
- Form CMS 855B—For supplier organizations billing carriers.
- Form CMS 855I—For individual health care practitioners billing carriers.
- Form CMS 855R—For individual health care practitioners to reassign benefits to an organization.
- Form CMS 855S—For DMEPOS Suppliers billing the NSC.

The CMS 855 applications will be used to gather information on providers and suppliers for the purpose of authorizing billing numbers and establishing eligibility to furnish services to Medicare beneficiaries. The information submitted will also uniquely identify the providers and suppliers for the purpose of enumeration and payment. OMB has approved the CMS 855 for these purposes (OMB approval number 0938–0685).

At proposed § 424.510(a)(1) we are requiring that a provider or supplier submit the following on its CMS 855: Complete and accurate responses to all information requested within each section as applicable to the provider or supplier type.

- Any documentation currently required by CMS under this or other statutory or regulatory authority to uniquely identify the provider or supplier (for example, a social security number (SSN) or a tax identification number (TIN)).
- Any documentation currently required by CMS under this or other statutory or regulatory authority to establish the provider or supplier's eligibility to furnish services to beneficiaries in the Medicare program (for example, a medical license or business license).

Under the authorities mentioned earlier in this preamble all providers, suppliers, and other health care related individuals and entities who will receive Medicare reimbursements, either directly or indirectly as a result of enrolling in the Medicare program, must furnish their SSN and/or TIN as a condition of maintaining an active enrollment status and billing privileges. We also maintain the right to require persons with ownership or control interests (as that term is defined in section 1124(a)(3) of the Act) in such providers and suppliers, and of all managing employees (as that term is defined in section 1126(b) of the Act and at 42 CFR 420.201) of such providers and suppliers to also furnish their SSN and/or TIN as a condition of enrollment.

We are proposing that providers and suppliers must certify that all the information furnished on the CMS 855 is accurate, complete, truthful, and verifiable. Any concealment or misrepresentation of material information in these applications constitutes a violation of this regulation and may result in the rejection, denial, or revocation of the provider or supplier's enrollment and billing privileges. In addition, such concealment or misrepresentation will be referred to the Office of Inspector General for investigation and appropriate criminal, civil or administrative action.

In § 424.510(a)(2), we propose that the CMS 855 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 subpart P. This person must be the individual practitioner or 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, be the provider's or supplier's 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 would attest that the information submitted is accurate, complete, and truthful, and the provider or supplier is aware of, and will abide by, Medicare rules and regulations.

To ensure that the individual signing the form can bind the enrollee from a financial and legal standpoint, we would require the following persons to sign the enrollment form:

- In the case of an individual practitioner, the applying practitioner.
- In the case of a sole proprietorship, the applying sole proprietor.
- In the case of a corporation, partnership, group, limited liability company (LLC), or other organization, an authorized official, as defined in § 424.502. When an authorized official signs the application, the signed application is considered binding upon the corporation partnership, organization, group, or LLC (hereafter referred to in this section as an organization), as applicable. This requirement establishes accountability for the accuracy of the information on the CMS 855 and ensures that the provider or supplier is committed to taking the necessary steps to comply with these requirements. In addition to the signature requirements, we are establishing a delegation of authority. As required above, the original and all subsequent revalidation CMS 855s submitted by an organization to enroll or maintain enrollment in the Medicare program must have certification statements signed by the current authorized official on file with Medicare. Any subsequent updates or changes made outside the enrollment or revalidation process may be signed by a delegated official of the enrolled organization.

The delegated official must be a W–2 managing employee of the provider or supplier who is enrolling in, or currently enrolled in, the Medicare program, or be an individual with ownership or control interest in the provider or supplier.

The delegation of signature authority will not apply for individual practitioners and sole proprietors. All CMS 855s submitted by individual practitioners or sole proprietors must be signed by the enrolling/enrolled individual.

As proposed in § 424.510(a)(2)(ii), the delegation of authority must be assigned by the authorized official currently on file with us or the authorized official who has signed the CMS 855 currently being submitted to us. All delegations of authority must be submitted via the CMS 855 and must include the title of each person delegated authority to update or change the organization's enrollment information. The assignment

must be signed by both the authorized official currently on file with Medicare and the person(s) being delegated as an official of the organization. The signature of the delegated official will bind the organization both legally and financially, as if the signature was that of the authorized official. Once the delegation of authority is established, the signatures of the authorized official or the assigned delegated official(s) will be the only acceptable signature(s) on correspondence to report updates or changes to the enrollment information.

As proposed in § 424.510(b), we would verify initial compliance with Medicare statutes and regulations before providers and suppliers are granted billing privileges, as well as on a continuing basis. The verifications would be based on information submitted by providers and suppliers on the CMS 855.

We are proposing in § 424.510(c) that providers and suppliers, including those that are deemed to meet Medicare health and safety requirements by virtue of their accreditation by a national accrediting body, must attest via signature on the CMS 855 that they have met all the requirements set forth in this regulation before they are granted billing privileges. Those providers for which certification is required must meet the provisions of 42 CFR Part 488 concerning mandatory State survey and certification requirements. Providers also must have completed a provider agreement in accordance with 42 CFR Part 489, which specifies the requirements for provider agreements. In addition, in paragraphs (d) and (e) in proposed § 424.510, we are requiring that providers and suppliers must be operational as defined in § 424.502 and must meet additional requirements that apply to both enrolling and currently enrolled providers and suppliers before receiving a Medicare billing number and becoming eligible for Medicare payments.

In recognition of the effectiveness of site visits, we are proposing, at § 424.510(f), a plan for integrating site visits as part of our enrollment validation process and general program oversight activities. We are reserving the right to perform on-site inspections of the provider or supplier when we deem necessary to ensure compliance with Medicare enrollment requirements. For certain providers and suppliers this practice has always been the case (for example, Hospitals, Skilled Nursing Facilities (SNFs), and Home Health Agencies (HHAs)), but we are extending this to all providers and suppliers when deemed necessary based on questionable enrollment information. Site visits for enrollment purposes will not affect those site visits performed for establishing conditions of participation. Our proposed site visits and on-site inspections to ensure compliance with Medicare enrollment requirements are unrelated to the compliance-related site visits already being conducted by the OIG. After a provider or supplier enters into a corporate integrity agreement with the OIG, usually as the result of a Federal False Claims Act settlement, the OIG may conduct a site visit as part of its work in monitoring the provider or supplier's compliance with the terms of the corporate integrity agreement. Upon the provider or supplier's successful completion of the enrollment process, including State survey and certification, accreditation, and approval of the CMS 855, we will grant Medicare billing privileges and issue a billing number if one has not already been issued. The effective date for reimbursement of Medicare covered services will continue to be determined based on current Medicare regulations and policy based on the type of provider or supplier submitting claims. Currently, the effective dates for reimbursement can be found at § 489.13 for providers and suppliers requiring State survey or certification or accreditation, §§ 424.5 and 424.44 for non-surveyed or certified/accredited suppliers, and § 424.57 and section 1834(j)(1)(A) of the Act for DMEPOS suppliers. For those providers and suppliers seeking accreditation from a CMS approved accreditation organization, the effective date for reimbursement will be the later of the date accreditation was received or the final approval of the CMS 855. Based on the regulations cited above, CMS will not issue Medicare billing numbers or grant Medicare billing privileges retroactive to the date that the provider or supplier received final approval of their enrollment application (CMS 855). We are proposing to use this process because we believe there is a relationship between fulfilling the requirements stipulated in the Medicare program statutes and related laws, the integrity of the provider and supplier, the quality of care furnished to Medicare beneficiaries, and the confidence of the public in the Medicare program.

In the future there will be universal provider and supplier numbers, as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), for uniquely identifying a provider or supplier and for purposes of billing all health plans, including Medicare and Medicaid. When this universal number is in place, it will still be necessary for providers and suppliers to apply for enrollment as a Medicare provider or supplier and be granted Medicare billing privileges.

D. Requirements for Reporting Changes and Updates To, and the Periodic Revalidation of, Medicare Enrollment Information

We propose that, under new § 424.515, a provider or supplier must update its enrollment information, and re-certify as to its accuracy when any changes are made. We will also periodically require revalidation of the enrollment information by all providers and suppliers when enrollment information has aged over three years. The revalidation process will ensure that we have complete and current information on all Medicare providers and suppliers and ensure continued compliance with Medicare requirements. In addition, this process further ensures that Medicare beneficiaries are receiving services furnished only by legitimate providers and suppliers, and strengthens our ability to protect the Medicare trust fund.

The accuracy of the data describing the individuals or organizations with whom we do business is essential to efficient and effective operation of the Medicare program. For this reason, we are proposing at § 424.520(b), that individuals and organizations are responsible for updating their CMS 855 information to reflect any changes in a timely manner. We define timely as meaning within 90 days, with the exception of a change in ownership or control of the provider or supplier which must be reported within 30 days. Failure to do so may result in deactivation or even revocation of their billing privileges.

We will determine, upon receipt of any changes, if continued enrollment in the Medicare program is proper. We expect that in the vast majority of cases, updates or changes will not affect the status of the provider or supplier. Where it does, we will follow the revocation procedures outlined later in this rule.

When no such changes or updates have been reported or submitted for a period of time, we believe that it is prudent to take steps to confirm the continued validity of the information that was previously submitted. We believe that this revalidation of enrollment information should be accomplished in a way that minimizes the reporting burden to the provider or supplier, but also mitigates the risk to the program of maintaining incomplete or inaccurate information that materially affects the relationship of the program to the provider or supplier. For

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

agencies to an administrative sanction imposed by any Federal agency. Specifically, the law provides that: ''No agency shall allow a party to participate in any procurement and non-procurement activity if any [other] agency has debarred, suspended, or otherwise excluded, that party from participation in a procurement or non-procurement activity.'' (FASA, section 2455). Therefore, consistent with FASA, its implementing regulation, and OIG regulations (42 CFR 1001.1901(b)), we would deny or revoke enrollment (revocation effective on the date of the exclusion) if the provider or supplier is subject to an OIG exclusion, or is debarred, suspended or otherwise excluded by any other Federal health care program or agency.

