CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 236	Date: February 1, 2008
	Change Request 5892

SUBJECT: Update to Chapter 10

I. SUMMARY OF CHANGES: This update to chapter 10 contains a number of revisions. First, it furnishes guidance on the handling on CMS-855 change of information requests that cannot be processed to completion. Second, it eliminates the need for the contractor to make a recommendation for approval to the regional office in certain situations. Third, it adds several supplier types to section 12, et al., of chapter 10. Finally, it provides instructions on the accreditation of suppliers of durable medical equipment, prosthetics, orthotics and supplies.

NEW / REVISED MATERIAL
EFFECTIVE DATE: JANUARY 1, 2008
IMPLEMENTATION DATE: March 3, 2008

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/Table of Contents
R	10/3.2/Returning the Application
R	10/4.21/National Provider Identifier (NPI)
R	10/7/Changes of Information
R	10/7.1/General Procedures
R	10/7.1.1/Changes of Information and Complete CMS-855 Applications
N	10/7.1.2/Incomplete or Unverifiable Changes of Information
R	10/7.2/Special Instructions for Certified Providers, ASCs, and Portable X-Ray Suppliers (PXRSs)
R	10/7.3/Voluntary Terminations
R	10/8/Electronic Fund Transfers (EFT)
D	10/11.9/Enrolling Indian Health Service (IHS) Facilities as Durable Medical Equipment, Prosthetics, Orthotics and Supplies

	(DMEPOS) Suppliers
R	10/12.2/Carrier-Enrolled Organizational Suppliers
R	10/12.2.2/CLIA Labs
R	10/12.2.3/Mammography Screening Centers
N	10/12.2.4/Pharmacies
N	10/12.2.5/Portable X-Ray Suppliers (PXRS)
N	10/12.2.6/Radiation Therapy Centers
N	10/12.2.7/Slide Preparation Facilities
R	10/12.4.10/Physicians
R	10/12.4.11/Physician Assistants (PAs)
R	10/12.4.12/Psychologists Practicing Independently
N	10/12.4.13/Registered Dietitians
R	10/13.1/CMS or Contractor Issued Deactivations
N	10/13.2.1/Revocations Involving Certified Suppliers and Providers
N	10/21/Special Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Instructions
N	10/21.1/DMEPOS Supplier Accreditation
N	10/21.2/Enrolling Indian Health Service (IHS) Facilities as DMEPOS Suppliers

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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: 236	Date: February 1, 2008	Change Request: 5892

SUBJECT: Update to Chapter 10

Effective Date: January 1, 2008

Implementation Date: March 3, 2008

I. GENERAL INFORMATION

A. Background: This update to chapter 10 (hereinafter referred to as "chapter 10") contains a number of revisions. First, it furnishes guidance on the handling of CMS-855 change of information requests that cannot be processed to completion. Second, it eliminates the need for the contractor to make a recommendation for approval to the regional office in certain situations. Third, it adds the following supplier types to section 12, et al., of chapter 10: mammography screening centers, pharmacies, physicians, radiation therapy centers and slide preparation facilities. Finally, it provides instructions on the accreditation of suppliers of durable medical equipment, prosthetics, orthotics and supplies.

With the exception of the items identified in the previous paragraph or in the business requirements below, all changes in this CR are editorial, grammatical, or structural in nature, and do not involve the revision or alteration of any existing provider enrollment policies.

B. Policy: The purpose of this change request is to ensure that chapter 10, of the Program Integrity Manual accurately reflects CMS existing provider enrollment policies.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
5892.1	Per section 3.2 of chapter 10, the contractor shall return the CMS-855 application to the provider if it discovers or determines that the provider submitted the application for the sole purpose of enrolling in Medicaid; the only exception to this is when the provider is required to submit a Medicare cost report in order to participate in a State Medicaid program.	X		X	X	X					
5892.2	With respect to DMEPOS suppliers, the National Supplier Clearinghouse (NSC) shall obtain the NPPES notification from the applicant or verify the NPI and the Type of NPI (i.e., Type 1 or Type 2) through the NPI Registry.										NSC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
5892.3	In situations where the contractor cannot process a particular CMS-855 change of information to completion because: (1) the provider failed to furnish requested clarifying data, (2) the information on the application cannot be appropriately verified, or (3) the provider does not have an enrollment record in the Provider Enrollment, Chain and Ownership System (PECOS) and fails to submit a complete CMS-855 in response to the contractor's request, the contractor shall follow the instructions in section 7.1.2 of chapter 10.	X		X	X	X					
5892.4	Per section 7.2 of chapter 10, if the contractor receives a CMS-855 change request that deletes a practice location or subunit, it may terminate the location/unit without making a recommendation to the State and RO; however, no later than 3 business days after the contractor has finished processing the deletion, it shall notify the State and RO thereof via letter, e-mail, or fax.	X		X	X	X					
5892.5	If a certified provider, ambulatory surgical center (ASC), or portable x-ray supplier (PXRS) submits a CMS-855 voluntary termination application, the contractor may terminate the entity without making a recommendation to the State and RO; however, no later than 3 business days after the contractor has finished processing the termination, it shall notify the State and RO thereof via letter, e-mail, or fax.	X		X	X	X					
5892.6	If one of the revocation reasons identified in section 13.2, of chapter 10, is implicated, the contractor may revoke the billing privileges of a certified provider, ASC or PXRS without making a recommendation to the State and RO; however, no later than 3 business days after issuing the revocation notice, the contractor shall contact the State and RO thereof via letter, e-mail or fax.	X		X	X	X					
5892.7	The contractor shall note that DMEPOS suppliers must be accredited prior to submitting an application to the NSC on or after March 1, 2008; the NSC shall not approve any DMEPOS supplier's enrollment										NSC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	application if the enrollment package does not contain an approved accreditation upon receipt or in response to a developmental request.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	None.										

IV. SUPPORTING INFORMATION

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

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Frank Whelan, frank.whelan@cms.hhs.gov, (410) 786-1302
Post-Implementation Contact(s): Frank Whelan, frank.whelan@cms.hhs.gov, (410) 786-1302

VI. FUNDING

A. For *Fiscal Intermediaries and Carriers:* No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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 - Healthcare Provider/Supplier Enrollment

Table of Contents
(Rev.236, 02-01-08)

3.2 – Returning the Application

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

A. Immediate Returns

The contractor shall immediately return the enrollment application to the provider in the instances described below. This policy applies to all applications identified in sections 2.1 and 2.2 of this manual:

- There is no signature on the CMS-855 application;
- The provider submits the 11/2001 version of the CMS-855 application;
- The application contains a copied or stamped signature;
- The signature on the application is not dated;
- The CMS-855I application was signed by someone other than the individual practitioner applying for enrollment;
- The applicant failed to submit all of the forms needed to process a reassignment package within 15 calendar days of receipt (as described in section 5.4 of this manual);
- The applicant sent its CMS-855 to the wrong contractor (e.g., the application was sent to Carrier X instead of Carrier Y);
- The applicant completed the form in pencil;
- The applicant submitted the wrong application (e.g., a CMS-855B was submitted to a fiscal intermediary);
- If a Web-generated application is submitted, it does not appear to have been downloaded off of CMS's Web site;
- An old owner or new owner in a CHOW submitted its application more than 3 months prior to the anticipated date of the sale. (This only applies to fiscal intermediaries.)
- The application was faxed or e-mailed in;
- The contractor received the application more than 30 days prior to the effective date listed on the application. (This does not apply to certified providers, ASCs, or portable x-ray suppliers.);

- The contractor can confirm that the provider submitted a new enrollment application prior to the expiration of the time period in which the provider is entitled to appeal the denial of its previously submitted application;

- The contractor discovers or determines that the provider submitted a CMS-855 application for the sole purpose of enrolling in Medicaid; *the only exception to this is when the provider is required to submit a Medicare cost report in order to participate in a State Medicaid program;*

- The CMS-855 is not needed for the transaction in question. (A common example is an enrolled physician who wants to change his reassignment of benefits from one group to another group and submits a CMS 855I and a CMS 855R. As only the CMS 855R is needed, the CMS-855I shall be returned.);

- The CMS-588 was sent in as a stand-alone change of information request (i.e., it was not accompanied by a CMS-855) but was (1) unsigned, (2) undated, or (3) contained a copied, stamped, or faxed signature.

The contractor need not request additional information in any of the scenarios described above. Thus, for instance, if the application was not signed, the contractor can return the application immediately.

NOTE: The difference between a "rejected" application and a "returned" application; the former is based on the provider's failure to respond to the contractor's request for missing or clarifying information. A "returned" application is considered a non-application.

