CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 347	Date: July 15, 2010
	Change Request 6938

Transmittal 344, issued on June 18, 2010, is being rescinded and replaced with Transmittal 347, dated July 15, 2010. The only change is the EFFECTIVE AND IMPLEMENTATION DATES. All other material remains the same.

SUBJECT: Chapter 10 Manual Redesign

I. SUMMARY OF CHANGES: This change request reorganizes and moves information in chapter 10 to chapter 15 and will incorporate a limited number of changes. This change request organizes the sections into more manageable content units that will be easily understood by the providers/suppliers.

EFFECTIVE DATE: July 30, 2010
IMPLEMENTATION DATE: July 30, 2010

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
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N	15/15.1.1/Definitions
N	15/15.1.2/Medicare Enrollment Application (CMS-855)
N	15/15.1.3/Medicare Contractor Duties
N	15/15.2/Provider and Supplier Business Structure
N	15/15.3/National Provider Identifier
N	15/15.4/Provider and Supplier Types/Services
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N	15/15.4.1.2/Comprehensive Outpatient Rehabilitation Facilities (CORFs)
N	15/15.4.1.3/End-Stage Renal Disease Facilities (ESRDs)
N	15/15.4.1.4/Federally Qualified Health Centers (FQHCs)

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III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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: 347	Date: July 15, 2010	Change Request: 6938

Transmittal 344, issued on June 18, 2010, is being rescinded and replaced with Transmittal 347, dated July 15, 2010. The only change is the EFFECTIVE AND IMPLEMENTATION DATES. All other material remains the same.

SUBJECT: Chapter 10 Manual Redesign

EFFECTIVE DATE: July 30, 2010
IMPLEMENTATION DATE: July 30, 2010

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) will reorganize and move the information contained in chapter 10 to chapter 15. In addition, CMS will incorporate a limited number of changes to these sections (see business requirements below.) Section 1.1, of chapter 10, includes three new definitions as referred to in the business requirements below. This change request will organize the sections into more manageable content units that will be easily understood by the providers and suppliers.

B. Policy: There are no changes in CMS policy other than those contained in the business requirements and corresponding manual change. Section 1.1, of chapter 10, includes three new definitions.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

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	
6938.1	Medicare contractors shall use contents of chapter 15 in lieu of chapter. 10.	X	X	X	X	X					NSC
6938.2	Contractors shall refer to section 1.1, for the definition of Accredited provider/supplier.	X	X	X	X	X					NSC
6938.3	Contractors shall refer to section 1.1, for the definition of Advanced diagnostic imaging service.	X	X	X	X	X					NSC
6938.4	Contractors shall refer to section 1.1, for the definition of CMS-approved accreditation organization.	X	X	X	X	X					NSC
6938.5	Contractors shall refer to section 1.2, for more instructions on physicians, providers and suppliers (except durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)) suppliers enrolling or updating their Medicare enrollment record.	X	X	X	X	X					
6938.6	Contractors shall refer to section 34.1, for new instruction regarding the quarterly reporting of contact information. Any updates should be sent directly via e-mail to the contractor's assigned DPSE liaison or Business Function Lead (BFL.)	X	X	X	X	X					

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	
6938.7	Contractors shall participate in UAT testing for each PECOS release.	X	X	X	X	X					NSC
6938.8	When requested, contractors shall attend scheduled PECOS training sessions.	X	X	X	X	X					NSC
6938.9	Contractors shall report PECOS validation and production processing problems through the designated tracking system for each system release.	X		X	X	X					NSC

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

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	None

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

V. CONTACTS

Pre-Implementation Contact(s): Ann Marie Reimer (Vale) (410) 786-4898
Post-Implementation Contact(s): Ann Marie Reimer (Vale) (410) 786-4898

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *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.

Medicare Program Integrity Manual
Chapter 15 - *Medicare Enrollment*

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(Rev. 347, 07/15/10)

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15.1 – Introduction to Provider Enrollment

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

This chapter specifies the resources and procedures Medicare fee-for-service contractors must use to establish and maintain provider and supplier enrollment in the Medicare program. These procedures apply to carriers, fiscal intermediaries, Medicare administrative contractors and the National Supplier Clearinghouse (NSC), unless contract specifications state otherwise.

No provider or supplier shall receive payment for services furnished to a Medicare beneficiary unless the provider or supplier is enrolled in the Medicare program. Further, it is essential that each provider and supplier enroll with the appropriate Medicare fee-for-service contractor.

15.1.1 – Definitions

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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

Accredited provider/supplier means a supplier that has been accredited by a CMS-designated accreditation organization.

Advanced diagnostic imaging service means any of the following diagnostic services:

- *(i) Magnetic resonance imaging.*
- *(ii) Computed tomography.*
- *(iii) Nuclear medicine.*
- *(iv) Positron emission tomography.*

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

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

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

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

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

CMS-approved accreditation organization means an accreditation organization designated by CMS to perform the accreditation functions specified.

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

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

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges.

Enroll/Enrollment means the process that Medicare uses to grant Medicare billing privileges.

Enrollment Application means a paper CMS-855 enrollment application or an electronic enrollment process approved by the Office of Management and Budget (OMB).

Final adverse action means one or more of the following actions:

(i) A Medicare-imposed revocation of any Medicare billing privileges;
(ii) Suspension or revocation of a license to provide health care by any State licensing authority;
(iii) Revocation or suspension by an accreditation organization;
(iv) A conviction of a Federal or State felony offense (as defined in §424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or
(v) An exclusion or debarment from participation in a Federal or State health care program.

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

Managing Employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or

supplier, either under contract or through some other arrangement, whether or not the individual is a W-2 employee of the provider or supplier.

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

(For Part A providers, the Medicare Identification Number (MIN) is the CMS Certification Number (CCN). For Part B suppliers other than suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), the MIN is the Provider Identification Number (PIN). For DMEPOS suppliers, the MIN is the number issued to the supplier by the NSC.)

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

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

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

Physician or non-physician practitioner organization means any physician or non-physician practitioner entity that enrolls in the Medicare program as a sole proprietorship or organizational entity.

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

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

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

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

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

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

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

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

*15.*1.2 –*Medicare Enrollment Application (CMS-855)*

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Physicians, providers and suppliers (except durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers enroll or update their Medicare enrollment record using:

- *The Internet-based Provider Enrollment, Chain and Ownership System (PECOS), or*

- *The paper enrollment application process (e.g., CMS-855I or the CMS-855R).*

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

- Ensure that the applicant is qualified and eligible to enroll in the Medicare program.

- Help determine the proper amount of Medicare payment.

The five forms are distinguished as follows:

- CMS-855I - This form should be completed by individual practitioners, including physicians and non-physician practitioners, who render Medicare Part B services to Medicare beneficiaries. (This includes a physician or practitioner who: (1) is the sole owner of a professional corporation, professional association, or limited liability company, and (2) will bill Medicare through this business entity.)

- CMS-855R - An individual who renders Medicare Part B services and seeks to reassign his or her benefits to an eligible entity should complete this form for each entity eligible to receive reassigned benefits. The person must be enrolled in the Medicare program as an individual prior to reassigning his or her benefits.

- CMS-855B - This application should be completed by a supplier organization (e.g., ambulance company) that will bill Medicare for Part B services furnished to Medicare beneficiaries. It is not used to enroll individuals.

- CMS-855A - This application should be completed by institutional providers (e.g., hospital) that will furnish Medicare Part A services to Medicare beneficiaries.

- CMS-855S – This application should be completed by DMEPOS suppliers. The NSC is responsible for processing this type of enrollment application.

A separate application must be submitted for each provider/supplier type. For example, a physician who wishes to bill as a DMEPOS supplier must submit two separate applications.

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

- The CMS Web site at which the applications can be accessed (www.cms.hhs.gov/MedicareProviderSupEnroll);

- Notification of any supporting documentation required for the applicant's provider/supplier type;

- The Electronic Funds Transfer Authorization Agreement (CMS-588) (Note: The NSC is only required to collect the CMS-588 with initial enrollment applications);

- The Electronic Data Interchange (EDI) agreement (Note: This does not apply to the NSC);

- The Medicare Participating Physician or Supplier Agreement (CMS-460), with an explanation of the purpose of the agreement and how it differs from the actual enrollment process. (This only applies to carriers.)

- The contractor’s address, so that the applicant knows where to return the completed application;

- If the applicant is a certified supplier or provider, notification that the applicant should contact the State agency for any state-specific forms and to begin preparations for a State survey. (This does not apply for those certified entities, such as FQHCs, that do not receive a State survey.) The notification can be given in any manner the contractor chooses.

*15.*1.3 – Medicare Contractor Duties

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor must adhere to the processing guidelines established in this chapter 1*5* (hereinafter generally referred to as "this manual"). In addition, the contractor shall assign the appropriate number of staff to the Medicare enrollment function to meet established processing timeframes.

The contractor shall provide training to new employees and provide refresher training, as necessary, to existing employees to ensure that each employee processes enrollment applications in a timely, consistent, and accurate manner. Training shall include, at a minimum:

- An overview of the Medicare program;
- A review of applicable regulations, manual instructions and other guidance issued by CMS;
- A review of the contractor's enrollment processes and procedures; and
- Training regarding the Provider Enrollment, Chain and Ownership System (PECOS).
- For new employees, the contractor shall also:
- Provide side-by-side training with an experienced provider enrollment analyst;
- Test the new employee to ensure that the analyst understands Medicare enrollment policy and contractor processing procedures, including the use of PECOS; and
- Conduct end-of-line quality reviews for 6 months after training or until the analyst demonstrates a clear understanding of Medicare enrollment policy and contractor procedures.
- Contractors shall process all enrollment actions (i.e., initials, changes, revalidations and reactivations) through PECOS.
- Contractors shall deactivate or revoke in MCS and FISS only if the provider or supplier is not in PECOS.
- Contractors shall close or delete any aged logging and trackings (L&Ts) that exceed 120 days for which there is not an associated enrollment application.
- *Contractors shall participate in UAT testing for each PECOS release.*
- *When requested, contractors shall attend scheduled PECOS training.*

- *Contractors shall report PECOS validation and production processing problems through the designated tracking system for each system release.*

Moreover, each contractor shall develop (and update as needed) a written training guide for new and current employees on the proper processing of CMS-855 applications as well as the appropriate entrance of data into PECOS.

Conduct Prescreening

- Review the application to determine that it is complete and that all information and supporting documentation required for the applicant's provider/supplier type has been submitted on and with the appropriate enrollment application.

Conduct Verification, Validation, and Final Processing

- Verify and validate the information collected on the enrollment application.

- Coordinate with State survey/certification agencies and regional offices (ROs), as needed .

- Collect and maintain the application's certification statement (in house) to verify and validate Electronic Funds Transfer (EFT) changes. The change request signature must be checked against the original signature to determine the validity of any change to EFT information. This check can be made against a digital/photo image kept in-house. (See section 8 of this manual for more information.)

- Confirm that the applicant, all individuals and entities listed on the application, and any names or entities ascertained through the use of an independent verification source, are not presently excluded from the Medicare program by the HHS Office of the Inspector General (OIG). Contractors shall confirm and validate data through Qualifier.net, the Medicare Exclusion Database (MED), and the General Services.

15.2 – Provider and Supplier Business Structure

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

This section explains the legalities of various types of business organizations that may enroll, including sole proprietorships. Note that the provider's organizational structure can have a significant impact on the type of information it must furnish on the CMS-855.

Business organizations are generally governed by State law. Thus, State X may have slightly different rules than State Y regarding certain entities. (In fact, X may permit the creation of certain types of legal entities that Y does not.) The discussion below gives only a broad overview of the principal types of business entities and does not take into account different State nuances.

Since CMS issues a 1099 based on an enrolled entity's business structure, providers and suppliers should consult with their accountant or legal advisor to ensure that they are establishing the correct business structure.

A. Sole Proprietorships

A business is a sole proprietorship if it meets all of the following criteria:

- It files a Schedule C (1040) with the IRS (this form reports the business's profits/losses);
- One person owns all of the business's assets; and
- It is not incorporated.

A sole proprietorship is not a corporation. Suppose a physician operates his/her business as a home health agency. If he/she incorporates his/her business, the business becomes a corporation (even though the physician is the only stockholder). Thus, the frequently-used term "unincorporated sole proprietorship" is a misnomer, because sole proprietorships by definition are unincorporated. In addition, merely because the sole proprietor hires employees does not mean that the business is no longer a sole proprietorship. Assume W is a sole proprietor and he hires X, Y, and Z as employees. W's business is still a sole proprietorship because he remains the 100% owner of the business. On the other hand, if W had sold parts of his sole proprietorship to X, Y, and Z the business would no longer be a sole proprietorship, as there is now more than one owner.

Note that professional associations (PAs) are generally not considered to be sole proprietorships; the PA designation is typically used in States that do not allow individuals to incorporate and form professional corporations. The PA will have its own EIN and is considered, like a professional corporation, to be a legal entity that is separate and distinct from the individual.

B. Partnerships

A partnership is an association of two or more persons/entities who carry on a business for profit. Each partner in a partnership is an owner. If A and B form the "Y Partnership" and each contributes $50,000 to start up the business, each partner owns one-half of Y.

In several respects, a partnership is the opposite of a corporation:

- Each partner is liable for all the debts of the partnership. Using the example above, suppose the Y Partnership breached a contract it had with Mr. X, who now sues for $10,000. Since each partner is liable for all debts, X can collect the entire $10,000 from A, or from B, or $5,000 from each, etc. This is because, unlike a corporation, a partnership is not really a separate and distinct entity from its partners/owners; the partners are the partnership. If Y had been a corporation, the owners (A and B) would likely have been be shielded from liability.

- There is no "double taxation" with partnerships. The partnership itself does not pay taxes, although each partner pays taxes on any income he/she earns from the business.

- Unlike a corporation, a partnership generally does not file papers with the State upon its creation (i.e., it does not file the equivalent of articles of incorporation). Instead, a partnership has a "partnership agreement," which amounts to a contract between the partners outlining duties, responsibilities, powers, etc.

- Each partner has the right to participate in running the business's day-to-day operations, unless the partnership agreement dictates otherwise.

An alternative type of partnership is a limited partnership (as opposed to a "general partnership," described above). While possessing many of the characteristics of a general partnership, there are some key differences. First, a limited partnership (LP) must file formal documents with the State. Second, a LP has two types of partners – general and limited. The general partner(s) runs the business, yet is personally responsible for all of the LP's debts. Conversely, the limited partner(s) have limited liability yet cannot participate in the management of the business.

C. Limited Liability Companies (LLC)

A limited liability company (LLC) is a legal entity that is neither a partnership nor a corporation, but has characteristics of both. Its owners have limited liability (just like stockholders in a corporation). In addition, the LLC does not pay Federal taxes (similar to a partnership), although its owners – usually referred to as "members" - must pay taxes on any dividends they reap. An LLC thus contains the best attributes of corporations and partnerships, which is why LLCs are rapidly gaining in popularity.

An LLC should not be confused with a limited liability corporation, which is a type of corporation in some States. A limited liability company is not a corporation or partnership, but a distinct legal entity created and regulated by special State statutes.

Note that certain CMS-855 information is required of different entities. The primary example of this is in section 6 (Managing Individuals). If the provider is a corporation, it must list its officers and directors on the form. Partnerships and LLCs, on the other hand, do not have officers or directors and thus need not list them.

D. Joint Ventures

A joint venture is when two or more persons/entities combine efforts in a business enterprise and agree to share profits and losses. It is very similar to a partnership, and is treated as a partnership for tax purposes. The key difference is that a partnership is an ongoing business, while a joint venture is a temporary, one-time business undertaking. A joint venture, therefore, can be classified as a "temporary partnership."

E. Corporations

A corporation is an entity separate and distinct from its owners (called stockholders, or shareholders). To form a corporation, various documents – such as articles of incorporation – must be filed with the State in which the business will incorporate. The key elements of a corporation are:

- Limited Liability – This is the main reason why a business chooses to operate as a corporation. Suppose Corporation X has ten stockholders, each owning 10% of the business. X breached a contract it had with Company Y, and now Y wants to sue X's owners. Unfortunately for Y, it can really only sue X itself; it cannot go after X's shareholders. The corporation's owners are essentially shielded from liability for the actions of the corporation because, as stated above, a corporation is separate and distinct from its owners.

Despite the concept of limited liability, there may be instances where a corporation's owners/stockholders can be held personally liable for the corporation's debts. This is known as "piercing the corporate veil" (PCV), whereby one tries to get past the brick wall of the corporation in order to collect money from the owners behind that wall. However, PCV is a difficult thing to do and many courts are unwilling to allow it, meaning that plaintiffs can only collect from the corporation itself.