F. Rejection of a Provider or Supplier's CMS 855 for Medicare Enrollment

In new § 424.525, we propose that if a provider or supplier enrolling in the Medicare program for the first time fails to furnish complete information on the CMS 855, or fails to furnish missing information or any necessary supporting documentation as required by CMS under this or other statutory or regulatory authority within 60 calendar days of our request to furnish the information, we would reject the provider or supplier's CMS 855 application. Rejection will not occur if the provider or supplier is actively communicating with CMS to resolve any issues regardless of any timeframes.

Upon notification of a rejected CMS 855, the provider or supplier must again begin the enrollment process by completing and submitting a new CMS 855 and all applicable documentation. We are specifying in § 424.525(b) that the new form must also update any information that is different from that originally submitted. This will ensure that we have the most recent information about the provider or supplier. The enrollment process would culminate in the granting of billing privileges, or denial or rejection of the application.

G. Denial of Enrollment

We would deny enrollment in the Medicare program to providers or suppliers whom we determine to be ineligible. Providers and suppliers who are denied enrollment would not receive Medicare billing privileges. In § 424.530(a) we are proposing that a provider or supplier applying for enrollment in the Medicare program may be denied enrollment for the following reasons:

- Under § 424.530 (a)(1), enrollment may be denied if the provider or supplier were found not to be in compliance (for example, failure to furnish required documentation, lack of qualified practice location) with the Medicare enrollment requirements applicable to the type of provider or supplier enrolling, unless the reason for non-compliance were corrected or the provider or supplier has submitted a plan of corrective action as outlined in Part 488 and under section 1812(h)(2)(c) of the Act.
- In § 424.530(a)(2) we propose that enrollment may also be denied if: (A) the provider or supplier, or any owner, managing employee, authorized or delegated official; or (B) any supervising physician, medical director, or other health care personnel furnishing Medicare reimbursable services who is required to be reported on the providers' or suppliers' CMS 855—(for example, an ambulance crew member.)
- Is excluded from the Medicare, Medicaid and any other Federal health care programs, as defined in § 1001.2, in accordance with § 1001.1901(a);
- Is debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with FASA section 2455; (See HHS Common Rule provisions that discuss the effect of a program exclusion under Title XI of the Act, as well as other Federal agency debarments, suspensions, and exclusions found at 45 CFR 76.100(c) and (d)).

We are required to ensure that no payments are made to any providers or suppliers who are excluded from participation in the Medicare program under authorities found in sections 1128, 1156, 1862, 1867, and 1892 of the Act, or who are debarred, suspended or otherwise excluded as authorized by FASA. This includes any individual, entity, or any provider or supplier that arranges or contracts with (by employment or otherwise) an individual or entity that the provider or supplier knows or should know is excluded from participation in a Federal health care program for the provision of items or services for which payment may be made under such a program (section 1128A(a)(6) of the Act), and any provider or supplier that has been debarred, suspended, or otherwise excluded from participation in any other Executive Branch procurement or non-procurement programs or activity (FASA, section 2455).

Therefore, when an individual or entity is excluded by the OIG under section 1128 of the Act, the exclusion is applicable to participation in all Federal health care programs (including Medicare and Medicaid as defined in section 1128B(f) of the Act). In addition, section 1862(e) of the Act prohibits the Secretary from paying for items and services furnished by excluded individuals. We believe that our general authorities, in combination with the prohibition against paying for items or services furnished by excluded individuals, provides authority for us to deny enrollment unless a provider or supplier terminates its relationship with the relevant individual. The denial would remain effective until that provider, supplier, managing employee, or an authorized or delegated official; or a medical director, supervising physician, or other health care personnel furnishing Medicare reimbursable services, is no longer excluded or sanctioned. Section 424.530(b)(3) also provides that the denial may be within 30 days of the denial notification.

We also propose, in § 424.530(a)(3), that we may deny enrollment in the Medicare program if the provider or supplier, or any owner of the provider or supplier, has been convicted of a Federal or State felony offense that we determine to be detrimental to the best interests of the Medicare program or its beneficiaries. This authority is afforded to us in many of the HIPAA fraud and abuse provisions and section 4302 of the BBA. In making assessments, we are proposing to include any felony convictions from the last 10 years or more. In addition, we will consider the severity of the underlying offense.

Felonies that we determine to be detrimental to the best interests of the Medicare program or its beneficiaries include:

- Within the last 10 years or more preceding enrollment or revalidation of enrollment, crimes against persons, such as rape, murder, kidnapping, assault and battery, robbery, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions. We believe it is reasonable for the Medicare program to question the ability of the individual or entity with such a history to respect the life and property of program beneficiaries.
- Within the last 10 years or more preceding enrollment or revalidation of enrollment, financial crimes, such as extortion, embezzlement, income tax evasion, making false statements, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions. We believe it is reasonable for the Medicare program to question the honesty and integrity of the individual or entity with such a history in providing services and

claiming payment under the Medicare program.

• Within the last 10 years or more preceding enrollment or revalidation of enrollment, 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.

• Any felonies referred to in section 1128 of the Act.

Under section 1128(a) of the Act, the Secretary must exclude individuals or entities convicted of certain crimes, such as program-related crimes, crimes related to patient abuse or neglect, and conviction of a felony related to health care fraud or controlled substances. In addition, the Secretary has authority to exclude individuals and entities for other adverse actions including when an individual or entity is owned or controlled by a sanctioned or convicted individual, in accordance with section 1128(b)(8) of the Act.

In cases where the provider or supplier is not a convicted individual but, rather, has an ownership or management relationship with a convicted or excluded individual, that provider or supplier may also be subject to civil monetary penalties (section 1128A(a)(6) of the Act). In addition, we may deny or revoke billing privileges if such a relationship exists. However, the denial may be reversed if, within 30 days of the denial notification, the provider or supplier terminates its ownership or management relationship with the convicted or excluded individual or organization. We specifically invite further comments on our approach to treating convicted felons, and any impact that may have on access to care for Medicare beneficiaries.

We propose in § 424.530(a)(4) that we may deny enrollment if the provider or supplier has deliberately submitted false or misleading information on their CMS 855 to gain enrollment in the Medicare program. Offenders may be subject to fines or imprisonment, or both, in accordance with current law and regulation.

In § 424.530(a)(5) we propose possible denial of enrollment where there are repeated instances in which, upon onsite review or other reliable evidence, we do not find present those licensed medical professionals required under the Medicare statute or regulations to supervise treatment or provide Medicare covered services for Medicare patients; or we determine that the provider or supplier is not operational to furnish Medicare covered services or supplies.

As outlined in proposed § 424.530(b), if the denied provider or supplier appeals the decision, and the denial is upheld, that provider or supplier may submit a new CMS 855 after we notify it that the original determination has been upheld. If the provider or supplier did not appeal the determination, it may submit a new CMS 855 when the time frame for appeal rights has lapsed. We are proposing this latter requirement to prevent administrative difficulties that might result in processing two enrollment forms if a new one is submitted during the time period when the provider or supplier may appeal an initial denial.

Medicare enrollment denials will impact the provider or supplier on a national scale. In proposed § 424.530(c), we state that when a provider or supplier is denied enrollment in Medicare, we will review 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.

H. Revocation of Enrollment and Billing Privileges from the Medicare Program

Revocation occurs when an enrolled provider or supplier's billing privileges are terminated. In proposed § 424.535, we outline the causes for revocation and what a provider or supplier would need to do to re-enroll in the Medicare program after revocation. In considering whether to revoke enrollment and billing privileges in the Medicare program, we would consider the severity of the offenses, mitigating circumstances, program and beneficiary risk if enrollment continued, possibility of corrective action plans, beneficiary access to care, and any other pertinent factors.

In general, we propose revocation criteria that are similar to our reasons for denial of initial Medicare program enrollment. In § 424.535(a)(1) we propose that a provider or supplier's enrollment and billing privileges may be revoked if, at any time, it is determined to be out of compliance with the Medicare enrollment requirements outlined in subpart P including failure to report changes to enrollment information timely or failure to adhere to corrective action plans, and has not corrected the problem within 30 days of notice of non-compliance or submitted a plan of corrective action as cited earlier. We are providing that we 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. If requested documentation as required by CMS under this or other statutory or regulatory authority is not submitted within 30 calendar days of our request, we would immediately begin revocation proceedings. If the documentation is received timely, we would review and verify the information to determine if we should proceed with the revocation. Providers requiring State survey and certification would continue to receive payment during the data verification review under current regulations found at Part 488 and under section 1819(h)(2)(c) of the Act. Providers and suppliers not subject to State survey and certification may have its payments suspended during the data review.

We are also proposing that we may revoke a provider or supplier's billing privileges if the provider or supplier establishes:

• Repeated instances in which, upon onsite review or other reliable evidence, we do not find present those licensed medical professionals required under the Medicare statute or regulation to supervise treatment of, or to provide Medicare covered service for, Medicare patients. Additional proposed reasons that may result in the revocation of billing privileges in § 424.535(a) include the following:

• In accordance with section 1862(e)(1) and (2) of the Act, the provider or supplier, any owner, managing employee, authorized or delegated official, supervising physician or other health care personnel who must be reported on the CMS 855 (for example, ambulance crew member), of the provider or supplier, becomes excluded from the Medicare, Medicaid or any other Federal health care programs, as defined in § 1001.2, in accordance with section 1128 or 1156 of the Act, or is debarred, suspended or otherwise by any Federal health care program or agency.