For CMS-855A and CMS-855B applications, if the form is signed but it appears the person does not have the authority to do so, the contractor shall process the application normally and follow the instructions in sections 4.15 and 4.16 accordingly. Returning the application on this basis alone is not permitted.

B. Procedures for Returning the Application

If the contractor returns the application:

- It shall notify the provider via letter or e-mail that the application is being returned, the reason(s) for the return, and how to reapply.

- It shall <u>not</u> enter the application into PECOS. No L & T record shall be created.

- Any application resubmission must contain a brand new certification statement page containing a signature and date. The provider cannot simply add its signature to the original certification statement it submitted.

- Return all other documents submitted with the application (e.g., CMS-588, CMS-460).

C. EFT Agreements

A non-signature on the CMS-588 EFT form (assuming that it is submitted in conjunction with a CMS-855 initial application or change request) is not grounds for returning the entire application package. The contractor shall simply develop for the signature using the procedures cited in section 5.3 of this manual. However, the EFT form must contain an original signature when it is finally submitted. Faxed EFT agreements are not permitted. (This is an exception to the general rule in section 5.3 that contractors can receive additional or clarifying information via fax.) Once the provider submits an EFT agreement with an original signature, any additional or clarifying information the contractor needs with respect to that document can be submitted by the provider via fax. (The provider must still, of course, furnish a new signature when it adds the new information.)

4.21 – National Provider Identifier (NPI)

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

A. Submission of NPI

Every provider that submits an enrollment application must furnish its NPI(s) in the applicable section(s) of the CMS-855. The provider need not submit a copy of the NPI notification it received from the National Plan and Provider Enumeration System (NPPES) unless requested to do so by the contractor. Similarly, if the provider obtained its NPI via the Electronic File Interchange (EFI) mechanism, the provider need not submit a copy of the notification it received from its EFI Organization (EFIO) unless requested to do so by the contractor. (The notification from the EFIO will be in the form of a letter or e-mail.) If paper documentation of a provider's NPI is requested by the contractor, the latter may accept a copy of the provider's NPI Registry's Details Page in lieu of a copy of the NPI notification. The Details Page contains more information than is contained on the NPI notification, and providers may be able to furnish NPI Registry Details Pages more quickly than copies of their NPI notifications.

The aforementioned requirement to list all applicable NPIs on the CMS-855 applies to all applications listed in sections 2.1 and 2.2 of this manual. (The only exceptions to this involve voluntary terminations, deactivations, deceased providers, and CHOW applications submitted by the old owner. NPIs are not required in these instances.) Thus, for instance, if a reassignment package (as described in section 5.4 of this manual) is implicated, the NPIs for all involved individuals and entities must be furnished; even if an individual is reassigning benefits to an enrolled group, the group's NPI must be furnished on the CMS-855R.

If the provider fails to submit the mandatory NPI data, the contractor shall follow the instructions in section 3.1 of this manual.

NOTE: *The NSC shall obtain the NPPES notification from the applicant or verify the NPI and the Type of NPI (i.e., Type 1 or Type 2) through the NPI Registry.*

B. Additional NPI Information

If a provider submits an NPI notice to the contractor as a stand-alone document (i.e., no CMS 855 was submitted), the contractor shall not create an L & T record in PECOS for the purpose of entering the NPI. The contractor shall simply place the notice in the provider file. Contractors shall only enter NPI data into PECOS that is submitted in conjunction with a CMS 855 (e.g., initial, change request). Thus, if a provider submits a CMS 855 change of information that only reports the provider's newly assigned NPI, or reports multiple NPIs that need to be associated with a single Medicare identification number, the contractor may treat this as a change request and enter the data into PECOS.

C. Subparts - General

The contractor shall review and become familiar with the principles outlined in the "Medicare Expectations Subpart Paper," the text of which follows below:

The CMS encourages all providers to obtain NPIs in a manner similar to how they receive OSCAR numbers (i.e., a "one-to-one relationship"). For instance, suppose a home health agency is enrolling in Medicare. It has a branch as a practice location. The main provider and the branch will typically receive separate (albeit very similar) OSCAR numbers. It would be advisable for the provider to obtain an NPI for the main provider and another one for the branch – that is, one NPI for each OSCAR number.

Further instructions on how contractors shall deal with NPI-related matters will be issued in the near future.

D. Medicare Subparts Paper - Text

MEDICARE EXPECTATIONS ON DETERMINATION OF SUBPARTS BY MEDICARE ORGANIZATION HEALTH CARE PROVIDERS WHO ARE COVERED ENTITIES UNDER HIPAA

January 2006

Purpose of this Paper

Medicare assigns unique identification numbers to its enrolled health care providers that are used to identify the enrolled health care providers in the HIPAA standard transactions that they conduct with Medicare (such as electronic claims, remittance advices, eligibility inquiries/responses, claim status inquiries/responses, and coordination of benefits) and in cost reports and other non-standard transactions.

This paper is a reference for Medicare carriers and fiscal intermediaries (FIs). It reflects the Medicare program's expectations on how its enrolled organization health care providers who are covered entities under HIPAA1 will determine subparts and obtain NPIs for themselves and any subparts. These expectations may change over time to correspond with any changes in Medicare statutes, regulations, or policies that affect Medicare provider enrollment.

These expectations are based on the NPI Final Rule, on statutory and regulatory requirements with which Medicare must comply, and on policies that are documented in Medicare operating manuals but have not yet been codified. These Medicare statutes, regulations and policies pertain to conditions for provider participation in Medicare, enrollment of health care providers in Medicare and assignment of identification numbers for billing and other purposes, submission of cost reports, calculation of payment amounts, and the reimbursement to enrolled providers for services furnished to Medicare beneficiaries.

---

1 Covered entities under HIPAA are health plans, health care clearinghouses, and those health care providers who transmit any health information in electronic form in connection with a health transaction for which the Secretary of HHS has adopted a standard (referred to in this paper as HIPAA standard transactions). Most Medicare Organization health care providers send electronic claims to Medicare (they are HIPAA standard transactions), making them covered health care providers (covered entities).

This paper categorizes Medicare's enrolled organization health care providers as follows:

- Certified providers and suppliers
- Supplier groups and supplier organizations
- Suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS)

This paper is not intended to serve as official HHS guidance to the industry in determining subparts for any covered health care providers other than those who are organizations and are enrolled in the Medicare program. This paper does not address health care providers who are enrolled in Medicare as individual practitioners. These practitioners are Individuals (such as physicians, physician assistants, nurse practitioners, and others, including health care providers who are sole proprietors). In terms of NPI assignment, an Individual is an Entity Type 1 (Individual) and is eligible for a single NPI. As Individuals, these health care providers cannot be subparts and cannot designate subparts. A sole proprietorship is a form of business in which one person owns all of the assets of the business and the sole proprietor is solely liable for all of the debts of the business. There is no difference between a sole proprietor and a sole proprietorship. In terms of NPI assignment, a sole proprietor/sole proprietorship is an Entity Type 1 (Individual) and is eligible for a single NPI. As an Individual, a sole proprietor/sole proprietorship cannot have subparts and cannot designate subparts.

Discussion of Subparts in the NPI Final Rule and its Applicability to Enrolled Medicare Organization Health Care Providers

The NPI Final Rule adopted the National Provider Identifier (NPI) as the standard unique health identifier for health care providers for use in HIPAA standard transactions. On or before May 23, 2007, all HIPAA covered entities (except small health plans), to include enrolled Medicare providers and suppliers that are covered entities, must obtain NPIs and must use their NPIs to identify themselves as "health care providers" in the HIPAA standard transactions that they conduct with Medicare and other covered entities. Covered organization health care providers are responsible for determining if they have "subparts" that need to have NPIs. If such subparts exist, the covered organization health care provider must ensure that the subparts obtain their own unique NPIs, or they must obtain them for them.

The NPI Final Rule contains guidance for covered organization health care providers in determining subparts. Subpart determination is necessary to ensure that entities within a covered organization health care provider that need to be uniquely identified in HIPAA standard transactions obtain NPIs for that purpose.

The following statements apply to **all** entities that could be considered subparts:

- A subpart is not itself a separate legal entity, but is a part of a covered organization health care provider that is a legal entity. (All covered entities under HIPAA are legal entities.)

- A subpart furnishes health care as defined at 45 CFR 160.103.

The following statements may relate to some or all of the entities that a Medicare covered organization health care provider could consider as subparts:

- A subpart may or may not be located at the same location as the covered organization health care provider of which it is a part.

- A subpart may or may not have a Taxonomy (Medicare specialty) that is the same as the covered organization health care provider of which it is a part.

