CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 404	**Date: January 20, 2012**
	Change Request 7579

SUBJECT: General Update to Chapter 15 of the Program Integrity Manual (PIM) - Part I

I. SUMMARY OF CHANGES: This change request (CR) is the first in a series of transmittals designed to update chapter 15 of the PIM. The vast majority of the revisions in these CRs will either: (1) be merely editorial in nature, or (2) incorporate existing policies directly into chapter 15. Any new policies will be reflected in the CR's business requirements.

EFFECTIVE DATE: April 22, 2012
IMPLEMENTATION DATE: April 22, 2012

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/Table of Contents
R	15/1.1/Definitions
R	15/2/Provider and Supplier Business Structures
R	15/3/National Provider Identifier (NPI)
R	15/4.1/Certified Providers and Certified Suppliers That Enroll Via the Form CMS-855A
R	15/4.1.1/Community Mental Health Centers (CMHCs)
R	15/4.1.2/Comprehensive Outpatient Rehabilitation Facilities (CORFs)
R	15/4.1.3/End-Stage Renal Disease Facilities (ESRDs)
R	15/4.1.4/Federally Qualified Health Centers (FQHCs)
R	15/4.1.5/Histocompatability Laboratories
R	15/4.1.7/Hospices
R	15/4.1.8/Hospitals and Hospital Units
R	15/4.1.9/Indian Health Services (IHS) Facilities
R	15/4.1.10/Organ Procurement Organizations (OPOs)
R	15/4.1.11/Outpatient Physical Therapy/Outpatient Speech pathology Services (OPT/OSP)
R	15/4.1.12/Religious Non-Medical Health Care Institutions (RNCHIs)
R	15/4.1.13/Rural Health Clinics
R	15/4.1.14/Skilled Nursing Facilities (SNFs)
R	15/4.2/Certified Suppliers That Enroll Via the Form CMS-855B
R	15/4.2.1/Ambulatory Surgical Centers (ASCs)
R	15/4.2.2/CLIA Labs
R	15/4.2.5/Portable X-Ray Suppliers (PXRSs)
R	15/4.4.9/Occupational and Physical Therapists in Private Practice
R	15/6/Timeliness and Accuracy Standards
R	15/6.1/Standards for Initial Applications
R	15/6.1.1/Paper Applications - Timeliness
R	15/6.1.2/Paper Applications - Accuracy
R	15/6.1.3/Web-Based Applications - Timeliness
R	15/6.1.4/Web-Based Applications - Accuracy
R	15/6.2.1/Paper Applications - Timeliness

R	15/6.2.2/Paper Applications - Accuracy
R	15/6.2.4/Web-Based Applications - Accuracy
R	15/6.3/General Timeliness Principles
R	15/7.4/Tie-In Notices
N	15/17.1/Effective Date for Certified Providers and Certified Suppliers
R	15/27.2.1/Special Instructions Regarding Revocations of Certified Providers and Certified Suppliers
D	15/17.4/Effective Date for Certified Providers and Certified Suppliers

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: 404	Date: January 20, 2012	Change Request: 7579

SUBJECT: General Update to Chapter 15 of the Program Integrity Manual (PIM) - Part I

Effective Date: **April 22, 2012**

Implementation Date: April 22, 2012

I. GENERAL INFORMATION

A. Background: This change request (CR) is the first in a series of transmittals designed to update chapter 15 of the PIM. The vast majority of the revisions in these CRs will either: (1) be merely editorial in nature, or (2) incorporate existing policies directly into chapter 15. Any new policies will be reflected in the CR's business requirements.

B. Policy: The purpose of this CR is to begin the process of updating chapter 15 of the PIM.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7579.1	If a community mental health center, comprehensive outpatient rehabilitation facility, hospice or portable x-ray supplier is adding a new practice location, the contractor shall conduct a site visit of the location after receiving notice of approval from the CMS regional office (RO) (e.g., tie-in notice, approval letter, other type of notice) but before the contractor switches the provider's enrollment record to an "Approved" status.	X		X	X	X					
7579.2	If a physical therapist's practice location is his or her home address and he or she exclusively performs services in patients' homes, nursing homes, etc., the contractor shall not be required to perform a site visit.	X			X						
7579.3	When sending a recommendation for approval letter to the RO for a federally qualified health center (FQHC) Form CMS-855A initial application, the contractor shall indicate in the letter the date on	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	
	which the FQHC's application was complete.										

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: N/A
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: Frank Whelan, frank.whelan@cms.hhs.gov, (410) 786-1302.

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

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

Table of Contents

(Rev.404, Issued: 01-20-12)

15.1.1 – Definitions

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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 (MRI).
(ii) Computed Tomography (CT).
(iii) Nuclear Medicine.
(iv) Positron Emission Tomography (PET).

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 an *entity that furnishes billing and collection services on behalf of a provider or supplier. A billing agency is not enrolled in the Medicare program. A billing agency submits claims to Medicare in the name and billing number of the provider or supplier that furnished the service or services. In order to receive payment directly from Medicare on behalf of a provider or supplier, a billing agency must meet the conditions described in § 1842(b)(6)(D) of the Social Security Act. (For further information, see CMS Publication 100-04, chapter 1, section 30.2.4.)*

Change in majority ownership occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a home health agency (HHA) during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sales, stock transfers, mergers, or consolidations). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.

Change of *o*wnership (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 *o*fficial means an individual who is delegated by the "Authorized Officia*l"* the authority to report changes and updates to the *provider/supplier's* 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 *a*pplication means a paper CMS-855 enrollment application or the equivalent 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.

Immediate family member or member of a physician's immediate family means – under 42 CFR § 411.351 - a husband or wife; birth or adoptive parent, child, or sibling;

stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Institutional provider means – for purposes of the Medicare application fee only - any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and non-physician practitioner organizations), Form CMS–855S or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application.

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 - 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. *(Note that for Part B and DMEPOS suppliers, the Medicare Identification Number may sometimes be referred to as the Provider Transaction Access Number (PTAN).)*

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

Operational – *under 42 CFR §424.502 – means that* 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.

Ownership or investment interest – under 42 CFR § 411.354(b) – means an ownership or investment interest in the entity that may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes designated health services.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a

chiropractor, as defined in section 1861(r) of the Social Security Act.

Physician-owned hospital – under 42 CFR § 489.3 – means any participating hospital in which a physician, or an immediate family member of a physician, has a direct or indirect ownership or investment interest, regardless of the percentage of that interest.

Physician owner or investor – under 42 CFR § 411.362(a) – means a physician (or an immediate family member) with a direct or an indirect ownership or investment interest in the hospital.

Prospective *p*rovider 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 *s*upplier 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, non-physician practitioner, or other supplier has granted a Medicare-enrolled provider or supplier the right to receive payment for the physician's, non-physician practitioner's or other supplier's services. (For further information, see § 1842(b)(6) of the Social Security Act, the Medicare regulations at 42 CFR §§ 424.70 - 424.90, and CMS Publication 100-04, chapter 1, sections 30.2 – 30.2.16.)*

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 *i*dentification *n*umber means the number (either the Social Security Number (SSN) or Employer Identification Number (EIN)) *that* the individual or organization uses to report tax information to the IRS.