• The provider or supplier, or any owner of the provider or supplier, is convicted of a Federal or State felony offense that we determine to be detrimental to the best interests of the program as outlined in ''Denial of Enrollment'' above.

• The provider or supplier certified as ''true'' deliberately submitted false or misleading information on the CMS 855 in order to enroll or maintain enrollment in the Medicare program. (Offenders may be subject to criminal or civil prosecution, in accordance with current laws and regulations).

• Upon onsite review, we determine that the provider or supplier is no longer operational to furnish Medicare covered services or supplies.

• The provider or supplier fails to furnish complete and accurate information on the CMS 855 and any applicable documentation within 60 calendar days of our notice to re-certify its enrollment information.

• The provider or supplier knowingly sells to or allows another individual or entity to use its billing number.

In addition to the revocation of the provider's or supplier's billing privileges, we propose at § 424.535(b) that any provider agreement in effect at the time of revocation will also be terminated effective with the date of revocation. We do not feel it would be prudent for CMS to maintain an active provider agreement for a provider or supplier whose business relationship with Medicare was adverse enough as to cause the revocation of their billing privileges. Section 1866(b)(2)(A) of the Act states that the Secretary may terminate a provider agreement after the Secretary ''has determined that the provider fails to comply substantially with the provisions of Title XVIII.'' We will amend §§ 489.53 and 498.3 to reflect this proposal.

In new § 424.535(c) we propose that upon notification of the revocation of its billing number, if the provider or supplier seeks to re-establish enrollment and billing privileges in the Medicare program (either after the appeals process is exhausted or in place of the appeals process), then the provider or supplier must complete and submit a new CMS 855 as a new provider or supplier and applicable documentation. Providers must be re-surveyed or re-certified by the State survey agency as a new provider and must establish a new provider agreement with our Regional Office.

If the billing privileges are revoked due to the adverse activity of an individual or organization other than the provider or supplier, the revocation may be reversed if the provider or supplier terminates their business relationship with the individual or organization that was responsible for the revocation within 30 days.

As with a denial of Medicare enrollment, revocations would impact the provider or supplier on a national scale. As proposed in § 424.535(d), if a provider or supplier's billing privileges are revoked, we would review 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.

I. Deactivation of Medicare Billing Privileges

When a provider or supplier's billing number is deactivated, billing privileges have been temporarily suspended, but can be restored upon the submission of updated or re-certified information. In new § 424.540, we propose to deactivate a provider or supplier's Medicare billing number if no Medicare claims are submitted for 2 consecutive calendar quarters (6 months) unless current policy or regulations specify otherwise for specific provider or supplier types. Our current policy requires deactivation of billing numbers after 4 consecutive calendar quarters (12 months) of no claim submissions. We are including this reduction to the current requirement because we are aware of a number of program integrity issues related to inactive Medicare billing numbers. We wish to prevent, for example, questionable businesses from deliberately obtaining multiple numbers so that they could keep one ''in reserve'' in the event their practices result in suspension of claims payment under their active number. We also wish to prevent fraudulent entities from obtaining information about discontinued providers or suppliers, for example, using the Medicare billing number of a deceased physician. While we are proposing to use 6 months of no billing as a criteria for deactivation, we are seeking comments on the feasibility and reasonableness of this time frame. We are interested in receiving comments on whether this time frame should apply to all categories of providers and suppliers, or whether there should be a special process for categories of providers and suppliers that would have reason to bill Medicare infrequently.

We are also proposing to deactivate a billing number if we discover changes to the information provided on the provider or supplier's CMS 855 that were not reported within 90 days of the change. This includes, but is not limited to, changes to billing services, a change in the practice location, or a change of any managing employee. A change in ownership or control must be reported within 30 calendar days.

Deactivation of Medicare billing privileges is considered a temporary action to protect the provider or supplier from misuse of their billing number and to also protect the Medicare trust fund from unnecessary overpayments. The temporary deactivation of a billing number will not have any effect on a provider or supplier's participation agreement or conditions of participation.

In proposed § 424.540(b), we state that a provider or supplier whose billing number has been deactivated for any reason other than non-submission of a claim for 6 months and who wants to reactivate its Medicare billing number must complete and submit a new CMS 855. Those providers and suppliers whose billing number has been deactivated after non-submission of a claim must re-certify that the enrollment information current on file with Medicare is correct before the claim will be paid. In addition, the provider or supplier must meet all current Medicare requirements in place at the time of the re-activation. The provider or supplier must also be prepared to submit a valid claim or risk subsequent deactivate of their billing number. Once notified, we will give all reactivations of Medicare billing numbers priority handling to ensure expedient payment of claims. Reactivation of a Medicare billing number would not require re-survey or certification by State agency, or the establishment of a new provider agreement.

J. Provider and Supplier Appeal

In new § 424.545, we propose that a provider or supplier that has been denied enrollment in the Medicare program, or whose enrollment has been revoked, may appeal our decision in accordance with our regulations at Part 405, Subpart H, for suppliers or Part 498, Subpart A, for providers. CMS is currently drafting a single regulatory appeals process for all providers and suppliers denied or revoked from participation in the Medicare program. In keeping with current policy, we also propose that no payments will be made during the appeals process. If the provider or supplier is successful in overturning a denial or revocation, unpaid claims for services furnished during the overturned period may be resubmitted.

In addition, we propose in new § 424.545(b) that a provider or supplier whose billing privilege has been deactivated may file a rebuttal using procedures found at § 405.74.

K. Prohibitions on the Sale or Transfer of Billing Privileges

We propose in new § 424.550 that a provider or supplier would be prohibited from selling its Medicare billing number to any individual or entity, or allowing another individual or entity to use its Medicare billing number. Similarly, we would prohibit a provider or supplier from transferring its Medicare billing privileges to any individual or entity, except during a change in ownership, as stated below. A

provider or supplier does not have independent authority to sell or transfer any billing number issued or the billing privileges granted with the billing number assigned.

We propose this policy because only we and our agents have the authority to issue Medicare billing numbers and grant Medicare billing privileges. These numbers are issued only after the information about the provider or supplier collected on the CMS 855 is verified. Because it is used to uniquely identify a provider or supplier, the Medicare billing number we issue is solely for use by the specific provider or supplier to whom it was issued.

In the case of a provider or supplier undergoing a change of ownership as described in part 489 subpart A, we would require at § 424.550(b) that a CMS 855 be completed and submitted by both the current owner and the new owner before the completion of the ownership change. Failure of the current owner to submit the CMS 855 prior to the change of ownership may result in sanctions and/or penalties, after the date of ownership change, in accordance with §§ 424.520, 424.540, and 489.53. Failure of the new owner to submit the CMS 855 prior to the change of ownership may result in the deactivation of the Medicare billing number until the CMS 855 has been submitted.

We may deactivate a Medicare billing number at any time before final transference of the provider agreement to the new owner. This may occur as a result of the submission of a CMS 855 with material omissions, or preliminary information received or determined by us that makes us question whether the new owner will ultimately be granted a final transference of the provider agreement. This allows us the right to ensure that billing privileges are given only to a new owner for which we have adequate information to, at a minimum, determine that the new owner should have billing privileges prior to the complete validation of their CMS 855 and the transfer of the provider agreement.

We understand that not all enrollment information is available before the change of ownership. We will work with the new owner(s) to ensure a seamless transition, but it is the provider's or supplier's responsibility to report this and any other changes to us to prevent us from imposing any adverse action against it.

For those providers and supplier not covered by Part 489, any change in the ownership or control of the provider or supplier must be reported on the CMS 855 within 90 days of the change as noted in § 424.540(a)(2). Generally, a change of ownership that also changes the tax identification number will require a new CMS 855 from the new owner.

L. Payment Liability

In new § 424.555, we propose that any expenses for services furnished to a Medicare beneficiary by those categories of suppliers covered by section 1834 of the Act (that is, suppliers of DMEPOS) are the responsibility of that supplier if the supplier has been denied Medicare billing privileges. We further propose that no payment may be made for covered services furnished to a Medicare beneficiary by a provider or supplier whose billing privileges have been deactivated or revoked. The Medicare beneficiary will have no financial responsibility for this type of expense, and the provider or supplier must refund on a timely basis any amounts collected from the beneficiary for those covered services.

We are proposing these provisions because a provider or supplier who fails to provide valid enrollment information, or who is not a valid provider or supplier type under the Medicare program, cannot be verified as a legitimate provider or supplier for purposes of this rule. Claims or bills submitted for covered Medicare services must have an active Medicare billing number. Claims or bills submitted by a provider or supplier who is not properly enrolled, and does not have an active Medicare billing number, would be considered incomplete and would be returned. The provider or supplier would then be in violation of the mandatory claims submission requirements and could be fined for each occurrence. An incomplete claim returned for this reason would not be afforded appeal rights for the provider or supplier. However, as described earlier, a provider or supplier may appeal a denial or revocation of enrollment in accordance with regulations elsewhere in this subpart.

Sections 1802(b), 1834(j), 1866, and 1870 of the Act, provide Medicare beneficiaries with certain protections against liabilities imposed by providers and suppliers. In section 1834(j)(4), for example, the statute protects the beneficiary against demands for payment for covered Medicare services by certain categories of suppliers that have not been granted Medicare billing privileges. Section 1866 of the Act prohibits providers that have entered into agreements described in that section from charging the beneficiary for covered items or services that are not paid by Medicare because the provider has failed to comply with certain requirements. Furthermore, section 1802(b) of the Act, which sets forth a variety of criteria under which physicians and practitioners may enter into private contracts with Medicare beneficiaries, provides for additional beneficiary protection. Section 1870 provides that, except under certain circumstances, any payment to a provider of services with respect to items or services furnished shall be considered a payment to the individual, but that the individual will not be liable for overpayment to the provider where the individual is without fault.