- Federal statutes or regulations pertaining to requirements for the unique identification of enrolled Medicare providers may relate to entities that could be considered subparts according to the discussion in the NPI Final Rule. Medicare covered organization health care providers must take any such statutes or regulations into account to ensure that, if Medicare providers are uniquely identified now by using Medicare identifiers in HIPAA standard transactions, they obtain NPIs in order to ensure they can continue to be uniquely identified. Medicare is transitioning from the provider identifiers it currently uses in HIPAA standard transactions (for organizations, these could be OSCAR Numbers, PINs, or NSC Numbers—known as legacy identifiers or legacy numbers) to NPIs. This makes it necessary that Medicare organization health care providers obtain NPIs because the NPIs will replace the identifiers currently in use in standard transactions with Medicare and with all other health plans. In addition, Medicare organization health care providers must determine if they have subparts that need to be uniquely identified for Medicare purposes (for example, in HIPAA standard transactions conducted with Medicare). If that is the case, the subparts will need to have their own unique NPIs so that they can continue to be uniquely identified in those transactions.

- A subpart that conducts any of the HIPAA standard transactions separately from the covered organization health care provider of which it is a part must have its own unique NPI.

Enrolled Medicare organization health care providers who are covered entities under HIPAA must apply for NPIs as Organizations (Entity Type 2). Organization health care providers as discussed in this paper are corporations or partnerships or other types of businesses that are considered separate from an individual by the State in which they exist. Subparts of such organization health care providers who apply for NPIs are also Organizations (Entity Type 2).

Medicare Statutes, Regulations, Manuals

The Social Security Act (sections 1814, 1815, 1819, 1834, 1861, 1865, 1866, and 1891) and Federal regulations (including those at 42 CFR 400.202, 400.203, 403.720, 405.2100, 409.100, 410.2, 412.20, 416.1, 418.1, 424, 482.1, 482.60, 482.66, 483, 484, 485, 486, 489, 491, and 493.12) establish, among other things, the Conditions for Participation for Medicare providers and set requirements by which Medicare enrolls providers, requires cost reports, calculates

2 Clinical laboratory certification is handled by the Food and Drug Administration.

reimbursement, and makes payments to its providers. These Medicare statutory and regulatory requirements are further clarified in various Medicare operating manuals, such as the State Operations Manual and the Program Integrity Manual, in which requirements and policies concerning the assignment of unique identification numbers, for billing and other purposes, are stated.

Medicare Organization Providers and Subparts: Certified Providers and Suppliers

Existing Medicare laws and regulations do not establish requirements concerning the assignment of unique identification numbers to Medicare certified providers and suppliers for billing purposes.

Certified Providers that bill Medicare fiscal intermediaries (hereinafter referred to as "providers"):

- Providers apply for Medicare enrollment by completing a CMS-855A.
- Most providers are surveyed and certified by the States[3] prior to being approved as Medicare providers.
- Providers have in effect an agreement to participate in Medicare.[4]
- Providers include, but are not limited to: skilled nursing facilities, hospitals[5], critical access hospitals, home health agencies, rehabilitation agencies (outpatient physical therapy, speech therapy), comprehensive outpatient rehabilitation facilities, hospices, community mental health centers, religious non-medical health care institutions.
- Providers are assigned OSCAR numbers to use to identify themselves in Medicare claims and other transactions, including cost reports for those providers that are required to file Medicare cost reports.
- In general, each entity that is surveyed and certified by a State is separately enrolled in Medicare and is considered a Medicare provider. (An exception involves home health agency branches. The branches are not separately enrolled Medicare providers.) In many cases, the enrolled provider is not itself a separate legal entity; i.e., it is an entity that is a part of an enrolled provider that is a legal entity and is, for purposes of the NPI Final Rule, considered to be a subpart.

Certified Suppliers, most of which bill Medicare carriers:

- Certified suppliers apply for Medicare enrollment by completing a CMS-855B.
- Certified suppliers include ambulatory surgical centers, portable x-ray suppliers, independent clinical labs (CLIA labs), rural health centers, and federally qualified health centers.
- Most certified suppliers bill the carriers; however, rural health centers and federally qualified health centers bill the fiscal intermediaries.

---

3 Religious non-medical health care institutions are handled differently.

4 Community mental health centers attest to such an agreement. Religious non-medical health care institutions are handled differently.

5 Hospitals bill carriers for certain types of services.

- Certified suppliers are typically surveyed and certified by the States prior to being approved for enrollment as Medicare certified suppliers. (For CLIA labs, each practice location at which lab tests are performed must obtain a separate CLIA Certificate for that location, though there are a few exceptions to this.)
- Certified suppliers may have in effect an agreement to participate in Medicare.
- Certified suppliers are assigned OSCAR numbers for purposes of identification within Medicare processes. However, the carriers assign unique identification numbers to certified suppliers for billing purposes. (For CLIA labs, a CLIA Number is typically assigned to each practice location for which a CLIA certificate is issued. A CLIA Number may not be used to identify a clinical laboratory as a "health care provider" in HIPAA standard transactions. The CLIA Number has no relation to the Medicare billing number.)

- In many cases, the enrolled certified supplier is not itself a separate legal entity; i.e., it is an entity that is a part of an enrolled provider or certified supplier that is a legal entity and is, for purposes of the NPI Final Rule, considered to be a subpart.

In general, Medicare bases its enrollment of providers and certified suppliers on two main factors: (1) whether a separate State certification or survey is required, and (2) whether a separate provider or certified supplier agreement is needed. (The Taxpayer Identification Number, or TIN, is a consideration as well, though not to the degree of the two main factors.) The CMS regional offices generally make the final determinations on both of these factors; hence, Medicare provider and certified supplier enrollment policy is dictated to a significant degree by the CMS regional offices' decisions in particular cases.

Medicare Expectations for NPI Assignments for Providers and Certified Suppliers: To help ensure that Medicare providers and certified suppliers do not experience denials of claims or delays in Medicare claims processing or reimbursement, Medicare encourages each of its enrolled providers and certified suppliers to obtain its own unique NPI. These NPIs will eventually replace the legacy numbers that are used today in HIPAA standard transactions and in other transactions, such as cost reports. In order for subpart determinations to mirror Medicare enrollment, each enrolled provider and certified supplier that is a covered organization health care provider would ensure the following:

- Obtain its own unique NPI.
- Determine if it has any subparts that are themselves enrolled Medicare providers. If there are subparts, ensure that they obtain their own unique NPIs, or obtain the NPIs for them. Example: An enrolled provider (a hospital) owns 10 home health agencies, all operating under the TIN of the hospital. Because the hospital and each of the 10 home health agencies is separately surveyed and enters into its own provider agreement with Medicare, a total of 11 unique NPIs should be obtained: one by the hospital, and one by each of the 10 home health agencies.

Regardless of how an enrolled provider or certified supplier that is a covered organization health care provider determines subparts (if any) and obtains NPIs (for itself or for any of its subparts, if

they exist), Medicare payments, by law, may be made only to an enrolled provider or certified supplier.

Medicare Organization Providers and Subparts: Supplier Groups and Supplier Organizations

Existing Medicare laws and regulations do not establish requirements concerning the assignment of unique identification numbers to supplier groups and supplier organizations for billing purposes.

- Supplier groups and supplier organizations apply for Medicare enrollment by completing a CMS-855B.
- Supplier groups and supplier organizations bill Medicare Part B carriers.
- Supplier organizations are certified by the States, or certified by the Food and Drug Administration (FDA), or must undergo an on-site inspection by the carrier. These requirements vary by type of supplier organization.
- Supplier groups are primarily group practices, such as a group of physicians or other practitioners.
- Supplier organizations include ambulance companies, mammography facilities, and independent diagnostic testing facilities (IDTFs).

Medicare enrolls supplier groups/supplier organizations based on Taxpayer Identification Numbers (TINs); that is, although a supplier group or supplier organization may have multiple locations, if each location operates under the same single TIN, Medicare does not separately enroll each location. There are exceptions:

1. When there is more than one Medicare specialty code associated with a single TIN. For instance, if a physician group practice is also an IDTF, it has two different Medicare specialties. The supplier group (the physician group practice) must enroll as a group and the supplier organization (the IDTF) must enroll as a supplier organization. The group practice would complete a CMS-855B and the IDTF would complete a CMS-855B. Each one would receive its own unique Medicare billing number.

2. If a separate site visit, State certification, or on-site inspection by the carrier or if FDA certification is required for each practice location of that supplier group/supplier organization.

In those above exceptions, Medicare separately enrolls each different Medicare specialty and each separately visited, certified or carrier-inspected practice location.