- "Double" Taxation – This is the principal reason why a business chooses not to be a corporation. "Double" taxation means that: (1) the corporation itself must pay taxes, AND (2) each shareholder must pay taxes on any dividends he/she receives from the business.

- Board of Directors – Most corporations are run by a governing body, typically called a Board of Directors.

Two special types of corporations contractors may encounter are:

- "Professional Corporation" or "PC." In general, a PC: (1) is organized for the sole purpose of rendering professional services (such as medical or legal), and (2) all stockholders in the PC must be licensed to render such services. Thus, if A, B and C want to form a physician practice (each is a 1/3 stockholder) and only A is a medical professional, the PC probably cannot be formed (depending, of course, on what the applicable State PC statute says). In addition, the title of a PC will usually end in "PC," "PA" (Professional Association) or "Chartered."

- "Close" Corporation (or "closely-held" corporation) – This is a type of corporation with a very limited number of stockholders. Unlike a "regular" corporation, the entity's board of directors generally does not run the business; rather, the shareholders do. The stock is typically not sold to outsiders.

Although PCs and CCs are considered "corporations" for enrollment purposes, State laws governing these entities are often different from those that govern "regular"

corporations (i.e., States have separate statutes for "regular" corporations and for PCs/CCs.) In many cases, an entity must specifically elect to be a PC or CC when filing its paperwork with the State.

F. Non-Profit Organizations

The term "non-profit organization" is misleading. It is not an organization that is forbidden to make a profit. Rather, it means that all of the organization's profits are put back into the entity to promote its goals, which are usually political, social, religious, or charitable in nature. In other words, the NPO is not organized primarily for profit, but instead to further some other goal. An entity can acquire NPO status by obtaining a 501(c)(3) certification from the IRS (meaning it is tax-exempt) or by acquiring such status from the State it is located in.

The NPO status is important for enrollment purposes because NPOs generally do not have owners. Thus, a NPO need not list any owners in sections 5 or 6 of the CMS-855.

G. Government-Owned Entities

For purposes of enrollment, a government-owned entity (GOE) exists when a particular government body (e.g., Federal, State, city or county agency) will be legally and financially responsible for Medicare payments received. For example, suppose Smith County operates Hospital X. Medicare overpaid X $100,000 last year. If Smith County is the party responsible for reimbursing Medicare this amount, X is considered a government-owned entity.

Note that:

- GOEs do not have "owners." Thus, section 5 of the CMS 855 need only contain the name of the government body in question. Using our example above, this would be Smith County.

- For section 6 (Managing Individuals), the only people that must be listed are "managing employees." This is because GOEs do not have corporate officers or directors.

The entity must submit a letter from the government body certifying that the government will be responsible for any Medicare payments.

15.3 – National Provider Identifier (NPI)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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. (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 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.

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.

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

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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).

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 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.

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

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 States3 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, hospitals5, 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.
- 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.

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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 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 valid6. 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.

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 providers7, nor is it permitted to reimburse providers who are not enrolled in the Medicare program. Medicare will return, with appropriate messages, any HIPAA standard transactions containing valid but unrecognizable NPIs.

15.4 – Provider and Supplier Types/Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Contractors shall consult other Medicare manuals for more information on how these providers and suppliers bill Medicare, their conditions of coverage and conditions of participation, etc.

15.4.1 – Intermediary-Enrolled Providers and Suppliers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.4.1.1 - Community Mental Health Centers (CMHCs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

A community mental health center (CMHC) is a facility that provides mental health services. A CMHC must perform certain **"core services."** These are:

1. **Outpatient services** (This includes services for (1) children, (2) the elderly, (3) persons who are chronically mentally ill, and (4) certain persons who have been discharged from a mental health facility for inpatient treatment.)

2. **24-hour**-a-day emergency psychiatric services

3. **Day treatment** or other **partial hospitalization (PH) services,** or psychosocial rehabilitation services; and

4. **Screening** for patients being considered for admission to State mental health facilities.

NOTE: Partial hospitalization is the only core service for which a CMHC can bill Medicare as a CMHC. Thus, while a facility must furnish certain "core" services in order to qualify as a CMHC, it can only get reimbursed for one of them – partial hospitalization. However, the facility may still be able to enroll with a Medicare carrier as a clinic if it does not perform partial hospitalization services.

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

In some instances, these core services can be furnished under arrangement. This generally means that the facility can arrange for another facility to perform the service if, among other things, CMS determines that the following conditions are met:

- The CMHC arranging for the service in question is authorized by State law to perform the service itself;

- The arranging CMHC accepts full legal responsibility for the service; and

- There is a written agreement between the two entities.

While the CMHC generally has the option to furnish services under arrangement, there is actually an instance where the facility must do so. If the CMHC is located in a State that prohibits CMHCs from furnishing screening services (service #4 above), it must contract with another entity to have the latter perform the services. Any such arrangement must be approved by the regional office (RO). (See Pub. 100-07, State Operations Manual (SOM), chapter 2, section 2250, for additional information of core services and arrangements.)

A CMHC must provide mental health services principally to individuals who reside in a defined geographic area (service area); that is, they must service a distinct and definable community. A CMHC (or CMHC site) that operates outside of this specific community must – unless the RO holds otherwise - have a separate provider agreement/number and enrollment, and must individually meet all Medicare requirements.

B. Enrollment and Certification

Once it is determined whether the CMHC complies with Federal, State, and local laws, the RO will either approve or deny the CMHC's enrollment. This is the same process that virtually all certified providers and certified suppliers follow. Unlike most such entities, however, CMHCs are not surveyed by the State agency to determine the CMHC's compliance with Medicare laws (although the State may do a survey to verify compliance with State laws). Instead, the RO (or CMS-contracted personnel) will perform a site visit. The RO will not approve the CMHC unless the latter demonstrates that it is furnishing the core services to a sufficient number of patients. In addition, CMS reserves the right to request at any time documentation from the CMHC verifying the provision of core services.

If the RO or CMS-contracted personnel plans to perform a site visit of an existing, enrolled CMHC, the intermediary shall furnish any and all background information requested by the RO. All inquiries and correspondence relating to the site visit shall be directed to the RO.

Prior to making a recommendation for approval or denial, the intermediary shall ensure that the provider has submitted a completed and signed CMHC attestation statement. If the CMHC does not submit one, the intermediary shall recommend denial. (The

attestation requirement also applies to new owners in a CHOW.) The CMHC attestation statement typically serves as the provider agreement.

If the intermediary issues a recommendation for approval, it shall send a copy of the Form CMS-855A to the State agency (or, for intermediaries in RO 9, the intermediary's RO) with its recommendation. The intermediary shall also contact the appropriate RO to initiate a site visit of the CMHC applicant; a copy of the request should be sent to the State agency.

C. Practice Locations/Alternative Sites

A CMHC must list in Section 4 of its Form CMS-855A all alternative sites where core services are provided (i.e., proposed alternative sites for initial applicants and actual alternative sites for those CMHCs already participating in Medicare). The RO will decide whether the site in question: (1) can be part of the CMHC's enrollment (i.e., a practice location), or (2) should be enrolled as a separate CMHC with a separate provider agreement. The practice location could be out-of-state if the RO determines that the location services the same "defined geographic area" as the main location. In all cases, the RO has the final call in determining whether a particular practice location qualifies as an alternative site or whether a separate enrollment, provider agreement, etc., is required.

Contractors may refer to Pub. 100-07, SOM, chapter 2, section 2252, for additional information on CMHC alternative sites. Particular attention should be paid to the following provisions in section 2252I, regarding alternative sites:

- If a CMHC operates a CMS-approved alternative site, the site is not required to provide all of the core services. However, a patient must be able to access and receive the services he/she needs at the approved primary site, or at an alternative site that is within the distinct and definable community served by the CMHC.

- RO approvals of such alternative sites should be very limited, as CMHCs must serve a distinct and definable community and also because CMS has not limited the number of CMHCs an entity may submit for Medicare approval as long as these proposed CMHCs serve different communities.

- The RO will inform the CMHC if it determines that the proposed alternative site must be separately approved because it is not a part of the community where the CMHC is located.

D. Additional CMHC Information

For more information on CMHCs, refer to the following:

- Section 1861(ff) of the Social Security Act;
- 42 CFR Parts 410.2, 410.43, and 410.110; and
- Pub. 100-07, chapter 2, sections 2250 – 2252P (State Operations Manual).

15.4.1.2 - Comprehensive Outpatient Rehabilitation Facilities (CORFs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

A CORF is a facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients by or under the supervision of a physician. Specific examples of such services include:

- Physician services (*)
- Physical therapy (*)
- Occupational therapy
- Respiratory therapy
- Speech pathology
- Social work or psychological services (*)
- Prosthetic/orthotic devices
- Lab services (must meet 42 CFR Part 493 requirements)

* Services that the CORF must provide

In addition:

- If the RO determines that sufficient functional and operational independence exists, a CORF may be able to share space with another Medicare provider. However, the CORF may not operate in the same space at the same time with another Medicare provider. (See Pub. 100-07, State Operations Manual, chapter 2, sections 2364 – 2364C for more information.)

- Like most certified providers, CORFs must be surveyed by the State agency and must sign a provider agreement.

- On occasion, an outpatient physical therapy/speech language pathology (OPT/SLP) location might convert to a CORF; of course, it must be surveyed to ensure the CORF conditions of participation are met prior to receiving a Medicare provider number.

B. CORF Enrollment

Notwithstanding the "single fixed location" language cited in subsection A above, there may be isolated cases where the RO permits a CORF to have an offsite location. This typically arises if the CORF wants to provide physical therapy (PT), occupational therapy (OT), or speech language pathology (SLP) services away from the primary location. (This is permitted under 42 CFR §485.58(e)(2)). The offsite location would

not necessarily be separately surveyed, but would be listed as a practice location on the CORF's Form CMS-855A.
For more information on CORFs, refer to:

- Section 1861(cc) of the Social Security Act;
- 42 CFR Part 485, Subpart B;
- Pub. 100-07, chapter 2, sections 2360 – 2366 (State Operations Manual);
- Pub. 100-07, chapter 3, section 3224 (State Operations Manual);
- Pub. 100-07, Appendix K (State Operations Manual); and
- Pub. 100-02, chapter 12 (Benefit Policy Manual).

*15.4*1.3 - End-Stage Renal Disease Facilities (ESRDs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. Types of ESRDs

The ESRD facilities are entities that perform renal services for patients with irreversible and permanent kidney failure. There are several types of ESRD facilities:

- Renal Transplantation Center (RTC) – An RTC is a hospital unit approved to furnish – directly - transplantation and other medical and surgical specialty services required for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. An RTC must be a member of the Organ Procurement and Transplantation Network (OPTN).

- Renal Dialysis Center (RDC) – An RDC is a hospital unit approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement and outpatient dialysis). Also:

    - The RDC need not furnish transplantation services;

    - An RTC can also be an RDC;

    - The RDC must be hospital-owned and operated, and the hospital must be enrolled in Medicare.

A separate, independent dialysis unit located in a Medicare-approved hospital cannot be approved as an RTC or RDC. (See 100-07, SOM, chapter 2, section 2280.1.)

- Renal Dialysis Facility (RDF) – This is a unit (but not necessarily a hospital unit) approved to furnish dialysis services directly to ESRD patients. A hospital (whether enrolled or not) can be an RDF if it is an outpatient provider of dialysis services that will not be furnishing inpatient dialysis services.

- A hospital-based RDF "satellite" is one that is hospital-owned and administered but is not located on the hospital's premises. A hospital can have multiple satellites.

- Self-Dialysis Unit (SDU) – An SDU is a unit of an approved RTC, RDC or RDF and that provides self-dialysis services.

- Special Purpose Renal Dialysis Facility (SPRDF) – SPRDFs are entities that perform ESRD services on a short-term basis in special situations for patients who cannot otherwise receive treatment in the geographical area. SPRDFs can be approved to serve vacation areas and in emergency situations. (See Pub. 100-07, chapter 2, section 2280D for more information on SPRDFs.) Like RTCs, RDCs, RDFs, and SDUs, SPRDFs must submit a Form CMS-855A to the fiscal intermediary.

B. ESRD Survey and Certification

The standard CMS survey and certification form used for ESRDs is the Form CMS-3427. Part I of this form must be completed, as must the Form CMS-855A, when the ESRD is initially enrolling, changing or adding a location, or undergoing a CHOW. Part I must also be completed for: (1) a change in service and (2) an expansion or addition of ESRD stations. However, the Form CMS-855A need not be furnished in these two latter instances (e.g., an ESRD station does not qualify as a practice location on the Form CMS-855A), though the RO may issue a tie-in notice to the intermediary as notification of the change. Also, because the "End-Stage Renal Disease Facility" category on the Form CMS-855A encompasses all five ESRD categories, it is not necessary for the facility to submit a Form CMS-855A if it is changing from one ESRD type to another, though it must complete the Form CMS-3427. (See Pub. 100-07, SOM, chapter 2, sections 2274 – 2276 and 2278 – 227, for more information on the Form CMS-3427 requirement.)

If the RO approves the station/service change or addition, it may send a tie-in notice to the intermediary updating the number of stations or types of services.

C. Miscellaneous ESRD Policies

- The ESRD Network is a group of organizations under contract with CMS that serve as liaisons between the agency and ESRD providers. (There are currently 18 Network organizations.) The organizations oversee the care ESRD patients receive, collect data, and furnish technical assistance to ESRD providers and patients.

- The provider-based rules for ESRD facilities are contained in 42 CFR §413.174 and are slightly different than those listed in the main provider-based regulation (42 CFR §413.65). (§413.174 uses the term "hospital-based" as opposed to "provider-based.")

- As ESRD facilities are technically "suppliers," they sign a supplier agreement rather than a provider agreement. Even if the ESRD facility is a hospital unit, it signs an agreement that is separate and distinct from the hospital's agreement.

D. ESRD Enrollment

Each type of ESRD must enroll as an ESRD facility via the Form CMS-855A. Since the Form CMS-855A does not distinguish between the different types of ESRDs, the following general principles apply:

- If an enrolled RTC also wants to become an RDC, the provider must submit a new, complete Form CMS-855A for the RDC. For enrollment purposes, the RTC and the RDC will be treated as two separate ESRD facilities.

- If an enrolled ESRD wants to change to another type of ESRD, the provider need not submit a Form CMS-855A change of information (assuming that this is the only change to the provider's enrollment data).

- ESRD facilities can have multiple practice locations – if the RO approves it - though this typically only occurs with RDFs.

E. Additional Information on ESRD Facilities

For further data on ESRD facilities, refer to:

- Section §1881 of the Social Security Act;
- 42 CFR Part 405, Subpart U;

- Pub. 100-07, chapter 2, section 2270 – 2287B (State Operations Manual);

- Pub. 100-02, chapter 11 (Benefit Policy Manual); and

- Pub. 100-04, chapter 8 (Claims Processing Manual).

*15.4*1.4 - Federally Qualified Health Centers (FQHCs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The FQHCs furnish services such as those performed by physicians, nurse practitioners, physician assistants, clinical psychologists, and clinical social workers. This includes certain preventive services like prenatal services, immunizations, blood pressure checks, hearing screenings and cholesterol screenings. (See Pub. 100-02, Medicare Benefit Policy Manual, chapter 13). Even though their services are billed to fiscal intermediaries, they are considered Part B certified suppliers.

The FQHCs are not required to obtain a State survey; there is little State agency involvement with FQHCs. As such, the intermediary will make its recommendation for approval or denial and forward it directly the RO. The RO will then make the final decision as to whether the supplier qualifies as a FQHC. Generally, in order to so qualify the facility must be receiving, or be eligible to receive, certain types of Federal grants (sometimes referred to as "grant status"), or must be an outpatient facility operated by an Indian tribal organization. The Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (DHHS)

may assist the RO in determining whether a particular supplier meets FQHC standards, since HRSA maintains a list of suppliers that met certain grant requirements. (See Pub. 100-07, SOM, chapter 2, sections 2825-2826D for more information.)

A few other notes about FQHCs:

- As stated above, there is no State agency involvement with FQHCs. However, FQHCs still must meet all applicable State and local requirements and submit all applicable licenses. Typically, HRSA will verify such State/local compliance by asking the FQHC to attest that it meets all State/local laws.

- The FQHCs can be based in a rural or urban area.

- To qualify as an FQHC, the facility must, among other things, either: (1) furnish services to a medically underserved population or (2) be located in a medically underserved area.

- The effective date for an FQHC's Medicare participation is the date the RO signs the FQHC agreement after determining that all Medicare requirements, including enrollment requirements, are met. However, if the application is complete and all requirements have been met when the RO reviews the application, the RO will use the date on the intermediary's recommendation letter as the effective date. (See Pub. 100-07, chapter 2, section 2826H).

