

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 280	Date: December 31, 2008
	Change Request 6282

SUBJECT: Incorporation of Recent Regulatory Revisions Pertinent to Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

I. SUMMARY OF CHANGES: This change request incorporates National Supplier Clearinghouse - Medicare Administrative Contractor (NSC-MAC) (hereinafter referred to as (NSC-MAC) instructions (currently found in the Scope of Work (SOW)) into Pub. 100-8, chapter 10 (hereinafter referred to as "chapter 10"), section 21, entitled "Special Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Instructions." These instructions evolved from recent regulatory revisions regarding the following topics: (1) the timeframe in which providers and suppliers must furnish developmental information to the contractor; (2) revocation reason number 11; (3) effective dates of certain types of revocations; (4) development and use of fraud level indicators; (5) alert codes; and (6) accreditation.

NEW / REVISED MATERIAL

EFFECTIVE DATE: February 2, 2009

IMPLEMENTATION DATE: February 2, 2009

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/1/1.1/Definitions
R	10/1/1.2/855 Medicare Enrollment Applications
R	10/3/3.1/Pre-Screening Process
R	10/13/13.2/Contractor Issued Revocations
R	10/13/13.3.2/CMS Satellite Office or Regional Office Identified Revocations
N	10/21/21.4/Development and Use of Fraud Level Indicators
N	10/21/21.4.1/Fraud Prevention and Detection
N	10/21/21.5/Alert Codes
N	10/21/21.6/Accreditation

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

Not Applicable.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-08	Transmittal: 280	Date: December 31, 2008	Change Request: 6282
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SUBJECT: Incorporation of Recent Regulatory Revisions Pertinent to Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

Effective Date: February 2, 2009

Implementation Date: February 2, 2009

I. GENERAL INFORMATION

A. Background: This change request incorporates National Supplier Clearinghouse – Medicare Administrative Contractor (NSC-MAC) (hereinafter referred to as “NSC-MAC”) instructions (currently found in the Scope of Work (SOW)) into Pub. 100-8, chapter 10 (hereinafter referred to as "chapter 10"), section 21, entitled “Special Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Instructions.” These instructions evolved from recent regulatory revisions regarding the following topics: (1) the timeframe in which providers and suppliers must furnish developmental information to the contractor; (2) revocation reason number 11; (3) effective dates of certain types of revocations; (4) development and use of fraud level indicators; (5) alert codes; and (6) accreditation.

NOTE: While the addition of new alert codes have no effect on claims payment, DME-MACs may use them as guidance in their review of claims payment or any claims related initiatives or investigations being performed or to be performed by the DME-MACs.

B. Policy: The purpose of this change request is to incorporate recent regulatory changes and applicable instructions for the NSC-MAC into chapter 10.

II. BUSINESS REQUIREMENTS TABLE

Use “Shall” to denote a mandatory requirement

Number	Requirement	Responsibility (place an “X” in each applicable column)									
		A / B M A C	D M M A C	F I	C A R I E R	R H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6282.1	The NSC-MAC shall note that definition for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) have been added to PIM chapter 10.										NSC-MAC
6282.2	The NSC-MAC shall note that definition for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers has been added to PIM chapter 10.										NSC-MAC
6282.3	The NSC-MAC shall note that definition for the NSC-MAC has been added to PIM chapter 10.										NSC-MAC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6282.4	The NSC-MAC shall note that in accordance with 42 CFR §424.525(a)(1), it may reject the supplier's CMS-855S application if the supplier fails to furnish complete information on the enrollment application, including all supporting documentation, within 30 calendar days from the date of the NSC-MAC's request for the missing information.										NSC-MAC
6282.5	The NSC-MAC shall note that per 42 CFR §405.874(b)(2), a revocation is effective 30 days after the NSC-MAC mails the notice of its determination to the provider or supplier.										NSC-MAC
6282.6	The NSC-MAC shall note that per 42 CFR §405.874(b)(2), a revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment.										NSC-MAC
6282.7	The NSC-MAC shall note that a revocation based on the revocation or suspension of the DMEPOS supplier's required license or certification can be made retroactive to the date of the license suspension/revocation.										NSC-MAC
6282.8	The NSC-MAC shall note that Revocation Reason 11 has been codified in 42 CFR §424.535(a)(8).										NSC-MAC
6282.9	The NSC-MAC shall perform a fraud potential analysis of all DMEPOS applicants and current DMEPOS suppliers.										NSC-MAC
6282.10	The NSC-MAC shall use four fraud level indicators to represent a DMEPOS supplier's potential for fraud and/or abuse.										NSC-MAC
6282.10a	The NSC-MAC shall use four fraud level indicator codes as follows: 1. Low Risk, 2. Limited Risk, 3. Medium Risk, and 4. High Risk.										NSC-MAC
6282.10b	Examples and guidance for defining the fraud level										NSC-MAC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
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	indicators will be found in PIM chapter 10.										
6282.11	High fraud areas shall be determined by the NSC-MAC's analysis with concurrence of the NSC-MAC's Project Officer.									NSC-MAC, CMS	
6282.12	In assessing a fraud level indicator, the NSC-MAC shall consider such factors as: <ul style="list-style-type: none"> 1. experience as a DMEPOS supplier with other payers, 2. prior Medicare experience, 3. the geographic area, 4. fraud potential of products and services listed, 5. site visit results 6. inventory observed and contracted, and 7. accreditation of the supplier. 									NSC-MAC	
6282.13	Suppliers who appear to be high risk in the assessment review may include the use of criminal background checks and a review of related businesses provided by an independent verification service as part of the assessment for a fraud level indicator. CMS shall contract for these services independently, as deemed necessary, per the NSC-MAC SOW.									NSC-MAC, CMS	
6282.14	After a fraud level indicator is assigned and the DMEPOS supplier is enrolled, the NSC-MAC shall establish a DMEPOS review plan based on the fraud level assessment. The DMEPOS review plan would contain information regarding: <ul style="list-style-type: none"> 1. Frequency of unscheduled site visits, 2. Maximum billing amounts before recommendation for prepay medical review, 3. Maximum billing spike amounts before recommendation for payment suspensions/prepay medical review, etc. 									NSC-MAC	
6282.15	The NSC-MAC shall update the fraud level indicator annually based upon information: <ul style="list-style-type: none"> 1. obtained through the Medicare enrollment 									NSC-MAC, CMS, PSCs/ ZPICs	