In addition, section 1128A(a)(6) of the Act provides for criminal penalties for providers and suppliers having knowledge of events affecting the right to benefit or payment, and concealing or failing to disclose such an event with an intent to fraudulently secure benefit or payment when it is not authorized.

IV. Data Requested on the CMS 855 and Its Iterations

Because we are intending to use the CMS 855 series of forms as the principal information collection instrument, we are providing the following information about the data requested on the CMS 855 forms. In addition to the legal authority already cited in this preamble, the following additional provisions of the statute grant us the authority to collect the information required to complete the CMS 855:

- Section 1814(a) of the Act states that payment for services furnished to an individual may only be made to providers eligible under section 1866 and only if a written request is filed in such a form and manner as the Secretary may prescribe.
- Sections 1815(a) and 1833(e) of the Act authorize the Secretary to withhold Medicare payments until the provider or supplier furnishes such information as may be necessary to determine amounts due.
- Section 1866(a)(1) of the Act establishes provider agreement requirements; including a requirement not to charge the beneficiary (except as provided in section 1866(a)(2)) for items or services for which the beneficiary would have been entitled to have payment had the provider complied with procedural requirements.

A. Information Collection on the CMS 855

Since its inception in April 1996, the CMS 855 has been revised three times, in May 1997, January 1998, and in November 2001. A new proposed revision of the CMS 855 series is being submitted with this proposed rule for

additional public comment. Each revision has been based on comments received from our contractors, the health care industry, and new requirements imposed through legislation. All revisions are submitted to OMB and published in the **Federal Register** for public comment before approval and implementation.

The primary function of the CMS 855 is to gather information from a provider or supplier that tells us who it is, whether it meets certain qualifications to be a health care provider or supplier, where it practices or renders its services, the identity of the owners of the enrolling entity, and information necessary to establish the correct claims payment. The goal of evaluating and revising the CMS 855 is to simplify and clarify the information collection without jeopardizing our need to collect specific information. Listed below are the various sections of the CMS 855 and the information that each section collects. Not all sections apply to all provider and supplier types. For specific information collection requirements by provider or supplier type, review the applicable CMS 855 as mentioned earlier in this preamble.

1. Provider or Supplier Application

To ensure efficient processing of the CMS 855, this section requires the provider or supplier to give the reason for submission of the CMS 855 and to state whether it is currently known (enrolled) in Medicare and for any current Medicare identifiers (billing numbers or Medicare contractor name(s)).

2. General Identification Information

This section collects personal and business information to uniquely identify the provider or supplier with such information as type or specialty, name, business name, address, date of birth, SSN, EIN, correspondence address, and other similar information. This information is needed to uniquely identify the provider or supplier. Moreover, as detailed above, section 1124(a)(1) of the Act requires disclosure of both EINs and SSNs. See also section 31001(I) of the DCIA.

3. Adverse Legal Action(s) and Overpayment(s)

The information obtained in this section enables us to determine if an individual or entity should have its Medicare billing number denied or revoked. Table A in this section cites specific adverse legal actions which have a direct bearing on the individual's or entity's professional competence, professional performance, or financial integrity that the provider or supplier must report to Medicare. These actions may serve as a basis for the Secretary, as set forth in section 1128 of the Act, to exclude an individual or entity from participation in Medicare and all other Federal health care programs.

4. Current Practice Location(s)

This section collects information to verify that the practice location where services are proposed to be or are being furnished by the enrolling provider or supplier meets Medicare requirements.

5. Ownership Interest and/or Managing Control Information (Organizations)

6. Ownership Interest and/or Managing Control Information (Individuals)

7. Chain Home Office Information

The information collected in the above three sections (5 through 7) is needed to ensure that all individuals and entities deriving financial benefit from the Medicare program are identified as required in sections 1124 and 1124A(a) of the Act, and in § 420.204. Those sections state that as a condition for approval or renewal of a contract or agreement, and for an entity to receive payment under Title XVIII, complete information as to the identity of each person and/or organization with an ownership or controlling interest of 5 percent or more and each managing employee as defined in section 1126(b) of the Act and § 420.201, must be disclosed.

8. Billing Agency

This section is needed to capture identifying information, such as legal business name and address, and to obtain information about the contract between the provider or supplier and the billing agency that submits bills or claims for Medicare payments on behalf of a Medicare provider or supplier. In addition, we need this information to verify that the biller has been authorized by the provider or supplier to submit bills or claims on the provider or supplier's behalf. We need to be able to monitor agreements made between billing and collection agents and providers and suppliers to ensure compliance with Medicare requirements found at 1842(b)(6) of the Act and §§ 424.73 and 424.80.

9. For Future Use

10. Staffing Company

This section is needed to capture identifying information, such as legal business name and address, and to obtain information about the contract between the provider or supplier and the staffing company that submits bills or claims for Medicare payments on behalf of a Medicare provider or supplier. In addition, we need this information to verify that the biller has been authorized by the provider or supplier to submit bills or claims on the provider or supplier's behalf. We need to be able to monitor agreements made between staffing companies and providers and suppliers to ensure compliance with Medicare requirements found at section 1842(b)(6) of the Act and §§ 424.73 and 424.80.

11. Surety Bond Information

This section will be used on an ''as needed'' basis and would furnish us with information regarding certain providers and suppliers that are required to obtain a surety bond under section 4312 of the BBA (codified at sections 1834(a)(16), 1861(o)(7), 1861(p)(4)(A)(v) and 1861(cc)(2)(I)) of the Act. The BBA further grants the Secretary the authority, at his or her discretion, to impose the requirements on other Medicare providers or suppliers (other than physicians or other practitioners as defined in section 1842(b)(18)(C) of the Act). See also section 1834(a)(16) of the Act.

12. Capitalization Requirements for Home Health Agencies (HHAs)

This section collects information required by § 489.28, which requires all HHAs enrolling in Medicare for the first time to submit proof of sufficient operating funds.

13. Contact Person(s)

This information will allow a Medicare contractor to establish a direct point of contact to resolve issues pertaining to the completion and validation of the information furnished in the CMS 855.

14. Penalties for Falsifying Information on this Enrollment Application

This section is informational only. It cites various statutory references in the United States Code and the Social Security Act concerning actual knowledge, deliberate ignorance or reckless disregard of the truth or falsity of the information contained therein on an application to receive payment.

15. Certification Statement

The certification statement is being revised. Statement 3 on the CMS 855A, CMS 855B, and CMS 855S forms and statement 4 on the CMS 855I form have been changed to provide a better understanding of Medicare policy. An additional statement is also being added to the CMS 855A and CMS 855B forms for providers and suppliers that receive

accreditation from an outside organization authorizing the release of the survey to us or our agents. By adding this language to the certification statement, the current CMS 1514 form will be eliminated for Medicare purposes.

16. Delegated Official (Optional)

The signature(s) obtained in sections 15 and 16 would attest that the provider or supplier has submitted accurate, complete, and truthful information as required by sections 1814(a) and 1833(e) of the Act, and that the person the provider or supplier has authorized to sign for the provider or supplier attests on behalf of the provider or supplier to having read and understood the information furnished and collected in the CMS 855, and that the information is accurate, complete, and truthful. By signing the certification statement, the provider or supplier, or the authorized or delegated official signing on behalf of the provider or supplier, is attesting, among other things, that the provider or supplier is aware of and will abide by all applicable Medicare laws and regulations.

17. Attachments

This section is a checklist of possible documents that should be submitted with the enrollment application. These documents are used as evidence or proof of the validity of the information furnished through the CMS 855.

B. Information Pertaining to Specific Provider and Supplier Types

1. Attachment 1 to Form CMS 855B—Ambulance Service Suppliers

We must collect specific information on ambulance service suppliers to verify their eligibility to receive payment for Medicare covered services. Section 410.41 (Requirements for ambulance suppliers) sets forth the requirements for ambulance service suppliers. An ambulance must be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all State and local laws governing an emergency transportation vehicle. We require that, at a minimum, an ambulance contain a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by State or local laws, and be equipped with emergency warning lights, sirens, and two-way telecommunications.

Note: This attachment replaced the HCFA R–88 (OMB Approval Number 0938–0460).

2. Attachment 2 to Form CMS 855B—Independent Diagnostic Testing Facilities (IDTFs)

IDTFs must submit specific information to us to justify their eligibility to receive payment for Medicare covered services. The information collected in this attachment allows us to assess compliance with 42 CFR § 410.33 (Independent diagnostic testing facility). In addition, 42 CFR § 440.30 (Other laboratory and x-ray services) defines laboratory and X-ray services. These services may be provided in an office or similar facility other than a hospital outpatient facility or clinic, and must be furnished by a laboratory that meets the requirements of Part 493 of chapter IV, 42 CFR.

C. Supplemental Applications

1. Supplemental Application CMS 855S (DMEPOS Supplier Application)

The information collected in this iteration of the CMS 855 allows us to assess compliance with § 424.57 (Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers), which outlines specific standards that must be met for the enrollment and renewal of enrollment for DMEPOS suppliers. This collection was previously approved by OMB via the HCFA 192 (OMB Approval Number 0938–0594). The CMS 855S has replaced the HCFA 192.

Note: A DMEPOS supplier is not required to submit a CMS 855B form in addition to a CMS 855S.