15.2 – Provider and Supplier Business Structures

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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 *Form* 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 *that* 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. *If, however,* 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 *Employer Identification Number* 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 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 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) *has* 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). *Also,* 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 *earn.* An LLC thus contains the best attributes of corporations and partnerships; LLCs are *therefore* 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 *Form* CMS-855 information is required of different entities. The primary example of this is in section *6.* 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 *that is* 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 for a business's decision* 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, *which now* wants to sue X's owners. Unfortunately for Y, it can *generally* only sue X itself; it cannot *sue* 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,"* whereby one tries to get past the brick wall of the corporation in order to *collect from* the owners behind that wall. However, *piercing the corporate veil* 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 *for a business's decision 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 *that* 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 *a* 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, *a* 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 close corporations (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" *(NPO)* is misleading. It *does not signify 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, *an* 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 *in which it is located.*

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 *Form* 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 *Form* 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 *of the Form CMS-855*, the only people that must be listed are "managing employees." This is because GOEs do not have corporate officers or directors.

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

15.3 – National Provider Identifier (NPI)

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. Submission of NPI

Every provider that submits an enrollment application must furnish its NPI(s) in the applicable section(s) of the *Form* 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 *the contractor requests it to do so.* 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 *the contractor requests it to do so.* (The notification from the EFIO will be in the form of a letter or e-mail.) *If the contractor requests paper documentation of a provider's NPI, the contractor* 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 *Form* CMS-855 applies to all applications. (The only exceptions to this involve voluntary terminations, deactivations, deceased providers, and *change of ownership (*CHOW*)* applications submitted by the old owner. NPIs are not required in these instances.) Thus, for instance, if a reassignment package is *submitted,* 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 *Form* CMS-855R.

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

B. Additional NPI Information

If a provider submits an NPI notice to the contractor as a stand-alone document (i.e., no *Form* CMS-855 was submitted), the contractor shall not create a *logging & tracking (*L & T*)* record in PECOS for the purpose of entering the NPI. The contractor shall simply place the notice in the provider file. *The c*ontracto*r s*hall only enter NPI data into PECOS that is submitted in conjunction with a *Form* CMS-855 (e.g., initial, change request). Thus, if a provider submits a *Form* 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. *It was originally issued in January 2006 and has since been slightly updated to reflect certain changes in Medicare terminology.*

*C*MS encourages all providers to obtain NPIs in a manner similar to how they receive *CMS Certification Numbers (CCNs)* (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) *CCNs.* 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 *CCN.*

D. Medicare Subparts Paper - Text

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

*P*urpose of this Paper

Medicare assigns unique identification numbers to its enrolled health care providers. *They* 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 *contractors.* It reflects the Medicare program's expectations on how its enrolled organization health care providers *that* 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 and other directives.* 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 *of* enrolled providers for services furnished to Medicare beneficiaries.

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

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

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

The NPI Final Rule adopted the National Provider Identifier (NPI) as the standard unique health identifier for health care providers for use in HIPAA standard transactions. On or before May 23, 2007, all HIPAA covered entities (except small

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).

health plans), to include enrolled Medicare providers and suppliers that are covered entities, *were required to* obtain NPIs and *to* 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 *CCNs, Provider Transaction Access Numbers (PTANs)*, 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 *have replaced* 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 *that* 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.

Medicare Organization Providers and Subparts: Certified Providers and *Certified* Suppliers

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

Certified Providers that bill Medicare *Part A* (hereinafter referred to as "providers"):

- Providers apply for Medicare enrollment by completing a *Form* 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,

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2 Clinical laboratory certification is handled by the Food and Drug Administration.
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 *Medicare Part B* for certain types of services.

hospices, community mental health centers, religious non-medical health care institutions.

- Providers are assigned *CCNs 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. (*One* 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, which* bill *Medicare Part B*:

- Certified suppliers apply for Medicare enrollment by completing a *Form CMS-855A or CMS-855B, depending on the supplier type.*
- Certified suppliers include ambulatory surgical centers, portable x-ray suppliers, independent clinical labs (CLIA labs), rural health centers, and federally qualified health center*s.*
- *C*ertified suppliers are typically surveyed and certified by the States prior to being approved for enrollment as Medicare certified suppliers. (For CLIA labs, each practice location at which lab tests are performed must obtain a separate CLIA Certificate for that location, though there are a few exceptions to this.)
- Certified suppliers may have in effect an agreement to participate in Medicare.
- Certified suppliers are assigned *CCNs* for purposes of identification within Medicare processes. However, the *contractors* assign unique identification numbers to *certain* certified suppliers for billing purposes. (For CLIA labs, a CLIA *n*umber is typically assigned to each practice location for which a CLIA certificate is issued. A CLIA *n*umber may not be used to identify a clinical laboratory as a "health care provider" in HIPAA standard transactions. The CLIA *n*umber has no relation to the Medicare *PTAN*.)
- 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 *have replaced* 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 *sh*ould:

- 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 *for* the hospital, and one *for* 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 *Form* CMS-855B.
- Supplier groups and supplier organizations bill Medicare Part *B.*
- *Certain s*upplier organizations are certified by the States*, c*ertified by the Food and Drug Administration (FDA), or must undergo an on-site inspection by the *contractor.* 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 TINs. A* supplier group or supplier organization may have multiple *locations; however,* 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 *Form* CMS-855B and the IDTF would complete a *Form* CMS-855B. Each one would receive its own unique Medicare *identification* number.

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

In th*e*se above exceptions, Medicare separately enrolls each different Medicare specialty and each separately visited, certified or *contractor*-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 *have replaced* 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 *sh*ould 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 *contractor*. 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:
DMEPOS Suppliers

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 *identification* number.

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

- Suppliers of DMEPOS bill *D*urable *M*edical *E*quipment *Medicare Administrative Contractors (DME MACs).*

- 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 *DME MAC* must be enrolled as a supplier of DMEPOS through the NSC. Sometimes, these are organizations *that* 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 *that* 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 *Contractor X* and also billing *Contractor Y* would use a single (the same) NPI to bill both *contractors.*

Enrolled organization health care providers or subparts *that* 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 *that* 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 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 *Part A/B Medicare Administrative Contractor (A/B MAC).* If the ambulatory surgical center also sells durable medical equipment, it must also enroll in Medicare as a Supplier of DME and bill a *DME MAC*. This ambulatory surgical center would obtain a single NPI and use it to bill the *A/B MAC* and the *DME MAC*. 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 *that* 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 *that* 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 *uses* 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 *ensures* that the NPIs it receives in HIPAA standard transactions are valid6. Medicare *rejects* 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 *that* are not enrolled in the Medicare program. Medicare *returns,* with appropriate messages, any HIPAA standard transactions containing valid but unrecognizable NPIs.