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	process, such as reported changes of information, 2. obtained by the Office of Inspector General, and/or 3. obtained from CMS, a payment safeguard contractor (PSC)/Zone program integrity contractor (ZPIC) or CMS satellite office.										
6282.16	The NSC-MAC should monitor and assess geographic trends which indicate or demonstrate that one geographic area has a higher potential for having fraudulent suppliers.										NSC-MAC
6282.17	Per 42 CFR §405.874(e), if a DMEPOS supplier completes a CAP and provides sufficient evidence to the NSC-MAC that it has complied fully with the Medicare requirements, the NSC-MAC shall have the option to reinstate the DMEPOS supplier's billing privileges. (The effective date is based on the date the DMEPOS supplier is in compliance with all Medicare requirements.)										NSC-MAC
6282.18	Prior to sending out a revocation letter, the NSC-MAC shall refer the matter to the Division of Provider and Supplier Enrollment (DPSE), which will make the determination as to the appropriate length of the re-enrollment bar under 42 CFR § 424.535(c).										NSC-MAC, CMS
6282.19	The NSC-MAC shall update their systems with four new alert codes indicating a DMEPOS supplier's fraud level indicator. These new alert codes are defined as: Q - Low Risk Fraud Level Indicator; R - Limited Risk Fraud Level Indicator; S – Medium Risk Fraud Level Indicator; and T - High Risk Fraud Level Indicator.										NSC-MAC
6282.20	The NSC-MAC shall append the DMEPOS supplier file the new alert codes (referenced in 6282.19), as applicable.										NSC-MAC
6282.21	The NSC-MAC shall advise the appropriate DME-MACs and PSCs/ZPICs of this information on a quarterly basis.		X								NSC-MAC, PSCs/ZPICs
6282.22	ViPS shall update the VMS reference manual with the								X		