2. Supplemental Application CMS 855R (Individual Reassignment of Benefits Application)

The CMS 855R will be used to link individual Medicare suppliers with Medicare entities to whom the individual reassigns his or her benefits and is used in conjunction with the CMS 855I or the CMS 855B during initial enrollment into the Medicare program, or whenever an individual supplier wishes to, or is required to, reassign its benefits. The CMS 855R contains only the information needed to identify and link individual suppliers reassigning their benefits to the individuals and entities to whom their benefits are being reassigned.

V. Sanctions and Penalties

The CMS 855 states that the following penalties may be imposed:

- 18 U.S.C. 1001 authorizes criminal penalties against an individual who in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes or uses any false, fictitious, or fraudulent statements or representations, or makes any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry. Individual offenders are subject to fines of up to $250,000 and imprisonment for up to 5 years. Offenders that are organizations are subject to fines of up to $500,000. 18 U.S.C. 3571(d) also authorizes fines of up to twice the gross gain derived by the offender.
- Section 1128B(a)(1) of the Act authorizes criminal penalties against an individual who ''knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program.'' The offender is subject to fines of up to $25,000 or imprisonment for up to 5 years, or both.
- The Civil False Claims Act, 31 U.S.C. 3729, imposes a civil penalty of $5,000 to $10,000 per violation, plus three times the amount of damages sustained by the Government and imposes civil liability, in part, on any person who—
- Knowingly presents, or causes to be presented, to an officer or an employee of the United States Government a false or fraudulent claim for payment or approval;
- Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; or
- Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.
- Section 1128A(a)(1) of the Act imposes administrative sanctions on a person for the submission to a Federal health care program of false or otherwise improper claims.

These administrative sanctions include a civil monetary penalty of up to $10,000 for each item or service falsely or fraudulently claimed an assessment of up to triple the amount claimed, and exclusion from participation in all Federal health care programs.

The government may assert common law claims such as ''common law fraud,'' ''money paid by mistake,'' and ''unjust enrichment.'' Remedies include compensatory and punitive damages, restitution, and recovery of the amount of the unjust profit.

In addition, the following two sanctions will be added to the CMS 855 form:

• 18 U.S.C. 1035 authorizes criminal penalties against individuals in any matter involving a health care benefit program who knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items, or services. The individual shall be fined or imprisoned up to 5 years or both.

• 18 U.S.C. 1347 authorizes criminal penalties against individuals who knowing and willfully execute, or attempt, to execute a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by or under the control of, any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services. Individuals shall be fined or imprisoned up to 10 years or both. If the violation results in serious bodily injury, an individual shall be fined or imprisoned up to 20 years, or both. If the violation results in death, the individual shall be fined or imprisoned for any term of years or for life, or both.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. To evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

• Whether the information collection is necessary and useful to carry out the proper functions of the agency;

• The accuracy of the agency's estimate of the information collection burden;

• The quality, utility, and clarity of the information to be collected; and

• Recommendations to minimize the information collection burden.

Therefore, we are soliciting public comment on each of these issues for the information collection requirement discussed below.

The following sections of this document contain information collection requirements:

Section 424.510 Requirements for Obtaining a Billing Number and Medicare Billing Privileges

To enroll in the Medicare program and obtain and activate a Medicare provider or supplier billing number, § 424.510(a) requires a provider or supplier to complete and submit a CMS 855 to us, demonstrating that the provider or supplier meets all of the requirements set forth in this section. The burden associated with these requirements are currently captured in the CMS 855 (OMB Approval Number 0938–0685) and shown below in Table 1.

TABLE 1.—CURRENT ESTIMATED HOURS FOR COMPLETION OF CMS 855 FORMS FOR INITIAL ENROLLMENT

CMS form number	Estimated number of respondents	Estimated time for completion per respondent	Total number of hours for completion	Total cost in dollars (million)
855A	5,000	8 Hours	40,000	$3
855B	10,000	8 Hours	80,000	$6
855I	50,000	5 Hours	250,000	$3
855R	100,000	15 Minutes	25,000	$.3
855S	9,000	8 Hours	72,000	$5.4
Total Estimated Hourly and Financial Burden			467,000	$17.7

The estimated number of respondents is based on current Medicare contractor workload reports. The cost in dollars is based on hourly salaries for applicable staff to complete the applications.

Section 424.510(f) states that we reserve the right to perform on-site inspections of a provider or supplier to verify and ensure validity of the information submitted to us or our agents and to determine compliance with Medicare requirements. We intend to conduct on-site visits of all new suppliers of DMEPOS before they can enroll in the Medicare program. The burden associated with these requirements are currently captured and approved in form HCFA–R–263 (OMB Approval Number 0938–0749).

We also intend to conduct approximately 490 on-site visits to Community Mental Health Centers. The burden associated with these requirements are currently captured and approved in form HCFA–R–273 OMB Approval Number 0938–0770). We also intend to conduct approximately 2800 visits to IDTFs on an annual basis. We will seek OMB approval for these visits. The burden associated with this requirement is the time and effort necessary for a facility to provide documentation to verify information provided on their CMS 855 and to demonstrate that they meet other necessary Medicare requirements and regulations.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

CFR sections	Annual number of responses	Frequency	Average burden per response (hours)	Annual burden (hours)	Annual cost
424.510(f)	2800	1	4	11,200	$0

Since these site visits are unannounced and performed to ensure proper physical location, equipment, and personnel to meet Medicare requirements, we do not expect the

provider or supplier to incur any financial burden.

We may also conduct on-site visits of providers or suppliers based on any information that leads us or our agents to believe that an administrative action, investigation or audit is warranted. Information collected under these situations is exempt from the PRA, as stipulated under 5 CFR 1320.4.

Section 424.515 Requirements for Reporting Changes and Updates to, and the Periodic Revalidation of, Medicare Enrollment Information

A provider or supplier must re-certify for revalidation its enrollment information no more than once every 3 years. Section 424.515(b) states that within 60 calendar days of our notice to re-certify their enrollment information for revalidation, a provider or supplier must submit any new or revised CMS 855 information and documentation necessary to demonstrate that they meet the requirements set forth in this section.

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN

CFR sections	Annual number of responses	Frequency	Average burden per response (minutes)	Annual burden (hours)	Annual cost (million)
424.515(b)	387,000	(**)	95	612,750	$15

** Frequency is no more than once every 3 years. (1.16 million providers and suppliers/3 years × 95 minutes/60 minutes.)

The burden hours shown above are for the most restrictive reporting. As indicated elsewhere in this preamble, we are exploring various options and are soliciting comments on ways of minimizing the burden on providers and suppliers during the process of revalidating their enrollment information.

The estimated cost is based on $40 per application per provider to review and return.

Section 424.520 Additional Provider and Supplier Requirements for Enrolling and Maintaining Active Enrollment Status in the Medicare Program

Following enrollment and periodic recertification of enrollment information, a provider or supplier must report to us any changes to the information furnished on the CMS 855 or supporting documentation within 90 calendar days of the change.

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN

CFR section	Annual number of responses	Frequency	Average burden per response (hours)	Annual burden (hours)	Annual cost (millions)
424.20	40,000	1	1	40,000	$1.6

Section 424.525 Rejection of a Provider or Supplier's CMS 855 for Medicare Enrollment

We will reject a provider or supplier's CMS 855 if the provider or supplier does not furnish missing or necessary information and documentation to us within 60 calendar days of a request. We believe that the burden associated with this requirement is captured in § 424.515, as we will merely be seeking the information initially requested in the CMS 855.

Section 424.525(b) states that upon notification of a rejected CMS 855, the provider or supplier must once again begin the enrollment process by completing and submitting a new CMS 855 and all applicable documentation if it wishes to obtain a Medicare billing number.

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN

CFR sections	Annual number of responses	Frequency	Average burden per response (minutes)	Annual burden (hours)	Annual cost
424.525(b)	11,250	1	95	17,812	$563,000

The annual dollar cost is based on $50 per respondent to update and resubmit a previously submitted enrollment application.

Section 424.535 Revocation of Enrollment and Billing Privileges From the Medicare Program

Section 424.535(b) states that upon notification of the revocation of its billing number and billing privileges, if the provider or supplier seeks to re-establish enrollment in the Medicare program it must re-enroll in the Medicare program through the completion and submission of a new CMS 855 and applicable documentation.

TABLE 6.—ESTIMATED ANNUAL REPORTING BURDEN

CFR sections	Annual number of responses	Frequency	Average burden per response (hours)	Annual burden (hours)	Annual cost (millions)
424.535(b)	2000	1	8	16,000	$1.2

The annual dollar cost is based on $600 per respondent to re-enroll in the Medicare program.

Providers must also be re-surveyed or re-certified by the State Survey Agency and must establish a new provider agreement with our Regional Office. The burden associated with the survey and certification requirement is exempt from the PRA, as provided in section 4204(c) of Pub. L. 100–203 COBRA 87, as amended by Pub. L. 100–360 (Medicare Catastrophic Coverage Act of 1988). The burden associated with the requirement to establish a new provider agreement (Form HCFA–460) is currently approved under OMB Approval Number 0938–0373.

Section 424.540 Deactivation of Medicare Billing Privileges

Section 424.540(a)(1) states that if no Medicare claims are submitted for two consecutive calendar quarters (6 months) we would deactivate a provider or supplier's Medicare billing number. The provider or supplier must complete and submit a CMS 855 for validation to reactivate its Medicare billing number and billing privileges.

TABLE 7.—ESTIMATED ANNUAL REPORTING BURDEN

CFR sections	Annual No. of responses	Frequency	Average burden per response (minutes)	Annual burden hours	Annual cost
424.540 (a)(1)	1200	1	95	1,900	$48,000

The annual cost is based on $40 per respondent to review and re-certify via signature their previously submitted enrollment application/information.

Table 8 below shows the total estimated hourly and financial burden for all requirements outlined and proposed in this rule.