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

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

15.4.1 – *Certified Providers and Certified Suppliers That Enroll Via the Form CMS-855A*

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

15.4.1.1 - Community Mental Health Centers (CMHCs)

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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 *in Medicare as a Part B* clinic if it does not perform partial hospitalization services.

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 *particular service 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 *on* 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, *it* 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. *Initial* Enrollment and Certification

1. Initial Site Visit

Unlike most certified providers and certified suppliers, 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 *contractor* shall *furnish all* background information *that the RO requests.* All inquiries and correspondence relating to the site visit shall be directed to the RO.

Prior to making a recommendation for *approval, the contractor* shall ensure that the provider has submitted a completed and signed CMHC attestation statement. If the CMHC *cannot* submit one, the *contractor* shall *deny the application*. (The attestation requirement also applies to new owners in a CHOW.) The CMHC attestation statement typically serves as the provider agreement.

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

2. Post-Tie-In Notice Site Visit

In addition to the site visit discussed in (B)(1) above, the contractor shall conduct a site visit after receiving the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the CMHC. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit shall be in accordance with the instructions in section 15.19.2.2(B) of this chapter.

C. Revalidations

If the CMHC submits a Form CMS-855A revalidation application, the contractor shall conduct a site visit prior to making a final decision regarding the revalidation application. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit shall be in accordance with the instructions in section 15.19.2.2(B) of this chapter.

D. 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 *makes the final determination as to* whether a particular practice location qualifies as an alternative site or whether a separate enrollment, provider agreement, etc., is required. *If the contractor is unsure as to whether the location requires a separate enrollment and provider agreement, it may contact the RO for clarification.*

The contractor shall conduct a site visit of the location after receiving notice of approval from the RO (e.g., tie-in notice, approval letter, other type of notice) but before the contractor switches the provider's enrollment record to an "Approved" status. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit shall be in accordance with the instructions in section 15.19.2.2(B) of this chapter.

The contractor 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 *because (1)* CMHCs must serve a distinct and definable community, *and (2) 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.

E. Other Site Visit Requirements

See sections 15.19.2.3 and 15.19.2.4 of this chapter for additional CMHC site visit requirements.

F. Additional Information

For more information on CMHCs, refer *to:*

- Section 1861(ff) of the Social Security *Act*
- 42 CFR *Sections* 410.2, 410.43, and 410.11*0*
- Pub. 100-07, chapter 2, sections 2250 – *2252P*

15.4.1.2 - Comprehensive Outpatient Rehabilitation Facilities (CORFs)

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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 *regional office (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 *(SOM)*, 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; *prior to enrolling in Medicare, however,* it must be surveyed to ensure *that* the CORF conditions of participation are *met.*

B. Enrollment

1. Offsite Locations

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, occupational* therapy, *or speech* language pathology 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 application.*

2. Site Visits

The contractor shall conduct a site visit in the following instances:

- *Initial application – If a CORF submits an initial application, the contractor shall conduct a site visit after receiving the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the provider. This is to ensure that the provider is still in compliance with CMS's enrollment requirements.*

- *Revalidation – If a CORF submits a revalidation application, the contractor shall conduct a site visit prior to making a final decision regarding the application.*

- *New location – The contractor shall conduct a site visit of the location after receiving notice of approval from the RO (e.g., tie-in notice, approval letter, other type of notice) but before the contractor switches the provider's enrollment record to an "Approved" status. This is to ensure that the provider is still in compliance with CMS's enrollment requirements.*

In each of these instances, the scope of the site visit shall be in accordance with section

15.19.2.2(B) of this chapter.

See sections 15.19.2.3 and 15.19.2.4 of this chapter for additional CORF site visit requirements.

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 *(SOM)*
- Pub. 100-07, chapter 3, section 3224 *(SOM)*
- Pub. 100-07, Appendix K *(SOM)*
- Pub. 100-02, chapter 12 (Benefit Policy Manual*)*

15.4.1.3 - End-Stage Renal Disease Facilities (ESRDs)

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. Types of ESR*D Facilities*

*E*SRD 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 *CMS Publication* 100-07 *(State Operations Manual),* 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. Note that 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 *RDF* satellites.

- Self-Dialysis Unit (SDU) – An SDU is a unit of an approved RTC, RDC or RD*F 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 *contractor.*

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 *change of ownership (*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 *or approval letter* to the *contractor* 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. 100-0*7, c*hapter 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 *or approval letter* to the *contractor* 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 *that* ESRD patients receive, collect data, and furnish technical assistance to ESRD providers and patients.

- The provider-based rules for ESRD facilities are *outlined* in 42 CFR §413.174 and are slightly different than *those 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 *facility* must enroll as an ESRD facility via the Form CMS-855A. Since the Form CMS-855A does not distinguish between the different types of ESRD *facilities,* the *following 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 – 2287*B*

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

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

15.4.1.4 - Federally Qualified Health Centers (FQHCs)

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

*F*QHCs furnish services such as those performed by physicians, nurse practitioners,

physician assistants, clinical psychologists, and clinical social workers. This *also* includes certain preventive services like prenatal services, immunizations, blood pressure checks, hearing screenings and cholesterol screenings. (See CMS *Publication* 100-0*2, c*hapter 13, *for more information*). *Even though they complete the Form CMS-855A application, FQHCs* are considered Part B certified suppliers.

*F*QHCs are not required to obtain a State survey; there is *no* State agency involvement with FQHCs. As such, the *contractor* will *either deny the application or* make *a* recommendation for *approval and* forward it directly the RO. The RO will then make the final decision as to whether the *entity* 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 *United States* 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 *CMS Pub. 100-07, c*hapter 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.

- *F*QHCs 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 *of* an FQHC's Medicare participation is the date *on which* 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 *contractor'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.

- *An* FQH*C* cannot have multiple sites or practice locations. Each location must be separately enrolled and will receive its own *CMS Certification Number.*

When sending a recommendation for approval letter to the RO for an initial FQHC application, the contractor shall indicate in the letter the date on which the FQHC's application was complete. To illustrate, assume that the FQHC submitted an initial application on March 1. Two data elements were missing; the contractor thus requested additional information. The two elements were submitted on March 30. The contractor shall therefore indicate the March 30 date in its letter.

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
- Pub. 100-04, chapter 9 (Claims Processing Manual)
- 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. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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 *submit a Form CMS-855A application.* 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, see *CMS* Pub. 100-04, chapter 1, section 20.

15.4.1.7 - Hospices

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. Multiple Practice Locations

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

B. Site Visits

The contractor shall conduct a site visit in the following instances:

- *Initial application - If a hospice submits an initial application, the contractor shall conduct a site visit after receiving the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the provider. This is to ensure that the provider is still in compliance with CMS's enrollment requirements.*

- *Revalidation – If a hospice submits a revalidation application, the contractor shall conduct a site visit prior to making a final decision regarding the application.*

- *New location – The contractor shall conduct a site visit of the location after receiving notice of approval from the RO (e.g., tie-in notice, approval letter, other type of notice) but before the contractor switches the provider's enrollment record to an "Approved" status. This is to ensure that the provider is still in compliance with CMS's enrollment requirements.*

In each of these instances, the scope of the site visit shall be in accordance with section 15.19.2.2(B) of this chapter.