Number	Requirement	Responsibility (place an "X" in each applicable column)																						
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	description of four new alert codes, Q, R, S and T for DMEPOS suppliers (referenced in 6282.19).																							
6282.23	VMS shall verify existing VMS functionality accepts from the NSC and stores on the Provider file (APPL/1/Alert Code/Provider Agreement subsystem) alert codes Q, R, S, and T.								X															
6282.24	<p>The NSC-MAC shall receive and maintain the following alert codes from the DME-MACs and PSCs/ZPICs:</p> <table border="0"> <tr> <td><u>Alert Code</u></td> <td><u>Definition</u></td> </tr> <tr> <td>A</td> <td>possible fraudulent or abusive claims identified;</td> </tr> <tr> <td>B</td> <td>overpayments;</td> </tr> <tr> <td>D</td> <td>violations of disclosure of ownership requirements;</td> </tr> <tr> <td>E</td> <td>violations of participation agreements;</td> </tr> <tr> <td>L</td> <td>suspended by Contractor outside alert code process; and</td> </tr> <tr> <td>M</td> <td>supplier is going through claims appeal process.</td> </tr> </table>	<u>Alert Code</u>	<u>Definition</u>	A	possible fraudulent or abusive claims identified;	B	overpayments;	D	violations of disclosure of ownership requirements;	E	violations of participation agreements;	L	suspended by Contractor outside alert code process; and	M	supplier is going through claims appeal process.		X							NSC-MAC, PSCs/ZPICs
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6282.25	<p>The NSC-MAC shall append the supplier file and transfer to the DME-MACs and PSCs/ZPICs the following alert codes in the following circumstances:</p> <table border="0"> <tr> <td><u>Alert Code</u></td> <td><u>Definition</u></td> </tr> <tr> <td>C</td> <td>violations of supplier standards;</td> </tr> <tr> <td>F</td> <td>sanctioned by the Office of Inspector General or excluded by the GSA;</td> </tr> <tr> <td>H</td> <td>meets supplier standards; however, the NSC-MAC recommends increased scrutiny by the Contractor (initiated by NSC-MAC only);</td> </tr> <tr> <td>N</td> <td>Supplier being investigated under the "Do Not Forward" initiative (initiated by NSC-MAC <u>only</u>);</td> </tr> <tr> <td>Q</td> <td>Low Risk Fraud Level Indicator;</td> </tr> <tr> <td>R</td> <td>Limited Risk Fraud Level</td> </tr> </table>	<u>Alert Code</u>	<u>Definition</u>	C	violations of supplier standards;	F	sanctioned by the Office of Inspector General or excluded by the GSA;	H	meets supplier standards; however, the NSC-MAC recommends increased scrutiny by the Contractor (initiated by NSC-MAC only);	N	Supplier being investigated under the "Do Not Forward" initiative (initiated by NSC-MAC <u>only</u>);	Q	Low Risk Fraud Level Indicator;	R	Limited Risk Fraud Level		X							NSC-MAC, PSCs/ZPICs
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							F I S S	M C S	V M S	C W F			
	S T												
6282.26	The NSC-MAC shall append an Alert Code "H" for any DMPOS supplier that meets current supplier standards but appears suspect in one of the areas that are verified by the NSC-MAC. This alert code notifies the DME-MACs and PSCs/ZPICs that a supplier may be inclined to submit a high percentage of questionable claims.		X										NSC-MAC, PSCs/ ZPICs
6282.27	The NSC-MAC shall share the above information with the DME-MACs and PSCs/ZPICs by sending alerts within 7 calendar days after identification of a supplier having common ownership or business ties with a sanctioned or suspect supplier for their research and/or action.		X										NSC-MAC, PSCs/ ZPICs
6282.28	The NSC-MAC shall forward alert codes submitted by the DME-MACs and/or PSCs/ZPICs with the other DME-MACs and/or PSCs/ZPICs within 7 calendar days after receipt.		X										NSC-MAC, PSCs/ ZPICs
6282.29	The NSC-MAC shall follow the accreditation requirements in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (individual medical practitioners, inclusive of group practices of same, shall not currently require accreditation for enrollment. The practitioner types are those specifically stated in Sections 1848(K)(3)(B) and 1842(b)(18)(C) of the Social Security Act as Amended) as well as physicians, orthotists, prosthetists, pedorthists, optometrists, opticians, audiologists, occupational therapists, physical therapists and suppliers who provide drugs and pharmaceuticals (only).												NSC-MAC
6282.30	The NSC-MAC shall note that suppliers (referenced in 6282.29) who provide other DMEPOS <u>outside</u> of their specialty are required to be accredited to bill Medicare as a DMEPOS supplier. DMEPOS companies that are owned by any exempted individuals are NOT exempt from accreditation.												NSC-MAC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
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6282.31	The NSC-MAC shall note that currently exempted suppliers (referenced in 6282.29) whose enrollment applications were previously returned for non-accreditation must resubmit their CMS-855S Medicare enrollment application to obtain/maintain Medicare billing privileges. Medicare billing privileges will not be retroactive due to new accreditation exemptions.										NSC-MAC

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6282.32	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										NSC-MAC, CMS

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact: Kimberly McPhillips, kimberly.mcphillips@cms.hhs.gov, (410) 786-5374.
Post-Implementation Contact: Kimberly McPhillips, kimberly.mcphillips@cms.hhs.gov, (410) 786-5374.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers and Regional Home Health Intermediaries (RHHIs)*:
not applicable

Section B: For *Medicare Administrative Contractors (MACs)*: The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Program Integrity Manual

Chapter 10 - Medicare Provider/Supplier Enrollment

Table of Contents
(Rev.280, 12-31-08)

21.4 – Development and Use of Fraud Level Indicators

21.4.1 Fraud Prevention and Detection

21.5 – Alert Codes

21.6 - Accreditation

1.1 – Definitions

(Rev.280, Issued: 12-31-08, Effective: 02-02-09, Implementation: 02-02-09)

Below is a list of terms commonly used in the Medicare enrollment process:

Applicant means the individual (practitioner/supplier) or organization who is seeking enrollment into the Medicare program.

Approve/Approval means the enrolling provider or supplier has been determined to be eligible under Medicare rules and regulations to receive a Medicare billing number and be granted Medicare billing privileges.

Authorized Official means an appointed official (e.g., chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.

Billing Agency means a company that the applicant contracts with to prepare, edit and/or submit claims on its behalf.

Change of Ownership (CHOW) is defined in 42 CFR §489.18 (a) and generally means, in the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law. In the case of a corporation, the term generally means the merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation. The transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.

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

Delegated Official means an individual who is delegated by the "Authorized Official," the authority to report changes and updates to the enrollment record. The delegated official must be an individual with an ownership or control interest in (as that term is defined in section 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of, the provider or supplier.

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges for Medicare covered items or services provided to Medicare beneficiaries.