- The FQHC must submit a signed and dated attestation statement (Exhibit 177). This attestation serves as the Medicare FQHC benefit (or provider/supplier) agreement. (See Pub. 100-07, chapter 2, section 2826B.) The FQHC must also submit, as indicated above, a HRSA "Notice of Grant Award" or Look-Alike Status. A completed FQHC crucial data extract sheet (Exhibit 178), however, is no longer required.

- The FQHC's cannot have multiple sites or practice locations. Each location must be separately enrolled and will receive its own OSCAR number.

For additional general information on FQHCs, refer to:

- Section 1861(aa)(3-4) of the Social Security Act;

- 42 CFR Part 491;

- Pub. 100-07, chapter 2, sections 2825 – 2826H (State Operations Manual);

- Pub. 100-04, chapter 9 (Claims Processing Manual); and

- Pub. 100-02, chapter 13 (Benefit Policy Manual)

For information on the appropriate contractor jurisdictions for incoming FQHC enrollment applications, see;

- Pub. 100-04, chapter 1, section 20;
- Pub. 100-04, chapter 9, section 10.3;
- CMS Change Request 6207.

15.4.1.5 – Histocompatibility Laboratories

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A histocompatibility laboratory does "matching" tests in preparation for procedures such as kidney transplants, bone marrow transplants, and blood platelet transfusions. It is the only type of laboratory that must enroll with the fiscal intermediary. Each histocompatibility lab must meet all applicable requirements in 42 CFR Part 493 (see 42 CFR §493.1278 in particular) and undergo a State survey.

For information on the appropriate contractor jurisdiction for incoming histocompatibility lab applications, please see Pub. 100-04, CPM, chapter 1, section 20.

15.4.1.6 - Reserved

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.4.1.7 - Hospices

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Hospices are not precluded from having multiple practice locations if permitted by the RO. If the RO disapproves the additional practice location, the location must seek Medicare approval as a separate hospice with its own Form CMS-855A enrollment, provider agreement and provider number. (See Pub. 100-07, SOM, chapter 2, section 2081, for the policies regarding multiple hospice locations.)

For more information on hospices, refer to:

- Sections 1861(u) and 1861(dd) of the Social Security Act;
- 42 CFR Part 418;
- Pub. 100-07, chapter 2, sections 2080 – 2087 (State Operations Manual);
- Pub. 100-04, chapter 11 (Claims Processing Manual); and
- Pub. 100-02, chapter 9 (Benefit Policy Manual)

15.4.1.8 - Hospitals and Hospital Units

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

- **Swing-Bed Designation** - A "swing-bed" hospital is one that is approved by CMS to furnish post-hospital SNF services. That is, hospital (or critical access hospital (CAH)) patients' beds can "swing" from furnishing hospital services to providing SNF care without the patient necessarily being moved to another part of the building. It receives a separate survey and certification from that of the hospital; thus, if swing-bed designation is terminated, the hospital still maintains its certification. In addition, the hospital is given an additional OSCAR number to bill for swing-bed services. (The third digit of the number will be the letter U, W, Y or Z.)

As stated in 42 CFR §482.66, in order to obtain swing-bed status the hospital – among other things – must: (1) have a Medicare provider agreement, (2) be located in a rural area, and (3) have fewer than 100 non-newborn or intensive care beds. Swing-bed hospitals, therefore, are generally small hospitals in rural areas where there may not be enough skilled nursing facilities; the hospital can thus be used to furnish SNF services.

A separate provider agreement and enrollment for the swing-bed unit is not required. (The hospital's provider agreement incorporates the swing-bed services.) The hospital can add the swing-bed unit as a practice location to its Form CMS-855A.

Additional data on "swing-bed" units can be found in Pub. 100-07, SOM, chapter 7, sections 2036 – 2040.

- **Psychiatric and Rehabilitation Units** – Though these units receive a State survey, a separate provider agreement and enrollment is not required. (The hospital's provider agreement incorporates these units.) The hospital can add the unit as a practice location to the Form CMS-855A.

- **Multi-Campus Hospitals** - A multi-campus hospital (MCH) is one with two or more hospital campuses operating under one OSCAR number; the MCH would report its various units/campuses as practice locations on the Form CMS-855A. A hospital that has its own main campus but also occupies space in another hospital has a "satellite facility" in that other hospital. For additional information on multi-campus hospitals, see Pub. 100-07, chapter 2, section 2024.

15.4.1.9 - Indian Health Services (IHS) Facilities

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

For purposes of provider enrollment only, there are several types of IHS facilities: (1) those that are wholly owned and operated by the IHS, (2) facilities owned by the IHS but tribally operated, and (3) facilities totally owned and operated by a tribe, though under the general IHS umbrella. When an IHS facility wishes to enroll with the fiscal intermediary, it may either check: (a) "Indian Health Services Facility", or (b) the specific provider type it is. For instance, if an IHS hospital is involved, the provider may check "Indian Health Services Facility" or "Hospital" on the application - or perhaps both. Even if it only checked "Hospital," the LBN or DBA Name will

typically contain some type of reference to Indian Health Services; as such, the intermediary will know it is dealing with an IHS facility.
The overwhelming majority of IHS facilities on the Part A side are either hospitals, SNFs, CAHs, or ESRD facilities. The contractor processes IHS applications in the same manner (and via the same procedures) as it would with a hospital, SNF, etc. (This also applies to procedures for PECOS entry.)

As for CCN numbers, the IHS facility uses the same series that its concomitant provider type does. In other words, an IHS hospital uses the same CCN series as "regular" hospitals; an IHS CAH utilizes the same series as regular CAHs; and so forth.

For additional general information on IHS facilities, see Pub. 100-04, chapter 19. For information regarding the appropriate contractor jurisdiction for incoming Part A IHS facility applications, please see Pub. 100-04, chapter 1, section 20.

15.4.1.10 - Organ Procurement Organizations (OPOs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

An OPO is an organization that performs or coordinates the procurement, preservation, and transport of organs, and maintains a system for locating prospective recipients for available organs. There are two general steps involved in becoming a Medicare OPO – certification and designation.

Certification means that CMS has determined that an OPO meets the requirements for certification at 42 CFR §486.303. It does not mean, however, that the OPO can begin billing for services. First, CMS must assign (or "designate") a geographic service area to the OPO. (The provider must also complete the Form CMS-576, Request for OPO Designation.) In practical terms, "designation" means that CMS has approved the OPO for coverage of services to transplant centers and that the OPO can begin submitting claims to Medicare.

There can be only <u>one</u> designated OPO per geographic service area. When an OPO is de-certified and its service area is opened for competition, the applicable CMS RO publishes a notice in local newspapers. CMS then selects an OPO to take over the service area, using the process at 42 CFR §486.316. As stated above, the OPO that CMS selects must first have been certified by CMS and the OPO must also meet the qualifications for designation at 42 CFR §486.304. The OPO must sign a provider agreement (Form CMS-576A) and participate in the Organ Procurement and Transplantation Network (OPTN). (See Pub. 100-07, chapter 2, sections 2810 and 2811.) Note that OPOs do not receive a State survey.
For more information on OPOs, refer to:

- Section 1138 of the Social Security Act;
- 42 CFR §486.301 - §486.348; and
- Pub. 100-07, chapter 2, sections 2810 – 2819 (State Operations Manual).

For guidance on the appropriate contractor jurisdiction for incoming OPO applications, please see Pub. 100-04, CPM, chapter 1, section 20. Note that a hospital-based OPO must enroll separately, be separately certified, and sign its own provider agreement. However, the hospital's Medicare contractor will service the OPO and the OPO will not receive its own CCN number.

15.4.1.11 - Outpatient Physical Therapy and Speech Language Pathology (OPT/SLP)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

There are three types of certified providers of OPT/SLP services:

- **Rehabilitation Agencies** – These facilities furnish services in a team environment and in accordance with a "multidisciplinary" program to assist handicapped and disabled individuals. They provide not only OPT or SLP services, but social or vocational adjustment services as well. (See Pub. 100-07, SOM, chapter 2, section 2292A.) The overwhelming majority of Part A OPT/SLP providers are rehabilitation agencies.

- **Clinics** – A clinic is created primarily for the provision of outpatient physician services. The entity's services must be furnished by a group of at least three physicians practicing medicine together, and at least one physician must be present in the clinic at all times to perform medical services.

- **Public Health Agency** – This is an agency created by a State or local government. Its primary purpose is to furnish environmental health services, preventive medical services and, in some instances, therapeutic services, as a means of sustaining the health of the general population.

Note further that:

- If an OPT/SLP provider elects to convert to a CORF, it must meet the CORF conditions of coverage and participation. A new Form CMS-855A enrollment application, State survey, and RO approval are also required.

- Only those clinics, as listed above, that provide OPT/SLP services have provider agreements under 42 CFR §489.2. Part B physician groups – the supplier type that most people normally associate with the term "clinics" – do not have provider or supplier agreements.

- Occupational therapy cannot be substituted for the physical therapy requirement. It may, however, be provided in addition to physical therapy or speech language pathology services. (See Pub. 100-07, SOM, chapter 2, section 2292A.)

B. Extension Locations

As discussed in Pub. 100-07, SOM, chapter 2, section 2298A, an OPT/SLP provider can furnish services from locations other than its primary site. (The provider must designate one location as its primary location.) These sites are called extension locations, and may include freestanding offices, suites in an office or medical building, or even space in an existing Medicare provider, such as a SNF or hospital; however, the separate area of the host provider or facility must be set aside for the provision of OPT/SLP services during the hours of the OPT's operations. (The area/room/unit would be considered the extension location.)

An OPT/SLP may also provide therapy services in a patient's home or in a patient's room in a SNF. Because they are not considered extension locations, neither the home nor a patient's room need be listed as a practice location on the provider's Form CMS-855A. (See Pub. 100-07, SOM, chapter 2, section 2298B.)

For an OPT/SLP provider to establish an extension location in an adjoining State, the two States involved must have a signed reciprocal agreement with each other allowing approval of the extension location. An extension location situated in a different State will bill under the primary site's provider number. (See Pub. 100-07, SOM, chapter 2, section 2302.)

C. Additional OPT/OSP Information

For more information on OPT/SLP providers refer to:

- Section 1861(p) of the Social Security Act;
- 42 CFR Part 485, subpart H;
- Pub. 100-07, chapter 2, sections 2290 – 2306 (State Operations Manual); and
- Pub. 100-07, Appendix E (State Operations Manual).

15.4.1.12 - Religious Non-Medical Health Care Institutions (RNCHIs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

RNHCIs furnish only nonmedical nursing services and items to people who choose to rely solely on obtaining a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious views. Such nonmedical services are performed by nonmedical nursing personnel and include activities like assistance in moving, comfort and support measures, and general assistance in performing day-to-day activities. (Of course, the nonmedical nursing personnel must be experienced in caring for the physical needs of nonmedical patients.) RNHCIs do not perform any medical screenings, examinations, diagnoses, or treatments, including the administration of drugs. It should also be noted that each beneficiary who wishes to receive services in an RNHCI must make a valid and formal written statement (or

"election") to do so. (The specific election requirements are discussed in 42 CFR §403.724 and Pub. 100-07, SOM, chapter 2, section 2054.1B.)
The Boston RO, has primary responsibility over the approval and certification of RNHCIs. RNHCIs are not certified by the State, but must meet all of the conditions of coverage outlined in 42 CFR §403.720, as well as all conditions of participation outlined in 42 CFR §403.730 through 746. For purposes of provider enrollment, the two most important conditions are:

- The provider must not be owned by, under common ownership with, or have an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in a provider of medical treatment or services. (Permissible affiliations are described in 42 CFR §403.738(c)); and

- The provider must be a non-profit organization per subsection (c)(3) of § 501 of the Internal Revenue Code of 1986, and exempt from taxes under subsection 501(a).

To this end, the contractor shall closely examine Sections 5 and 6 of the CMS-855A, as well as verify the provider's non-profit status, to ensure that the two aforementioned requirements are met.

For more information on RNCHIs, refer to:

- Section 1861(ss)(1) of the Social Security Act;

- 42 CFR Part 403, subpart G;

- Pub. 100-07, SOM, chapter 2, sections 2054, 2054.1, 20541A and 2054.1 (State Operations Manual);

- Pub. 100-04, chapter 3, sections 170 - 180 (Claims Processing Manual); and

- Pub. 100-02, chapter 1, sections 130 – 130.4.2 (Benefit Policy Manual).

For guidance on the appropriate contractor jurisdiction for incoming RNCHI applications, please see Pub. 100-04, chapter 1, section 20.

15.4.1.13 - Rural Health Clinics (RHCs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

Rural health clinics (RHCs):

- Are considered to be Part B certified suppliers, even though they enroll with and bill fiscal intermediaries.

- Must be primarily engaged in furnishing outpatient services. However, the services can in certain instances be performed in locations outside of the four walls of the clinic. (See Pub. 100-02, chapter 13 for more information.)

There are certain services performed by RHCs that do not actually qualify as RHC services. As such, they must be billed to the carrier – meaning that the clinic must enroll with the carrier as a "Multi-Specialty Clinic." It is not uncommon to see RHCs enrolled with both the intermediary (to get paid for RHC services) and the carrier (to get paid for non-RHC services).

- Sign a supplier agreement with CMS (akin to those signed by certified providers). Specifically, RHCs sign the Health Insurance Benefit Agreement (Form CMS-1561A).

- Can be either mobile in nature or fixed/permanent locations.

Note that a facility cannot be simultaneously enrolled as an FQHC and an RHC. Though there are similarities between these two provider types, there are key differences:

- Unlike FQHCs, which can service rural or urban regions, an RHC may only service an area that: (1) is rural, and (2) contains a shortage of health services or qualified medical personnel, otherwise known as a "shortage area." (See Pub. 100-02, chapter 13, section 10, which states that RHCs are clinics located in areas that are designated both by the Bureau of the Census as rural and by the Secretary of DHHS or the State as medically underserved.)

- FQHCs furnish preventive services while RHCs do not.

- RHCs are surveyed by the State; FQHCs are not.

B. Additional RHC Information

For more information on RHCs, refer to:

- Section 1861(aa)(1-2) of the Social Security Act;

- 42 CFR Part 491, subpart A;

- Pub. 100-07, chapter 2, sections 2240 – 2249 (State Operations Manual);

- Pub. 100-04, chapter 9 (Claims Processing Manual); and

- Pub. 100-02, chapter 13 (Benefit Policy Manual).

For guidance on the appropriate contractor jurisdictions for incoming RHC applications, please see:

- Pub. 100-04, chapter 1, section 20;
- Pub. 100-04, chapter 9, section 10.3;
- CMS Change Request 6207.

15.4.1.14 - Skilled Nursing Facilities (SNFs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

As stated in Pub. 100-07, chapter 7, section 7004B, a SNF is an entity that:

- Is primarily engaged in providing to residents skilled nursing care and related services for residents who require medical or nursing care; or
- Is primarily engaged in providing to residents skilled rehabilitation services for the rehabilitation of injured, disabled, or sick persons and is not primarily for the care and treatment of mental diseases;
- Has in effect a transfer agreement (meeting the requirements of §1861(1) of the Social Security Act with one or more hospitals having agreements in effect under §1866 of the Social Security Act); and
- Meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of §1819 of the Social Security Act.

A SNF may provide Part B outpatient physical therapy, speech therapy, or occupational therapy services either directly or under arrangement. (See Pub. 100-07, chapter 7, section 7010.)

As stated above, a SNF must have a "transfer agreement" with a Medicare-enrolled hospital. The agreement must provide for the transfer of patients between the hospital and the SNF, as well as the interchange of patient information. This requirement is needed since patients that are discharged from hospitals may then go to a SNF for follow-up or additional nursing care. The transfer agreement need not be submitted with the SNF's Form CMS-855A enrollment application; the State and/or RO will verify that the agreement exists.

Like other certified providers, SNFs receive a State survey and sign a provider agreement. Note that it is extremely rare for a SNF to have multiple practice locations; in any event, the RO will make the final decision as to whether the site can be treated as a practice location or must enroll as a separate SNF.

B. SNF Distinct Parts

A SNF can be a separate institution or a "distinct part" of an institution. The term "distinct part" means an area or portion of an institution (e.g., a hospital) that is certified to furnish SNF services. For instance, suppose Hospital X is located in a five-story building. The fifth floor is reserved for SNF services. For enrollment and certification purposes, and subject to RO approval, X could enroll as a hospital while the "5th floor" could enroll as a SNF. Of course, "distinct part" is not just limited to physical considerations. The distinct part must be fiscally separate from the other institution with respect to cost reporting. The hospital and the SNF distinct part will each receive a separate provider number, and separate Forms CMS-1539 will be prepared. Also:

- A hospital is permitted to have only one SNF distinct part.