See sections 15.19.2.3 and 15.19.2.4 of this chapter for additional hospice site visit requirements.

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 (*SOM)*
- Pub. 100-04, chapter 11 (Claims Processing *Manual)*
- Pub. 100-02, chapter 9 (Benefit Policy *Manual)*

15.4.1.8 - Hospitals and Hospital Units

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. Swing-Bed Designation

A "swing-bed" hospital is one that is approved by CMS to furnish post-hospital *skilled nursing facility (*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*. T*hus, if swing-bed designation is terminated, the hospital still maintains its certification. In addition, the hospital is given an additional *CMS Certification Number (CCN)* to bill for swing-bed services. (The third digit of the *CCN* 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 *SNFs. T*he hospital *is thus 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 *via the* Form CMS-855A.

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

B. 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.

C. Multi-Campus Hospitals

A multi-campus hospital (MCH) *has* two or more hospital campuses operating under one *CCN* 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.

D. Physician-Owned Hospitals

A physician-owned hospital means any participating hospital (as defined in 42 CFR § 489.24) in which a physician, or an immediate family member of a physician has an ownership or investment interest in the hospital. The ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital. (This definition does not include a hospital with physician ownership or investment interests that satisfy the requirements at 42 CFR § 411.356(a) or (b).)

Section 2(A)(4) of the Form CMS-855A asks the applicant to identify whether it is a physician-owned hospital. If the applicant indicates in section 2(A)(2) that it is a hospital, it must complete section 2(A)(4). Applicants that are not hospitals need not complete section 2(A)(4).

Attachment 1 of the Form CMS-855A must be completed if the applicant is a physician-owned hospital – even if it furnishes similar information in section 5 and/or 6 of the Form CMS-855A.

15.4.1.9 - Indian Health Services (IHS) Facilities

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. General Background Information

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 *wholly* owned and operated by a tribe, though under the general IHS umbrella. When an IHS facility wishes to enroll with the *Part A contractor*, it may *check either:* (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. *The contractor will therefore know that* it is dealing with an IHS facility.

The overwhelming majority of IHS facilities on the Part A side are either hospitals, *skilled nursing facilities (SNFs), critical access hospitals, or end-stage renal disease 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. *That is,* an IHS hospital uses the same CCN series as *a* "regular" hospital, an IHS CAH utilizes the same series as a regular CAH, and so *forth.*

B. IHS Enrollment

Effective September 1, 2010, IHS facilities and tribal providers seeking to initially

enroll *in Medicare or* submit a change of information may utilize Internet-based PECOS or use the paper form CMS-855 enrollment application.

If *an* IHS facilit*y* or tribal provide*r chooses* to use Internet-based PECOS, *it* will be responsible for mailing to TrailBlazer Health Enterprises, LL*C* (TrailBlazer), the designated Medicare contractor, the following:

- The Internet-based PECOS certification statement; and
- Any other applicable supporting documentation.

If the IHS facility or tribal provider sends this information to a Medicare contractor other than Trailblazer, that contractor shall forward the information directly to Trailblaze*r* at one of the following addresses:

Part A Provider Enrollment
TrailBlazer Health Enterprises, LLC
Provider Enrollment
P.O. Box 650458
Dallas, TX 75265-0458

Part B Provider Enrollment
TrailBlazer Health Enterprises, LLC
Provider Enrollment
P.O. Box 650544
Dallas, TX 75265-0544

Note that in Section 2 of the Form CMS-855A and Form CMS-855B applications, the provider or supplier must identify whether it is an Indian Health Facility enrolling with Trailblazer Health Enterprises.

C. Licensure Requirements for Physicians and Practitioners Enrolling to Work in or Reassign Benefits to an Indian Tribe or Tribal Organization

The Affordable Care Act (Pub. L 111-148) amended Section 221 of the Indian Health Care Improvement Act (IHCIA) to provide as follows:

> *Licensed health professionals employed by a tribal health program shall be exempt, if licensed in any State, from the licensing requirements of the State, in which the tribal program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act (ISDEAA) (25 U.S.C. 450, et seq.).*

Pursuant to this statutory provision, any physician or practitioner need only be licensed in one State – regardless of whether that State is the one in which the practitioner practices – if he or she is employed by a tribal health program performing services as permitted under the ISDEAA (see CMS Publication 100-04, chapter 19, section 10 for definitions).

The contractor shall apply this policy when processing applications from these individuals. In terms of the effective date of Medicare billing privileges, the contractor shall continue to apply the provisions of 42 CFR §424.520(d) and section 15.17 of this chapter.

For additional general information on IHS facilities, see Pub. 100-04, chapter 19.

15.4.1.10 - Organ Procurement Organizations (OPOs)

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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 *three* general steps involved in becoming a Medicare OPO*: enrollment,* 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. *C*MS must *first* 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 *regional office* 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. *T*he OPO that CMS selects must first have been certified by CMS *and must meet* the qualifications for designation at 42 CFR §486.304. The OPO must *also* sign a provider agreement (Form CMS-576A) and participate in the Organ Procurement and Transplantation *Network.* (See *CMS* 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 Ac*t*
- 42 CFR §486.301 - §486.34*8*
- Pub. 100-07, chapter 2, sections 2810 – 2819 (State Operations Manual).

For guidance on the appropriate contractor jurisdiction for incoming OPO applications, see *CMS* Pub. 100-04*, c*hapter 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 *CMS Certification Number.*

15.4.1.11 - *Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)*

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. General Background Information

There are three types of certified providers of OPT/*OSP* services:

1. **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/OSP* services, but social or vocational adjustment services as well. (See *CMS* Pub. 100-0*7,* chapter 2, section 2292A.) The overwhelming majority of Part A OPT*/OSP* providers are rehabilitation agencies.

2. **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.

3. **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 that:

- If an OPT*/OSP* provider elects to convert to a *comprehensive outpatient rehabilitation facility (CORF)*, it must meet the CORF conditions of coverage and participation. *An initial* Form CMS-855A enrollment application, State survey, and *CMS regional office* approval are also required.

- Only those clinics *(*as listed above*)* that provide OPT*/OSP* 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 pathology* services. (See Pub. 100-*07, c*hapter 2, section 2292A.)

B. Extension Locations

As discussed in Pub. 100-07*, c*hapter 2, section 2298A, an OPT*/OSP* provider can furnish services from locations other than its primary site. (The provider must designate one location as its primary location*, however*.) These sites are called extension locations*. They* may include freestanding offices, suites in an office or

medical building, or even space in an existing Medicare provider, such as a *skilled nursing facility* or hospital. *Yet* the separate area of the host provider or facility must be set aside for the provision of OPT*/OSP* services during the hours of the OPT*/OSP provider's* operations. (The area/room/unit would be considered the extension location.)
An OPT*/OSP provider* may also *furnish* 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 *the* patient's room need be listed as a practice location on the provider's Form CMS-855A. (See Pub. 100-07*, c*hapter 2, section 2298B.)