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) means (1) durable medical equipment (as defined in section 1861(n) of the Social Security Act); (2) prosthetic devices (as described in section 1861(s)(8) of the Social Security Act); (3)

orthotics and prosthetic (as described in section 1861(s)(9) of the Social Security Act); (4) surgical dressings (as described in section 1861(s)(5) of the Social Security Act); (5) such other items as the Secretary may determine; (6) home dialysis supplies and equipment (as described in section 1861(s)(2)(F) of the Social Security Act); (7) immunosuppressive drugs (as described in section 1861(s)(2)(J) of the Social Security Act); (8) therapeutic shoes for diabetics (as described in section 1861(s)(12) of the Social Security Act); (9) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1861(s)(2)(Q) of the Social Security Act); and (10) self-administered erythropoietin (as described in section 1861(s)(2)(P) of the Social Security Act).

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier means a business or individual that furnishes durable medical equipment, prosthetics, orthotics and supplies.

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

- Identification of a provider or supplier;
- Validation of the provider or supplier's eligibility to provide items or services to Medicare beneficiaries;
- Identification and confirmation of the provider or supplier's practice locations and owners; and
- Granting the provider or supplier Medicare billing privileges.

Enrollment Application means a CMS-approved paper enrollment application or an electronic Medicare enrollment process approved by the Office of Management and Budget (OMB).

Legal Business Name is the name that is reported to the Internal Revenue Service (IRS).

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.

Medicare Identification Number is the generic term for any number, other than the National Provider Identifier, used by a provider or supplier to bill the Medicare program.

(For Part A providers, the Medicare Identification Number (MIN) is the CMS Certification Number (CCN). For Part B suppliers other than suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), the MIN is the

Provider Identification Number (PIN). For DMEPOS suppliers, the MIN is the number issued to the supplier by the NSC, *referred to as the Medicare supplier PTAN.*)

National Provider Identifier is the standard unique health identifier for health care providers (including Medicare suppliers) and is assigned by the National Plan and Provider Enumeration System (NPPES).

National Supplier Clearinghouse Medicare Administration Contractor (NSC-MAC) is the nationwide DMEPOS enrollment contractor (referred to as the NSC or the NSC-MAC).

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 items being rendered) to furnish these items or 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 sections 1124 and 1124(A) of the Social Security Act.

Prospective Provider means any entity specified in the definition of “provider” in 42 CFR §498.2 that seeks to be approved for coverage of its services by Medicare.

Prospective Supplier means any entity specified in the definition of “supplier” in 42 CFR §405.802 that seeks to be approved for coverage of its services under Medicare.

Provider is defined at 42 CFR §400.202 and generally means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency or hospice, that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services; or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Reassignment means that an individual physician or non-physician practitioner, except physician assistants, has granted a clinic or group practice the right to receive payment for the practitioner’s services.

Reject/Rejected means that the provider or supplier’s enrollment application was not processed due to incomplete information or that additional information or corrected information was not received from the provider or supplier in a timely manner.

Revoke/Revocation means that the provider or supplier’s billing privileges are terminated.

Supplier is defined in 42 CFR §400.202 and means a physician or other practitioner, or an entity other than a provider that furnishes health care services under Medicare.

Tax Identification Number means the number (either the Social Security Number (SSN) or Employer Identification Number (EIN)) the individual or organization uses to report tax information to the IRS.

1.2 – CMS-855 Medicare Enrollment Applications

(Rev.280, Issued: 12-31-08, Effective: 02-02-09, Implementation: 02-02-09)

The Medicare enrollment applications (CMS-855I, CMS-855R, CMS-855B, CMS-855A and CMS-855S) are forms issued by CMS and approved by OMB. (When available, the forms can be accessed through the Provider Enrollment, Chain and Ownership System's (PECOS) Web-based enrollment process, which is based off of the information collected on the CMS-855 forms.) The forms collect general information about providers, suppliers, and DMEPOS suppliers in order to:

- Ensure that the applicant is qualified and eligible to enroll in the Medicare program.
- Help determine the proper amount of Medicare payment.

The five forms are distinguished as follows:

- CMS-855I - This form should be completed by individual practitioners, including physicians and non-physician practitioners, who render Medicare Part B services to Medicare beneficiaries. (This includes a physician or practitioner who: (1) is the sole owner of a professional corporation, professional association, or limited liability company, and (2) will bill Medicare through this business entity.)
- CMS-855R - An individual who renders Medicare Part B services and seeks to reassign his or her benefits to an eligible entity should complete this form for each entity eligible to receive reassigned benefits. The person must be enrolled in the Medicare program as an individual prior to reassigning his or her benefits.
- CMS-855B - This application should be completed by a supplier organization (e.g., ambulance company) that will bill Medicare for Part B services furnished to Medicare beneficiaries. It is not used to enroll individuals.
- CMS-855A - This application should be completed by institutional providers (e.g., hospital) that will furnish Medicare Part A services to Medicare beneficiaries.
- CMS-855S – This application should be completed by DMEPOS suppliers. The NSC is responsible for processing this type of enrollment application.

A separate application must be submitted for each provider/supplier type. For example, a

physician who wishes to bill as a DMEPOS supplier must submit two separate applications.