Medicare Expectations for NPI Assignments for Supplier Groups and Supplier Organizations: To help ensure that Medicare supplier groups and supplier organizations do not experience delays in Medicare claims processing or reimbursement, Medicare encourages each of its enrolled supplier groups and supplier organizations to obtain its own unique NPI. These NPIs will eventually replace the legacy numbers that are used today in HIPAA standard transactions and in other transactions, such as cost reports. In order for subpart determinations to mirror

Medicare enrollment, each enrolled supplier group and supplier organization that is a covered organization health care provider would ensure the following:

- Obtain its own unique NPI.
- Determine if it has any subparts that are themselves enrolled Medicare providers.

If there are subparts, ensure that they obtain their own unique NPIs, or obtain the NPIs for them. Example: An enrolled IDTF has four different locations, and each one must be separately inspected by the carrier. All four locations operate under a single TIN. Because each location is separately inspected in order to enroll in Medicare, a total of four unique NPIs should be obtained: one for each location.

Regardless of how an enrolled supplier group or supplier organization that is a covered organization health care provider determines subparts (if any) and obtains NPIs (for itself or for any of its subparts, if they exist), Medicare payments, by law, may be made only to an enrolled supplier group or supplier organization.

Medicare Organization Providers and Subparts: Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, or Supplies (DMEPOS)

Medicare regulations require that each practice location of a supplier of DMEPOS (if it has more than one) must, by law, be separately enrolled in Medicare and have its own unique Medicare billing number.

- A supplier of DMEPOS enrolls in Medicare through the National Supplier Clearinghouse (NSC) by completing a CMS-855S.

- Suppliers of DMEPOS bill durable medical equipment regional carriers (DMERCs).

- Suppliers of DMEPOS include but are not limited to pharmacies, oxygen suppliers, and outpatient physical therapy agencies. (Any organization that sells equipment or supplies that are billed to Medicare through the DMERCs must be enrolled as a supplier of DMEPOS through the NSC. Sometimes, these are organizations who also furnish services that are covered by Medicare, such as ambulatory surgical centers. In order to be reimbursed for the DME supplies that they sell, they must separately enroll in Medicare as a supplier of DME.)

Medicare Expectations for NPI Assignments for Suppliers of DMEPOS: Each enrolled supplier of DMEPOS that is a covered entity under HIPAA must designate each practice location (if it has more than one) as a subpart and ensure that each subpart obtains its own unique NPI.

Final Notes About NPIs

Enrolled organization health care providers or subparts who bill more than one Medicare contractor: An enrolled organization health care provider or subpart is expected to use a single (the same) NPI when billing more than one Medicare contractor. For example, a physician group

practice billing a Maryland carrier and also billing a Pennsylvania carrier would use a single (the same) NPI to bill both carriers.

Enrolled organization health care providers or subparts who bill more than one type of Medicare contractor: Generally, the type of service being reported on a Medicare claim determines the type of Medicare contractor who processes the claim. Medicare will expect an enrolled organization health care provider or subpart to use a single (the same) NPI when billing more than one type (fiscal intermediary, carrier, RHHI, DMERC) of Medicare contractor. However, in certain situations, Medicare requires that the organization health care provider (or possibly even a subpart) enroll in Medicare as more than one type of provider. For example, an ambulatory surgical center enrolls in Medicare as a certified supplier and bills a carrier. If the ambulatory surgical center also sells durable medical equipment, it must also enroll in Medicare as a Supplier of DME and bill a DMERC. This ambulatory surgical center would obtain a single NPI and use it to bill the fiscal intermediary and the DMERC. Medicare expects that this ambulatory surgical center would report two different Taxonomies when it applies for its NPI: (1) that of ambulatory health care facility—clinic/center--ambulatory surgical (261QA1903X) and (2) that of suppliers—durable medical equipment & medical supplies (332B00000X) **or** the appropriate sub-specialization under the 332B00000X specialization.

Enrolled organization health care providers who determine subparts for reasons unrelated to Medicare statutes, regulations or policies:

Consistent with the NPI Final Rule, covered organization health care providers designate subparts for reasons that are not necessarily related to Medicare statutes or regulations. If a Medicare organization health care provider designates as subparts entities other than those who are enrolled Medicare providers, and those subparts obtain their own NPIs and use those NPIs to identify themselves in HIPAA standard transactions with Medicare, those NPIs will not identify enrolled Medicare providers. Medicare is not required to enroll them. (NPI Final Rule, page 3441: "If an organization health care provider consists of subparts that are identified with their own unique NPIs, a health plan may decide to enroll none, one, or a limited number of them (and to use only the NPIs of the one(s) it enrolls."))

Medicare will, of course, use NPIs to identify health care providers and subparts in HIPAA standard transactions. (NPI Final Rule, page 3469: section 162.412(a): "A health plan must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.") Medicare will ensure that the NPIs it receives in HIPAA standard transactions are valid[6]. Medicare will reject HIPAA standard transactions that contain invalid NPIs. Valid NPIs, however, like the provider identifiers used today, must be "known" to Medicare. Medicare is not permitted to make payments for services rendered by non-Medicare providers[7], nor is it permitted to reimburse providers who are not enrolled in the Medicare

6 The check-digit algorithm will determine the validity of an NPI. This is not the same as knowing the health care provider being identified by a particular NPI.

7 There may be exceptions for emergency or very unusual situations.

program. Medicare will return, with appropriate messages, any HIPAA standard transactions containing valid but unrecognizable NPIs.

7 – Changes of Information

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

Unless indicated otherwise, the instructions in *sections 7.1, 7.1.1, 7.1.2, and 7.3 of this manual* apply to carriers and fiscal intermediaries.

7.1 – General Procedures

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

Unless otherwise specified in this manual, if an enrolled provider is adding, deleting, or changing information under its *existing* tax identification number, it must report this change using the applicable CMS-855 form. Letterhead is not permitted.

The provider shall furnish the changed data in the applicable section of the form and sign and date the certification statement. In addition:

- **Unsolicited Additional Information** - Any new or changed information submitted by a provider prior to the date the contractor finishes processing a *previously submitted* change request is considered *to be an* update to *that* change request. It is not considered to be a separate change of information. *To illustrate,* suppose a provider submits a change *request.* On the 24th day, it submits *additional* information that it *wants to change.* Because the contractor *has* not finished processing the first change request, it should – for processing purposes – treat the data in the second change request as being part of the first one.

- **Unavoidable Phone Number or Address Changes** – Unless *specified otherwise by CMS, any* change in the provider's phone number or address that is not caused by the provider (i.e., area code change, municipality renames the provider's street) must still be updated via the CMS-855.

- ***Application Signatures*** - *If* the signer has never been reported in section 6 of the CMS-855, section 6 must be completed in full with information about the individual. The contractor shall check the individual against Qualifier.net and note in the enrollment file that this *task* was performed. This policy applies regardless of whether the provider *already* has a CMS-855 on *file.*

- **Notifications** – For changes of information that do *not require* RO approval (e.g., CMS-855I changes, CMS-855B changes not involving ASCs or *PXRSs,* minor CMS-855A changes), the contractor shall furnish written, e-mail, or telephonic confirmation to the provider that the change has been made. Document (per section 10 of this manual) in the file the date and time the confirmation was *made. If, however, the transaction only involves an area code/ZIP Code change, it is not necessary to send confirmation to the provider that the change has been processed.*

7.1.1 – Changes of Information and Complete CMS-855 Applications

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

A provider must submit a complete CMS-855 application if *it: (1) submits any change request, and (2) does not have an established enrollment record in PECOS.* (For purposes of this requirement, the term "change request" includes EFT changes.) *It is immaterial: (1) whether the provider, bank, or other party (e.g., change in bank name via merger; local government changes the street name) was responsible for triggering the changed data, or (2) the signer of the change request or EFT form already has a signature on file with the contractor.*

If the contractor receives a change request from a provider that is not in PECOS, the contractor shall not return the application/change request. It shall simply develop for the entire application *in accordance with* the procedures described in section*s* 3.1 and 5.3 of this manual; *the contractor, in other words,* shall treat the *transaction* as a request for additional information. *Consistent with existing policies for requesting additional data*, *the* provider has 60 calendar days from the date of the contractor's request to furnish the entire CMS-855 application. During this period, the contractor should "hold" (i.e., not process) the change request until the entire application arrives; no L & T record shall be created in PECOS at this point.