For an OPT*/OSP* provider to establish an extension location in an adjoining State, the two States involved must have a signed reciproc*ity* 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*, c*hapter 2, section 2302.)

C. Additional OPT*/OSP* Information

For more information on OPT*/OSP* providers*,* refer to:

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

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

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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 *such as* assistance in moving, comfort and support measures, and general assistance in performing day-to-day activities. *(T*he 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. *E*ach 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 *CMS* Pub. 100-07*, c*hapter 2, section 2054.1B.)

CMS's Boston *regional office* 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 *403.*746. For purposes of provider enrollment, the *three* most important conditions are *that the provider:*

1. 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.

2. Must not be 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)).

3. 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*: (1)* examine Sections 5 and 6 of the CMS-855A*, and (2)* verify the provider's non-profit status to ensure that *the aforementioned conditions* 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*, c*hapter 2, sections 2054, 2054.1, 20541A and 2054.1 (State Operations Manual*)*
- Pub. 100-04, chapter 3, sections 170 - 180 (Claims Processing Manual*)*
- 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

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. General Background Information

Rural health clinics (RHCs):

- Are considered to be Part B certified suppliers, even though they enroll *in Medicare* via the *Form CMS-855A.*
- 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 *CMS* Pub. 100-02, chapter 13 for more information.)

There are certain services performed by RHCs that do not actually qualify as RHC services. *To bill for these services, the clinic must enroll as a Clinic/Group Practice via the Form CMS-855B.* It is not uncommon to see RHCs *simultaneously enrolled in Medicare via the Form CMS-855A* (to *bill* for RHC services) and the *Form* CMS-855B (to *bill* 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 supplier types, there are key differences *as well*:

- 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 by *(1)* the Bureau of the Census as rural, and *(2)* the Secretary of the Department of Health and Human Services or the State as medically underserved.)

- FQHCs furnish preventive services. 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*)*

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

For guidance on the appropriate contractor jurisdictions for incoming RHC applications, *refer to:*

- Pub. 100-04, chapter 1, section 2*0*

- Pub. 100-04, chapter 9, section 10.3

15.4.1.14 - Skilled Nursing Facilities (SNFs)

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. General Background Information

As stated in *CMS* 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 *indicated* 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 *CMS regional office (RO)* will verify that the agreement exists.

Like other certified providers, SNFs receive a State survey and sign a provider agreement. *While* it is extremely rare for a SNF to have multiple practice locations*, 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 *CMS Certification Number (CCN)*. Also:

- A hospital *may* 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 *equivalent to* being "provider-based." (A provider-based SNF, like a distinct part SNF, receives *a CCN that is* separate from that of the hospital.)

A SNF distinct part unit must enroll separately (*i.e.*, 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 – *Certified Suppliers That Enroll Via the Form CMS-855B*

15.4.2.1 - Ambulatory Surgical Centers (ASCs)

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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 *via the Form CMS-855B*; 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

- 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. *It must* independently enroll *via the Form CMS-855B* 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 AS*C.*

2. Hospital outpatient department – If the ASC is treated as a hospital outpatient department, it will not independently enroll *via the Form CMS-855B* as an ASC. It *will be* considered part of the hospital. *(*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 via the Form CMS-855B.*

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.)

C. Additional Information

For more information on ASCs, refer to:

- 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)

- 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. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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 a* small part. *L*aboratories are subject to CLIA - unless an exemption applies - regardless of the complexity or amount of testing that the *laboratory performs.*

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 *that* serve only as collection stations.

(See Pub. 100-07, chapter 6, section 6002, for additional laboratories *that are* 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*s* 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.)*

- 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 *their respective* State. The *State agency* 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 *the* 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 *the latter verifies this*. The laboratory will identify on the Form CMS-116 the organization from which *it 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 *a* Certificate of Accreditation, it will initially pay for and receive a Registration *Certificate.*

C. **CLIA Enrollment**

Note the *following:*

- Prior to enrolling the laboratory, the contractor shall require *the submission of* 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 *simply* 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 *contractor* 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.*

D. Site Visits of Independent CLIA Labs

If the lab is an independent CLIA lab, the contractor shall perform site visits in accordance with the following:

- *Initial application – If the lab submits an initial Form CMS-855B application, the contractor shall conduct a site visit prior to the contractor's final decision regarding the application.*

- *Revalidation – If the lab submits a revalidation application, the contractor shall conduct a site visit prior to making a final decision regarding the application.*

- *New location – If the lab submits an application to add a new practice location, the contractor shall conduct a site visit of the location prior to making a final decision regarding the application.*

In each of these instances, the scope of the site visit shall be in accordance with section 15.19.2.2(B) of this chapter.

See sections 15.19.2.3 and 15.19.2.4 of this chapter for additional lab site visit requirements.

E. Additional Information

For additional data on CLIA laboratories, refer to:

- 42 CFR Part 49*3*

- Publication 100-07, chapter 6 (State Operations Manual*)*

- Publication 100-04, chapter 16 (Claims Processing Manual*)*

- Form CMS-116 (CLIA Application for Certification)

15.4.2.5 - Portable X-Ray Suppliers (PXRSs)

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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:

- Possession 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 *services* 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 purposes (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 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.

PXRSs do not have a supplier agreement.

B. Enrollment of PXRS*s*

1. Section 4 of the Application

In order to enroll as a PXRS, a supplier must complete a Form CMS-855B, undergo a State survey, and *obtain* RO approval. *In Section 4 of the Form CMS-855B*, the PXRS *must furnish certain information, including:*

- 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 inside 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 locatio*n.*

- 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.

2. Site Visits

The contractor shall perform site visits in accordance with the following:

- *Initial application - If the PXRS submits an initial application, the contractor shall conduct a site visit after receiving the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the supplier.*

- *Revalidation – If the PXRS submits a revalidation application, the contractor shall conduct a site visit prior to making a final decision regarding the application.*

- *New location – If the PXRS submits an application to add a new practice location, the contractor shall conduct a site visit of the location after receiving notice of approval from the RO (e.g., tie-in notice, approval letter, other type of notice) but before the contractor switches the supplier's enrollment record to an "Approved" status. This is to ensure that the provider is still in compliance with CMS's enrollment requirements.*

In each of these instances, the scope of the site visit shall be in accordance with section 15.19.2.2(B) of this chapter.

See sections 15.19.2.3 and 15.19.2.4 of this chapter for additional PXRS site visit requirements.