When a prospective provider or supplier contacts the contractor to obtain a CMS-855 application, the contractor shall furnish:

- The CMS Web site at which the applications can be accessed (www.cms.hhs.gov/MedicareProviderSupEnroll);
- Notification of any supporting documentation required for the applicant's provider/supplier type;
- The Electronic Funds Transfer Authorization Agreement (CMS-588) (*Note: The NSC is only required to collect the CMS-588 with initial enrollment applications*);
- The Electronic Data Interchange (EDI) agreement (*Note: This does not apply to the NSC*);
- The Medicare Participating Physician or Supplier Agreement (CMS-460), with an explanation of the purpose of the agreement and how it differs from the actual enrollment process. (This only applies to carriers.)
- The contractor's address, so that the applicant knows where to return the completed application;
- If the applicant is a certified supplier or provider, notification that the applicant should contact the State agency for any state-specific forms and to begin preparations for a State survey. (This does not apply for those certified entities, such as FQHCs, that do not receive a State survey.) The notification can be given in any manner the contractor chooses.

3.1 – Pre-Screening Process

(Rev.280, Issued: 12-31-08, Effective: 02-02-09, Implementation: 02-02-09)

A. Rejection

In accordance with 42 CFR §424.525(a)(1) and (2), respectively, the contractor, *including the NSC-MAC* may reject the provider/*supplier's* application if the provider/*supplier* fails to furnish complete information on the enrollment application, including all supporting documentation, within 30 calendar days from the date of the contractor's request for the missing information or documentation.

The 30-day clock starts on the date the pre-screening letter was sent to the provider/*supplier*. If the contractor makes a follow-up request for information, the 30-day clock does not start anew; rather, it keeps running from the date the pre-screening

letter was sent. To illustrate, suppose that the contractor sent out a pre-screening letter on March 1 (thus triggering the 30-day clock) that asked for clarifying information in Sections 4 and 5 of the CMS-855B. (All supporting documentation was provided.) The provider sent in most, but not all of the requested data. Though not required to make an additional contact beyond the pre-screening letter, the contractor telephoned the provider on March 20 to request the remaining missing data. The provider failed to respond. The contractor can reject the application on March 31, which is 30 days after the initial request.

NOTE: The contractor has the discretion to extend the 30-day time period if it determines that the provider or supplier is actively working with the contractor to resolve any outstanding issues. However, if the contractor elects to extend the 30-day period, this does not stop or restart the 30-day clock; in other words, the clock keeps running from the date the initial request for information was made.

The contractor shall also note the following with respect to rejections:

- **PECOS** – The contractor (*with the exception of the NSC-MAC*) shall create an L & T record within the 15-day period prescribed in sections 2.3 and 15 of this *chapter*. If the contractor rejects the application and was unable to create an L & T record due to missing data, the contractor shall document the provider/*supplier* file accordingly. If the contractor was able to create the L & T record but rejected the application, the contractor shall flip the status to “rejected” in PECOS.
- **Resubmission after Rejection** – If the provider/*supplier's* application is rejected, the provider/*supplier* must complete and submit a new CMS-855 and all supporting documentation.
- **Appeals** – The provider/*supplier* may not appeal a rejection of its enrollment application.
- **Policy Application** – Unless stated otherwise in this *chapter*, the policies contained in this section 3.1 apply to all CMS-855 applications identified in sections 2.1 and 2.2 above (e.g., changes of information, reassignments). Thus, suppose an enrolled provider submits a CMS 588. If any information is missing from the form, the contractor shall send a pre-screening letter to the provider.

NOTE: The NSC-MAC only collects the CMS-588 for initial DMEPOS supplier enrollment applications (CMS-855S). The NSC-MAC does not have to include the CMS-588 in any pre-screening letter to a DMEPOS supplier that is not initially applying for a Medicare billing number.

- **Incomplete Responses** – The provider/*supplier* must furnish all missing and clarifying data requested by the contractor within the applicable timeframe. Whether the provider/*supplier* indeed furnished all the information is a decision that rests with the contractor. Moreover, if the provider/*supplier* furnishes some,

but not all, of the requested data within the applicable time period, the contractor is not required to contact the provider/*supplier* again to request the rest of the information. The contractor has the discretion to wait until the expiration of the applicable timeframe and then reject the application.

- **Notice of Rejection** – If the contractor rejects the application under this section 3.1, it shall notify the provider *or supplier* via letter or e-mail that the application is being rejected, the reason(s) for the rejection, and how to reapply. The contractor is free to keep the original application on file after rejection. If the provider *or supplier* requests a copy of its application, the contractor may fax it to the provider/*supplier*.
- **Documentation** – The contractor shall document in the file the date on which it completed its pre-screening of the application.
- **Commencement of Timeframe** – The 30-day clock identified in 42 CFR §424.525(a) commences when the contractor mails, faxes, or e-mails the pre-screening letter.
- **Acknowledgment of Receipt** – The contractor may, but is not required to, send out acknowledgment letters.
- **“Not Applicable”** - It is unacceptable for the provider *or supplier* to write “N/A” in response to a question that requires a “yes” or “no” answer. This is considered an incomplete reply, thus warranting the issuance of a pre-screening letter based on missing information.
- **“Pending”** – “Pending” is an acceptable response, requiring no further development, in the following situations:
 - **Section 2B2 of the CMS 855** - The license or certification cannot be obtained until after a State survey is performed or RO approval is granted.
 - **Section 4 of the CMS 855** - The license/certification cannot be obtained (or the practice location cannot be considered fully established) until after a State survey is performed or RO approval is granted.
 - **Medicare Identification Number** - New enrollees who have no Medicare billing number can write “pending” in the applicable “Medicare Identification Number” boxes. (This policy, however, does not apply to NPIs.)