If the provider fails to submit a complete application within the aforementioned 60-day period, the contractor shall *abide by the instructions in section 7.1.2 of this manual.*

If the provider does submit the application, the contractor shall process *it* in full accordance with all of the instructions in this manual. This includes:

- Processing the complete application within 60 calendar days of *receipt. Assume* the contractor received the change request on March 1. It requested a complete application from the provider on March 10 *and received it on April 1.* The contractor *in this scenario* has until June 1 to process the complete CMS-855.

- Verifying all data elements on the CMS-855, just as it would with an initial enrollment application. The contractor shall not approve the change request until all data on the CMS-855 has been validated. Moreover, the provider must submit all supporting documentation with the application.

- *Creating an L & T record and enrollment record in PECOS prior to approving the change request. (This is an exception to the general rule that an L & T record must be created no later than 15 calendar days after the contractor received the application.) The transaction should be treated as an initial enrollment in PECOS; internally, the contractor shall treat it as a change of information. As the completed application will presumably incorporate the changed data reported on the initial CMS-855 change request, the contractor shall not take two separate counts (one initial and one change request) for the transaction.*

7.1.2 – Incomplete or Unverifiable Changes of Information
(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

Certain changes of information cannot be processed to completion: (1) due to the provider's failure to furnish requested clarifying data, (2) because the information on the application cannot be appropriately verified, or (3) the provider does not have an established enrollment record in PECOS and fails to submit a complete CMS-855 in response to the contractor's request. In such cases, the contractor shall abide by the instructions in this section 7.1.2.

A. Provider is in PECOS

Assume that a provider submits a CMS-855 change of information and: (1) fails to timely respond to the contractor's request for additional or clarifying information, or (2) the contractor is otherwise unable to validate the new information. In this circumstance, the contractor obviously shall reject the change request in accordance with section 3.1 of this manual; however, the contractor shall also deactivate the provider's Medicare billing privileges if the information in question is of such materiality that the contractor cannot determine whether the provider still meets all applicable requirements for maintaining enrollment in the Medicare program. (For instance, if the data involves a change in the provider's lone practice location and the contractor cannot verify the validity of the new site, this clearly raises questions as to the provider's continued compliance with Medicare requirements.) Note that the deactivation letter can, if the contractor wishes, be combined with the rejection notice into a single letter.

B. Provider is Not in PECOS

As stated in sections 7.1.1 and 8 of this manual, if a provider does not have an established enrollment record in PECOS and wants to change any of its existing enrollment of EFT information, it must submit a complete CMS-855 form before the contractor can effectuate the change. If the provider refuses to or otherwise fails to submit the completed form within the applicable 60 day period, the contractor shall request that the provider revalidate its Medicare enrollment information per 42 CFR § 424.515.

7.2 - Special Instructions for Certified Providers, ASCs, and *Portable X-Ray Suppliers (PXRSs)*
(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

Unless *otherwise stated*, the instructions in this section 7.2 apply *only* to certified providers, ASCs, and *PXRSs.*

A. RO Approval Needed

Certain change of information requests require: (1) a recommendation for approval/denial, (2) referral to the State/RO, and/or (3) a *tie-in notice* or other type of RO approval. Conversely, some changes are so minor that there is no real need to refer the matter to the State or RO.

The following is a list of transactions that *require a* recommendation and referral to the State/RO (unless the RO specifies otherwise). Note that this list is not necessarily exhaustive:

- The *addition of* a practice location or *subunit*, regardless of whether a tie-in or tie-out notice would normally be issued.

- *Any change in the address of an existing practice location or subunit.*

- *Any* change in hospital type (e.g., from long-term to acute care) not involving a critical access hospital.

- Large-scale stock transfer.

- *A c*hange in the *provider's* legal business name or TIN that does not involve a CHOW.

For those transactions that generally do not require a recommendation and referral to the *State/RO, the* contractor can simply notify the provider via letter, e-mail, or telephone that the change has been made *and* need not send a *concomitant* notification to the *State/RO*. However, since each RO may have different preferences as to the changes it wishes to *review/approve*, the *contractor is* strongly advised to contact the applicable RO(s) to *confirm: (1) those change requests that should be referred to the RO, and (2) whether the RO will issue a formal approval notice for said changes.* This will also dictate when the PECOS status can be flipped to "approved." If, *for instance,* the contractor *verifies* that a particular change request does not require notification of the State/RO or does not otherwise need State/RO approval, the contractor can "flip" the PECOS status to "approved" once the change has been processed. *In* cases where a tie-in or RO approval is required, the contractor *shall not* switch the record's status to "approved" until such approval has been received from the RO*; so as not to keep the record in "approval recommended" status interminably, if the contractor does not receive notification of approval from the RO after an excessive amount of time*, it *may* contact the RO to see if *said* approval is forthcoming.

In situations where the provider has no CMS-855 on file and submits a full one as part of a change of information (e.g., EFT change), it is not automatically necessary to send the application to the *State/RO.* Whether or not a recommendation for approval and referral to the State/RO is required depends on what the underlying change involves. For instance, if the provider *merely submits* a change of EFT information, this can be approved without a referral. If the provider *is adding a practice location,* however, the *contractor* should make a recommendation *and referral* to the State. (The *contractor* should forward the whole application to the State with a note *explaining* that the only matter the State needs to consider is the *practice location* addition.)

B. Deletion of Practice Location or Subunit

If the contractor receives a CMS-855 change request that deletes a practice location or subunit, it may terminate the location/unit without making a recommendation to the State and RO. No later than 3 business days after the contractor has finished processing the deletion, however, it shall notify the State and RO thereof; said notification can be made via letter, e-mail, or fax.

C. Timeframe for RO Approval

In situations where RO approval of the change of information is required, it is strongly recommended that the contractor advise the provider that it may take 6 months (or longer) for the request to be approved. The manner and timing in which this information is relayed lies solely within the contractor's discretion.

D. Post-Recommendation Changes

If an applicant submits a change request after the contractor makes *a* recommendation on the *provider's* initial CMS-855 *application* but before the RO issues a tie-in/approval notice, *the contractor shall process the newly-submitted data as a separate change of information; it* shall *not take* the changed information/corrected pages and, immediately upon receipt, send them directly to the State/RO to be incorporated into the existing application. *The contractor, however,* need not enter the change request into PECOS until the tie-in notice is issued.

E. Hospital Addition of Practice Location

In situations where *a* hospital is adding a practice location, the intermediary shall notify the provider in writing that its recommendation for approval does not constitute approval of the facility or group as provider-based under 42 CFR §413.65.

7.3 – Voluntary Terminations

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

Voluntary terminations shall be processed in accordance with the timeframes in section 2.2 of this manual (e.g., 80 percent within 45 calendar days).

If the termination involves a certified provider, ASC, or PXRSs, *the contractor may terminate the entity without making a recommendation to the State and RO. No later than 3 business days after the contractor has finished processing the termination, however, it shall notify the State and RO thereof; said notification can be made via letter, e-mail, or fax.*

Upon receipt of a voluntary termination, the contractor may ask the provider to complete the "Special Payments" portion of section 4 so that future payments can be sent *thereto.* If the provider has no *special payments address already* on file, *the addition* should be included in the same transaction as the *termination (i.e., one transaction incorporating both items).* If the

provider wants to change its existing *special payments* address, the transaction should be treated as a separate change request (i.e., one termination and one change request). The provider is not required to submit a CMS-588 in conjunction with a termination.

8 – Electronic Fund Transfers (EFT)

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

If a *provider does not have an established enrollment record* in PECOS *and wants to change any* of its EFT information (e.g., bank routing number), it must submit a complete CMS-855 form before the contractor can effectuate the change. It is immaterial *whether: (1) the* provider or the bank (e.g., change in bank name via merger) was responsible for triggering the changed data or (2) the signer of the CMS-588 already has a signature on file with the contractor. (For more information *on how the contractor should handle this type of situation*, see section*s* 7.1.1 and *7.1.2* of this manual.)

In addition:

- **EFT Requirement** - All providers (including Federal, State and local governments) entering the Medicare program for the first time must use EFT in order to receive payments. Moreover, any provider not currently on EFT that submits any change to its existing enrollment data must also submit a CMS-588 form and *thereafter* receive payments via EFT. If the provider's bank of choice does not or will not participate in the provider's proposed EFT transaction, the provider must select another financial institution.

- **Verification** - The contractor shall verify that all EFT *changes comply* with Pub. 100-04, chapter 1, section *30.2.5.*

- **Sent to the Wrong Unit** - If a provider submits *an* EFT change request to the contractor but not to the latter's enrollment unit, the recipient unit shall forward it to the enrollment *staff,* which shall then process the change. The enrollment unit is ultimately responsible for processing EFT changes. As such, while it may send the original EFT form back to the recipient unit, the enrollment unit shall keep a copy of the EFT form and append it to the provider's CMS-855 in the file.