- The hospital will typically submit to the State a diagram/floor plan outlining the distinct part's area.

- "Distinct part" designation is not the same thing as being "provider-based." (A provider-based SNF, like a distinct part SNF, receives an OSCAR number separate from that of the hospital.)

A SNF distinct part unit must enroll separately (it cannot be listed as a practice location on the hospital's Form CMS-855A), be separately surveyed and sign a separate provider agreement. (Note how this is different from "swing-bed" units, which do not enroll separately and do not sign separate provider agreements.) (See Pub. 100-07, chapter 2, section 2762B, subsection 4, for more information on SNF distinct parts.)

C. Additional Information

For more information on SNFs, refer to:

- Section 1819(a) of the Social Security Act;

- 42 CFR Part 488, subpart E;

- Pub. 100-07, chapter 7 (State Operations Manual);

- Pub. 100-02, chapter 8 (Benefit Policy Manual); and

- Pub. 100-04, chapter 6 (Part A) and chapter 7 (Part B) (Claims Processing Manual).

15.4.2 – Carrier-Enrolled Organizational Suppliers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.4.2.1 - Ambulatory Surgical Centers (ASCs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

An ASC is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients. The ASC signs a supplier agreement (Form CMS-370) with CMS and enrolls with the carrier; the supplier agreement is very similar to provider agreements signed by Part A providers. Note that ASCs can be fixed locations or mobile in nature.

Under 42 CFR §416.26(a), CMS may deem an ASC to be in compliance with the ASC conditions of coverage if the ASC:

- Is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;

- In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

- The ASC authorizes the release to CMS, of the findings of the accreditation survey.

- Unless CMS deems the ASC to be in compliance with the ASC conditions of coverage, a State survey will be performed.

B. ASCs and Hospitals

There are three main enrollment situations involving ASCs and hospitals:

1. The ASC is operated by a hospital – If the ASC is operated by a hospital, the ASC enrolls, participates and is paid only as an ASC. In other words, it still must independently enroll with the carrier and cannot be paid as a hospital outpatient department. The ASC agreement (Form CMS-370) will be made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC. Also, costs for the ASC are treated as a non-reimbursable cost center on the hospital's cost report. (See 42 CFR §416.30(f).)

2. Hospital outpatient department – If the ASC is treated as a hospital outpatient department, it will not independently enroll with the carrier as an ASC. It will simply be considered part of the hospital, and the services furnished therein will be billed to the fiscal intermediary. (See Pub. 100-04, chapter 14, section 10.1.)

3. The ASC is not hospital-operated (i.e., not a part of a provider of services or any other facility) – In this case, the ASC simply enrolls with the carrier normally.

In short, if an ASC is hospital-operated, it has the option of being covered under Medicare as an ASC, or of being treated as a hospital-affiliated outpatient surgery department. (See Pub. 100-02, chapter 15, section 260.1.) If a hospital-based facility

decides not to become a certified ASC, it bills the fiscal intermediary via the Form CMS-1450.

C. Additional Information

For more information on ASCs, refer to:

- Section 5.6 of this manual;
- Section 1832(a)(2)(F) of the Social Security Act;
- 42 CFR Part 416;
- Pub. 100-07, chapter 2, section 2210 and Appendix L (State Operations Manual);
- Pub. 100-02, chapter 15, sections 260 – 260.5.3 (Benefit Policy Manual); and
- Pub. 100-04, chapter 14 (Claims Processing Manual).
- Also, see Pub. 100-07, chapter 2, section 2210, for information regarding the sharing of space between ASCs and other providers.

*15.4*2.2 - CLIA Labs

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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 Pub. 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.

C. 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.

D. 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).

*15.4*2.3 - Mammography Screening Centers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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)

15.4.2.4 - Pharmacies

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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.

15.4.2.5 - Portable X-Ray Suppliers (PXRSs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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 inside or from 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:

- 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).

15.4.2.6 - Radiation Therapy Centers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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.

For additional background on radiation therapy services, see:

- Section 1861(s)(4) of the Social Security Act;

- 42 CFR §410.35;

- Pub. 100-04, chapter 13; and
- Pub. 100-02, chapter 15, section 90.

15.4.2.7 - Suppliers of Ambulance Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Per 42 CFR §410.40(d), Medicare covers ambulance services, including fixed wing and rotary wing ambulance services, only if they are furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated.

A. Types of Ambulance Services

There are several types of ambulance services covered by Medicare. They are defined in 42CFR §414.605 as follows:

1. **Advanced Life Support, level 1** (ALS1) - Transportation by ground ambulance vehicle, medically necessary supplies and services, and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

NOTE: Per 42CFR §414.605, ALS personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. The EMT-Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT-Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a limited number of medications.

2. **Advanced Life Support, level 2** (ALS2) - Either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the seven ALS procedures specified in 42CFR §414.605.

3. **Air Ambulance** (Fixed-Wing and Rotary-Wing) - Air ambulance is furnished when the patient's medical condition is such that transport by ground ambulance, in whole or in part, is not appropriate. Generally, this type of transport may be necessary because: (1) the patient's condition requires rapid transport to a treatment facility and either greater distances or other obstacles (e.g., heavy traffic) preclude such rapid delivery to the nearest appropriate facility; or (2) the patient is inaccessible by ground or water vehicle.

4. **Basic Life Support** (BLS) - Transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by an individual who is qualified in

accordance with State and local laws as an emergency medical technician-basic (EMT-Basic).

5. **Paramedic ALS Intercept Services** (PI) - Per 42CFR §414.605, EMT-Paramedic services furnished by an entity that does not furnish the ground transport, provided that the services meet the requirements in 42CFR §410.40(c). PI typically involves an arrangement between a BLS ambulance supplier and an ALS ambulance supplier, whereby the latter provides the ALS services and the BLS supplier provides the transportation component. Per 42CFR §410.40(c), PI must meet the following requirements:

- Be furnished in an area that is designated as a rural area;

- Be furnished under contract with one or more volunteer ambulance services that meet the following conditions:

    - Are certified to furnish ambulance services as required under 42CFR §410.41.

    - Furnish services only at the BLS level.

    - Be prohibited by State law from billing for any service.

- Be furnished by a paramedic ALS intercept supplier that meets the following conditions:

    - Is certified to furnish ALS services as required in 42CFR §410.41(b)(2).

- Bills of all the recipients who receive ALS intercept services from the entity, regardless of whether or not those recipients are Medicare beneficiaries.

6. **Specialty Care Transport** (SCT) - Inter-facility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area (e.g., nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.)

B. Ambulance Qualifications

1. Vehicle Design and Equipment

As specified in 42CFR §410.41(a), a vehicle used as an ambulance must meet the following requirements:

- Be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all State and local laws governing an emergency transportation vehicle.

- Be equipped with emergency warning lights and sirens, as required by State or local laws.
- Be equipped with telecommunications equipment as required by State or local law to include, at a minimum, one two-way voice radio or wireless telephone.

- Be equipped with a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by State or local laws.

2. Vehicle Personnel

Per 42CFR §410.41(b)(1)(i) & (ii), a BLS vehicle must be staffed by at least two people, one of whom must be: (1) certified as an emergency medical technician by the State or local authority where the services are furnished, and (2) legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

An ALS vehicle, in addition to meeting the BLS vehicle staff requirements described in 42CFR §410.41(b)(2), the previous paragraph, must also have one of the two staff members be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

C. Ambulance Claims Jurisdiction

Ambulance claims jurisdiction policies are specified in Pub. 100-04, chapter 1, section 10.1.5.3, and Pub. 100-04, chapter 15, section 20.1.2.

D. Completion of the CMS-855B

Pub. 100-02, chapter 10, section 10.1.3 states that, in determining whether the vehicles and personnel of the ambulance supplier meet all of the above requirements, the contractor may accept the supplier's statement (absent information to the contrary) that its vehicles and personnel meet all of the requirements. The contractor shall note that this provision in no ways obviates the need for the supplier to complete and submit to the contractor the CMS-855B enrollment form (including Attachment 1 thereto and all supporting documents), and does not excuse the contractor from having to verify the data on the CMS-855B enrollment form in accordance with the provisions of Pub. 100-08, chapter 10. In other words, the "statement" referred to in section 10.1.3, does not supplant or replace the CMS-855B provider enrollment process.

E. Miscellaneous Information

1. **Payment Amounts** - Per 42CFR §414.610(a), Medicare payment for ambulance services is based on the lesser of the actual charge or the applicable fee schedule amount.

2. **Non-Emergency Transport** - As stated in 42CFR §410.40(d), non-emergency transportation by ambulance is appropriate if either: (1) the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or (2) if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required.

3. **Point of Pick-Up** - The point of pick-up (POP), which is reported by the 5-digit ZIP Code, determines the basis of payment under the fee schedule. (See Pub. 100-04, chapter 15, section 20.1.5 for more information on the POP.)

4. **Destinations** - As discussed in 42CFR §410.40(e), Medicare covers the following ambulance transportation:

- From any point of origin to the nearest hospital, CAH, or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

- From a hospital, CAH, or SNF to the beneficiary's home.

- From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip.

- For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

Per Pub. 100-02, chapter 10, section 10.3.8, ambulance service to a physician’s office is covered only if: (1) transport is en route to a Medicare-covered destination, as described in Pub. 100-02, chapter 10, section 10.3; and (2) during the transport, the ambulance stops at a physician's office because of the patient's dire need for professional attention, and immediately thereafter, the ambulance continues to the covered destination.

(See Pub. 100-02, chapter 10, section 10.3.2 for information on “institution-to-institution” ambulance services; as stated therein, there may be instances where the institution to which the patient is initially taken is found to have inadequate or unavailable facilities to provide the required care, and the patient is then transported to a second institution having appropriate facilities. Also see Pub. 100-02, chapter 10, section 10.4.4, for information on hospital-to-hospital air ambulance transport; the air transport of a patient from one hospital to another may be covered if the medical appropriateness criteria are met - that is, transportation by ground ambulance would

endanger the beneficiary's health and the transferring hospital does not have adequate facilities to provide the medical services needed by the patient.)

5. **Local** - Per Pub. 100-02, chapter 10, section 10.3, as a general rule, only local transportation by ambulance is covered, and therefore, only mileage to the nearest appropriate facility equipped to treat the patient is covered.

6. **Part A** - For information on the Part A intermediary's processing of claims for ambulance services furnished under arrangements by participating hospitals, SNFs, and HHAs, see Pub. 100-02, chapter 10, section 10.1.4.

7. **Air Ambulance and Acute Care Hospitals** - As stated in Pub. 100-02, chapter 10, section 10.4.5, air ambulance services are not covered for transport to a facility that is not an acute care hospital, such as a nursing facility, physician's office, or a beneficiary's home.

For additional information on ambulance services, refer to:

- Section 1834(l) of the Social Security Act
- 42CFR410.40, 410.41, and 414.605.
- Pub. 100-02, chapter 10
- Pub. 100-04, chapter 15

15.4.3 - Medicare Advantage and Other Managed Care Organizations

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Medicare Advantage (MA) and other managed care organizations (MCOs) are allowed to bill Part B fee-for-service under certain situations. Such fee-for-service claims would include services provided to a beneficiary under the following situations: (1) the beneficiary has enrolled but their enrollment is not yet effective; (2) services provided by an attending physician or services unrelated to a terminal illness furnished to an enrollee who has elected hospice benefits; and (3) services furnished to an enrollee, but which are excluded under Section 1852(a)(5) of the Social Security Act from the MA/MCO contract.

NOTE: Specialty code 88 should be used.

15.4.4 - Individual Practitioners

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

This section furnishes background information on certain types of non-physician practitioners (NPPs). While Medicare has established Federal standards governing these supplier types, these practitioners must also comply with all applicable State and local laws as a precondition of enrollment.

The qualifications listed below for each NPP type – whether they were quoted from the applicable regulation or the appropriate manual instruction – represent current CMS policy.

15.4.4.1 - Anesthesiology Assistants

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

As stated in Pub. 100-04, chapter 12, section 140.1, an anesthesiology assistant is a person who:

- Is permitted by State law to administer anesthesia; and

- Has successfully completed a 6-year program for anesthesiology assistants, of which 2 years consists of specialized academic and clinical training in anesthesia.

For more information on anesthesiology assistants, refer to:

- Section 1861(bb)(2) of the Social Security Act

- 42 CFR §410.69(b)

- Pub. 100-04, chapter 12, sections 140 – 140.4.4 (Claims Processing Manual)

15.4.4.2 - Audiologists

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Under 42 CFR §440.110(c)(3), a "qualified audiologist" is an individual who:

- Has a master's or doctoral degree in audiology; and

- Is licensed as an audiologist by the State in which the individual furnishes such services and that State's requirements meet or exceed those in 42 CFR §440.110(c)(3)(ii)(A) or 42 CFR §440.110(c)(3)(ii)(B) (both of which are identified below).

If the person: (1) furnishes audiology services in a State that does not license audiologists, or (2) is exempted from State licensure based on practice in a specific institution or setting, the person must meet one of the following conditions:

- Have a Certificate of Clinical Competence in Audiology granted by the American Speech-Language-Hearing Association. (42 CFR §440.110(c)(3)(ii)(A))

OR

- Successfully completed a minimum of 350 clock-hours of supervised clinical practicum (or is in the process of accumulating that supervised clinical experience under the supervision of a qualified master or doctoral-level audiologist); and

- Performed at least 9 months of full-time audiology services under the supervision of a qualified master or doctoral-level audiologist after obtaining a master's or doctoral degree in audiology, or a related field; and

- Successfully completed a national examination in audiology approved by the Secretary. (42 CFR §440.110(c)(3)(ii)(B))

Thus, if the individual does not have a State license for either of the reasons stated in 42 CFR §440.110(c)(3)(ii), the person must meet the certification requirement in 42 CFR §440.110(c)(3)(ii)(A), OR all three of the criteria listed in 42 CFR §440.110(c)(3)(ii)(B), in order to be eligible to enroll in Medicare.

For more information on audiologists, refer to:

- Section 1861(ll)(3)(B) of the Social Security Act

- Pub. 100-02, chapter 15, sections 80.3 and 80.3.1(Benefit Policy Manual)

15.4.4.3 - Certified Nurse-Midwives

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

As stated in Pub. 100-02, chapter 15, section 180, a certified nurse-midwife must:

(1) Be currently licensed to practice in the State as a registered professional nurse; and

(2) Meet one of the following requirements:

a. Be legally authorized under State law or regulations to practice as a nurse-midwife and have completed a program of study and clinical experience for nurse-midwives, as specified by the State; OR

b. If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, the individual must:

1. Be currently certified as a nurse-midwife by the American College of Nurse-Midwives; or

2. Have satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives; or

3. Have successfully completed a formal education program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and have practiced as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976, to July 16, 1982.

All certified nurse-midwives, therefore, must: (1) be State-licensed as a registered nurse in the State in which the person seeks to practice as a nurse-midwife, (2) be legally authorized by the State to practice as a nurse-midwife, and (3) have completed a State-specified program of study and clinical experience for nurse-midwives. If the State does not specify such a program of study and clinical experience, the individual must meet one of the three criteria in 2(b) above.

For more information on certified nurse midwives, refer to:

- Section 1861(gg) of the Social Security Act
- 42 CFR §410.77
- Pub. 100-04, chapter 12, section 130 – 130.2 (Claims Processing Manual)

15.4.4.4 - Certified Registered Nurse Anesthetists (CRNAs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Per 42 CFR 410.69(b), a certified registered nurse anesthetist means a registered nurse who:

(1) Is licensed as a registered professional nurse by the State in which the nurse practices;

(2) Meets any licensure requirements the State imposes with respect to non-physician anesthetists;

(3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) Meets the following criteria:

(i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) Is a graduate of a program described in paragraph (3) and within 24 months after that graduation meets the requirements of paragraph (4)(i).

For more information on CRNAs, refer to:

- Section 1861(bb) of the Social Security Act;
- 42 CFR §410.69(b); and

- Pub. 100-04, chapter 12, sections 140 through 140.4.4 (Claims Processing Manual).

15.4.4.5 - Clinical Nurse Specialists (CNS)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Per Pub. 100-02, chapter 15, section 210, a clinical nurse specialist must meet all of the following requirements:

- Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to furnish the services of a clinical nurse specialist in accordance with State law.

- Have a master's degree in a defined clinical area of nursing from an accredited educational institution. (Effective January 1, 2009, a doctor of nursing practice (DNP) doctoral degree will also meet this educational requirement.)

- Be certified as a clinical nurse specialist by a recognized national certifying body that has established standards for CNSs.