***NOTE:** “Pending” as an acceptable response does not apply to DMEPOS supplier applicants.*

- **Licensure** - For certified suppliers and certified providers, there may be instances where a license may not be obtainable until after the State conducts a survey. Since the license is therefore not “required,” the contractor shall not consider this to be “missing” information or documentation. *This policy does not apply to DMEPOS suppliers.*
- **Section 6** – If an authorized or delegated official is not listed in section 6 of the CMS-855, this qualifies as an incomplete application and thus triggers the need for a pre-screening letter.

To summarize, if - during the pre-screening process - the contractor finds that data or documentation is missing, it shall send a pre-screening letter the provider *or supplier* within the 15-day pre-screening period. The provider/*supplier* must furnish all of the missing material or documentation within the applicable timeframe. If the provider/*supplier* fails to do so, the contractor may reject the application.

13.2 – Contractor Issued Revocations

(Rev.280, Issued: 12-31-08, Effective: 02-02-09, Implementation: 02-02-09)

A. Revocation Reasons

The contractor may issue a revocation (or recommend a revocation) using revocation reasons 1 through 10 below without prior approval from CMS. Section 13.3 lists an additional revocation reason that requires DPSE review and approval.

When issuing a revocation, the contractor shall insert the appropriate regulatory basis (e.g., 42 CFR §424.535(a)(1)) into its determination letter. The contractor shall not use provisions from this chapter 10 as the basis for revocation.

Revocations based on non-compliance:

Revocation 1 (42 CFR §424.535(a)(1))

The provider or supplier is determined not to be in compliance with the enrollment requirements described in this section or in the enrollment application applicable to its provider or supplier type, and has not submitted a plan of corrective action as outlined in 42 CFR Part 488.

Noncompliance includes, but is not limited to the provider or supplier no longer having a physical business address or mobile unit where services can be rendered and/or does not have a place where patient records are stored to determine the amounts due such provider or other person and/or the provider or supplier no longer meets or maintains general enrollment requirements.

Revocation 2

The provider or supplier has lost its license(s) or is not authorized by the Federal/state/local government to perform the services for which it intends to render. (In its revocation letter, the contractor shall cite the appropriate statutory and/or regulatory citations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the revocation letter the exact provision within said statute/regulation that the provider/supplier has failed to comply with.)

Revocation 3

The provider or supplier no longer meets CMS regulatory requirements for the specialty for which it has been enrolled. (In its revocation letter, the contractor shall cite the appropriate statutory and/or regulatory citations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the revocation letter the exact provision within said statute/regulation that the provider/supplier is not in compliance with.)

Revocation 4 (42 CFR §424.535(a)(1))

The provider or supplier (upon discovery) does not have a valid SSN/employer identification number for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or delegated or authorized official.

Revocations based on provider or supplier conduct:

Revocation 5 (42 CFR §424.535(a)(2))

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 42CFR §1001.2 , in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

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

If an excluded party is found, notify DPSE immediately. DPSE will notify the Government Task Leader (GTL) for the appropriate PSC. The GTL will, in turn, contact the Office of Inspector General's office with the findings for further investigation.

Revocations based on felony:

Revocation 6 (42 CFR §424.535(a)(2))

The provider, supplier, or any owner of the provider or supplier, within the 10 years preceding enrollment or revalidation of enrollment, was convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries to continue enrollment.

(i) Offenses include—

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(ii) Revocations 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.

Revocations based on false or misleading information:

Revocation 7 (42 CFR §424.535(a)(4))

The provider or supplier certified as “true” misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current law and regulations.)

If it is discovered that the provider or supplier deliberately falsified, misrepresented, or omitted information contained in the application or deliberately altered text on the application form, issue a revocation or recommendation for revocation.

Revocations based on misuse of billing number

Revocation 8 (42 CFR §424.535(a)(7))

The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers who enter into a valid reassignment of benefits as specified in 42CFR §424.80 or a change of ownership as outlined in 42CFR §489.18.

Additional revocation reasons:

Revocation 9 (42 CFR §424.535(a)(5))

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

(i) A Medicare Part A provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) A Medicare Part B supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

Revocation 10 (42 CFR §424.535(a)(6))

The provider or supplier fails to furnish complete and accurate information and all supporting documentation within 30 calendar days of the provider or supplier's notification from CMS to submit an enrollment application and supporting documentation.