- **CMS 588 Changes and PECOS –** *In situations where the only data the provider is changing is on the CMS-588 (i.e., no data is changing on the CMS-855), the contractor shall process the EFT change using the timeframes cited in section 2.2 of this manual; moreover, and notwithstanding any instruction to the contrary in this manual, the contractor shall create an L & T record using the "Other" button in PECOS.*

- **Comparing Signatures** - If the contractor receives an EFT change request, it shall compare the signature thereon with the same official's signature on file to ensure that it is indeed the same person. *(See also Pub. 100-04, chapter 24, section 40.7)* If the person's signature is not already on file, the contractor shall request that *he/she* complete section 6 of the CMS-855 and

furnish his/her signature in section 15 or 16 of the CMS-855. (This shall be treated as part of the EFT change request for purposes of timeliness and reporting.)

- **Bankruptcies and Garnishments** – *If the contractor receives a copy of a court order to send payments to a party other than the provider, it shall contact the applicable RO's Office of General Counsel. (In general, all court orders take precedence over the instructions in this manual.)*

- **Closure of Bank Account** – There may be situations where a provider has closed its bank/EFT account but will remain enrolled in Medicare. The contractor shall place the provider on payment withhold until an EFT agreement (and CMS-855, if applicable) is submitted and approved by the contractor. If such an agreement is not submitted within 90 days after the contractor first learned that the account was closed, the contractor shall commence revocation procedures in accordance with the instructions in this manual.

- **Reassignments** – If a physician or practitioner is reassigning all of his/her benefits to another supplier, neither the practitioner nor the group needs to submit a CMS-588 form. This is because (1) the practitioner is not receiving payment directly, and (2) accepting a reassignment does not qualify as a change of information request. Of course, if the group later submits a change of information request (e.g., adding a new owner in section 6) *and is not currently on EFT, it must submit a CMS-588.*

- ***Final Payments*** - In situations where a non-certified supplier (e.g., physician, ambulance company) voluntarily withdraws from Medicare and needs to obtain its final payments, *the contractor* shall send *said* payments to the provider's EFT account of record. If the account is defunct, the *contractor* can send *payments* to the provider's "special payments" address or, if none is on file, *to* any of the provider's practice locations on record. If neither the EFT account nor the addresses discussed above are in existence, the provider shall submit a CMS-855 or CMS-588 request identifying where it wants payments to be sent.

- **Chain Organizations** - Per Pub. 100-04, chapter 1, section 30.2, a chain organization may have payments to its providers *be* sent to the chain home office. However, any mass EFT changes (involving large numbers of chain providers) must be processed in the same fashion as any other change in EFT data. For instance, if a chain has 100 providers and *each wants to change its EFT* account to that of the chain home office, 100 separate CMS 588s must be *submitted.* If any of *the* chain providers have never completed a CMS-855 before, they must do so at that time.

12.2 – Carrier-Enrolled *Organizational* Suppliers

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

12.2.2 – *CLIA Labs*

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

A. General Background Information

Through the Clinical Laboratory Improvements Amendments (CLIA) program, CMS regulates all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of humans. CLIA mandates that virtually all laboratories, including physician office laboratories, meet applicable Federal requirements and have a CLIA certificate in order to operate. It is largely immaterial whether the entity itself is a lab (and does nothing but lab tests) or is a provider that performs many different types of services, of which lab testing is just a small part; laboratories are subject to CLIA- unless an exemption applies - regardless of the complexity or amount of testing that the laboratory will perform.

Under 42 CFR Part 493, all entities that perform laboratory testing must, among other things:

- Pay user fees as assessed by CMS to finance the administration of the CLIA program (the amount of the fee each lab pays depends largely on the type of certificate being requested and the complexity of the tests that will be performed);

- Undergo surveys to assess compliance with applicable CLIA requirements; and

- Apply for and obtain CLIA certificates based on the complexity of testing performed in the laboratory or based on accreditation by a CMS-approved accreditation organization.

Certain types of laboratories and laboratory tests are not subject to CLIA requirements. These include, but are not limited to:

- Entities (or components thereof) that perform testing strictly for forensic purposes;

- Research laboratories that test – but do not report - patient specific results (although they test human specimens) for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individuals;

- Laboratories licensed in a State whose laboratory licensure program is approved by CMS; and

- Facilities which serve only as collection stations.

(See Publication 100-07, chapter 6, section 6002 for additional laboratories not subject to CLIA. Though these CLIA-exempt laboratories do not receive a CLIA certificate, they do receive a CLIA number for identification purposes.)

B. Form CMS-116 and CLIA Certificates

Prior to performing laboratory services - again, irrespective of whether it plans to enroll in Medicare - a laboratory must submit a Form CMS-116 to the local State Agency (which may also require the laboratory to complete State-specific forms). The Form CMS-116 requests information such as the:

- CLIA certificate being requested;
- Type of laboratory (e.g., hospital, physician office, ASC);
- Hours during which laboratory testing will take place;
- Sites where testing will occur; and
- Type of tests that will be performed.

After completing the Form CMS-116, the lab must be inspected (unless the lab meets the requirements for a Certificate of Waiver). The survey will typically be performed by CMS, with two key exceptions:

- If the lab is located in a CLIA-exempt State – meaning that the State's standards for labs meet or exceed CLIA standards – the State itself will conduct the inspection. (Not surprisingly, these labs are known as "CLIA-exempt labs." While they are not required to obtain a CLIA certificate, they still receive a CLIA number for payment purposes.)

- If the lab seeks accreditation (in lieu of a CMS survey) by a CMS-approved accrediting body, that body will conduct the survey.

State agencies are responsible for survey and certification activity (including data entry) for non-Federal laboratories within its State. The SA recommends to the RO whether to certify the laboratory.

There are several types of CLIA certificates, *including*:

- Certificate of Waiver (COW) – There are certain laboratory tests that are "waived," meaning that the laboratory is not subject to routine CLIA inspections. In general, waived tests have been determined by Centers for Disease Control (CDC) and/or Food and Drug Administration (FDA) to be so simple that there is minimal risk of error. If a COW is issued, the laboratory can only perform waived tests, must still register with CLIA, and pay all necessary fees; CLIA laboratories are not CLIA-exempt.

- Certificate of Accreditation – Issued when a lab meets the standards of a CMS-approved accreditation organization and this is verified by the latter. The laboratory will identify on the Form CMS-116 the organization from which it has received accreditation.

- Certificate for Provider-Performed Microscopy *(PPM)* Procedures - Issued if the laboratory indicates that a physician or practitioner performs only the microscopy tests listed at 42 CFR 493.19*(c)*, or performs only the listed microscopy tests in any combination with waived tests.

- Certificate of Compliance – Issued when it is determined through a survey to be in compliance with applicable requirements for laboratories performing tests of moderate and/or high complexity.

If the laboratory is applying for a Certificate of Compliance or Certificate of Accreditation, it will initially pay for and receive a Registration *Certificate.*

The State agency is responsible for survey and certification activity (including data entry) for non-Federal laboratories within its State. It will send to the RO its recommendation as to whether the laboratory should be certified.

B. CLIA Enrollment

Note the following on CLIA Medicare enrollment:

- Prior to enrolling the laboratory, the contractor shall require a Certificate of Waiver, Compliance, Accreditation, *PPM Procedures, or Registration.*

- Each practice location at which laboratory tests are performed must submit to the contractor a separate CLIA certificate for that location. The only exceptions to this rule are:

    - Laboratories within a hospital that are located at contiguous buildings, on the same campus, and under common direction;

    - Non-profit or governmental laboratories that engage in limited public health testing;

    - Laboratories that are not at a fixed location (i.e., are mobile)

(See Pub. 100-07, chapter 6, sections 6008, 6026 and 6034 – 6036A for more information.)

- The laboratory must submit to the contractor a separate certificate for each State in which testing is performed.

- If a lab is under the same ownership and at the same location as the "main provider," it generally does not need to enroll separately. The enrolling provider will just furnish its CLIA number in the practice location section. Conversely, if a lab is an "independent CLIA lab," it must enroll separately.

- A separate enrollment record need not be created for each CLIA number. For instance, suppose a physician is enrolling in Medicare and has a CLIA number. The carrier need only create a single enrollment record that will encompass the Medicare number and the CLIA number.

- The CLIA number is a 10-digit number, and the CLIA data system is a subset of the OSCAR system.