The following organizations are recognized national certifying bodies for CNSs at the advanced practice level:

- American Academy of Nurse Practitioners;

- American Nurses Credentialing Center;

- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;

- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);

- Oncology Nurses Certification Corporation;

- AACN Certification Corporation; and

- National Board on Certification of Hospice and Palliative Nurses.

Under 42 CFR §410.76(c)(3), clinical nurse specialist services are covered only if, among other things, the CNS performed them while working in collaboration with a physician. Collaboration is a process in which a CNS works with one or more physicians to deliver health care services within the scope of the CNS's professional expertise, with medical direction and appropriate supervision as required by the law of the State in which the services are furnished.

For more information on clinical nurse specialists, refer to:

- 42 CFR §410.76
- Pub. 100-02, chapter 15, section 210 (Benefit Policy Manual)
- Pub. 100-04, chapter 12, sections 120 and 120.1 (Claims Processing Manual)

15.4.4.6 - Clinical Psychologists

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Under 42CFR §410.71(d), to qualify as a clinical psychologist a practitioner must meet the following requirements:

- Hold a doctoral degree in psychology; and

- Be licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

A clinical psychologist must agree to meet the consultation requirements of 42 CFR §410.71(e)(1) through (e)(3). Under 42 CFR §410.71(e), the practitioner's signature on the Form CMS-855I indicates his or her agreement.

For more information on clinical psychologists, refer to:

- Pub. 100-04, chapter 12, sections 170 (Claims Processing Manual)

- Pub. 100-02, chapter 15, section 160 (Benefit Policy Manual).

15.4.4.7 - Clinical Social Workers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Under 42 CFR §410.73(a), to qualify as a clinical social worker a practitioner must meet the following requirements:

1. Possesses a master's or doctor's degree in social work;

2. After obtaining the degree, has performed at least 2 years of supervised clinical social work; and

3. Either is licensed or certified as a clinical social worker by the State in which the services are performed or, in the case of an individual in a State that does not provide for licensure or certification as a clinical social worker—

   a. Is licensed or certified at the highest level of practice provided by the laws of the State in which the services are performed; and

b. Has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's degree level social worker in an appropriate setting, such as a hospital, SNF, or clinic.

For more information on clinical social workers, refer to:

- Section 1861(hh) of the Social Security Act
- Pub. 100-02, chapter 15, section 170 (Benefit Policy Manual)
- Pub. 100-04, chapter 12, section 150 (Claims Processing Manual)

15.4.4.8 - Nurse Practitioners

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Effective January 1, 2009, in order to bill Medicare a nurse practitioner must, as stated in 42 CFR §410.75(b), be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law, and must meet one of the following:

(1) Obtained Medicare billing privileges as a nurse practitioner for the first time on or after January 1, 2003, and meets the following requirements:

(i) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

(ii) Possess a master’s degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

(2) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2003, and meets the standards in (1)(i) above.

(3) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2001.

As stated in Pub. 100-02, chapter 15, section 200, the following organizations are recognized national certifying bodies for NPs at the advanced practice level:

- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;

- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);

- Oncology Nurses Certification Corporation;

- AACN Certification Corporation; and

- National Board on Certification of Hospice and Palliative Nurses.

In addition, under 42 CFR §410.75(c)(3) nurse practitioner services are covered only if, among other things, the nurse practitioner performed them while working in collaboration with a physician. Collaboration is a process in which a nurse practitioner works with one or more physicians to deliver health care services within the scope of the nurse practitioner's professional expertise, with medical direction and appropriate supervision as required by the law of the State in which the services are furnished.

For more information on nurse practitioners, refer to:

- Pub. 100-02, chapter 15, section 200 (Benefit Policy Manual)

- Pub. 100-04, chapter 12, sections 120 and 120.1 (Claims Processing Manual)

- 42 CFR §410.150(b)(16)

15.4.4.9 - Occupational and Physical Therapists in Private Practice

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. Occupational Therapists (OTs)

As stated in Pub. 100-02, chapter 15, section 230.2(B), a qualified occupational therapist for program coverage purposes is an individual who meets one of the following requirements:

- Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education of the American Medical Association and the American Occupational Therapy Association;

- Is eligible for the National Registration Examination of the American Occupational Therapy Association; or

- Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

B. Physical Therapists (PTs)

As stated in Pub. 100-02, chapter 15, section 230.1(B), a qualified physical therapist for program coverage purposes is a person who is licensed as a physical therapist by the state in which he or she is practicing and meets one of the following requirements:

- Has graduated from a physical therapy curriculum approved by (1) the American Physical Therapy Association, or by (2) the Committee on Allied Health Education and Accreditation of the American Medical Association, or (3) Council on Medical Education of the American Medical Association, and the American Physical Therapy Association; or

- Prior to January 1, 1966, (1) was admitted to membership by the American Physical Therapy Association, or (2) was admitted to registration by the American Registry of Physical Therapists, or (3) has graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education; or

- Has 2 years of appropriate experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination conducted, approved or sponsored by the Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking qualification as a physical therapist after December 31, 1977; or

- Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

- If trained outside the United States, (1) was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy, (2) meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

For more information on physical and occupational therapists, refer to:

- 42 CFR §410.59(c) (occupational therapists)

- 42 CFR §410.60(c) (physical therapists)

- Pub. 100-02, chapter 15, sections 230.2 and 230.4 (Benefit Policy Manual) (occupational therapists)

- Pub. 100-02, chapter 15, sections 230.1 and 230.4 (Benefit Policy Manual) (physical therapists)

15.4.4.10 - Physicians

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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. In addition, refer to Pub. 100-04, chapter 19, section 40.1.2, for special licensure rules regarding practitioners who work in or reassign benefits to hospitals or freestanding ambulatory care clinics operated by the IHS or by an Indian tribe or tribal organization.

15.4.4.11 - Physician Assistants (PAs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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
- 42 CFR §410.150(b)(15)
- Pub. 100-04, chapter 12, sections 110 through 110.3 (Claims Processing Manual)

15.4.4.12 - Psychologists Practicing Independently

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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:

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

15.4.4.13 - Registered Dietitians

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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

15.4.4.14 – Speech Language Pathologists in Private Practice

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Effective July 1, 2009, in order to qualify as an outpatient speech-language pathologist in private practice, an individual must, under, meet the following requirements:
(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of speech-language pathology by the State in which he or she practices, and practice only within the scope of his or her license and/or certification.
(ii) Engage in the private practice of speech-language pathology as an individual, in one of the following practice types:

(A) An unincorporated solo practice.

(B) An unincorporated partnership or unincorporated group practice.

(C) An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated speech-language pathology practice.

(D) An employee of a physician group.

(E) An employee of a group that is not a professional corporation.

For more information on speech language pathologists in private practice, refer to:

Pub. 100-02, chapter 15, section 230.

15.4.5 - Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an ASC

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Since carriers make payments for implantable prosthetics and DME to hospitals, physicians or ASCs, carriers shall not enroll manufacturers of implantable or non-implantable and prosthetics DME into the Medicare program. Manufacturers of non-implantable prosthetics and DME and replacement parts and supplies for prosthetic implants and surgically implantable DME may enroll in the Medicare program as a supplier with the NSC if they meet the definition of a supplier as well as the requirements set forth in 42 CFR § 424.57.

15.4.6 - Other Part B Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.4.6.1 - Diabetes Self-Management Training (DSMT)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

The DSMT is not a separately recognized provider type like a physician or nurse practitioner. A person or entity cannot enroll in Medicare for the sole purpose of performing DSMT. Rather, DSMT is merely an extra service that a currently-enrolled provider or supplier can bill for, assuming it meets all of the necessary DSMT requirements.

All DSMT programs must be accredited as meeting quality standards by a CMS-approved national accreditation organization. Currently, CMS recognizes the American Diabetes Association (ADA) and the Indian Health Service as approved national accreditation organizations. A Medicare-enrolled provider or non-DMEPOS supplier that wishes to bill for DSMT may simply submit the ADA certificate to its contractor. No Form CMS-855 paperwork is required, unless the provider or supplier is not in PECOS, in which case - per section 7.1.1 of this manual – a complete Form CMS-855 application is required.

If the supplier is exclusively a DMEPOS supplier, it must complete and submit a Form CMS-855B application to its local carrier. This is because DMERCs do not pay DSMT claims, but carriers can. Thus, the DMEPOS supplier must separately enroll with its carrier, even if it has already completed a Form CMS-855S. If a carrier receives an application from a DMEPOS supplier that would like to bill for DMST, it shall verify with the National Supplier Clearinghouse that the applicant is currently enrolled and eligible to bill the Medicare program.

For more information on DSMT, refer to:

- Section 1861(qq) of the Social Security Act
- 42 CFR Part 410 (subpart H)
- Pub. 100-02, chapter 15, sections 300 – 300.5.1 (Benefit Policy Manual)

15.4.6.2 - Mass Immunizers Who Roster Bill

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

An entity or individual who wishes to furnish mass immunization services, but may not otherwise qualify as a Medicare provider, may be eligible to enroll as a "Mass Immunizer" via the Form CMS-855I (individuals) or the Form CMS-855B (entities). Such providers, among other things, must meet the following requirements:

- They may not bill Medicare for any services other than pneumococcal pneumonia vaccines (PPVs), influenza virus vaccines, and their administration.
- They must submit claims through the roster billing process.

- All personnel who administer the shots must meet all applicable State and local licensure or certification requirements.

The roster billing process was developed to enable Medicare beneficiaries to participate in mass PPV and influenza virus vaccination programs offered by public health clinics and other organizations and persons who give the vaccine to a group of beneficiaries at sites such as clinics, shopping malls, grocery stores, senior citizen homes, and health fairs.

For more information on mass immunization roster billing, refer to:

- Pub. 100-02, chapter 15, section 50.4.4.2 (Benefit Policy Manual)

    - Pub. 100-04, chapter 18, sections 10 through 10.3.2.3 (Claims Processing Manual)

NOTE: Section 10.3.1 outlines the requirements for submitting roster bills.

15.4.7 - Medicaid State Agencies

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Only recognized providers and suppliers of services that have a National Provider Identifier (NPI) number can enroll in the Medicare program. Medicaid State agencies are not eligible to apply for an NPI. As such, Medicaid State agencies are not eligible to enroll in the Medicare program and shall not be issued billing privileges or be allowed to maintain billing privileges.

If a Medicaid State agency is enrolled or is seeking enrollment as a provider or supplier in the Medicare program, the fee-for-service contractor shall deny or revoke Medicare billing privileges. In denying a Medicaid State agency's application to enroll in the Medicare program, fee-for-service contractors shall use denial reason five (5) found in section 6.2 of this chapter. In revoking a Medicaid State agency billing privileges, a fee-for-service contractor shall use revocation reason three (3) found in section 13 of this chapter. The revocation letter should indicate that the revocation will be effective 30 days after the date of the revocation letter

15.4.8 - Suppliers Not Eligible to Participate

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The following is a list of suppliers who frequently attempt to enroll in Medicare but are not eligible to do so; no statute permits them to bill Medicare. Note that this list is not exhaustive.

If the contractor receives an enrollment application with one of the following types listed thereon, the contractor shall deny the application without development.

- Acupuncturist

- Assisted Living Facilities
- Birthing Centers
- Certified Alcohol and Drug Counselor
- Certified Social Worker
- Drug and Alcohol Rehabilitation Counselor
- Hearing Aid Center/Dealer
- Licensed Alcoholic and Drug Counselor
- Licensed Massage Therapist (LMT)
- Licensed Practical Nurse (LPN)
- Licensed Professional Counselor
- Marriage Family Therapist (MFT)
- Masters of Social Work
- Mental Health Counselor
- National Certified Counselor
- Occupational Therapist Assistant
- Physical Therapist Assistant
- Registered Nurse
- Speech and Hearing Center
- Substance Abuse Facility

15.17 – Establishing an Effective Date of Medicare Billing Privileges
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

(This section ***17*** only applies to the following individuals and organizations: physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives; clinical social workers; clinical psychologists; registered dietitians or nutrition professionals; and physician and non-physician practitioner organizations (e.g., group practices) consisting of any of the categories of individuals identified in this paragraph.)

In accordance with 42 CFR §424.520(d), the effective date for the individuals and organizations identified above is the later of the date of filing or the date they first began furnishing services at a new practice location. Note that the date of filing for Internet-based PECOS applications for these individuals and organizations is the date that the contractor received an electronic version of the enrollment application and a signed certification statement.

In accordance with 42 CFR §424.521(a), the individuals and organizations identified above may, however, retrospectively bill for services when:

- The supplier has met all program requirements, including State licensure requirements, and

- The services were provided at the enrolled practice location for up to—

1. 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or
2. 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§5121-5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

Medicare contractors shall interpret the phase "circumstances precluded enrollment" shown above to mean that that the physician, non-physician practitioner or physician or non-physician practitioner organization meets all program requirements, including State licensure, during the 30 days before an application was submitted and no final adverse action, as identified in 42 CFR § 424.502 precluded enrollment. If a final adverse action precluded enrollment during the 30 day period prior to date of filing, the Medicare contractor shall only establish an effective billing date the day after the date the final adverse action was resolved as long as it is not more than 30 days prior to the date the application was submitted.

15.24 – Model Correspondence Letters

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor shall use the following model provider enrollment letter format or some similar variation and standard language paragraphs.

NOTE: These are model letters and should be adjusted on a case by case basis, if needed. The fill-in-the-blank information (specific to each contractor determination) is in brackets. The contractor must ensure that the information identified in each section of the model letters below are included and addressed, as needed.

*15.2*4.1 – Model Acknowledgement Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Supplier name]:

Your Medicare enrollment application [insert application type] was received on [date] and is/are currently being reviewed. You will receive a letter within 30 calendar days if we need any additional information.

[Insert this language if a reference number is provided: Your application reference number is: (insert reference number)]
Please retain this letter [insert this language if a reference number is provided: (insert reference number)] in the event that you must submit additional information in support of your application. If you have any questions, please contact our office at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.2 – Model Development Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

[Insert application reference number]

Dear [Insert Provider/Suppler name]:

We have received your Medicare enrollment application(s). In order to complete processing your application(s), we request the following revisions and/or supporting documentation. Consistent with regulations found at 42 CFR 424.525, we may reject your application(s) if you do not furnish complete information within 30 calendar days of the postmark date of this letter.

Requested Revisions:

(The following are examples)

- [Insert section number and subsection letter (if applicable)]

    - [Insert a brief description of the revision(s) needed. Try to limit the description(s) to two sentences or less. (See examples below.)]

- Section 1A
    - National Provider Identifier
- Section 6 and 16
    - Complete these sections for each Delegated Official
- Section 15
    - Print, sign and date this section to approve the changes requested
- Section 17
    - Completed Form CMS-460, Medicare Participating Physician or Supplier Agreement
- If a Change of Ownership (CHOW), provide your Medicare Year-End Cost Report date (Month & Day)

To facilitate the processing of your application(s), you should submit the requested revisions and/or supporting documentation within 30 days to the address listed below:

[Insert contact address]

Finally, please attach a copy of this letter with your revised application(s). If you have any questions, please contact our office at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]
[Enclosure]

*15.2*4.3 – Model Rejection Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

Dear [Insert Provider/Suppler name]:

We received your Medicare enrollment application(s) on [insert date]. We are rejecting your Medicare enrollment application(s) and returning your application(s) for the following reason(s):
FACTS: [Insert ALL rejection reason(s) and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

In compliance with Federal regulations found at 42 CFR 424.525, providers and suppliers are required to submit complete application(s) and all supporting documentation within 30 calendar days from the postmark date of the contractor request for missing/incomplete information. If you would like to resubmit an application, you must complete a new Medicare enrollment application(s). Please make sure to address the issues stated above as well as sign and date the new certification statement page on your resubmitted application(s).

Providers and suppliers (except DMEPOS suppliers) can enroll in the Medicare program using either the:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper application process. To apply by paper, download and complete the Medicare enrollment application(s) from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll. DMEPOS suppliers that would like to apply should download and complete the paper application(s) and sent to the National Supplier Clearinghouse (NSC).

You should return the complete application(s) to the address listed below:

[Insert contact address]

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.4 – Model Returned Application Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

[Insert application reference number]

Dear [Insert Provider/Suppler name]:

We received your Medicare enrollment application(s) on [insert date]. We are closing this request and returning your application(s) for the following reason(s):

FACTS: [Insert ALL return reason(s) and cite the applicable regulatory authority, if applicable]

In order to resubmit your application(s) you must complete the [insert application type] application(s) with an original signature and date before we can begin processing your application(s). Please make sure to address the issues stated above on your resubmitted application(s).