B. Revocation Letters

In accordance with 42 CFR §405.874(b), all revocation letters shall be sent by certified mail and shall contain sufficient factual and background information so that the reader understands exactly why the revocation occurred. It is not enough to simply list one of the revocation reasons. All applicable regulations, as well as a detailed factual rationale for the contractor's decision, must be identified in the letter. For instance, if a provider is revoked based on the submission of false information, the contractor must identify in its letter the falsified information, how and why the contractor determined it was false, the regulation in question, etc. If there were multiple reasons for revocation, the letter shall state as such and shall furnish all of the aforementioned statutes, regulations, facts, etc. applicable to each reason. The notice must also identify the provider's right to appeal under 42 CFR Part 498 and the address to which the written appeal must be mailed. For more detailed information on the appropriate composition of revocation letters, see sections 14 and 19 of this chapter.

When a provider or supplier number is revoked, the contractor must maintain documentation as required by section 10 of this chapter. In addition, when a provider's or supplier's billing privileges are revoked, the provider agreement in effect at the time of revocation is also terminated.

Prior to issuing a revocation for a Part A provider or a certified Part B supplier, the contractor shall notify DPSE.

C. Effective Date of Revocations

Per 42 CFR §405.874(b)(2), a revocation is effective 30 days after CMS or the CMS contractor, *including the NSC-MAC*, mails the notice of its determination to the provider or supplier. However, a revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment. In addition, if the revocation was due to the revocation or suspension of the provider/supplier's license or certification to perform Medicare services, said revocation can be made retroactive to the date of the license suspension/revocation.

As stated in 42 CFR §424.535(d), if the revocation was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare services *and/or supplies*, the revocation may be reversed if the provider or supplier submits proof that it has terminated its business relationship with that individual or organization within 30 days of the revocation notification. The contractor, however:

- Need not solicit or ask for such proof in its recommendation letter. It is up to the provider/*supplier* to furnish this data on its own volition.
- Has the ultimate discretion to determine whether sufficient "proof" exists.

D. Payment

Per 42 CFR §405.874(b)(3), Medicare does not pay and a CMS contractor rejects claims for items or services submitted with a service date on or after the effective date of a provider's or supplier's revocation.

E. Corrective Action

Per 42 CFR §405.874(e), if a provider or supplier completes a corrective action plan and provides sufficient evidence to the contractor that it has complied fully with the Medicare requirements, the contractor may reinstate the provider's or supplier's billing privileges. The contractor may pay for services furnished on or after the effective date of the reinstatement. The effective date is based on the date the provider or supplier is in compliance with all Medicare requirements.

A contractor's refusal to reinstate the provider or supplier's billing privileges based on a corrective action plan is not an initial determination under 42CFR part 498.

F. Reapplying After Revocation

As stated in 42 CFR §424.535(c), after a provider, supplier, *DMEPOS supplier*, delegated official, or authorizing official that has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation. For instance, a revocation on the grounds that the provider *or DMEPOS supplier* is no longer operational will generally warrant a 2 year bar; a revocation based on a felony conviction or the submission of false information will typically result in a 3 year bar.

Prior to sending out the revocation letter, the contractor, *including the NSC-MAC*, shall refer the matter to DPSE, which will make the determination as to the appropriate length of the re-enrollment bar.

13.3.2 - CMS Satellite Office or Regional Office Identified Revocations *(Rev.280, Issued: 12-31-08, Effective: 02-02-09, Implementation: 02-02-09)*

If a CMS satellite office or regional office believes that the use of revocation 11 (see 42 CFR §424.535(a)(8) and section 13.2 of this chapter) is appropriate, the CMS satellite office or regional office will develop a case file, including the reason(s) for revocation, and submit the case file and all supporting documentation to DPSE. The CMS satellite office or regional office will provide the DPSE with the name, all known billing numbers, including the NPI and associated Medicare billing numbers, and locations of the provider or supplier in question as well as detailed information to substantiate the revocation action.

If DPSE concurs with revocation recommendation, DPSE will instruct the applicable contractor to revoke the billing number and notify DBIMO of the action taken.

Revocation 11 (42 CFR §424.535(a)(8))

The provider, supplier or *DMEPOS supplier* submits a claim or claims for services *or supplies* that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

21.4 - Development and Use of Fraud Level Indicators
(Rev.280, Issued: 12-31-08, Effective: 02-02-09, Implementation: 02-02-09)

The NSC-MAC shall perform a fraud potential analysis of all DMEPOS applicants and current DMEPOS suppliers. The fraud level indicator shall represent the potential for fraud and/or abuse. The NSC-MAC shall use four fraud level indicator codes as follows:

- 1. Low Risk (e.g., national drug store chains),*
- 2. Limited Risk (e.g., prosthetist in a low fraud area),*
- 3. Medium Risk (e.g., midsize general medical supplier in a high fraud area), and*
- 4. High Risk (e.g., very small space diabetic supplier with low inventory in a high fraud area whose owner has previously had a chapter 7 bankruptcy). High fraud areas shall be determined by contractor analysis with concurrence of the NSC-MAC's project officer.*

In assessing a fraud level indicator, the NSC-MAC shall consider such factors as:

- 1. Experience as a DMEPOS supplier with other payers,*
- 2. Prior Medicare experience,*
- 3. The geographic area,*
- 4. Fraud potential of products and services listed,*
- 5. Site visit results,*
- 6. Inventory observed and contracted, and*
- 7. Accreditation of the supplier.*

After a fraud level indicator is assigned and the DMEPOS supplier is enrolled, the NSC-MAC shall establish a DMEPOS Review Plan based on the fraud level assessment. The DMEPOS Review Plan would contain information regarding:

- 1. Frequency of unscheduled site visits,*
- 2. Maximum billing amounts before recommendation for prepay medical review,*
- 3. Maximum billing spike amounts before recommendation for payment suspensions/prepay medical review, etc.*

The fraud level indicator shall be updated based upon information obtained through the Medicare enrollment process, such as reported changes of information.