C. Additional Information

For additional data on CLIA laboratories, refer to:

- *42 CFR Part 493;*
- *Publication 100-07, chapter 6 (State Operations Manual);*
- *Publication 100-04, chapter 16 (Claims Processing Manual); and*
- *Form CMS-116 (CLIA Application for Certification).*

12.2.3 – *Mammography Screening Centers*

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

As stated in 42 CFR §410.34(a)(2), a screening mammography is a radiological procedure "furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure." All mammography centers must apply for and receive certification from the Food and Drug Administration (FDA), which is responsible for collecting certificate fees and surveying mammography facilities (screening and diagnostic). The FDA provides CMS with a listing of all providers that have been issued certificates to perform mammography services and CMS notifies contractors accordingly.

Prior to enrollment, the contractor shall require the center to submit a copy of its FDA certificate. Note that per 42 CFR §410.34 (a)(7)(i), the contractor may accept a "provisional" certificate.

For more information on mammography screening centers, refer to:

- *§1834(c) of the Social Security Act*
- *21 CFR Part 900*
- *42 CFR §410.34*

- *Pub. 100-04, chapter 18, sections 20 through 20.8 (Claims Processing Manual)*

- *Pub. 100-02, chapter 15, section 280.3 (Benefit Policy Manual)*

12.2.4 – Pharmacies

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

Pharmacies typically enroll with the NSC. However, there are certain covered drugs that are billed through the physician fee schedule and not the DMEPOS schedule. Such drugs must be billed to the carrier and, therefore, any pharmacy furnishing them must enroll with the carrier via a CMS-855B.

See Pub. 100-04, chapter 17 and Pub. 100-02, chapter 15, sections 50 through 50.6 for more information on the billing procedures for drugs.

12.2.5 – Portable X-Ray Suppliers (PXRSs)

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

A. General Background Information

A portable x-ray supplier (PXRS) moves its x-ray equipment from place to place, performing x-ray services at various locations. To qualify as a PXRS, an entity must meet the conditions for coverage discussed in 42 CFR §486.100-110. These include, but are not limited to:

- *Possess a State license or registration to perform the services (assuming the State licenses/registers PXRSs) (42 CFR §486.100(a));*

- *All personnel operating the equipment are licensed/registered in accordance with State and local laws (and meet certain other training requirements) (42 CFR §486.100(b));*

- *All PXRS equipment is licensed/registered in accordance with State and local laws (42 CFR §486.100(c));*

- *All suppliers of PXRS agree to render such services in conformity with Federal, State and local laws relating to safety standards (42 CFR §486.100(d));*

- *The PXRS services are provided under the supervision of a qualified physician. (42 CFR §486.102(a)). Additionally, the supervising physician must either:*

    - *Own the equipment (which must be operated only by his/her employees); or*

- *Certify on a yearly basis that he/she periodically checks the procedural manuals and observes the operators' performance, and that the equipment and personnel meet all Federal, State, and local requirements*

- *The PXRS are provided under the supervision of a licensed doctor of medicine or osteopathy who is qualified in advanced training and experience in the use of x-rays for diagnostic purpose (42 CFR §486.102(b));*

- *The PXRS has an orientation program for its personnel (42 CFR §486.104(b));*

- *All equipment is inspected at least every 2 years. (42 CFR §486.110).*

A PXRS can be simultaneously enrolled as a mobile IDTF, though they obviously cannot bill for the same service. Note that PXRSs require a State survey, while mobile IDTFs do not (although IDTFs do require a site visit); moreover, PXRSs can bill for transportation and set-up, while mobile IDTFs cannot.

Unlike most other certified suppliers and providers, PXRSs do not have supplier agreements.

B. Enrollment of PXRS

In order to enroll as a PXRS, a supplier must complete a Form CMS-855B, undergo a State survey, and secure RO approval. One of the most important parts of any PXRS's enrollment application is Section 4. Here, the PXRS must furnish, among other things, the following information:

- *Whether it furnishes services from a "mobile facility" or "portable unit." The former term typically describes a vehicle that travels from place to place to perform services <u>inside</u> the vehicle. Examples of such vehicles include mobile homes or trailers. A "portable unit" exists when a supplier transports medical equipment to a particular location. Unlike with mobile facilities, the equipment on a portable unit is separate from and unattached to the vehicle.*

- *A PXRS can be either a mobile facility or portable unit, although it usually is the latter. A mobile IDTF, on the other hand, while it too can be either, is typically a mobile facility.*

- *Its base of operations. This is where personnel are dispatched from and where equipment is stored. It may or may not be the same address as the practice location(s).*

- *All geographic locations at which services will be rendered.*

- *Vehicle information IF the services will be performed <u>inside</u> or <u>from</u> the vehicle. Copies of all licenses and registrations must be submitted as well.*

As stated in Pub. 100-07, chapter 2, section 2422, the "residence used as the patient's home" can include a SNF or hospital that does not provide x-ray services for its patients and arranges for

these services through a PXRS, such as a mobile unit. However, the mobile unit can neither be fixed at any one location nor permanently located in a SNF or a hospital.

C. Additional Information

For more information on PXRSs, refer to:

- *Sections 5.6 and 7.2 of this manual;*
- *Section 1861(s)(3) of the Social Security Act;*
- *42 CFR Parts 486.100 – 486.110;*
- *Pub. 100-07, chapter 2, sections 2420 – 2424B (State Operations Manual);*
- *Pub. 100-02, chapter 15, sections 80.4 – 80.4.4 (Benefit Policy Manual); and*
- *Pub. 100-04, chapter 13, sections 90 – 90.5 (Claims Processing Manual).*

12.2.6 - Radiation Therapy Centers

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

Under 42 CFR 410.35, Medicare Part B pays for x-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment. As radiation therapy centers (RTCs) furnish therapeutic services, they are not IDTFs.

For additional background on radiation therapy services, see Pub. 100-04, chapter 13, as well as Pub. 100-02, chapter 15, section 90.

12.2.7 – Slide Preparation Facilities

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

A slide preparation facility furnishes slide preparation and other kinds of services that are payable through the technical component of surgical pathology services. It does not furnish the professional component of surgical pathology services or other kinds of laboratory tests. As such, a slide preparation facility is not an IDTF.

12.4.10 - *Physicians*

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

As described in §1861(r)(1) of the Social Security Act and in 42 CFR §410.20(b), a physician must be legally authorized to practice medicine by the State in which he/she performs such services in order to enroll in the Medicare program and to retain Medicare billing privileges. Such individuals include:

1. Doctors of:

- *Medicine or osteopathy*
- *Dental surgery or dental medicine*
- *Podiatric medicine*
- *Optometry*

2. A chiropractor who meets the qualifications specified in 42 CFR §410.22

For information on physician billing, refer to Pub. 100-04, chapter 12.

12.4.11 - *Physician Assistants (PAs)*

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

As stated in Pub. 100-02, chapter 15, section 190, a physician assistant (PA) must meet the following Medicare requirements:

1. Have graduated from a physician assistant educational program that is accredited by the Accreditation Review Commission on Education for the Physician Assistant (its predecessor agencies, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and the Committee on Allied Health Education and Accreditation (CAHEA); or

2. Have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants (NCCPA); and

3. Be licensed by the State to practice as a physician assistant.

As indicated in Pub. 100-02, chapter 15, section 190(D):

- *Payment for the PA's services may only be made to the PA's employer, not to the PA himself/herself. In other words, the PA cannot individually enroll in Medicare and receive direct payment for his or her services. This also means that the PA does not reassign his or her benefits to the employer, since the employer must receive direct payment anyway.*

- *The PA's employer can be either an individual or an organization. If the employer is a professional corporation or other duly qualified legal entity (e.g., LLC, LLP) in a State that*

permits PA ownership in the entity (e.g., as a stockholder, member), the entity may bill for PA services even if a PA is a stockholder or officer of the entity – so long as the entity is eligible to enroll as a provider or supplier in the Medicare program. PAs may not otherwise organize or incorporate and bill for their services directly to the Medicare program, including as, but not limited to, sole proprietorships or general partnerships. Accordingly, a qualified employer is not a group of PAs that incorporate to bill for their services. Moreover, leasing agencies and staffing companies do not qualify under the Medicare program as "providers of services" or suppliers of services.