D. 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)
- Pub. 100-04, chapter 13, sections 90 – 90.5 (Claims Processing Manual)

15.4.4.9 - Occupational and Physical Therapists in Private Practice

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. Occupational Therapists

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 Therapist*s*

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 *S*tate 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, (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, (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 *S*tate 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 *S*tate 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, and (2) meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

C. Site Visits of Physical Therapists

Subject to the instructions in subsection D below, the contractor shall perform site visits in accordance with the following:

- *Initial application – If a physical therapist or physical therapist group submits an initial application, the contractor shall conduct a site visit prior to the contractor's final decision regarding the application.*

- *Revalidation – If a physical therapist or physical therapist group submits a revalidation application, the contractor shall conduct a site visit prior to making a final decision regarding the application.*

- *New location – If a physical therapist or physical therapist group submits an application to add a new practice location, the contractor shall conduct a site visit of the new location prior to making a final decision.*

- *Reactivation - If a physical therapist or physical therapist group submits a reactivation application, the contractor shall conduct a site visit prior to making a final decision.*

In each of these instances, the scope of the site visit shall be in accordance with section 15.19.2.2(B) of this chapter.

D. Additional Site Visit Information

The contractor shall also note the following:

- *In section 2A of the Form CMS-855B application, physical and occupational therapy groups are denoted as "Physical/Occupational Therapy Group(s) in Private Practice." If a supplier that checks this box in section 2A is exclusively an occupational therapy group in private practice – that is, there are no physical therapists in the group – the contractor shall process the application using the procedures in the "limited" screening category. No site visit is necessary. If there is at least one physical therapist in the group, the application shall be processed using the procedures in the "moderate" screening category. A site visit is required.*

- *If an entity is enrolled as a physician practice and employs a physical therapist (PT) within the practice, the practice falls within the "limited" screening category. This is because the entity is enrolled as a physician practice, not a physical therapy group in private practice.*

- *The site visit requirement applies to all physical therapists, including those who are reassigning their benefits to a physical therapy group practice or multi-specialty group practice. This may mean that the contractor will need to perform site visits at the same group practice as additional PTs join that group.*

- *If a newly-enrolling physical therapist lists several practice locations, the contractor has the discretion to decide the location at which it will perform the required site visit.*

- *A site visit will be required when a physical therapist submits an application for initial enrollment and reassignment of benefits (Form CMS-855I and Form CMS-855R). However, a site visit is not required for an enrolled physical therapist who is reassigning his or her benefits only (Form CMS-855R).*

- *If the physical therapist's practice location is his or her home address and it exclusively performs services in patients' homes, nursing homes, etc., no site visit is necessary.*

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)

15.6 - Timeliness and Accuracy Standards

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

Sections *15*.*6*.1 through *15*.6.3 of this chapter address the timeliness and accuracy standards applicable to the processing of *Form* CMS-855 applications. Even though the provisions of 42 CFR § 405.874(h) contain processing timeframes that are longer than those in sections *15*.6.1 through *15*.6.3, the contractor shall adhere to the standards specified in sections *15*.6.1 through *15*.6.3.

A. General Processing Activities

Unless indicated otherwise in this chapter or in another CMS directive, the processing of an application generally includes - but is not limited to - the following activities:

- Receipt of the application in the contractor's mailroom and forwarding it to the appropriate office for revie*w*
- Prescreening the application in accordance *with existing instructions*
- Creating an L & T record and an enrollment record in PECO*S*
- Verification of the *data on the* application in accordance *with existing instructions*
- Requesting and receiving clarifying information in accordance *with existing instructions*
- Site visit (if *required*);

- Formal notification of the contractor's decision or recommendation (and providing the appropriate appeal rights, as necessary*).*

B. Commencement of Processing and Receipt Date

As stated in section 15.19.1 of this chapter, an enrollment application submitted by a provider or supplier that is required to pay an application fee should not be processed until the fee is paid or a hardship exception request is approved. Consequently, for such applications - and unless stated otherwise below or in another CMS directive - the contractor shall not perform any processing activities prior to the following:

a. The date on which the provider paid the fee – as confirmed by either the Fee Submitter List or the provider's submission of a receipt of payment from Pay.gov, or

b. The date on which the Provider Enrollment Operations Group (PEOG) approved the provider's hardship exception request (or, in the case of suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), the date on which the National Supplier Clearinghouse (NSC) approved the hardship exception request).

As applicable, the date in (a) or (b) – whichever occurs first - shall be used as the application receipt date in the Provider Enrollment, Chain and Ownership System (PECOS). The processing timeliness clock will begin on said date. The contractor shall, however, note in the provider file and the "Comments" section of PECOS the date on which the contractor received the application (or, for Internet-based PECOS applications, the certification statement) in its mailroom.

The term "receipt," as used in sections 15.6.1 through 15.6.3 of this chapter, thus means the following:

- *For suppliers that are not required to pay an application fee under 42 CFR §424.514 (e.g., physicians, non-physician practitioners) – "Receipt" means the date on which the contractor received the Form CMS-855 application or Internet-based PECOS certification statement in its mailroom, as stated in section 15.6.3(C) below.*

- *For providers and suppliers that are required to pay an application fee – "Receipt" means:*

  - *The date on which the provider paid the fee – as confirmed by either the Fee Submitter List or the provider's submission of a receipt of payment from Pay.gov, or*

  - *The date on which the PEOG approved the provider's hardship exception request (or, for DMEPOS suppliers, the date on which the NSC approved the hardship exception request).*

NOTE: *In situations where the provider's effective date of enrollment is predicated in part upon the application receipt date (such as with 42 CFR §424.520(d)), the contractor shall*

use the date the application or Internet-based PECOS certification statement was received in its mailroom, rather than the receipt date entered into PECOS from which the timeliness clock starts.

The term "processing activities," as used above, includes prescreening and entering the data into PECOS. It does not include, however, determining whether the application should be returned for one of the reasons identified in section 15.8.1 of this chapter. This activity may be performed prior to the fee payment or the hardship exception approval.

15.6.1 – Standards for Initial Applications

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

For purposes of sections *15.*6.1.1 through *15.*6.1.4 of this chapter, the term "initial applications" also includes:

1. CHOW, acquisition/merger, and consolidation applications submitted by the new owner; *and*

2. "Complete" *Form* CMS-855 applications submitted by enrolled providers: (a) voluntarily, (b) as part of any change request if the provider does not have an established enrollment record in PECOS, (c) as part of a reactivation, or (d) as part of a revalidation*.*

15.6.1.1 - Paper Applications - Timeliness

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

For purposes of sections *15.*6.1.1.2 though *15.*6.1.1.4 below, the term "development" *means that the contractor needs* to contact the supplier for additional information. (A prescreening letter to the provider is considered to be the first developmental request.)

15.6.1.2 - Paper Applications – Accuracy

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

The contractor shall process 98 percent of paper CMS-855 initial applications in full accordance with all of the instructions in *this* chapter *(*with the exception of the timeliness standards identified in section*s 15.*6.1.1*.1* through *15.6.1.1.4 of this chapter*) and all other applicable CMS directives.