Providers and suppliers (except DMEPOS suppliers) can enroll in the Medicare program using either the:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper application process. To apply by paper, download and complete the Medicare enrollment application(s) from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll. DMEPOS suppliers that would like to apply should download and complete the paper application(s) and sent to the National Supplier Clearinghouse (NSC).

You should return the complete application(s) to the address listed below:

[Insert contact address]

If you have any questions regarding this letter, please call [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]

[Title]

*15.2*4.5 – Model Revalidation Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

Dear [Insert Provider/Suppler name]:

Consistent with Medicare regulations found at 42 CFR 424.515, [insert contractor name], a Medicare contractor, requires that you complete and submit a Medicare enrollment application(s) and submit all applicable supporting documentation within 60 calendar days of the postmark date of this letter.

Providers and suppliers (except DMEPOS suppliers) can enroll in the Medicare program using either the:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper application process. To apply by paper, download and complete the Medicare enrollment application(s) from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll. DMEPOS suppliers that would like to apply should download and complete the paper application(s) and sent to the National Supplier Clearinghouse (NSC).

While the submission of your Medicare enrollment application(s) will start your 5-year revalidation cycle, you are required by regulations found at 42 CFR 424.516 to submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Failure to submit complete enrollment application(s) and all supporting documentation within 60 calendar days of the postmark date of this letter may result in your Medicare billing privileges being revoked.

Please return the completed application(s) to:

[Insert application return address]

If you have any questions regarding this letter, please call [insert phone number] between the hours of [insert office hours] or visit our Web site at [insert Web site] for additional information regarding the enrollment process or the [insert application type].

Sincerely,

[Your Name]
[Title]
[Enclosure]

*15.2*4.6 – Model Approval Recommended Letter for Part A Providers & Certified Suppliers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

[Name of contractor] has processed your Medicare enrollment application [insert application type] to enroll in the Medicare Program and *have made our preliminary assessment and forwarded it* to the *Centers for Medicare & Medicaid Services (CMS)* regional office for review. The next step of the enrollment process involves a site visit or survey conducted by a State Survey Agency or *a CMS approved deemed* accrediting organization to ensure compliance with the Conditions of Participation for your provider or supplier type. *Once the regional office confirms that your organization meets the Conditions of Participation for your provider or supplier type, we will finalize our review of your enrollment application.*

If you have any questions concerning this letter, please contact the State or *CMS* regional office at [insert phone number(s)].

Sincerely,

[Your Name]
[Title]
Enclosure
cc:

*15.2*4.7 – Model Approval Letter for Initial Enrollment

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

NOTE: Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision. Accordingly, a physician, non-physician practitioner and a physician or non-physician practitioner group may not formally appeal the established effective date of billing. Of course, if a physician or non-physician practitioner and a physician or non-physician practitioner group notify a Medicare contractor that an error may have occurred, the contractor should review this matter.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

We are pleased to inform you that your Medicare enrollment application is approved. Listed below is the information reflected in your Medicare enrollment record, including your National Provider Identifier (NPI) and Provider Transaction Access Number (PTAN).

If you are an existing Medicare provider and currently do not submit claims electronically, or are new to the Medicare program and plan on filing claims electronically, please contact our EDI department at [insert phone number]. To start billing the Medicare program, you must use your NPI on all Medicare claim submissions. Your PTAN is also activated for use and will be the required authentication element for all inquiries to customer service representatives (CSRs), written inquiry units and the interactive voice response (IVR) system for inquiries concerning claims status, beneficiary eligibility and to check status or other supplier related transactions, therefore keep your PTAN secure. Because the PTAN is not considered a Medicare legacy identifier, do not report this identifier to the National Plan and Provider Enumeration System (NPPES) as an “other” provider identification number.

Medicare Enrollment Information

Provider \ Supplier name:	[Insert name]
Practice location:	[Insert address]
National Provider Identifier (NPI):	[Insert NPI]
Provider Transaction Access Number (PTAN):	[Insert PTAN]
Specialty:	[Insert provider/supplier specialty]
You are a:	[Insert participating or non-participating]
Effective date [Insert "of termination" if the applicant is voluntarily terminating Medicare participation]	[Insert effective date or effective date of termination]

(Repeat for multiple, if necessary, for each additional location and NPI/PTAN combination)

Please verify the accuracy of your enrollment information. If you disagree with this initial determination or have any questions regarding the information above, call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation]. Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision.

You are required by regulations found at 42 CFR 424.516 to submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Providers and suppliers may enroll or make changes to their existing enrollment in the Medicare program using the Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS or to download the CMS-855 enrollment applications, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

Additional information about the Medicare program, including billing, fee schedules, and Medicare polices and regulations can be found at our Web site at [insert Web site address] or the Centers for Medicare & Medicaid Services' (CMS) Web site at http://www.cms.hhs.gov/home/medicare.asp.

Sincerely,

[Your Name]
[Title]

*15.2*4.8 – Model Approval Letter for Change of Information

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

NOTE: Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision. Accordingly, a physician, non-physician practitioner and a physician or non-physician practitioner group may not formally appeal the established effective date of billing. Of course, if a physician or non-physician practitioner and a physician or non-physician practitioner group notify a Medicare contractor that an error may have occurred, the contractor should review this matter.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

We have approved your information change request. Listed below is the [insert "new" or "updated"] information reflected in your Medicare enrollment record.

Medicare Enrollment Information

Provider \ Supplier name:	[Insert name]
[Insert revised item on the application]:	[Insert updated or changed item on the application]
National Provider Identifier (NPI):	[Insert NPI]
Provider Transaction Access Number (PTAN):	[Insert active or inactive PTAN]
Specialty:	[Insert provider/supplier specialty]
You are a:	[Insert participating or non-participating]
Effective date [Insert "of termination" if the applicant is voluntarily terminating Medicare participation]	[Insert effective date or effective date of termination]
If a Change of Ownership (CHOW, insert Medicare Year-End Cost Report date:	[Insert Month and Day]

(Repeat for multiple, if necessary, for each additional location and NPI/PTAN combination)

Please verify the accuracy of your enrollment information. If you disagree with the information above, call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation]. Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision.

ADDITIONAL INFORMATION

If you are an existing Medicare provider and currently do not submit claims electronically, or are new to the Medicare program and plan on filing claims electronically, contact our EDI department at [insert phone number]. To start billing the Medicare program, you must use your NPI on all Medicare claims submissions. Your PTAN will be the required authentication element for all inquiries to customer service representatives (CSRs), written inquiry units and the Interactive Voice Response (IVR) system for inquiries concerning claims status, beneficiary eligibility and to check status or other supplier related transactions, therefore keep your PTAN secure.

To maintain an active enrollment status in the Medicare program, regulations found at 42 CFR 424.516 require that you submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Providers and suppliers may enroll or make changes to their existing enrollment in the Medicare program using the Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS or to download the CMS-855 enrollment applications, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

Sincerely,

[Your Name]
[Title]

*15.2*4.9 – Model Revalidation Approval Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

NOTE: Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision. Accordingly, a physician, non-physician practitioner and a physician or non-physician practitioner group may not formally appeal the established

effective date of billing. Of course, if a physician or non-physician practitioner and a physician or non-physician practitioner group notify a Medicare contractor that an error may have occurred, the contractor should review this matter.
CMS alpha representation
Contractor

[Month Day & Year]
[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

We have processed your Medicare enrollment application(s) to revalidate your Medicare enrollment information.

Listed below is the information reflected in your Medicare enrollment record.

Medicare Enrollment Information:

Provider Name:	[Insert name]
Practice Location:	[Insert address]
National Provider Identifier (NPI):	[Insert NPI]
Provider Transaction Access Number (PTAN):	[Insert PTAN]
You are a:	[Insert participating or non-participating]
Effective Date:	[Insert month day, year]

(Repeat for multiple, if necessary, for each additional location and NPI/PTAN combination)

Please verify the accuracy of your enrollment information. If you disagree with the information above, call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation]. Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision.

To maintain an active enrollment status in the Medicare program, regulations found at 42 CFR 424.516 require that you submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from

participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Providers and suppliers may enroll or make changes to their existing enrollment in the Medicare program using the Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS or to download the CMS-855 enrollment applications, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

Sincerely,

[Your Name]
[Title]

*15.2*4.10 – Model Denial Letter for Certified Providers & Suppliers: Denial Based on a Condition of Participation

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.530 to view circumstances that warrant a fee-for-service contractor to deny a provider or supplier's enrollment in the Medicare program. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is denied based on a condition of participation, then the applicant or enrolled entity must submit a reconsideration or a corrective action plan with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Denial

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., hospital, skilled nursing facility, hospice]

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed by the authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.11 – Model Denial Letter for Certified Providers & Suppliers:

Denial Based on an Enrollment Reason(s)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.530 to view circumstances that warrant a fee-for-service contractor to deny a provider or supplier's enrollment in the Medicare program. If the certified provider or certified supplier is denied (i.e., ambulatory surgery center (ASC) and portable x-ray) based on an enrollment reason(s), then the applicant or enrolled entity must file a reconsideration with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Denial

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., hospital, skilled nursing facility, hospice].

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed and dated by the individual provider or the authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.12 – Model Denial Letter for Suppliers, Non-IDTF, Furnishing Part B Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.530 to view circumstances that warrant a fee-for-service contractor to deny a provider or supplier's enrollment in the Medicare program.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

RE: [insert decision]

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., doctor of medicine, physicians assistant, nurse practitioner].

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Insert contact address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

[Insert contact address]

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.13 – Model Denial Letter for IDTFs

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 410.33 for the IDTF performance standards and requirements.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Re: [Subject]

Dear [Insert Provider/Suppler Name]:

We have received your request to enroll in the Medicare program. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirements to qualify as an Independent Diagnostic Testing Facility (IDTF). Accordingly, your application(s) to enroll in the Medicare program is denied.

In order to obtain Medicare billing privileges, an IDTF must meet all of the performance standards found at 42 CFR 410.33. [Insert Provider Name] failed to meet the following standards:

STANDARDS: [Insert ALL performance standards not met].

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority that corresponds to the performance standards not met e.g., 42 CFR 410.33(c), 42 CFR 410.33(g)(4)(i) and 42 CFR 410.33(g)(5)(ii)].

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Contractor Address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the

postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

[Contractor Address]

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.14 – Model Revocation Letter for Certified Providers & Suppliers: Revocation Based on a Condition of Participation

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is revoked based on a condition of participation, then the applicant or enrolled entity must submit a reconsideration or corrective action plan with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare privileges are being revoked effective [insert effective date of revocation]. Pursuant to 42 CFR 424.545(a), this action will also terminate your corresponding provider agreement.
FACTS: [Insert ALL reason(s) for revocation and cite the applicable regulatory authority]

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed and dated by the authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

Pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

If you have any questions regarding this determination, please contact [insert contact name] at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

Enclosure [Attach a copy of the development letter if applicable]

*15.2*4.15 – Model Revocation Letter for Certified Providers & Suppliers: Revocation Based on an Enrollment Reason(s)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is revoked based on an enrollment reason(s), then the applicant or enrolled entity must file a reconsideration with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare billing privileges are being revoked effective [insert effective date of revocation]. Pursuant to 42 CFR 424.545(a), this action will also terminate your corresponding provider agreement.

FACTS: [Insert ALL the reason(s) for revocation and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

Pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.16 – Model Revocation Letter for Suppliers Furnishing Part B Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare billing privileges are being revoked effective [insert effective date of revocation]. Note: The revocation date in this letter must comport to the provisions found in 42 CFR 424.535(g).

FACTS: [Insert ALL reason(s) for revocation and cite the applicable regulatory authority]

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Insert contract address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

[Insert contact address]

Pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

[The following statement should only be used if a contractor determines that a Final Adverse Action occurred: Finally, in accordance with 42 CFR 424.565, [insert name of contractor] is assessing an overpayment in the amount of [insert dollar amount] because the physician or non-physician practitioner continued to furnish services to Medicare beneficiaries after a final adverse action precluded enrollment in the Medicare program.] [Note: As stated in 42 CFR 424.565, Medicare contractors should assess an overpayment back to January 1, 2009, not the date of the final adverse action if the adverse action occurred prior to January 1, 2009.]

If you have any questions regarding this determination, please contact [insert contact name] at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.17 – Model Revocation Letter for OIG Sanctioned Providers/Suppliers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Supplier name]:

This letter is to inform you that your Medicare Provider Transaction Access Number (PTAN) [insert PTAN number] that is associated to the National Provider Identifier (NPI) [insert NPI number] has been revoked effective [insert date of OIG debarment or exclusion].

According to federal regulations 42 CFR 424.535(a)(2), the provider or any owner, managing employee, authorized or delegated official, medical director, supervising physician or other health care personnel of the provider or supplier who has been debarred, suspended or excluded from the Medicare, Medicaid or any other Federal health care or other government program, cannot maintain enrollment in the Medicare

program. According to information obtained from the U.S. Department of Health & Human Services (Office of Inspector General), [insert provider/supplier name] has been excluded from participating in the Medicare program.

FACTS: The Department of Health and Human Services, Office of Inspector General notified us that you are excluded from the Medicare, Medicaid, or any other Federal health care program as defined in 42 CFR 1001.2; in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Social Security Act. You are excluded as of [insert effective date of exclusion] for [Cite the regulatory basis for exclusion. For example: 1128(b)(14)-Default on health education loan and scholarship obligations].

You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action. However, if you believe that this revocation is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

[For Part B Supplier, insert contractor address]
[For Certified Providers/Suppliers, insert CMS address]

Finally, in accordance with 42 CFR 424.565, [insert name of contractor] is assessing an overpayment in the amount of [insert dollar amount] because the physician or non-physician practitioner continued to furnish services to Medicare beneficiaries after a final adverse action precluded enrollment in the Medicare program.] [Note: As stated in 42 CFR 424.565, Medicare contractors should assess an overpayment back to January 1, 2009, not the date of the final adverse action if the adverse action occurred prior to January 1, 2009.]

If you have any questions regarding this letter, please call [insert phone number] between the hours of [insert office hours]

Sincerely,

[Your name]
[Title]

*15.2*4.18 – Model Revocation Letter for National Supplier Clearinghouse (NSC)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Supplier Name]
[Address]
[City, State & Zip Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Supplier Name]:

This is to inform you that your Medicare billing privileges are being revoked effective [insert date 30 days from the date of the letter], 30 days from the postmark date of this letter.

The durable medical equipment Medicare administrative contractors (DME MACs) use these numbers to identify suppliers. This revocation has the concurrence of the Centers for Medicare & Medicaid Services (CMS). In addition, pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time] year(s) from the effective date of the revocation. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your supplier type.

[This next paragraph will be included if a response to the development request was received in the field below, remember the date needs to be written out.]
The Supplier Audit and Compliance Unit (SACU) reviewed and evaluated the documents you submitted in response to the developmental letter dated [insert date]. This developmental letter afforded you the opportunity to demonstrate your full compliance with the durable medical equipment, prosthetics & orthotics standards (DMEPOS) supplier standards and/or to correct the deficient compliance requirement(s). However, after review of the information, it has been determined that you have not demonstrated compliance with the supplier standards noted below:

STANDARDS: [Insert ALL performance standard(s) not met and cite the applicable regulatory authority that corresponds to the performance standard(s) not met e.g., 42 CFR 410.33(c), 42 CFR 410.33(g)(4)(i) and 42 CFR 410.33(g)(5)(ii)].

[The next paragraph will be included if a response to the development request was not received.]

The Supplier Audit and Compliance Unit (SACU) has not received a response to the developmental letter sent to you on [insert date]. This request afforded you the opportunity to demonstrate your full compliance with the durable medical equipment, prosthetics & orthotics standards (DMEPOS) supplier standards and/or to correct the deficient compliance requirement(s). Therefore, we have determined that you are not in compliance with the supplier standards noted below:

STANDARDS: [Insert ALL performance standard(s) not met and cite the applicable regulatory authority that corresponds to the performance standard(s) not met e.g., 42 CFR 410.33(c), 42 CFR 410.33(g)(4)(i) and 42 CFR 410.33(g)(5)(ii)].

For Example: Supplier standard number one states that a supplier "Operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements." Explanation of specific deficiency goes here [regulatory cite to applicable standard(s) for revocation]

Section 1834 (j) of the Social Security Act states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items furnished by a supplier unless the supplier has a valid Medicare billing number. Therefore, any expenses for items you supply to a Medicare beneficiary on or after the effective date of the revocation of your billing numbers are your responsibility and not the beneficiary's, unless you have proof that you have notified the beneficiary in accordance with section 1834 (a) (18) (ii) of the Social Security Act, and the beneficiary has agreed to take financial responsibility if the items you supply are not covered by Medicare. You will be required to refund on a timely basis to the beneficiary (and will be liable to the beneficiary for) any amounts collected from the beneficiary for such items. If you fail to refund the beneficiary as required under 1834 (j) (4) and 1879 (h) of the Social Security Act, you may be liable for Civil Monetary penalties.