Information obtained by the Office of Inspector General (OIG), CMS (including CMS satellite office) and/or a PSC shall be reported to the NSC-MAC project officer or its designee. The NSC-MAC shall update the fraud level indicator based on information obtained by the OIG, CMS (including CMS satellite office) and/or a PSC only after the review and concurrence of the NSC-MAC project officer or its designee.

In addition, the NSC-MAC should monitor and assess geographic trends which indicate or demonstrate that one geographic area has a higher potential for having fraudulent suppliers.

21.4.1 - Fraud Prevention and Detection

(Rev.280, Issued: 12-31-08, Effective: 02-02-09, Implementation: 02-02-09)

The NSC-MAC shall have documented evidence that they have, as a minimum, met the requirements shown below:

- *Assign an appropriate fraud level indicator for at least 95 percent of all DMEPOS suppliers, upon initial or reenrollment. The fraud level indicator shall accurately reflect the risk the supplier poses to the Medicare program based on pre-defined criteria above.*
- *Update the DMEPOS fraud level indicator for each enrolled DMEPOS supplier on an annual basis.*

21.5 - Alert Codes

(Rev.280, Issued: 12-31-08, Effective: 02-02-09, Implementation: 02-02-09)

The NSC-MAC shall receive and maintain the following “alert indicators” from the DME-MACs and payment safeguard contractors (PSCs)/zone program integrity contractors (ZPICs):

<u>Alert Code</u>	<u>Definition</u>
<i>A</i>	<i>possible fraudulent or abusive claims identified;</i>
<i>B</i>	<i>overpayments;</i>
<i>D</i>	<i>violations of disclosure of ownership requirements;</i>
<i>E</i>	<i>violations of participation agreements;</i>
<i>L</i>	<i>suspended by Contractor outside alert code process; and</i>
<i>M</i>	<i>supplier is going through claims appeal process.</i>

The NSC-MAC shall append the supplier file and transfer to the DME-MACs and PSCs/ZPICs the following alert codes in the following circumstances:

<u>Alert Code</u>	<u>Definition</u>
<i>C</i>	<i>Violations of supplier standards;</i>
<i>F</i>	<i>Sanctioned by the Office of Inspector General or excluded by the GSA;</i>
<i>H</i>	<i>Meets supplier standards; however, the NSC-MAC recommends increased scrutiny by the contractor (initiated by NSC-MAC only);</i>

<i>N</i>	<i>Supplier being investigated under the "Do Not Forward" initiative (initiated by NSC-MAC <u>only</u>);</i>
<i>Q</i>	<i>Low Risk Fraud Level Indicator;</i>
<i>R</i>	<i>Limited Risk Fraud Level Indicator;</i>
<i>S</i>	<i>Medium Risk Fraud Level Indicator; and</i>
<i>T</i>	<i>High Risk Fraud Level Indicator.</i>

The NSC-MAC shall append an Alert Code "H" for any supplier that meets present supplier standards but appears suspect in one of the areas that are verified by the NSC-MAC. This alert code notifies the contractors that a supplier may be inclined to submit a high percentage of questionable claims.

The NSC-MAC shall share the above information with the DME-MACs and PSCs/ZPICs by sending alerts within 7 calendar days after identification of a supplier having common ownership or business ties with a sanctioned or suspect supplier for their research and/or action. The NSC-MAC also shall forward alert codes submitted by the contractors with the other contractors within 7 calendar days after receipt.

21.6 - Accreditation

(Rev.280, Issued: 12-31-08, Effective: 02-02-09, Implementation: 02-02-09)

The NSC-MAC shall follow the accreditation requirements in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

Individual medical practitioners, inclusive of group practices of same, shall not currently require accreditation for enrollment. The practitioner types are those specifically stated in Sections 1848(K)(3)(B) and 1842(b)(18)(C) of the Social Security Act as Amended. In addition, the practitioner categories of physicians, orthotists, prosthetists, optometrists, opticians, audiologists, occupational therapists, physical therapists and suppliers who provide drugs and pharmaceuticals (only) shall not currently require accreditation for enrollment.

Suppliers that provide only drugs and pharmaceuticals are exempt from the accreditation requirement; however, if the supplier provides equipment to administer drugs or pharmaceuticals, the supplier must be accredited.

If a previously exempted supplier enrollment application was returned for non-accreditation, the supplier must resubmit its CMS-855S Medicare enrollment application to the NSC to obtain/maintain Medicare billing privileges.