15.6.1.3 - Web-Based Applications - Timeliness

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

The contractor shall process 90 percent of *Form* CMS-855 Web-based initial applications within 45 calendar days of receipt, process 95 percent of *Form* CMS-855 Web-based initial applications within 60 calendar days of receipt, and process 99 percent of *Form* CMS-855 Web-based initial applications within 90 calendar days of receipt. This process generally includes, but is not limited to:

- Receipt of the provider's certification statement in the contractor's mailroom and forwarding it to the appropriate office for review.

- Verification of the application in accordance with *existing instructions.*

- Requesting and receiving clarifying information in accordance with *existing instructions.*

- Supplier site visit (if *required).*

- Formal notification of the contractor's decision or recommendation (and providing the appropriate appeal rights, as necessary*).*

15.6.1.4 - Web-Based Applications - Accuracy

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

The contractor shall process 98 percent of *Form* CMS-855 Web-based initial applications in full accordance with all of the instructions in *this chapter* (with the exception of the timeliness standards identified in section *15.*6.1.3 above) and all other applicable CMS directives.

*15.*6.2.1 - Paper Applications - Timeliness

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

The contractor shall process 80 percent of paper *Form* CMS-855 changes of information within 60 calendar days of receipt, process 90 percent of paper *Form* CMS-855 changes of information within 90 calendar days of receipt, and process 95 percent of paper *Form* CMS-855 changes of information within 120 calendar days of receipt. This process generally includes, but is not limited to, the following activities:

- Receipt of the change request in the contractor's mailroom and forwarding it to the appropriate office for review.

- Prescreening the change request in accordance with *existing instructions.*

- Creating an L & T record and, if applicable, tying it to an enrollment record in PECOS.

- Verification of the change request in accordance with *existing instructions.*

- Requesting and receiving clarifying information in accordance with *existing instructions.*

- Supplier site visit (if necessary*).*

- Formal notification of the contractor's decision or recommendation (and providing the appropriate appeal rights, as necessary).

15.6.2.2 - Paper Applications - Accuracy

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

The contractor shall process 98 percent of paper *Form* CMS-855 changes of information in full accordance with all of the instructions in *this chapter* (with the exception of the timeliness standards identified in section *15*.6.2.1 above) and all other applicable CMS directives.

15.6.2.4 - Web-Based Applications – Accuracy

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

The contractor shall process 98 percent of *Form* CMS-855 Web-based change of information applications in full accordance with all of the instructions in *this chapter* (with the exception of the timeliness standards identified in section 6.2.3 above) and all other applicable CMS directives.

15.6.3 - General Timeliness Principles

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

Unless stated otherwise *in this chapter or in another CMS directive*, the principles discussed below apply to all applications discussed in sections *15*.6.*1* through *15*.6.2.4 *of this chapter* (e.g., *change of ownership (*CHOW*)* applications submitted by old and new owners, CMS-588 forms).

A. Clock Stoppages

The processing time clocks identified in sections *15*.6.1 and *15*.6.2.*3* of this *chapter* cannot be stopped or suspended for any reason. This includes, but is not limited to, the following situations:

- Referring an application to the *Office of Inspector General (OIG)* or the *Zone Program Integrity Contractor.*

- Waiting for *a* final sales agreement (e.g., CHOW, acquisition/merger*)*.

- Waiting for the *regional office (*RO*)* to make a provider-*based or CHOW* determinatio*n.*

- Referring a provider to the Social Security *Administration to* resolve a discrepancy involving a social security numbe*r.*

- Contacting the *Provider Enrollment Operations Group (PEOG)* or an RO's survey/certification staff with a question regarding the *application or* CMS policy.

Notwithstanding the prohibition on clock stoppages and suspensions, the contractor should always document any delays by identifying when the referral to CMS, the OIG, etc., was made, the reason for the referral, and when a response was received. By doing so, the contractor will be able to furnish explanatory documentation to CMS should applicable time limits be exceeded. To illustrate, assume *that a* contractor received an initial *Form* CMS-855*I* application on March 1. On March 30, the contractor sent *a question* to CMS, and received a reply on April 7. The processing time clock did not stop from March 31 to April 7. However, the contractor should document its files to explain that it forwarded the question to CMS, the dates involved, and the reason for the referral.

B. Calendar Days

Unless otherwise stated in this *chapter*, all days in the processing time clock are "calendar" days, not "business days." If the 60th day (for initials) or 45th day (for changes of information) falls on a weekend or holiday, this is still the day by which the application must be processed. If the contractor is unable to finish processing the application until the next business *day, it* should document the file that the 60th day fell on a Saturday/Sunday/holiday and furnish any additional explanation as needed.

C. Date-Stamping

As a general rule, all incoming correspondence must be date-stamped on the da*y* it was received in the contractor's mailroom. This includes, but is not limited to:

- Any CMS-855 application, including initials, changes, CHOWs, etc. (The first page of the application must be date-stamped.)

- Letters from providers. (The first page of the letter must be date-stamped.)

- Supporting documentation, such as licenses, certifications, articles of incorporation, and billing agreements. (The first page of the document or the envelope must be date-stamped.)

- Data *that the provider furnishes* (via mail or fax) per the contractor's request for additional information. (All submitted pages must be date-stamped. This is because many contractors interleaf the new/changed pages within the original application. *Thus*, it is necessary to determine the sequence in which the application and the additional pages were received.)

For applications that do not require the submission of an fee, the timeliness clock begins on the date on which the application/envelope is date-stamped in the contractor's mailroom, not *the date on which* the application is date-stamped or received by the provider enrollment unit. As such, the date-stamping activities described in the *above* bullets must be performed in the contractor's mailroom. In cases where the mailroom staff fails to date-stamp a particular document, the provider

enrollment unit may date-stamp the page in question. However, there shall not be long lapses between the time it was received in the mailroom and the time the provider enrollment unit date-stamped the pages.

In addition, and unless stated otherwise in this *chapter* or *in an*other CMS directive, all incoming enrollment applications (including change requests) must be submitted via mail.

D. When the Processing Cycle Ends

For (1) Form CMS-855A applications, and (2) Form CMS-855B applications submitted by ambulatory surgical centers (ASC*s)* or portable x-ray suppliers, the processing cycle ends on the date *that* the contractor:

- *Sends its recommendation of approval to the State agency*
- *Denies the application*

In situations involving a change request that does not require a recommendation (i.e., it need not be forwarded to and approved by the State or RO), the cycle ends on the date *that* the contractor sends notification to the provider that the change has been processed. If notification to the provider is made via telephone, the cycle ends on the date *that* the telephone call is made (e.g., the date the voice mail message is left).

For (1) Form CMS-855I applications, (2) Form CMS-855R applications, and (3) Form CMS-855B applications from suppliers other than ASCs and portable x-ray suppliers, the processing cycle ends on the date that the *contractor* sends its approval/denial letter to the supplier. For change request approval/denial notifications made via telephone, the cycle ends on the date *that* the telephone call is made (e.g., the date the voice mail message is left).