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The National Supplier Clearinghouse (NSC), with Centers for Medicare & Medicaid Services (CMS) approval, may reinstate your supplier number after it reviews your CAP and any additional evidence you submit and determines you are now in compliance with all supplier standards [see 42 C.F.R. 424.57(c)]. CAP requests should be sent to:

[Insert contract address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the

postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. The request must be made in writing and signed by an authorized official, owner or partner of the business. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

[Insert contact address]

If you choose not to request a reconsideration of this decision, or you do not receive a favorable decision through the administrative review process, you must wait [insert number of year(s)] before resubmitting your CMS-855S application, per the re-enrollment bar cited above. Applications received in the NSC prior to this timeframe will be returned.

If you have any questions regarding this determination, please contact [insert contact name] at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.19 – Model Reconsideration Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

[Reference number]

Dear [Insert Provider/Suppler name]:

This decision letter is in response to your reconsideration request received by [insert contractor name]. The reconsideration request is based on the above referenced

provider or suppliers [revocation or denial]. The initial determination letter was dated [insert date of initial determination letter] and thus, this appeal is timely submitted. This letter contains the decision.

The decision is based on Social Security Act, Medicare regulations and/or CMS manual instructions. This decision is based on the evidence in the file, and any information that you may have sent with or since the time of your hearing request.

FACTS: [Insert Regulation]

RATIONALE: [Insert denial/revocation rationale based on the regulation]

(Repeat for multiple, if necessary)

SUMMARY OF SUBMITTED DOCUMENTATION: [Insert all documentation/supporting information submitted]

EVALUATION OF SUBMITTED DOCUMENTATION: [Insert evaluation of documentation/supporting information submitted]

DECISION: All of the documentation in the file for this case has been reviewed and the decision has been made in accordance with Medicare guidelines as outlined in [insert regulation]. Specifically, [name of provider/supplier] [has or has not] provided evidence to show you have fully complied with the standards for which you were [revoked or denied]. Therefore, we [grant or cannot grant] you access to the Medicare Trust Fund (by way or issuance) of a Medicare number.

This decision is [a FAVORABLE DECISION (or) an UNFAVORABLE DECISION]. Please see below for additional appeal rights.

FURTHER APPEAL RIGHTS: ADMINISTRATIVE LAW JUDGE (ALJ)

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request a final ALJ review, you must act quickly and you must meet the requirements for requesting a final ALJ review. You must file your appeal within 60 calendar days after the date of receipt of this decision by writing to the following address:

Department of Health and Human Services
Departmental Appeals Board
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Building, Room G-644
Washington, D.C. 20201
Attn: CMS Enrollment Appeal

Appeal rights can be found at 42 CFR 498. The regulation explains the appeal rights following the determination by the Centers for Medicare & Medicaid Services as to

whether such entities [meet and/or continue to meet] the requirements for enrollment in the Medicare program.

If you have any questions regarding this decision, please call [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

*15.2*4.20 – Model Identity Theft Prevention Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor shall use the following model letter for changes of information and reassignment enrollment applications received, paper and web-submitted, where suspicious provider/supplier enrollment activity may be suspected, except in circumstances where the application can be returned based on the manual instructions. This model letter shall be sent to the address previously established and on file.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier]
[Address]
[City, State & ZIP Code]

Dear [Insert Provider/Suppler]:

As a security precaution, we are writing to confirm that you submitted a Medicare enrollment application(s) to enroll or change an existing enrollment at the following address:

[Insert Provider/Supplier Address]

If this application was submitted without your authorization, please call the Medicare contractor that processes your claims. The Medicare Fee-For-Service contact information can be found at www.cms.hhs.gov/MedicareProviderSupEnroll.

We will process your application(s) according to The Centers for Medicare & Medicaid (CMS) timeliness standards and will contact you if there is a need for additional information. We will notify you once processing is complete.

Please contact our office with any questions at [insert phone number] between the hours of [insert office hours] and refer to your application(s) reference number [insert reference number].

Sincerely,

[Your Name]
[Title]

15.25 – Appeals Process

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A provider or supplier whose Medicare enrollment is denied or whose Medicare billing privilege is revoked can request an appeal of that determination. In addition, some providers and suppliers may submit an appeal for any type of application submitted (i.e., initial application, change request or reassignment) that resulted in a denial.

This appeal process applies to all providers and suppliers, not just those defined in 42 CFR §498, and ensures that all applicants receive a fair and full opportunity to be heard. With the implementation of the appeals provision of Section 936 of the Medicare Prescription Drug Modernization and Improvement Act (MMA), all providers and suppliers that wish to appeal will be given the opportunity to request an appeal of a reconsideration decision to an administrative law judge (ALJ) of the Department of Health and Human Services (DHHS). Providers and suppliers then can seek review by the Departmental Appeals Board (DAB) and then may request judicial review.

Denial/Revocation of Medicare Billing Privileges

A. Carriers (including NSC and A/B MACs)

If a Medicare contractor reviews an initial enrollment application for a provider or supplier and finds a basis for denying the application pursuant to 42 CFR §424.530, such as; the provider or supplier does not meet one or more of the Federal or State requirements, the Medicare contractor shall deny the application and notify the provider or supplier by letter. The denial letter shall contain:

- A legal (i.e., regulatory) basis for each reason for the denial;

- A clear explanation of why the application is being denied, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to enroll in the Medicare program;

- Procedures for submitting a corrective action plan (CAP); and

- Complete and accurate information about the provider or supplier's further appeal rights.

Similarly, when a Medicare contractor discovers that there is a basis for revoking a provider or supplier's billing privileges, such as; the provider or supplier no longer meets one of the requirements for billing privileges, the contractor shall revoke billing privileges and notify the provider or supplier by letter. The revocation letter shall contain:

- A legal (i.e., regulatory) basis for each reason for revocation;
- A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to maintain enrollment in the Medicare program;

- The effective date of the revocation (30 days from the date the notice is mailed for providers or suppliers, or 15 days from the date the notice is mailed for DMEPOS suppliers. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment. The effective date of a license suspension/revocation is effective with the date of the suspension/revocation;

- Procedures for submitting a CAP; and

- Complete and accurate information about the provider or supplier's further appeal rights.

Corrective Actions Plan (CAP)

A CAP is the process that gives the provider or supplier an opportunity to correct the deficiencies (if possible) that resulted in the denial or revocation of billing privileges. The CAP should provide evidence that the provider or supplier is in compliance with Medicare requirements.

The Medicare contractors shall emphasize to the providers and suppliers, through denial/revocation letters, that the submission of a CAP addressing the issues that resulted in the denial or revocation of billing privileges will expedite the enrollment process and issue a faster determination.

The Medicare contractor, including the NSC, shall accept, for review, the submission of a CAP for denied or revoked billing privileges if the CAP is submitted within 30 days

from the date of the notice. All part B certified supplier CAP requests should be forwarded to CMS for processing at:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

The CAPs shall be submitted in the form of a letter and shall contain, at a minimum, verifiable evidence of provider or supplier compliance with enrollment requirements. The letter shall be signed and dated by the individual provider, the authorized or delegated official or a legal representative. Contractors may also create a standard CAP form to be sent out with their denial letters to easily identify it as a CAP when it is returned.

Contractors may accept a CAP by fax. If all the missing information originally requested is not received contractors should make one contact to the provider or supplier, preferably via e-mail or fax, to obtain the additional information before making a final determination. Contractor may use the model development letter, found in section 14 of this chapter, to request the information.

If a CAP for a denied application or revoked billing privileges is approved by a Medicare contractor, billing privileges can be issued. Contractors shall notify the applicant via letter that the enrollment has been approved. The effective date of Medicare billing privileges is based on the date the provider or supplier came into compliance with all Medicare requirements or the receipt date of the application. For an approved CAP, contractors shall use the receipt date of the CAP request as the receipt date they enter in PECOS.

For DMEPOS suppliers the effective date is the date it is awarded by the NSC. CMS' approval is required prior to restoring billing privileges.

The Medicare contractor shall process a CAP within 60 days. During this process, the contractor shall not toll the filing requirements associated with an appeal. However, the contractor can make a good cause determination in order to accept any appeal that has been submitted beyond the timely filing period.

NOTE: If a CAP and a reconsideration request (i.e., appeal request) are submitted concurrently, the Medicare contractor shall first process and make a determination on the CAP. The reconsideration request should then be processed by a Hearing Officer (HO) unrelated to the initial determination or CAP to ensure the applicant receives an independent review of their reconsideration. The Medicare contractor and the HO shall coordinate prior to acting on a CAP or reconsideration request to determine if the other party has received a request. If the CAP is accepted, the standard approval letter shall be sent to the provider or supplier acknowledging enrollment into Medicare and that their reconsideration request should be withdrawn. If the CAP is denied, the provider or supplier shall be notified by letter and may continue with the appeals process if it has

filed a request for reconsideration or is preparing to submit such a request and has not exceeded the timeframe to do so. Providers and suppliers may not appeal a corrective action plan decision.

Reconsideration (formerly Contractor Hearing)

A provider, supplier or DMEPOS supplier that wishes to request a reconsideration must file its request, in writing, with the Medicare contractor within 60 days after the postmark of the notice to be considered timely filed. Medicare contractors shall extend the filing period an additional 5 days to allow for mail time. Reconsideration requests submitted on the 65th day of which falls on a weekend or holiday should still be considered timely filed and not rejected. The date the request is received by the Medicare contractor is treated as the date of filing. The request must be signed by the physician, non-physician practitioner, a legal representative, or any responsible authorized official within the entity. For DMEPOS suppliers, the request must be signed by the authorized representative, delegated official, owner or partner. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

Medicare contractor reconsiderations shall be conducted by a HO or senior staff having expertise in provider enrollment and who was independent from the initial decision to deny or revoke enrollment.

The NSC reconsiderations shall be conducted by a HO. All part B certified supplier reconsiderations will be conducted by CMS and shall be forwarded to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

Upon receipt of the reconsideration, the HO shall send a letter to the provider or supplier to acknowledge receipt of their request. In its acknowledgment letter, the HO shall advise the requesting party that the reconsideration will be conducted and a determination issued within 90 days from the date of the request. The HO shall include a copy of its acknowledgment letter in the reconsideration file.

If a timely request for a reconsideration is made, the HO, not involved in the original adverse determination, must hold an on-the-record reconsideration and issue a determination within 90 days from the date of the appeal request. The provider, supplier or the Medicare contractor may offer new evidence. It is the responsibility of the provider or supplier to show that its enrollment application was incorrectly denied or that its billing privileges were revoked erroneously.

In reviewing an initial enrollment decision or a revocation, the HO should limit the scope of its review to the Medicare contractor's reason for imposing a denial or revocation at the time it issued the action and whether the Medicare contractor made

the correct decision (i.e., denial/revocation). Medicare contractors cannot introduce new denial or revocation reasons or change a denial or revocation reason listed in the initial determination during the reconsideration process. If a provider or supplier provides evidence that demonstrates or proves that they met or maintained compliance after the date of denial or revocation, the HO shall exclude this information from the scope of its review.

If a request for reconsideration is filed late, the HO shall make a finding of good cause before taking any other action on the appeal. The time limits may be extended if good cause for late filing is shown. Good cause may be found when the record clearly shows, or the party alleges and the record does not negate that the delay in filing was due to one of the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

The HO shall issue a written decision within 90 days from the date of the request and forward the decision to the Medicare contractor and by mail to the provider, supplier or the authorized representative. The reconsideration letter shall include:

- The re-stated facts and findings, including the regulatory basis for the action as determined by the contractor in their initial determination;

- A summary of the documentation submitted by the prospective provider/supplier or the enrolled provider/supplier;

- A clear explanation of why the HO is upholding or overturning the denial or revocation action in sufficient detail for the provider or supplier to understand the nature of its deficiencies;

- If applicable, the regulatory basis to support each reason or reasons for the denial or revocation;

- An explanation of how the provider or supplier does not meet the enrollment criteria or requirements to enroll;

- Further appeal rights, procedures for requesting an administrative law judge (ALJ) hearing, and the address to which the written appeal must be mailed; and

- Information the appellant must include with their appeal (name/legal business name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision).

If an appeal for a denied application or revoked billing privileges is approved by a Medicare contractor, billing privileges can be issued. The effective date of Medicare billing privileges is based on the date the provider or supplier came into compliance with all Medicare requirements or the receipt date of the application being appealed. Contractors shall use the receipt date of the appeal as the receipt date they enter in PECOS.

A request for reconsideration may be withdrawn at any time prior to the mailing of the reconsideration decision either by the party that filed the appeal request or their authorized representative. The request for withdrawal must be in writing, signed, and filed with the Medicare contractor.

When the Medicare contractor receives a withdrawal request, it sends a letter to the provider or supplier acknowledging its receipt and advising that the reconsideration action will be terminated.

Medicare contractors shall maintain a report detailing the number of reconsideration requests they receive and their outcome (e.g., decision withheld, reversed, or further appeal requested or requests withdrawn). Medicare contractors are not required to submit this information to CMS but it must be provided upon request.

Administrative Law Judge (ALJ) Hearing

The CMS, a Medicare contractor, or a provider or supplier dissatisfied with a reconsidered determination is entitled to a hearing before an ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

Upon receipt of the request to file an ALJ hearing, an ALJ at the DAB will issue a letter by certified mail to the provider or supplier, CMS and the regional office of General Counsel (OGC) acknowledging receipt of an appeals request and detailing a scheduled pre-hearing conference. The OGC will assign an attorney that will represent CMS during the appeals process and who will also serve as the DAB point of contact. Neither CMS nor the Medicare contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the

pre-hearing to discuss any issues. The Medicare contractors shall work with and provide the OGC attorney with all necessary documentation. Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS.

Departmental Appeals Board (DAB) Hearing

The CMS, a Medicare contractor, or a provider or supplier dissatisfied with the ALJ hearing decision may request Board review by the DAB. Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented orally to the DAB, then a transcript will be prepared and made available to any party upon request.

Judicial Review

A provider or supplier dissatisfied with a DAB decision has a right to seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.

B. Fiscal Intermediary

If a Medicare contractor reviews an initial enrollment application for a provider or certified supplier and finds that the application should be denied pursuant to 42 CFR §424.530, such as a facility's failure to meet one or more of the Federal or State requirements, the Medicare contractor shall deny/recommend denial to the regional office (RO) and notify the provider or certified supplier by letter (see section 14 of this chapter). The denial letter shall contain:

- A legal (i.e., regulatory) basis for each reason for the denial;

- A clear explanation of why the application is being denied, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to enroll in the Medicare program;

- Procedures for submitting a corrective action plan (CAP); and

- Complete and accurate information about the provider or supplier's further appeal rights.

Similarly, when a Medicare contractor discovers that there is a basis for revoking a provider or certified supplier's billing privileges, such as the provider or certified supplier no longer meets one of the requirements for billing privileges, the Medicare contractor shall revoke billing privileges and notify the provider or certified supplier by letter with a copy to the State and the RO. The revocation letter must contain:

- A legal (i.e., regulatory) basis for each reason for revocation;
- A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence used by the contractor in making their determination;
- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to maintain enrollment in the Medicare program;
- The effective date of the revocation (30 days from the date the notice is mailed. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment. The effective date of a license suspension/revocation is effective with the date of the suspension/revocation);
- Procedures for submitting a CAP; and
- Complete and accurate information about the provider or supplier's further appeal rights.

Corrective Action Plan (CAP)

A CAP is the process that gives the provider or certified supplier an opportunity to correct the deficiencies (if possible) that resulted in the denial or revocation of billing privileges. The CAP should provide evidence that the provider or certified supplier is in compliance with Medicare requirements.

The Medicare contractors shall emphasize to the providers and suppliers, through denial/revocation letters, that the submission of a CAP addressing the issues that resulted in the denial or revocation of billing privileges will expedite the enrollment process and issue a faster determination.

The submission of a CAP for denied or revoked billing privileges must be submitted within 30 days from the date of the notice. The CAP shall contain, at a minimum, verifiable evidence of the provider or certified supplier's compliance with enrollment requirements. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16

Baltimore, MD 21244-1850

If a CAP for a denied application or revoked billing privileges is approved by the CMS, billing privileges can be issued. The effective date is based on the date the provider or certified supplier came into compliance with all Medicare requirements. That is, once the provider or certified supplier has passed the state survey and been issued a certification date.

CAP requests will be processed within 60 days. During this process, the CMS will not toll the filing requirements associated with an appeal. However, the CMS can make a good cause determination in order to accept any appeal that has been submitted beyond the timely filing period.