TABLE 8.—ESTIMATED HOURLY AND FINANCIAL BURDEN FOR ALL REQUIREMENTS

CFR section	Annual No. of responses	Annual burden hours	Annual cost (million)
424.500	618,250	1.2 million	$36.6

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in §§ 424.510, 424.515, 424.520, 424.525, 424.535, and 424.540 and related forms in the addendum. These requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies directly to the following:

Centers for Medicare and Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Division of CMS Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn.: John Burke CMS–6002–P.

And,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington. DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VII. Regulatory Impact Analysis

We have examined the impacts of this proposed rule under Executive Order (E.O.) 12866, the Unfunded Mandate Reform Act of 1995, and the Regulatory Flexibility Act. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. In addition, a Regulatory Impact Analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year). This proposed rule would establish in regulations specific provider and supplier initial enrollment procedures and the periodic revalidation of eligibility. It is not expected to have an impact that would meet the threshold criteria to be considered economically significant.

The Unfunded Mandate Reform Act of 1995, in section 202, requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million adjusted for inflation. The rule has no consequential adverse impact on State, local, or tribal governments. This rule may reduce some State burdens since they will no longer certify providers that are not qualified to participate in the Medicare program. The impact on the private sector is well below the threshold.

Consistent with the Regulatory Flexibility Act, we prepare a Regulatory Flexibility Analysis (RFA) unless we certify that a rule would not have a

significant economic impact on a substantial number of small entities. The RFA is to include a justification of why action is being taken, the kinds and number of small entities that the proposed rule will affect, and an explanation of any considered meaningful options that achieve the objectives and would lessen any significant adverse economic impact on the small entities. For purposes of the RFA, entities with annual revenues of $5 million to $25 million depending on the type of health care provider and non-profit organizations are considered to be small entities. Because of the scope of this rule, all small entities that participate in the Medicare program are considered providers and suppliers and will be affected, but we do not expect that effect to be of a significant nature. As we show in section B of this impact analysis, the annual burden on providers and suppliers for completing the CMS 855 forms would not rise to the level of a significant burden.

The following analysis, together with the rest of this preamble, explains the rationale, purpose, and alternatives considered in the proposed rule. This is an administrative initiative that may result in Medicare program savings but at this time those savings are inestimable. We believe the probable costs providers or suppliers would incur as a result of this rule to be negligible.

A. Rationale, Purpose, and Alternatives Considered

As noted elsewhere in this preamble, we are responsible for protecting the Medicare trust fund by ensuring that unqualified, fraudulent, or excluded providers and suppliers do not bill the Medicare program. Past experience with a number of program integrity efforts have identified that granting billing privileges to entities that do not exercise sound business practices can result in uncollectable overpayments. The ease of obtaining a billing number in the past has paved the way for unscrupulous businesses to defraud the government deliberately by billing for services never furnished or furnished at inflated prices.

The provisions of this proposed rule supplement, but do not replace or nullify, existing regulations concerning the establishment of provider or supplier agreements, the issuance of provider or supplier billing numbers, and payment for Medicare covered services or supplies to eligible providers and suppliers. Basically, this rule consolidates current regulations found throughout the Code of Federal Regulations and more clearly defines what Medicare expects from providers and suppliers rendering services to the Medicare beneficiaries. Moreover, we have revised the ''Provider Supplier Enrollment Application (CMS 855)'' which will greatly decrease the current burden to the provider or supplier when applying for billing privileges. We expect this rule to ensure that the Medicare program has adequate information on those who seek to bill the program for services. Furthermore, it assures us that information will be periodically updated and reviewed. We believe that establishing the foundation for a sound business relationship with providers and suppliers will minimize billing problems and otherwise protect the Medicare trust fund. Similarly, we believe it is necessary for us to impose the requirements of this regulation on existing providers and suppliers and to establish safeguards that enable us to deny enrollment of unqualified providers and suppliers, and to revoke the billing privileges of egregious offenders whose actions place the Medicare trust fund at risk.

The primary goal of this rule, through standard enrollment requirements and periodic revalidation of the enrollment information, is to allow us to collect and maintain (keep current) a unique and equal data set on all current and future providers and suppliers that are or will bill the Medicare program for services rendered to our beneficiaries. By achieving this goal, we will be better positioned to combat and reduce the number of fraudulent and abusive providers and suppliers in the Medicare program, thereby protecting the trust fund and the Medicare beneficiaries. This rule will also allow us to develop, implement, and enforce national provider and supplier enrollment procedures to be administered uniformly by all Medicare contractors. Over time, we strongly believe that any current burden imposed on the providers and suppliers will be greatly diminished through the use of computer storage and web based internet technology.

Studies performed by our contractors, the GAO and OIG have shown numerous instances of fictitious applicants being granted Medicare billing numbers. This proposed rule would integrate the request for enrollment with sufficient data to substantiate an appropriate level of performance on the part of a new or continuing business. In prior studies, the OIG has found applicants who had submitted applications with nonexistent addresses. In some instances suppliers had no inventory of goods to be sold, lacked business licenses, had no financial investment, or lacked any experience in the business venture.

The GAO report concluded: ''Weaknesses in CMS' current provider enrollment process have made Medicare vulnerable to dishonest providers. To protect the integrity of Medicare, CMS and its contractors must have effective practices for reviewing applicants to verify that they are eligible for enrollment in the program, as well as the authority to deny or revoke enrollment to those that are not.'' This report also concluded that, '': Periodic revalidation of provider enrollment data should be a valuable means of ensuring that CMS has current, useful data on active providers and that providers no longer eligible to participate in Medicare are dropped from the program.'' Therefore, based on the above recommendation and our own successes with our 3-year re-enrollment policy currently in effect for DME suppliers, we are seeking to expand this requirement to all providers and suppliers billing the Medicare program.

We have already stepped up our efforts to seek more uniformity in the enrollment process. However, our experience clearly shows that the best means for preventing payment errors and, in worst cases, abuse by providers and suppliers, is to discourage and prevent their entry into the Medicare program through this rule and the authority to deny enrollment or revoke their billing number.

We realize that some entities will perceive our proposed requirements as a barrier to their access to serving Medicare beneficiaries. We do not believe that bona fide businesses will experience any difficulty in obtaining or maintaining a Medicare billing number. We also do not believe that the impact of these proposed requirements would fall any more heavily on underserved areas than on major metropolitan areas. We estimate that furnishing the requested information would require no more than 8 hours of a provider or supplier's time. Most businesses should have the information readily available.

B. Rural Hospital Impact Statement

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As noted above, there is a minimum amount of time needed to gather data and provide the information requested on the CMS 855

when initially enrolling or when resubmitting enrollment information to obtain and maintain a Medicare billing number. We are not preparing a rural impact statement since we have determined, and certify, that we do not expect this rule to impose any additional burden or otherwise significantly impact the operations of a substantial number of small rural hospitals. By default, due to their smaller size, the burden to small rural hospitals would actually be less than the average provider.

There are currently about 1.2 million providers (hospitals, home health agencies, rural health clinics, skilled nursing facilities, etc.) and suppliers (physicians, nurses, ambulance companies, clinical laboratories, durable medical equipment suppliers, etc.) enrolled in the Medicare program. In addition, about 74,000 new providers and suppliers apply to enroll in Medicare each year. Listed below is the current estimated annual burden on the affected public in both hours and dollars.

1. Estimated Costs for Completion of CMS 855 Forms for Initial Enrollment

Assumptions:

a. The monetary cost to the respondents is calculated as follows based on the following assumptions:

- The CMS 855I and CMS 855R will be completed by clerical staff (secretary), and
- The CMS 855A, CMS 855B, and CMS 855S will be completed by professional staff (attorney or accountant).

b. Estimated Cost per Form

The monetary cost to the respondent to complete and submit the necessary CMS 855 form is:

- $600 for the CMS 855A, CMS 855B, and CMS 855S
- $60 for the CMS 855I, and
- $3 for the CMS 855R

c. Estimated Hourly Wage for Staff Completing Forms. The cost per respondent per form has been determined using the following wages:

- $12.00 per hour (clerical wage)
- $75.00 per hour (professional wage)

CURRENT ESTIMATED HOURS FOR COMPLETION OF CMS 855 FORMS FOR INITIAL NEW ENROLLMENTS

CMS form number	Estimated number of respondents	Estimated time for completion per respondent	Total number of hours for completion	Total costs in dollars (million)
855A	5,000	8 Hours	40,000	$3
855B	10,000	8 Hours	80,000	$6
855I	50,000	5 Hours	250,000	$3
855R	100,000	15 Minutes	25,000	$.3
855S	9,000	8 Hours	72,000	$5.4
Total Estimated Hourly and Financial Burden			467,000	$17.7

The estimated number of respondents is based on current Medicare contractor workload reports.

2. Completing Forms to Report Changes to Enrollment Information

The hourly burden and monetary cost estimate for this activity for all forms is:

- 100,000 respondents X 1 hour each = 100,000 hours

Average cost per respondent = $420
Total cost for all respondents = $42 million

3. Completing Forms to Re-Certify Enrollment Information (3 yr cycle)

The hourly burden and monetary cost estimate for this activity for all forms is:

- 330,000 respondents X 2 hours each = 660,000 hours Average cost per respondent = $40

Total cost for all respondents = $13.2 million

Based on the above, the estimated current total annual hour burden for all classes of providers (hospitals, home health agencies, rural health clinics, skilled nursing facilities, etc.) and suppliers (physicians, nurses, ambulance companies, clinical laboratories, durable medical equipment suppliers, etc.) is 1,227,000 hours.