For any application that is rejected *per existing instructions,* the processing time clock ends on the date *that* the contractor sends notification to the provider that the application has been rejected.

E. PECOS

Unless stated otherwise in this *chapter or in another CMS directive*, the contractor must create *a logging & tracking (L & T)* record in PECOS:

- *For applications that do not require an application fee, no later than 20 calendar days after its receipt of the provider's application in the contractor's mailroom.*
- *For applications that require an application fee, no later than 20 calendar days after:*
-

- *The date on which the provider paid the fee – as confirmed by either the Fee Submitter List or the provider's submission of a receipt of payment from Pay.gov, or*

- *The date on which PEOG approved the provider's hardship exception request (or, for suppliers of durable medical requirement, prosthetics, orthotics and supplies, the date on which the NSC approved the hardship exception request).*

Moreover, the contractor must establish a complete enrollment record in PECOS – if applicable - prior to its approval*, recommendation of approval, or denial* of the provider's application*. T*o the maximum extent possible, the contractor shall establish the enrollment record at one time, rather than on a piecemeal basis.

The L & T and enrollment record requirements in the previous paragraph apply to all applications identified in sections *15.*6.1 *through 15.6.2.4 of this chapter* (e.g., reassignments, CHOW applications submitted by old and new owners).

In situations where the contractor cannot create an L & T record within *20* days due to missing information (e.g., no NPI was furnished), the contractor shall document the provider file accordingly.

15.7.4 - Tie-In Notices

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

Although it may vary by *regional office (RO)*, tie-in and tie-out notices are generally issued in the following circumstances:

- Initial enrollment
- *Change of Ownership (CHOW) under 42 CFR §489.18*
- Acquisition/Merger
- Consolidation
- Addition or deletion of *home health agency (HHA)* branch, hospital unit, or *outpatient physical therapy* extension site
- Voluntary and involuntary termination of billing numbers

As each RO may have different practices for issuing tie-in and tie-out notices, the *contractor* should contact its RO to find out the specific circumstances in which such notices are *issued. This* also applies to instances where the RO delegates the task of issuing tie-in or tie-out notices to the State agency. The *contractor* may accept such notices from the State in lieu of those from the RO. However, the *contractor* should first contact the applicable RO to confirm: (1) that the latter has indeed delegated this function to the State, and (2) the specific transactions (e.g., CHOWs, HHA branch additions) for which this function has been delegated.

In addition:

- ***Approval Letters*** *– Depending on the RO, an approval letter may be issued in*

lieu of a tie-in notice.

- **Review for Consistency** - When the contractor receives a tie-in notice or approval letter from the RO, it shall review its contents to ensure that the data on the notice/letter matches that on the CMS-855. If there are discrepancies (e.g., different legal business name, address), the contractor *shall contact* the RO to determine why the data is different.

- **Receipt of Tie-In When CMS-*855* Not Completed** - If the contractor receives a tie-in notice from the RO but the provider never *submitted* the necessary *Form* CMS-*855 application*, the contractor shall immediately *alert the RO of* the situation. *The contractor shall also* contact the provider and have *it* complete and submit *the required application.* (This applies to initial applications, CHOWs, practice location additions, etc.)

- ***Creation of New Logging & Tracking (L & T) Record Unnecessary*** - *The contractor is not required to create a new L & T record in the Provider Enrollment, Chain and Ownership System when the tie-in notice comes in, as the existing record should not be in a final status and can therefore be modified. Simply changing the L & T status is sufficient.*

Note that 42 CFR *§*489.13 governs the determination of the effective date of a Medicare provider agreement or supplier approval for health care facilities that are subject to survey and certification. *Section 489*.13 has been revised to *state* that: *(1)* the date of a Medicare provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met, and *(2) such* requirements include the *contractor's* review and verification of an application to enroll in the Medicare *program. (See sections 15.17.4 and 15.26.3 of this chapter for more information.)*

15.17.1 - Effective Date for Certified Providers and Certified Suppliers

The final Fiscal Year (FY) 2011 Hospital Inpatient Prospective Payment System (IPPS) final rule was published on August 16, 2010 (75 FR 50042) and became effective October 1, 2010. Several provisions in the rule directly affect areas of survey and certification responsibility.

Section 489.13 governs the determination of the effective date of a Medicare provider agreement or supplier approval for health care facilities that are subject to survey and certification. Section 489.13 was revised to clarify that the date of a Medicare provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met. Such requirements include the Medicare contractor's review and verification of the provider/supplier's Form CMS-855 application.

These clarifications were necessary because of a September 28, 2009 decision of the Appellate Division of the Department Appeals Board (DAB). The DAB's interpretation

of §489.13 was that it did not include enrollment application processing as among the Federal requirements that must be met. In that case, a State Agency (SA) had conducted a survey of an applicant on July 6, 2007, prior to receiving the November 21, 2007 notice from the Medicare contractor that was recommending approval of the applicant's enrollment application. The CMS Regional Office (RO) issued a provider approval effective November 21, 2007, consistent with our traditional interpretation of §489.13. The DAB, however, ruled that the effective date must be July 6, 2007. The DAB agreed with the applicant that the requirement for the Medicare contractor to verify and determine whether an application should be approved is not a requirement for the provider to meet [under §489.13], but rather a requirement for Medicare contractor action (DAB Decision No. 2271, page 5).

Although SAs and accreditation organizations (AOs) are aware that - in accordance with Section 2003B of the State Operations Manual (SOM) - they should not perform a survey of a new facility until the Medicare contractor has made a recommendation for approval, circumstances do occur where the sequence is reversed. AOs, in particular, often find it challenging to confirm whether the Medicare contractor has made its recommendation. This is because AOs are dependent upon the applicant providing copies of the pertinent notices. When the survey occurs prior to the enrollment verification activities, we believe it is essential that the provider agreement or supplier approval date be based on the later date, i.e., the date on which the contractor determined that the enrollment application verification.

Accordingly, §489.13(b) now states that:

"Federal requirements include, but are not limited to –

> *(1) Enrollment requirements established in part 424, Subpart P, of this chapter. CMS determines, based upon its review and verification of the prospective provider's or supplier's enrollment application, the date on which enrollment requirements have been met;*
>
> *(2) The requirements identified in §§489.10 and 489.12; and*
>
> *(3) The applicable Medicare health and safety standards, such as the applicable conditions of participation, the requirements for participation, the conditions for coverage, or the conditions for certification."*

*15.*27.2.1 – *Special Instructions Regarding* Revocations *of Certified Providers and Certified Suppliers*

(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

If the contractor determines that one or more of the revocation reasons identified in section *15.27.2 of this chapter* are applicable, the contractor may revoke the billing privileges of a certified provider or certified supplier without making a recommendation *for revocation* to the State and *CMS regional office (RO).* It can, in other words, revoke billing privileges at the contractor *level.*

In revoking the provider or supplier, the contractor shall:

- Issue the revocation letter in accordance with section *15.*27.2 *of this chapter;* the contractor shall copy the RO and/or the State on said letter.

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

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