Reconsideration

A provider or certified supplier that wishes to request a reconsideration must file its request, in writing, with the CMS within 60 days after the postmark of the notice to be considered timely filed. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

The date the request is received by the CMS is treated as the date of filing. The request may be signed by the authorized official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

If a timely request for a reconsideration is made, the CMS will hold an on-the-record reconsideration and issue a determination within 90 days from the date of the appeal request. The provider, certified supplier or the Medicare contractor may offer new evidence. It is the responsibility of the provider or certified supplier to show that its enrollment application was incorrectly denied or that its billing privileges were revoked erroneously.

In reviewing an initial enrollment decision or a revocation, the CMS will limit the scope of its review to the Medicare contractor/RO's initial reason for imposing a denial or revocation at the time that it issued the action and whether the Medicare contractor/ RO made the correct decision (i.e., denial/revocation). The Medicare contractor/ RO cannot introduce new denial or revocation reasons or change a denial or revocation reason listed in the initial determination during the reconsideration process. If a provider or certified supplier provides evidence that demonstrates or proves that they met or maintained compliance, after the date of denial or revocation, the CMS will exclude this information from the scope of its review.

If a reconsideration request is filed late, the CMS will make a finding of good cause before taking any other action on the appeal. These time limits may be extended if

good cause for late filing is shown. Good cause may be found when the record clearly shows, or the party alleges and the record does not negate that the delay in filing was due to one of the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

The CMS will issue a written decision within 90 days from the date of the request and forwards the decision by certified mail to the Medicare contractor, the provider, certified supplier or the authorized representative. The reconsideration letter shall include:

- The re-stated facts and findings, including regulatory basis for the action as, determined by the Medicare contractor/ RO in their initial determination;

- A summary of the documentation submitted by the prospective provider/supplier or the enrolled provider/supplier;

- A clear explanation of why the CMS is upholding or overturning the denial or revocation action in sufficient detail for the provider or certified supplier to understand the nature of its deficiencies;

- If applicable, the regulatory basis to support each reason or reasons for the denial or revocation;

- An explanation of how the provider or certified supplier does not meet the enrollment criteria or requirements to enroll;

- Further appeal rights, procedures for requesting an ALJ hearing, and the address to which the written appeal must be mailed; and

- Information the appellant must include with their appeal (name/legal business name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision).

A request for reconsideration may be withdrawn at any time prior to the mailing of the reconsideration decision either by the party that filed the appeal request or their authorized representative. The request for withdrawal must be in writing, signed, and filed with the CMS.

When the CMS receives a withdrawal request, it sends a letter to the provider or certified supplier acknowledging its receipt and advising that the reconsideration action will be terminated.

ALJ Hearing

The CMS, a Medicare contractor, or a provider or certified supplier dissatisfied with a reconsidered determination is entitled to a hearing before the ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from the receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request the ALJ hearing is deemed a waiver of all rights to further administrative review.

Upon receipt of the request to file an ALJ hearing, an ALJ at the Departmental Appeals Board (DAB) will issue a letter by certified mail to the provider or certified supplier, CMS, the RO and the RO of General Counsel (OGC) acknowledging receipt of an appeals request and detailing a scheduled prehearing conference. The OGC will assign an attorney that will represent CMS during the appeal's process and who will also serve as the DAB point of contact. Neither CMS, the RO, nor the Medicare contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the pre-hearing to discuss any issues. The Medicare contractor shall work with and provide the OGC attorney with all necessary documentation. Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS.

DAB Hearing

The CMS, a Medicare contractor, or a provider or certified supplier dissatisfied with the ALJ hearing decision may request Board review by the DAB. Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented

orally to the DAB then a transcript will be prepared and made available to any party upon request.

Judicial Review

A provider or certified supplier dissatisfied with DAB review has a right to seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision

15.28 – Deceased Practitioners

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. Reports of Death from the Social Security Administration (SSA)

Contractors will receive from CMS a monthly file that lists individuals who have been reported as deceased to the SSA. To help ensure that Medicare maintains current enrollment and payment information and to prevent others from utilizing the enrollment data of deceased individuals, the contractor shall undertake the activities described below.

B. Verification Activities

1. Physicians and Non-Physician Practitioners

For physicians and non-physicians, the contractor shall determine whether the individual is enrolled in Medicare. If the person is not, no further action by the contractor is needed. If the person is enrolled, the contractor shall verify the death by:

- Obtaining oral or written confirmation of the death from an authorized or delegated official of the group practice to which the individual practitioner had reassigned his or her benefits; or

- Obtaining an obituary notice from the newspaper; or

- Obtaining oral or written confirmation from the State licensing board (e.g., telephone, e-mail, computer screen printout); or

- Obtaining oral or written confirmation from the State Bureau of Vital Statistics; or

- Obtaining a death certificate, Form SSA-704, or Form SSA-721 (statement of funeral director).

Upon verification, the contractor shall undertake all actions (e.g., switching the PECOS record to "voluntary withdraw") normally associated with the termination of a practitioner's billing privileges - with the exception, of course, of sending a termination

letter to the individual. The contractor shall place verification documentation in the provider file in accordance with section 10 of this manual.

2. Individuals Other than Physicians or Non-Physician Practitioners

If the person is an owner, managing employee, director, officer, authorized official, etc., the contractor shall verify and document that the person is deceased using the verification process described in 16(B) above.

Once the contractor verifies the report of death, it shall notify the provider organization with whom the individual is associated that it needs to submit a CMS-855 change request that deletes the individual from the provider's enrollment record. If the provider fails to submit this information within 90 calendar days of the contractor's request, the contractor shall deactivate the provider's Medicare billing privileges in accordance with 42 CFR §424.540(a)(2).

The contractor need not, however, solicit a CMS-855 change request if:

- The associate was the sole owner of his or her professional corporation or professional association. The contractor can simply terminate that organization's enrollment in Medicare and then undertake all actions normally associated with a termination of a supplier's billing privileges, including sending a termination letter to the supplier; or

- The organization is enrolled with another contractor. Here, the contractor shall notify (via fax or e-mail) the contractor with which the organization is enrolled of the situation, at which time the latter contractor shall take actions consistent with this section 16(A).

C. Reports of Death from Third-Parties

If a contractor receives a report of death from a third-party (State provider association, State medical society, academic medical institution, etc.), the contractor shall verify that the individual practitioner is deceased by:

- Obtaining oral or written confirmation of the death from an authorized or delegated official of the group practice to which the individual practitioner had reassigned his or her benefits; or

- Obtaining an obituary notice from the newspaper; or

- Obtaining oral or written confirmation from the State licensing board (e.g., telephone, e-mail, computer screen printout); or

- Obtaining oral or written confirmation from the State Bureau of Vital Statistics; or

- Obtaining a death certificate, Form SSA-704, or Form SSA-721 (statement of funeral director).

Once the contractor verifies the death, it shall:

1. Undertake all actions normally associated with the termination of a supplier's billing privileges, with the exception of sending a termination letter to the practitioner.

2. Search PECOS to determine whether the individual is listed therein as an owner, managing employee, director, officer, partner, authorized official, or delegated official.

3. If the person is not in PECOS, no further action with respect to that individual is needed.

4. If the supplier is indeed identified in PECOS as an owner, officer, etc., the contractor shall notify the organization with whom the person is associated that it needs to submit a CMS-855 change request that deletes the individual from the entity's enrollment record. If the provider fails to submit this information within 90 calendar days of the contractor's request, the contractor shall deactivate the provider's billing privileges in accordance with 42 CFR §424.540(a)(2).

The contractor need not, however, ask for a CMS-855 change request if:

a. The practitioner was the sole owner of his/her professional corporation or professional association. The contractor can simply terminate the organization's enrollment in Medicare. It shall then undertake all termination actions normally associated with the termination of a supplier's billing privileges, including sending a termination letter to the supplier; or

b. The organization is enrolled with another contractor. In this situation, the contractor shall notify (via fax or e-mail) the contractor with which the organization is enrolled of the situation, at which time the latter contractor shall take actions consistent with this section 16(C).

The contractor shall place verification documentation in the provider file in accordance with section 10 of this manual.

D. Education & Outreach

The contractor shall conduct outreach to State provider associations, State medical societies, academic medical institution, and group practices, etc., regarding the need to promptly inform contractors of the death physicians, non-physician practitioners participating in the Medicare program.

E. Trustees/Legal Representatives

1. NPI - The trustee/legal representative of a deceased provider's estate may deactivate the NPI of the deceased provider by providing written documentation to the NPI enumerator.

2. Special Payment Address - In situations where an individual practitioner has died, the contractor can make payments to the individual's estate per the instructions in Pub. 100-04, chapter 1. When the contractor receives a request from the trustee or other legally-recognized representative of the provider's estate to change the provider's special payment address, the contractor shall, at a minimum, ensure that the following information is furnished:

- CMS-855I change of information request that updates the "Special Payment" address in section 4 of the application. The CMS-855I can be signed by the trustee/legal representative.

- Any evidence – within reason - verifying that the practitioner is in fact deceased.

- Legal documentation verifying that the trustee/legal representative has the legal authority to act on behalf of the provider's estate.

The policies in this section 16(E)(1) and (2) apply only to individual practitioners who operated their business as sole proprietors. It does not apply to solely-owned corporations, limited liability companies, etc., nor does it apply to situations in which the practitioner reassigned his or her benefits to another entity.

15.34 – Customer Service*/Outreach*

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.34.1 - Web Sites

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Contractors must provide a link to CMS' provider/supplier enrollment Web site located at http: www.cms.hhs.gov/MedicareProviderSupEnroll. The link shall be available on the contractor's existing provider outreach Web site (which should be an established subdomain of the contractor's current commercial Web site) and it must comply with the guidelines stated in the Provider/Supplier Information and Education Web site section (Activity Code 14101) under the Provider Communications (PCOM) Budget and Performance Requirements (BPRs). Bulletins, newsletters, seminars/workshops and other information concerning provider enrollment issues shall also be made available on the existing provider outreach Web site. All contractor Web sites must comply with section 508 of the Rehabilitation Act of 1973 in accordance with, 36 CFR §1194, and must comply with CMS' Contractor Web site Standards and Guidelines posted on CMS's Web site.

The CMS Provider/Supplier Enrollment Web site, http://www.cms.hhs.gov/MedicareProviderSupEnroll, furnishes the user with access to provider/supplier enrollment forms, specific requirements for provider/supplier types, manual instructions, frequently asked questions (FAQs), contact information, hot topics, and other pertinent provider/supplier information. The contractor shall not duplicate content already provided at the CMS provider/supplier enrollment Web site, and shall not reproduce the forms or establish the contractor's own links to forms. It shall, however, have a link on its Web site that goes directly to the forms section of the CMS provider/supplier enrollment site.

On a quarterly basis, each contractor shall review and provide updates regarding their information that we show at URL:
http://www.cms.hhs.gov/MedicareProviderSupEnroll/downloads/contact_list.pdf
If the contractor services several States with a universal address and telephone number, the contractor shall report that information. In situations where no actions are required, a response from the contractor is still required (i.e., the contact information is accurate). In addition, only information that pertains to provider enrollment activity for the contractor's jurisdiction is to be reported. All updates shall be sent directly via e-mail to the *contractor's assigned DPSE liaison or Business Function Lead (BFL.)*

15.34.2 - Provider Enrollment Inquiries

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor's customer service unit may handle provider enrollment inquiries that do not involve complex enrollment issues. Examples of inquiries that can be processed by customer service units include:

- Application status checks (e.g., "Has the contractor finished processing my application?");

- Furnishing information on where to access the CMS-855 forms (and other general enrollment information) on-line;

- Explaining to providers/suppliers which CMS-855 forms should be completed.

- Contractors may wish to consider establishing electronic mechanisms by which providers can obtain updates on the status of their enrollment applications via the contractor's Web site or via automated voice response (AVR).

Contractors are strongly encouraged to establish e-mail "listserves" with the provider community to disseminate important information thereto, such as contractor address changes, new CMS enrollment policies or internal contractor procedures, reminders about existing policies, etc. By being proactive in distributing information to their providers on a regular basis (e.g., weekly, bi-weekly), contractors can reduce the number of policy inquiries they receive and help facilitate the submission of complete and accurate CMS-855 applications.

15.34.3 – Mailing Annual "Supplier Responsibilities" Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.34.3.1 – Mailing Annual Material to Physicians

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.34.3.2 – Mailing Annual Material to Non-physician Sole Practitioners

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.34.3.3 – Mailing Annual Material to Physicians and Non-physician Practitioner Organizations

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.36 – Document Retention

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.36.1 – Security

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor shall ensure that the highest level of security is maintained for all systems and its physical and operational processes, in accordance with the CMS/Business Partners Systems Security Manual (BPSSM) and the Program Integrity Manual.

Applications shall never be removed from the controlled area to be worked on at home or in a non-secure location. Additionally, provider enrollment staff must control and monitor all applications accessed by other contractor personnel.

All contractor staff shall be trained on security procedures as well as relevant aspects of the Privacy Act and the Freedom of Information Act. This applies to all management, users, system owners/managers, system maintainers, system developers, operators and administrators, including contractors and third parties, of CMS information systems, facilities, communication networks and information.

Note that these instructions are in addition to, and not in lieu of, all other instructions issued by CMS regarding security.

15.36.2 - Release of Information

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

On October 13, 2006, CMS published System of Records Notice for the Provider Enrollment, Chain and Ownership System (PECOS) in the Federal Register. Consistent

with this notice, once the provider has submitted an enrollment application (as well as after it has been enrolled), the contractor shall not release – either orally or in writing - provider-specific data to any other person or entity. This includes, but is not limited to, national or State medical associations or societies, clearinghouses, billing agents, provider associations, or any person within the provider's organization other than the provider's authorized official (section 15 of the CMS-855), delegated official (section 16) or contact person (section 13). The only exceptions to this policy are:

- A routine use found in the aforementioned System of Records applies;

- The provider (or, in the case of an organizational provider, an authorized or delegated official): (1) furnishes a signed written letter on the provider's letterhead stating that the release of the provider data is authorized, and (2) the contractor has no reason to question the authenticity of the person's signature.

- The release of the data is specifically authorized in some other CMS instruction or directive.

(These provisions also apply in cases where the provider requests a copy of any CMS-855 paperwork the contractor has on file.)

It is recommended that the contractor notify the provider of the broad parameters of the aforementioned policy as early in the enrollment process as possible.

In addition:

- When sending e-mails, the contractor shall not transmit sensitive data, such as SSNs or EINs.

- The contractor may not send PECOS screen printouts to the provider.

- Carriers shall not send Medicare provider numbers (PINs) to groups or organizations, including the group's authorized or delegated official. If a group/organization needs to know the PIN number of an individual provider, it must contact the provider directly for this information or have the individual provider request this information in writing from the carrier. If the individual provider requests its PIN number, the carrier can mail it to the provider's practice location. The contractor should never give this information over the phone.

15.36.3 – File Maintenance

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Contractors shall maintain and store all documents relating to the enrollment of a provider into the Medicare program. These documents include, but are not limited to, Medicare enrollment applications and all supporting documents, attachments, correspondence, and appeals submitted in conjunction with an initial enrollment, reassignment, change of enrollment, revalidation, etc.

Supporting documentation includes, but is not limited to:

- Copies of Federal, State and/or local (city/county) professional licenses, certifications and/or registrations;
- Copies of Federal, State, and/or local (city/county) business licenses, certifications and/or registrations;
- Copies of professional school degrees or certificates or evidence of qualifying course work; and
- Copies of CLIA certificates and FDA mammography certificates.

Medicare contractors shall dispose of the aforementioned records as described below:

1) Provider/Supplier and Durable Medical Equipment Supplier Application

a. Rejected applications as a result of provider failing to provide additional information

Disposition: Destroy when 7 years old.

b. Approved applications of provider/supplier

Disposition: Destroy 15 years after the provider/supplier's enrollment has ended.

c. Denied applications of provider/supplier.

Disposition: Destroy 15 years after the date of denial.

d. Approved application of provider/supplier, but the billing number was subsequently revoked.

Disposition: Destroy 15 years after the billing number is revoked.

e. Voluntary deactivation of billing number

Disposition: Destroy 15 years after deactivation.

f. Provider/Supplier dies

Disposition: Destroy 7 years after date of death.

2) Electronic Mail and Word Processing System Copies

a. Copies that have no further administrative value after the recordkeeping copy is made. These include copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories on hard disk or network drives,

and copies on shared network drives that are used only to produce the recordkeeping copy.

Disposition: Delete within 180 days after the recordkeeping copy has been produced.

b. Copies used for dissemination, revision or updating that are maintained in addition to the recordkeeping copy.

Disposition: Delete when dissemination, revision, or updating is complete.