Based on the above, the estimated current annual monetary burden for all classes of providers (hospitals, home health agencies, rural health clinics, skilled nursing facilities, etc.) and suppliers (physicians, nurses, ambulance companies, clinical laboratories durable medical equipment suppliers, etc.) is $32.9 million. The 1997 revenue receipts for all classes of providers and suppliers is $913.7 billion. The cost of obtaining and maintaining billing privileges in the Medicare program on average is less than 1 percent of the total revenue.

Although it is possible that a few entities may be significantly affected by these proposed rules, we do not expect that a substantial number of affected entities will experience a significant increase in the reporting burden; therefore, the Secretary certifies that this rule is not expected to impose any additional burden or otherwise significantly impact a substantial number of small entities. We also invite comments on our impact analysis and regulatory flexibility analysis.

C. Alternatives Considered

Since this proposed rule is a codification of our current policies on provider and supplier enrollment, with the exception of imposing a cyclical revalidation process, we did not seek alternatives to this process. However, the current process was reviewed and, when possible, proposed or made that would reduce the current burden, such as the time frame for reporting changes.

Although we do not expect this rule to have a significant economic impact, we are revising the requirements for reporting changes to the provider or supplier's enrollment information to reduce the current burden. Currently, provides and suppliers must report any changes to their enrollment information within 30-days. We are proposing to change this requirement to 90-days (or quarterly). We considered retaining the current requirement but determined the 30-day timeframe as too stringent in light of the rapid changes seen in today's health care industry. This change is expected to reduce the administrative burden for the providers, suppliers, our contractors, and us.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by OMB.

VIII. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will

respond to the major comments in the preamble to that document.

List of Subjects

42 CFR Part 420

Fraud, Health facilities, Health professions, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in this preamble, 42 CFR chapter IV is proposed to be amended as set forth below:

PART 420—PROGRAM INTEGRITY: MEDICARE

1. The authority citation for part 420 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 420.201, the definition for managing employee is revised to read as follows:

* * * * *

Managing employee means a general manager, business manager, administer, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the institution, organization, or agency, either under contract or through some other arrangement, whether or not the individual is a W–2 employee.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 424.1, the introductory text to paragraph (a)(1) is republished, and the following statutory reference is added to paragraph (a)(1) in numerical order to read as follows:

§ 424.1 Basis and scope.

(a) *Statutory basis.* (1) This part is based on the indicated provisions of the following sections of the Act:

* * * * *

1833(e)—Requirement to furnish information to determine payment.

* * * * *

3. Subparts N and O are added and reserved.

4. Subpart P is added to read as follows:

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

Sec.

424.500 Scope.
424.502 Definitions.
424.505 Basic enrollment requirement.
424.510 Requirements for obtaining a billing number and Medicare billing privileges.
424.515 Requirements for reporting changes and updates to, and the periodic revalidation of, Medicare enrollment information.
424.520 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.
424.525 Rejection of a provider or supplier's CMS 855 for Medicare enrollment.
424.530 Denial of enrollment.
424.535 Revocation of enrollment and billing privileges in the Medicare program.
424.540 Deactivation of Medicare billing privileges.
424.545 Provider and supplier appeal rights.
424.550 Prohibitions on the sale or transfer of billing privileges.
424.555 Payment liability.

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

§ 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.

Note to § 424.500: Throughout subpart P, references to ''supplier'' or ''suppliers'' do not include those physicians or practitioners who have elected to ''opt-out'' of Medicare as described in part 405, subpart D of this chapter.

§ 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 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 laws, regulations, and program instruction of the Medicare program.

Deactivate means that the provider or supplier's billing privileges have been temporarily stopped, but can be restored upon the submission of updated information.

Delegated official means an individual who has been 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 services provided to Medicare beneficiaries. Providers and suppliers who have been denied Medicare enrollment cannot bill for Medicare covered services.

Enroll/Enrollment means the process that Medicare uses to—

(1) Identify a provider or supplier;

(2) Validate its eligibility to provide services to Medicare beneficiaries;

(3) Identify and confirm the provider or supplier's practice location(s) and owner(s); and

(4) Grant the provider or supplier Medicare billing privileges.

Managing employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W–2 employee of the provider or supplier.

Operational means the provider or supplier has a qualified physical practice location, is open to the public for the purpose of providing health care related services, is prepared to submit valid Medicare claims, *and* is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or supplies being rendered), to furnish these services.

Owner means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of the provider or supplier as defined in section 1124A(a) of the Act.

Reject/Rejected means that the provider or supplier's enrollment application has not been processed due to incomplete information or that additional information or corrected information was not received from the provider or supplier within 60 days after it was requested.

Revoke/Revocation means that the provider or supplier's billing privileges have been terminated.

§ 424.505 Basic enrollment requirement.

To receive payment for covered Medicare services from either Medicare (in the case of assigned claims) or a Medicare beneficiary (in the case of unassigned claims), a provider or supplier must have a valid Medicare billing number and been granted billing privileges for the date the service or supplies were furnished.

§ 424.510 Requirements for obtaining a billing number and Medicare billing privileges.

Providers and suppliers must submit enrollment information via the applicable form CMS 855 for verification by the Medicare program to obtain a Medicare billing number and be granted billing privileges. Upon the provider or supplier's successful completion of the enrollment process, including State survey and certification, accreditation, and approval of the CMS 855, The Centers for Medicare & Medicaid Services (CMS) issues a billing number and grants billing privileges that enable the provider or supplier to bill the Medicare program or the Medicare beneficiaries for Medicare covered services. Currently, the effective dates for reimbursement can be found at § 489.13 of this chapter for providers and suppliers requiring State survey or certification or accreditation, § 424.5 and § 424.44 for non-surveyed or certified/accredited suppliers, and § 424.57 and section 1834(j)(1)(A) of the Act for DMEPOS suppliers. For those providers and suppliers seeking accreditation from a CMS approved accreditation organization, the effective date for reimbursement will be the later of the date accreditation was received or the final approval of the CMS 855. CMS will not issue Medicare billing numbers or grant Medicare billing privileges retroactive to the date that the provider or supplier received final approval of their enrollment application (CMS 855). To obtain a billing number and be granted billing privileges, the following enrollment requirements must be met:

(a) *Form CMS 855.* A provider or supplier must submit to CMS the applicable completed CMS 855—Medicare Health Care Provider/Supplier Enrollment Application. The completed form will provide information for the purpose of establishing eligibility to receive payment for covered services furnished to Medicare beneficiaries. The information obtained uniquely identifies the provider and supplier for the purpose of enumeration, and provides information to CMS necessary for CMS to verify that the provider or supplier is not, and should not be, excluded from participation in the Medicare program, and that it renders services covered by the Medicare program.

(1) *Content.* The submitted CMS 855 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) Any documentation required by CMS under this or other statutory or regulatory authority 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), and owners of the business.

(iii) Any documentation required by CMS under this or other statutory or regulatory authority to establish the provider or supplier's eligibility to furnish services to beneficiaries in the Medicare program, including copies of pertinent licenses.

(2) *Signature(s).* The certification statement found on the CMS 855 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, be 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 will abide by, all applicable Medicare laws, regulations, and program instructions.

(i) *Requirements.* The signature requirements set forth below outline who must sign the CMS 855 for an enrolling provider or supplier:

(A) In the case of an individual practitioner, the applying practitioner.

(B) In the case of a sole proprietorship, the applying sole proprietor.

(C) In the case of 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 CMS 855 submitted for an organization's initial enrollment and all subsequent CMS 855s 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 CMS 855 to report updates or changes to the enrollment information will be 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 will be those of the authorized official and the person(s) to whom this authority has been delegated in accordance with the procedures detailed herein. Individual practitioners and sole proprietors can not delegate signature authority when submitting a CMS 855 for any reason. All CMS 855s submitted by individual practitioners and sole proprietors must be signed by the enrolling/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 via the CMS 855;

(C) Include the title of each person delegated authority to update or change the organization's enrollment information;

(D) Include the SSN of the delegated individual where that individual 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.

(*1*) *Verification of information.* The information submitted by the provider or supplier on the applicable CMS 855 must be such that CMS can validate it for accuracy as of the time of submission.

(*2*) *Completion of any applicable State surveys, certifications, and provider agreements.* The providers or suppliers who are mandated under the provision in Part 488 of this chapter to be surveyed or certified by the State Survey and Certification Agency, and to also 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.

(*3*) *Ability to furnish Medicare covered services or supplies.* The provider or supplier must be operational to furnish Medicare covered services and/or supplies before being granted Medicare billing privileges.

(*4*) *Additional requirements.* Providers and suppliers must meet the provisions of § 424.520 regarding additional compliance and reporting requirements.

(*5*) *On-site inspections.* CMS reserves the right, when we deem 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 will not affect those site visits performed for establishing conditions of participation.

(b) [Reserved]

§ 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 must resubmit and re-certify as to the accuracy via an authorized signature, its enrollment information for validation no more than once every 3 years. Initially, all providers and suppliers currently in or initially enrolling in the Medicare program will be required to complete the applicable CMS 855 at least once. The provider or supplier will enter the three-year revalidation cycle once a completed CMS 855 has been submitted and validated. (Ambulance service providers will continue to resubmit enrollment information in accordance with § 410.41(c)(2) and DME suppliers will continue to renew enrollment in accordance with § 424.57(e) of this chapter). The requirements for the resubmission, recertification and reverification of enrollment information include the following:

(a) *Submission of form CMS 855 and supporting documentation.* The provider or supplier must meet the submission, content, signature, verification, operational, inspection, and other requirements outlined in § 424.510.

(b) *Processing time.* A provider or supplier must submit to us the applicable CMS 855 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.

(c) *Completion of any applicable State surveys, certifications and provider agreements.* A new survey and 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 subchapter, if applicable.

(d) *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 will not affect those site visits performed for establishing conditions of participation.