For more information on physician assistants, refer to:

- *42 CFR §410.74*
- *Pub. 100-04, chapter 12, sections 110 through 110.3 (Claims Processing Manual)*

12.4.12 - *Psychologists Practicing Independently*

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

As stated in Pub. 100-02, chapter 15, section 80.2, a psychologist practices independently when:

- *They render services on their own responsibility, free of the administrative and professional control of an employer such as a physician, institution or agency;*
- *The persons they treat are their own patients;*
- *They have the right to bill directly, collect and retain the fee for their services; and*
- *The psychologist is State-licensed or certified.*

A psychologist practicing in an office located in an institution may be considered an independently practicing psychologist when both of the following conditions exist:

- *The office is confined to a separately-identified part of the facility which is used solely as the psychologist's office and cannot be construed as extending throughout the entire institution; and*
- *The psychologist conducts a private practice (i.e., services are rendered to patients from outside the institution as well as to institutional patients).*

The key distinction between independently practicing psychologists and clinical psychologists is that the latter requires a doctoral degree and has certain consultation requirements.

For more information on independently practicing psychologists, refer to:

- *Section 4.2.7 of this manual*

- *Pub. 100-04, chapter 12, sections 160 and 160.1 (Claims Processing Manual)*

12.4.13 - Registered Dietitians
(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

Per 42 CFR §410.134, a registered dietitian (or nutrition professional) means an individual who, on or after December 22, 2000:

1. Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose;

2. Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

3. Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian"' by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (A) and (B) above.

There are two caveats to these requirements:

- *A dietitian or nutritionist licensed or certified in a State as of December 21, 2000, is not required to meet the requirements of A and B above.*

- *A registered dietitian in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of A and B above.*

For more information on registered dietitians, refer to:

- *Sections 1861(vv) of the Social Security Act*

- *42 CFR §410.130 through § 410.134*

13.1 – CMS or Contractor Issued Deactivations
(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)
A. General Instructions

The contractor may deactivate a provider or supplier's Medicare billing privileges when:

- A provider or supplier does not submit any Medicare claims for 12 consecutive calendar months. The 12 month period begins on the 1st day of the 1st month without a claims submission through the last day of the 12th month without a submitted claim;

- A provider or supplier fails to report a change to the information supplied on the enrollment application within 90 calendar days of when the change occurred. Changes that must be reported include, but are not limited to, a change in practice location, a change of any managing employee, and a change in billing services; or

- A provider or supplier fails to report a change in ownership or control within 30 calendar days.

The deactivation of Medicare billing privileges does not affect a supplier's participation agreement (CMS-460).

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

Providers and suppliers that fail to promptly notify the contractor of a change (as described above) must submit a complete Medicare enrollment application to reactivate their Medicare billing privileges or, when deemed appropriate, recertify that the enrollment information currently on file with Medicare is correct. Reactivation of Medicare billing privileges does not require a new State survey or the establishment of a new provider agreement or participation agreement.

Each contractor shall forward a copy of the Deactivation Summary Report provided by the Multi-Carrier System (MCS) to its designated DPSE contractor liaison within 20 calendar days of the end of each quarter in which deactivations occurred (i.e., January, April, July, and October).

B. DMEPOS Deactivation

The NSC shall require a DMEPOS supplier whose billing privileges are deactivated for non-submission of claims (see CFR 42 CFR 424.540) to submit a new Medicare enrollment application and meet all applicable enrollment criteria, including a site visit, and accreditation when applicable, before an applicant can be approved. The NSC may not establish a retrospective billing date for a DMEPOS supplier whose billing privileges were deactivated due to claims inactivity.

13.2.1 - Revocations Involving Certified Suppliers and Providers

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

If the contractor determines that one or more of the revocation reasons identified in section 13.2 of this manual are applicable, the contractor may revoke the billing privileges of a certified provider or certified supplier without making a recommendation for approval or denial to the State and RO. It can, in other words, revoke billing privileges at the contractor level. However, as indicated in section 13.2, the contractor shall first notify DPSE prior to initiating any revocation action.

In revoking the provider or supplier, the contractor shall:

- *Issue the revocation letter in accordance with section 13.2; the RO and the State shall be copied on said letter;*

- *No later than 3 business days after issuing the revocation notice, contact the State and RO via letter, e-mail or fax to notify the latter of the revocation action;*

- *After determining the effective date of the revocation, end-date the entity's enrollment record in PECOS in the same manner as it would upon receipt of a tie-out notice from the RO.*

- *Afford the appropriate appeal rights per section 19 of this manual*

21 – Special Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Instructions

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

This section instructs the NSC on the appropriate handling of certain situations involving DMEPOS suppliers.

21.1 – DMEPOS Supplier Accreditation

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

The DMEPOS suppliers must be accredited prior to submitting an application to NSC on or after March 1, 2008. The NSC shall not approve any DMEPOS supplier's enrollment application if the enrollment package does not contain an approved accreditation upon receipt or in response to a developmental request. The NSC may reject an enrollment application if the DMEPOS supplier fails to provide supporting documentation which demonstrates that the supplier has an approved accreditation. Moreover, for any application that is pending (i.e., not processed to completion) as of March 1, 2008, the contractor shall develop for accreditation.

The DMEPOS suppliers that are enrolled for the first time with the NSC between January 1, 2008, and February 28, 2008, must obtain and submit an approved accreditation to the NSC by January 1, 2009. The NSC shall revoke a DMEPOS supplier's billing privileges if the DMEPOS supplier fails to obtain and submit supporting documentation that the DMEPOS supplier has been accredited.

The DMEPOS suppliers enrolled in the Medicare program prior to January 1, 2008, are required to obtain and submit an approved accreditation to the NSC by September 30, 2009. The NSC shall revoke a DMEPOS supplier's billing privileges if the DMEPOS supplier fails to obtain and submit supporting documentation that the DMEPOS supplier has been accredited.

21.2 – Enrolling Indian Health Service (IHS) Facilities as DMEPOS Suppliers

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

The NSC shall enroll IHS facilities as DMEPOS suppliers in accordance with the general enrollment procedures cited in chapter 10 and the statement of work contained in the NSC contract with Medicare, with the addition of the special procedures and clarifications cited in this section.

For enrollment purposes Medicare recognizes two types of IHS facilities. They are: a) those facilities wholly owned and operated by the IHS and b) facilities which are owned by the IHS but tribally operated or totally owned and operated by a tribe. CMS shall provide the NSC with a list of IHS facilities which distinguish between these two types.

On the list the NSC shall use the column entitled, "FAC OPERATED BY", for this purpose.

1. Completion of the Medicare Supplier Enrollment Application: CMS-855S Application for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers. The CMS-855S shall be completed in accordance with the instructions shown therein except as follows:

a. Facilities that are totally owned and operated by the IHS are considered a governmental organization. An Area Director of the IHS must sign the section 15 Certification Statement of the CMS–855S, be listed in section 6 of the form and sign the letter required by section 5 of the form which attests that the IHS will be legally and financially responsible in the event that there is any outstanding debt owed to CMS.

b. Facilities that are tribally operated are considered tribal organizations. The section 15 Certification Statement of the CMS–855S must be signed by a tribal official who meets the definition of an authorized official in accordance with the page 2 definitions shown on the CMS–855S. The same authorized official must be listed in section 6 of the CMS–855S and must sign the letter required by section 5 of the form which attests that the tribe will be legally and financially responsible in the event that there is any outstanding debt owed to CMS.

2. The DMEPOS Supplier Standards, Exceptions for Liability Insurance and State Licensure, and Site Visits

All IHS facilities, whether operated by the IHS or a tribe, enrolled by the NSC, shall meet all required standards as verified by the review procedures for all other DMEPOS suppliers except as discussed herein.

All IHS facilities, whether operated by the IHS or a tribe, shall be exempt from the comprehensive liability insurance requirements under 42 CFR 424.57(c)(10).

All IHS facilities, whether operated by the IHS or a tribe, shall be exempt from the requirement to provide any State Licenses for their facility/business. For example, if the DMEPOS supplier indicates on its application that it will be providing hospital beds and is located in a State that requires a bedding license, such licensure is not required. However, if they provide a DMEPOS item that requires a licensed professional in order to properly provide the item, they shall provide a copy of the professional license. The licensed professional can be licensed in any State or have a Federal license. For example, a pharmacy does not need a pharmacy license, but shall have a licensed pharmacist.

Site visits shall be required for all IHS facilities (whether operated by the IHS or a tribe) enrolling for DMEPOS. This includes all hospitals and pharmacies.

3. Provider Education for IHS Facilities

The NSC shall modify its Web site to include the information contained in this section which is specific to enrollment of IHS facilities (whether operated by the IHS or a tribe).

4. Specialty Codes

The NSC shall apply the specialty code A9 (IHS) for all IHS enrollments (whether operated by the IHS or a tribe). However, the specialty code A9/A0 shall be applied for facilities that are IHS/tribal hospitals. Additionally other specialty codes should be applied as applicable (e.g., pharmacy).