(e) *Adjustments to 3-year re-validation cycle and non-routine re-validations.* (1) Revalidation of enrollment information will occur no more than once every 3 years. CMS reserves the right to adjust this schedule if it is determined that revalidation should occur on a more frequent basis due to complaints or evidence received 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 it is determined that the integrity of and compliance with the Medicare statute and regulations by specific provider or supplier types indicate that less frequent validation is justified. CMS will continue to revalidate enrollment information for Ambulance Service Suppliers in accordance with regulations set forth at § 410.41(c)(2) of this chapter (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).

(2) CMS also reserves 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 random checks, information indicating local problems, national initiatives, complaints, or other reasons that cause CMS 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.

§ 424.520 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 Social Security 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—

(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; or

(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.* Following enrollment, a provider or supplier must report to CMS any changes to the information furnished on the CMS 855 or supporting documentation within 90 calendar days of the change, with the exception of changes in ownership or control of the provider or supplier which must be reported within 30 calendar days. Failure to do so may result in the deactivation or revocation of the provider or supplier's Medicare billing number.

§ 424.525 Rejection of a provider or supplier's CMS 855 for Medicare Enrollment

(a) *Reasons for rejection.* CMS rejects a provider or supplier's CMS 855 for the following reasons:

(1) The provider or supplier fails to furnish complete information within 60 calendar days of CMS's request for the information as required.

(2) The provider or supplier fails to furnish supporting documentation within 60 calendar days of CMS's request for the documentation as required.

(b) *Extension of 60-day period.* CMS will not reject any provider or supplier enrollment application if the provider or supplier is actively communicating with CMS to resolve any issues regardless of the length of time it takes to resolve those issues.

(c) *Resubmission after rejection.* To enroll in Medicare and obtain a Medicare billing number and billing privileges after notification of a rejected CMS 855, the provider or supplier must complete and submit a new CMS 855 and all applicable documentation for CMS review and approval.

§ 424.530 Denial of enrollment.

(a) *Reasons for denial.* CMS may deny a provider 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 the CMS 855 enrollment form applicable 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 and under section 1819(h)(2)(c) of the Act.

(2) *Provider or supplier conduct.* The provider or supplier, or any owner, managing employee, or an authorized or delegated official; or any medical director, supervising physician, or other health care personnel furnishing Medicare reimbursable services who is required to be reported on the CMS 855, in accordance with section 1862(e)(1) of the Act,—

(i) Is excluded from the Medicare, Medicaid and any other Federal health care programs, as defined in § 1001.2 of this title, in accordance with section 1128 or 1156 of the Act; or

(ii) Is debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with FASA section 2455; or

(3) *Felonies.* The provider, supplier, or any owner of the provider or supplier, has been 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. The conviction must have occurred within the last 10 years or more and CMS will consider the severity of the underlying offense.

(i) Offenses include—

(A) Felony crimes against persons (such as rape, murder, or assault) and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial 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 pre-trial 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 CMS 855 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) *Onsite review.* Upon onsite review or other reliable evidence—

(i) There are repeated instances in which we do not find present or available those medical professionals required under the Medicare statute and regulations to supervise treatment of, or provide Medicare covered services for, Medicare patients; or

(ii) We determine that the provider or supplier is not operational to furnish Medicare covered services.

(b) *Resubmission after denial.* A provider or supplier that is denied enrollment in the Medicare program must not submit a new CMS 855 until the following has occurred:

(1) If the denial was not appealed, the provider or supplier may reapply after its appeal rights have lapsed.

(2) If the denial was appealed, the provider or supplier may reapply after CMS notification that the original determination has been upheld.

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

§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.

(a) *Reasons for revocation.* We may revoke a currently enrolled provider or supplier's Medicare billing privileges and any corresponding provider agreement for the following reasons:

(1) Non-compliance. The provider or supplier, at any time is determined not to be in compliance with the enrollment requirements described in the CMS 855 enrollment form applicable to its provider or supplier type and has not submitted a plan of corrective action as outlined in part 488 of this chapter and under section 1819(h)(2)(C) of the Act. All providers and suppliers will be granted an opportunity to correct the deficient compliance requirement prior to a final determination to revoke billing privileges.

(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 title, in accordance with section 1128 or 1156 of the Act; or

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

(3) *Felonies.* The provider, supplier, or any owner of the provider or supplier, has been 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. The conviction must have occurred within the last 10 years or more and CMS will consider the severity of the underlying offense.

(i) Offenses include—

(A) Felony crimes against persons (such as rape, murder, or assault) and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial 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 pre-trial 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 certified as ''true'' false or misleading information on the CMS 855 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) *Onsite review.* CMS determines, upon onsite review, that the provider or supplier is no longer operational to furnish Medicare covered services or supplies, or we do not find present or available those professionals required under Medicare statute or regulation to supervise treatment of, or to provide Medicare covered services for, Medicare patients.

(6) *Inadequate re-verification information.* The provider or supplier fails to furnish complete and accurate information and any applicable documentation within 60 calendar days of the provider or supplier's notification from CMS to resubmit and certify to the accuracy of its enrollment information.

(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 outlined in § 424.80.

(b) *Effect of revocation on provider agreements.* When a provider's or supplier's billing privilege has been revoked, any provider agreement in effect at the time of revocation will be terminated effective with the date of revocation.

(c) *Re-enrollment after revocation.* If a provider or supplier seeks to re-establish enrollment in the Medicare program after notification that its billing number and billing privileges have been 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 CMS 855 and applicable documentation, as a new provider or supplier, for validation by CMS.

(2) Providers must be re-surveyed and/or re-certified by the State Survey Agency as a new provider and must establish a new provider agreement with CMS's Regional Office.

(d) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, debt, 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.

(e) *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.

§ 424.540 Deactivation of Medicare billing privileges.

(a) *Reasons for deactivation.* CMS deactivates a provider or supplier's Medicare billing privileges for the following reasons:

(1) The provider or supplier does not submit any Medicare claims for two consecutive calendar quarters (6 months), unless current policy or regulations specify otherwise for your provider or supplier type.

(2) The provider or supplier does not report a change to the information supplied on its CMS 855 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 stated in §§ 424.520(b) and 424.550(b).

(b) *Reactivation of billing privileges.* The provider or supplier must either complete and submit a new CMS 855 to reactivate its Medicare billing number and billing privileges or, at a minimum, re-certify that the enrollment information currently on file with Medicare is correct. 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. Reactivation of a Medicare billing number does not require a new survey and certification of the provider or supplier by the State Survey Agency or the establishment of a new provider agreement.

(c) *Effect of deactivation.* Deactivation of Medicare billing privileges is considered a temporary action to protect the provider or supplier from misuse of Medicare billing numbers and to protect the Medicare trust fund from unnecessary overpayments. The temporary deactivation of a Medicare billing number will 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) A provider or supplier that has been denied enrollment in the Medicare program or whose Medicare enrollment has been revoked may appeal CMS's decision in accordance with part 405, subpart H, for suppliers, or part 498, subpart A for providers, of this chapter, which set forth the appeals process for providers and suppliers. When revocation of billing privileges also results in the termination of a corresponding provider agreement, the provider may appeal CMS's decision in accordance with part 489 with the final decision of the appeal applying to both the billing privileges and the provider agreement. No payment will be made during the appeals process. If the provider or supplier is successful in overturning a denial or revocation unpaid claims for services furnished during the overturned period may be resubmitted.

(b) A provider or supplier whose billing privileges have been deactivated may file a rebuttal in accordance with § 405.374 of this chapter.

§ 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 a CMS 855 before completion of the change of ownership. If the current owner fails to complete and submit a CMS 855 to report the change, they 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 CMS 855 containing information concerning the new owner within 30 days of the change of ownership, CMS may deactivate the Medicare billing number. If an incomplete CMS 855 is submitted, CMS may also deactivate the Medicare billing number based upon material omissions on the submitted CMS 855, or based on preliminary information received or determined by CMS that makes CMS question whether the new owner will be ultimately granted a final transference of the provider agreement.

(c) *Providers and suppliers not covered by part 489 of this chapter.* For those providers and suppliers not covered by part 489, any change in the ownership or control of the provider or supplier must be reported on their CMS 855 within 30 days of the change as noted in § 424.540(a)(2). Generally, a change of ownership which also changes the tax identification number will require the completion and submission of a new CMS 855 from the new owner.

§ 424.555 Payment liability.

(a) No payment may be made for 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 covered services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier have been deactivated, denied, or revoked. The Medicare beneficiary has no financial responsibility for such 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 covered services.

(c) If any provider or supplier furnishes a service for which payment may not be made by reason of paragraph (b) of this section, any expense incurred for such 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 1128A(a)(6) of the Act.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

7. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

8. In § 489.53, paragraph (a)(15) is added to read as follows:

§ 489.53 Termination by CMS.

(a) * * *

(15) It had its enrollment in the Medicare program revoked pursuant to § 424.535 of this chapter.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFS/MR AND CERTAIN NFS IN THE MEDICARE PROGRAM

9. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

10. In § 498.3, paragraph (b)(16) is added to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(16) Whether a provider or supplier has had its Medicare enrollment revoked pursuant to § 424.535 of this chapter.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: October 19, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 10, 2003.

Tommy G. Thompson,

Secretary.

BILLING CODE 4120–01–P

MEDICARE

FEDERAL HEALTH CARE
PROVIDER/SUPPLIER ENROLLMENT APPLICATION

Application for Health Care Providers that will Bill Medicare Fiscal Intermediaries

CENTERS FOR MEDICARE & MEDICAID SERVICES

CMS 855A (01/2003)

OMB Approval No. 0938-0685

Keep a copy of this completed package for your own records

Upon completion, return this application and all necessary documentation to: