CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 414	**Date: April 6, 2012**
	Change Request 7763

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

I. SUMMARY OF CHANGES: This change request (CR) is the fourth in a series of transmittals designed to update chapter 15 of the PIM. Most of the revisions in this CR: (1) are merely editorial in nature, or (2) incorporate existing policies directly into Chapter 15. New policies are reflected in the CR"s business requirements.

EFFECTIVE DATE: May 7, 2012
IMPLEMENTATION DATE: May 7, 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	15/15.3.1/NPI-Legacy Combinations
R	15/15.4.1.1/Community Mental Health Centers (CMHCs)
R	15/15.4.1.2/Comprehensive Outpatient Rehabilitation Facilities (CORFs)
R	15/15.4.1.7/Hospices
R	15/15.4.2.2/CLIA Labs
R	15/15.4.2.4/Pharmacies
R	15/15.4.2.5/Portable X-Ray Suppliers (PXRSs)
R	15/15.4.2.6/Radiation Therapy Centers
R	15/15.4.2.8/Intensive Cardiac Rehabilitation (ICR)
R	15/15.4.3/Medicare Advantage and Other Managed Care Organizations
R	15/15.4.4/Individual Practitioners
R	15/15.4.4.1/Anesthesiology Assistants
R	15/15.4.4.2/Audiologists
R	15/15.4.4.3/Certified Nurse-Midwives
R	15/15.4.4.4/Certified Registered Nurse Anesthetists (CRNAs)
R	15/15.4.4.5/Clinical Nurse Specialists
R	15/15.4.4.6/Clinical Psychologists
R	15/15.4.4.8/Nurse Practitioners
R	15/15.4.4.9/Occupational and Physical Therapists in Private Practice
R	15/15.4.4.10/Physicians
R	15/15.4.4.11/Physician Assistants (PAs)
R	15/15.4.4.12/Psychologists Practicing Independently
R	15/15.4.4.13/Registered Dietitians
R	15/15.4.4.14/Speech Language Pathologists in Private Practice
R	15/15.4.5/Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an ASC
R	15/15.4.6.1/Diabetes Self-Management Training (DSMT)
R	15/15.4.6.2/Mass Immunizers Who Roster Bill
R	15/15.4.7/Medicaid State Agencies
R	15/15.4.8/Suppliers Not Eligible to Participate
R	15/15.5.1/Basic Information (Section 1 of the Form CMS-855)
R	15/15.5.2.2/Correspondence Address

R	15/15.5.2.4/Section 2 of the Form CMS-855A
R	15/15.5.4.1/Section 4 of the Form CMS-855A
R	15/15.5.19.5/Supervising Physicians
R	15/15.5.19.6/Desk and Site Reviews
R	15/15.19.2.1/Background
R	15/15.19.2.2/Scope of Site Visit
R	15/15.19.2.3/Changes of Information and Ownership
R	15/15.19.2.5/Movement of Providers and Suppliers into the High Level
R	15/15.19.2.4/Reactivations

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: 414	Date: April 6, 2012	Change Request: 7763

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

Effective Date: **May 7, 2012**

Implementation Date: May 7, 2012

I. GENERAL INFORMATION

A. Background: This change request (CR) is the fourth in a series of transmittals designed to update chapter 15 of the PIM. The majority of the revisions in these CRs will either: (1) be 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 continue 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	
7763.1	If an ambulance supplier, independent clinical laboratory (ICL), independent diagnostic testing facility (IDTF), physical therapist or physical therapist group submits an initial enrollment application, the contractor shall order a site visit via the Provider Enrollment, Chain and Ownership System (PECOS).	X			X						
7763.1.1	In the situation described in business requirement 7763.1, the contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the National Site Visit Contractor's (NSVC) site visit and the contractor's review of the results.	X			X						
7763.2	If an ambulance supplier, ICL, IDTF, physical therapist or physical therapist group submits a revalidation application, the contractor shall order a site visit via PECOS.	X			X						
7763.2.1	In the situation described in business requirement 7763.2, the contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.	X			X						
7763.3	If (1) an ambulance supplier, ICL, physical therapist	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	
	or physical therapist group is adding a new practice location, or (2) an ambulance supplier, ICL, IDTF, physical therapist or physical therapist group is changing the physical location of an existing practice location, the contractor shall order a site visit via PECOS.										
7763.3.1	In the situation described in business requirement 7763.3, the contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.	X			X						
7763.4	If a community mental health center (CMHC), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), hospice or portable x-ray supplier (PXRS) submits an initial application, the contractor shall order a site visit after the contractor receives the tie-in notice (or approval letter) from the regional office (RO) but before the contractor conveys Medicare billing privileges to the provider/supplier.	X		X	X	X					
7763.4.1	In the situation described in business requirement 7763.4, the contractor shall not convey Medicare billing privileges to the provider/supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.	X		X	X	X					
7763.5	If a CMHC, CORF, HHA, hospice or PXRS submits a revalidation application, the contractor shall order a site visit via PECOS.	X		X	X	X					
7763.5.1	In the situation described in business requirement 7763.5, the contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.	X		X	X	X					
7763.6	If a CMHC, CORF, HHA, hospice or PXRS is adding a new practice location/branch or changing the physical location of an existing practice location/branch, the contractor shall order a site visit via PECOS after the contractor receives notice of approval from the RO but before the contractor switches the provider/supplier's enrollment record to "Approved."	X		X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7763.6.1	In the situation described in business requirement 7763.6, the contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.	X		X	X	X					
7763.7	If a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) is changing the physical location of an existing practice location, the National Supplier Clearinghouse (NSC) shall perform a site visit in accordance with existing instructions.										NSC
7763.8	With the exception of DMEPOS suppliers and HHAs, if a provider or supplier in the "moderate" or "high" screening category undergoes a change of ownership resulting in a new tax identification number, the contractor shall (1) process the application in accordance with existing instructions, and (2) order a site visit through PECOS in accordance with business requirements 7763.8.1 and 7763.8.2.	X		X	X	X					
7763.8.1	For ownership changes that must be approved by the RO under current CMS instructions, the site visit shall be ordered and performed after the contractor receives notice of approval from the RO but before the contractor switches the provider/supplier's enrollment record to an "Approved" status.	X		X	X	X					
7763.8.1.1	In the situation described in business requirement 7763.8.1, the contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.	X		X	X	X					
7763.8.2	For ownership changes that do not require RO approval under current CMS instructions, the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.	X		X	X	X					
7763.8.2.1	In the situation described in business requirement 7763.8.2, the contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.	X		X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7763.9	With respect to HHAs, if (1) the contractor determines that one of the exceptions to the 36-month rule applies, and (2) the ownership change is one that requires a recommendation for approval to the RO, the contractor shall ensure that its recommendation letter specifies (a) that the transaction qualifies as a change in majority ownership and (b) the particular exception that applies.			X		X					
7763.10	If an enrolled IDTF wants to perform additional procedures that are <u>not</u> similar to those previously reported (e.g., an IDTF that conducts sleep studies wants to perform ultrasound tests or skeletal x-rays), the contractor shall order an NVSC site visit through PECOS.	X			X						
7763.11	If an enrolled IDTF: (1) originally listed only general supervision codes, (2) was only reviewed for general supervision tests, and (3) now wants to perform tests that require direct or personal supervision, the contractor shall order a site visit through PECOS.	X			X						
7763.12	In the situations described in business requirements 7763.10 and 7763.11, the contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.	X			X						

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

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 Representative (COR) 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

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(Rev.414, Issued: 04-06-12)

15.3.1 – NPI-Legacy Combinations

(Rev.414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

If the contractor determines that a provider is having claim payment issues due *solely* to an incorrect NPI-Provider Transaction Access Number *(PTAN)* combination or NPI-CMS Certification Number *(CCN)* combination entered into the Provider Enrollment, Chain and Ownership System (PECOS*), t*he contractor shall request that the provider submit the correct NPI-legacy combination via a Form CMS-855 change of information. The change request can be faxed, *although the contractor shall* verify the faxed signature against the *provider's* or authorized official's signature on file before any changes are made in PECOS.

The contractor shall not use this process to resolve any enrollment issue other than the correction of the NPI-legacy identifier combination. Moreover, the contractor shall not use this process for providers that have not submitted a complete Form CMS-855 enrollment application during or after May 2006. For instance, assume a provider first enrolled in Medicare in December 2005 and has not submitted a complete enrollment application after that date. The provider would be unable to utilize the process described in *this section.*

15.4.1.1 - Community Mental Health Centers (CMHCs)

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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 this 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), the contractor shall *order* a site visit *through the Provider Enrollment, Chain and Ownership System (PECOS)* after the contractor receiv*es* 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 *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.*

C. Revalidations

If the CMHC submits a Form CMS-855A revalidation application, the contractor *shall order a site visit through PECOS.* This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

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.

If a CMHC is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." This is to ensure that the new/changed location is in compliance with CMS's enrollment

requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

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. ***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 410.110
- Pub. 100-07, chapter 2, sections 2250 – 2252P

See sections 15.19.2.2 through 15.19.2.4 of this chapter for additional information on CMHC site visits.

15.4.1.2 - Comprehensive Outpatient Rehabilitation Facilities (CORFs)

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

- Initial application – If a CORF submits an initial application, the contractor shall *order* a site visit *through the Provider Enrollment, Chain and Ownership System (PECOS)* after the contractor receive*s* 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 *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The National Site Visit Contractor (NSVC) will perform the site visit. The contractor*

shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

- Revalidation – If a CORF submits a revalidation application, the contractor *shall order a site visit through PECOS.* This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- New*/changed* location - *If a CORF is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

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)

See also sections 15.19.2.2 through 15.19.2.4 of this chapter for additional CORF site visit information.

15.4.1.7 - Hospices

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

- Initial application – If a *hospice* submits an initial application, the contractor shall *order* a site visit *through the Provider Enrollment, Chain and Ownership System (PECOS)* after the contractor receiv*es* the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the hospice. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- Revalidation – If a *hospice* submits a revalidation application, the contractor *shall order a site visit through PECOS.* This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- New*/changed* location - *If a hospice is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

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)

See sections 15.19.2.2 through 15.19.2.4 of this chapter for additional hospice site visit information.

15.4.2.2 – CLIA Labs

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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. Laboratories 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
- Types 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

- Initial application – If an independent CLIA lab submits an initial application, the contractor shall *order* a site visit *through the Provider Enrollment, Chain and Ownership System (PECOS).* This is to ensure that the *supplier* is still in compliance with CMS's enrollment requirements. The scope of the site visit *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- Revalidation – If an *independent CLIA lab* submits a revalidation application, the contractor *shall order a site visit through PECOS.* This is to ensure that the *supplier* is still in compliance with CMS's enrollment requirements. The scope of the site visit *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- New*/changed* location - *If an independent CLIA lab is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the supplier's enrollment record to "Approved." This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

E. Additional Information

For additional data on CLIA laboratories, refer to:

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

See sections 15.19.2.2 through 15.19.2.4 of this chapter for additional lab site visit information.

15.4.2.4 - Pharmacies

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Pharmacies typically enroll with the *National Supplier Clearinghouse*. However, there are certain covered drugs that are billed through the physician fee schedule and not the schedule for *durable medical equipment, prosthetics, orthotics and supplies*. *These* drugs must be billed to *the Part A/B Medicare Administrative Contractor (A/B MAC), meaning that the pharmacy must enroll with the A/B MAC* via the Form CMS-855B.

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

15.4.2.5 - Portable X-Ray Suppliers (PXRSs)

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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: The PXRSs requires 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 PXRSs

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 location.

- 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

- Initial application – If *a PXRS* submits an initial application, the contractor shall *order* a site visit *through the Provider Enrollment, Chain and Ownership System (PECOS) after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the PXRS.* This is to ensure that the *supplier* is still in compliance with CMS's enrollment requirements. The scope of the site visit *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- Revalidation – If a *PXRS* submits a revalidation application, the contractor *shall order a site visit through PECOS.* This is to ensure that the *supplier* is still in compliance with CMS's enrollment requirements. The scope of the site visit *wi*ll be *consistent* wit*h s*ection 15.19.2.2(B) of this chapter. *The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- New*/changed* location - *If a PXRS is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the supplier's enrollment record to "Approved." This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

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)

See also sections 15.19.2.2 through 15.19.2.4 of this chapter for additional PXRS site visit information.

15.4.2.6 - Radiation Therapy Centers

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Under 42 CFR § 410.35, Medicare Part B pays for *X*-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

For additional background on radiation therapy services, see:

- Section 1861(s)(4) of the Social Security Act
- 42 CFR § 410.35
- Publication 100-04, chapter 13
- Publication, chapter 15, section 90

15.4.2.8 – Intensive Cardiac Rehabilitation (ICR)

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. *Background*

Effective January 1, 2010, Medicare Part B covers Intensive Cardiac Rehabilitation (ICR) program services for beneficiaries who have experienced one or more of the following:

- An acute myocardial infarction within the preceding 12 months
- A coronary artery bypass surgery
- Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty or coronary stenting
- A heart or heart-lung transplant

The ICR programs must be approved by CMS through the national coverage determination (NCD) process. Individual sites *that seek* to provide ICR services via an approved ICR program must enroll with their local Medicare *contractor as* an ICR program supplier.

B. ICR Enrollment

In order to enroll as an ICR site, a supplier must complete a Form CMS-855B, with the supplier type of "Other" selected. *The* contractor shall *ensure* that CMS *has approved the ICR program* through the NCD process. A list of approved ICR programs will be identified through the NCD listings, the CMS Web site and the Federal Register.

An ICR supplier must separately and individually enroll each of its practice locations. The supplier can therefore only have one practice location – which shall receive its own Provider Transaction Access Number - on its Form CMS-855B enrollment application. The contractor shall use specialty code 31 for these enrollments.

The contractor shall only accept and process reassignments (Form CMS-855Rs) to ICR suppliers from physicians defined in section 1861(r)(1) of the Social Security Act.

C. Additional Information

For more information on ICR suppliers, refer to:

- 42 CFR § 410.49

- Publication 100-04, chapter 32, sections 140.2.2 – 140.2.2.6 (Medicare Claims Processing Manual)

- Publication 100-02, chapter 15, section 232 (Medicare Benefit Policy Manual)

15.4.3 - Medicare Advantage and Other Managed Care Organizations

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

The MA/MCO must submit a Form CMS-855B to its local Medicare contractor as a prerequisite for enrolling in Medicare to bill for these services. The entity shall check the "Other" box in section 2A of the Form CMS-855B. The contractor shall use specialty code 88 when enrolling these organizations.

15.4.4 - Individual Practitioners

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

15.4.4.1 - Anesthesiology Assistants

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

- Is permitted by State law to administer anesthesia; and
- Has successfully completed a 6-year program for anesthesiology assistants, of which 2 years consists of specialized academic and clinical training in anesthesia.

For more information on anesthesiology assistants, refer to:

- Section 1861(bb)(2) of the Social Security Act
- 42 CFR §410.69(b)
- Pub. 100-04, chapter 12, sections 140 – 140.4.4 (Claims Processing Manual)

15.4.4.2 - Audiologists

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

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

OR

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

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

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

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

For more information on audiologists, refer to:

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

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

15.4.4.3 - Certified Nurse-Midwives

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

(2) Meet one of the following requirements:

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

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

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

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

3. Have successfully completed a formal education program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and have

practiced as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976, to July 16, 1982.

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

For more information on certified nurse midwives, refer to:

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

15.4.4.4 - Certified Registered Nurse Anesthetists (CRNAs)

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Per 42 CFR *§* 410.69(b), a *CRNA is* a registered nurse who:

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

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

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

(4) Meets the following criteria:

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

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

For more information on CRNAs, refer to:

- Section 1861(bb) of the Social Security Ac*t*

- 42 CFR §410.69(b)

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

15.4.4.5 - Clinical Nurse Specialists

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

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

The following organizations are recognized national certifying bodies *for certified nurse specialists* at the advanced practice level:

- American Academy of Nurse Practitioners

- American Nurses Credentialing Center

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

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

- Oncology Nurses Certification Corporation

- AACN Certification Corporation

- National Board on Certification of Hospice and Palliative Nurse

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

and appropriate supervision as required by the law of the State in which the services are furnished.

For more information on clinical nurse specialists, refer to:

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

15.4.4.6 - Clinical Psychologists

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

For more information on clinical psychologists, refer to:

- *Publication* 100-04, chapter 12, sections 170 (Claims Processing Manual)
- *Publication* 100-02, chapter 15, section 160 (Benefit Policy Manual*)*

15.4.4.8 - Nurse Practitioners

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

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

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

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

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

- American Academy of Nurse Practitioner*s*
- American Nurses Credentialing Cente*r*
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialtie*s*
- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses*)*
- Oncology Nurses Certification Corporatio*n*
- AACN Certification Corporatio*n*
- National Board on Certification of Hospice and Palliative Nurse*s*

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

For more information on nurse practitioners, refer to:

- Pub. 100-02, chapter 15, section 200 (Benefit Policy Manual)
- Pub. 100-04, chapter 12, sections 120 and 120.1 (Claims Processing Manual)
- 42 CFR §410.150(b)(16)

15.4.4.9 - Occupational and Physical Therapists in Private Practice

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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 Therapists

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

- Has graduated from a physical therapy curriculum approved by (1) the American Physical Therapy Association, (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 State department of education; or

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

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

- If trained outside the United States, (1) was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy, 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 s*ubsection D below, *site visits will be performed* in accordance with the following:

- *Initial application – If a physical therapist (PT) or PT group submits an initial application, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS). This is to ensure that the supplier is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- *Revalidation – If a PT or PT group submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the supplier is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- New*/changed* location – *Unless CMS has directed otherwise, if a PT or PT group is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS. This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

D. Additional Site Visit Information

***NOTE**: The contractor shall also view 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 *by the NSVC* is required, *unless CMS has directed otherwise.*

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

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

- *Unless CMS has directed otherwise*, a site visit *by the NSVC* is 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)

15.4.4.10 - Physicians

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

1. Doctors of:

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

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

For information on physician billing, refer to Pub*lication* 100-04, chapter 12. In addition, refer to Pub. 100-04, chapter 19, section 40.1.2, for special licensure rules regarding practitioners who work in or reassign benefits to hospitals or freestanding ambulatory care clinics operated by the *Indian Health Service* or by an Indian tribe or tribal organization.

15.4.4.11 - Physician Assistants (PAs)

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

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

As indicated in *Publication* 100-02, chapter 15, section 190(D):

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

- The PA's employer can be either an individual or an organization. If the employer is a professional corporation or other duly qualified legal entity (e.g., *limited liability company*) in a State that permits PA ownership in the entity (e.g., as a stockholder, member), the entity may bill for PA services even if a PA is a stockholder or officer of the entity – so long as the entity is eligible to enroll as a provider or supplier in the Medicare program. PAs may not otherwise organize or incorporate and

bill for their services directly to the Medicare program, including as, but not limited to, sole proprietorships or general partnerships. Accordingly, a qualified employer is not a group of PAs that incorporates to bill for *its* services. Moreover, leasing agencies and staffing companies do not qualify under the Medicare program as providers *or suppliers* of services.

For more information on *PAs*, refer to:

- 42 CFR § 410.74
- 42 CFR § 410.150(b)(15)
- Pub*lication* 100-04, chapter 12, sections 110 through 110.3 (Claims Processing Manual)

15.4.4.12 - Psychologists Practicing Independently

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

- *He/she* render services on *his/her* own responsibility, free of the administrative and professional control of an employer, such as a physician, institution or agency;
- The persons *he/she* treat*s* are *his/her* own patients;
- *He/she* ha*s* the right to bill directly, collect and retain the fee for *his/her* services; and
- The psychologist is State-licensed or certified.

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

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

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

For more information on independently practicing psychologists, refer to Pub*lication* 100-04, chapter 12, sections 160 and 160.1 (Claims Processing Manual).

15.4.4.13 - Registered Dietitians

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

3. Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian"' by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs *(1)* and *(2)* above.

There are two *exceptions* to these requirements:

- A dietitian or nutritionist licensed or certified in a State as of December 21, 2000, is not required to meet the requirements of *(1) and (2)* above.

- A registered dietitian in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of *(1) and (2)* above.

For more information on registered dietitians, refer to:

- Sections 1861(vv) of the Social Security Act

- 42 CFR § 410.130 through § 410.134

15.4.4.14 – Speech Language Pathologists in Private Practice

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Effective July 1, 2009, in order to qualify as an outpatient speech-language pathologist in private practice, an individual *must meet* the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of speech-language pathology by the State in which he or she practices, and practice only within the scope of his or her license and/or certification.

(ii) Engage in the private practice of speech-language pathology as an individual, in one

of the following practice types:

(A) An unincorporated solo practice

(B) An unincorporated partnership or unincorporated group practice

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

(D) An employee of a physician group

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

For more information on speech language pathologists in private practice, refer to Publication 100-02, chapter 15, section 230.

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

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Since *Part A/B Medicare Administrative Contractors (A/B MACs)* make payments for implantable prosthetics and DME to hospitals, physicians or ASCs, *A/B MACs* shall not enroll manufacturers of implantable or non-implantable and prosthetics DME into the Medicare program. *A manufacturer* of non-implantable prosthetics and DME and replacement parts and supplies for prosthetic implants and surgically implantable DME may enroll in the Medicare program as a supplier with the *National Supplier Clearinghouse* if *it* meets the definition of a supplier as well as the *requirements in 42* CFR § 424.57.

15.4.6.1 - Diabetes Self-Management Training (DSMT)

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. Background

Diabetes self-management training (DSMT) is not a separately recognized provider type, *such as* a physician or nurse practitioner. A person or entity cannot enroll in Medicare for the sole purpose of performing DSMT. Rather, DSMT *is an* extra service that *an enrolled* provider or supplier can bill for, assuming it meets all of the necessary DSMT requirements.

All DSMT programs must be accredited as meeting quality standards by a CMS-approved national accreditation organization. Currently, CMS recognizes the American Diabetes Association (ADA) *and the* American Association of Diabetes *Educators (AADE) as* approved national accreditation organizations. A Medicare-enrolled provider or non-DMEPOS supplier that wishes to bill for DSMT may simply submit the ADA *or AADE* certificate to its contractor. No Form CMS-*855 i*s required, unless the

provider or supplier is not in *the Provider Enrollment, Chain and Ownership System (PECOS)*, in which case a complete Form CMS-855 application *must be submitted.*

If the supplier is exclusively a DMEPOS supplier, it must complete and submit a Form CMS-855B application to its local *Part A/B Medicare Administrative Contractor (A/B MAC)*. This is because *A/B MACs, rather than Durable Medical Equipment Medicare Administrative Contractors*, pay DSMT claim*s*. Thus, the DMEPOS supplier must separately enroll with *its A/B MAC*, even if it has already completed a Form CMS-855S. If a*n A/B MAC* receives an application from a DMEPOS supplier that would like to bill for DMST, it shall verify with the National Supplier Clearinghouse that the applicant is currently enrolled and eligible to bill the Medicare program.

For more information on DSMT, refer to:

- Section 1861(qq) of the Social Security Act
- 42 CFR Part 410 (subpart H)
- Pub*lication* 100-02, Medicare Benefit Policy Manual, chapter 15, sections 300 – 300.5.*1*

15.4.6.2 - Mass Immunizers Who Roster Bill

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

- They may not bill Medicare for any services other than pneumococcal pneumonia vaccines (PPVs), influenza virus vaccines, and their administration.
- They must submit claims through the roster billing process.
- All personnel who administer the shots must meet all applicable State and local licensure or certification requirements.

The roster billing process was developed to enable Medicare beneficiaries to participate in mass PPV and influenza virus vaccination programs offered by public health clinics and other organization*s*.

NOTE: The following information regarding the enrollment of mass immunizers:

- *The effective date provision in 42 CFR § 424.520(d) does not apply to the enrollment of mass immunizers. This is because the individual/entity is not enrolling as a physician, non-physician practitioner, physician group or non-physician practitioner group.*

- *In section 4 of the Form CMS-855, the supplier need not list each off-site location (e.g., county fair, shopping mall) at which it furnishes services. It need only list its base of operations (e.g., county health department headquarters, drug store location).*

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

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

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

NOTE: *S*ection 10.3.1 outlines the requirements for submitting roster bills.

15.4.7 - Medicaid State Agencies

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Medicaid State agencies do not have a National Provider Identifier and are not otherwise eligible to enroll in the Medicare program. If a Medicaid State agency is enrolled or seeks enrollment as a provider or supplier in the Medicare program, the contractor shall deny or revoke its Medicare billing privileges using, respectively, § 424.530(a)(5) (denials) and § 424.535(a)(3) (revocations) as the basis.

15.4.8 - Suppliers Not Eligible to Participate

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Below is a list of *individuals and entities that* frequently attempt to enroll *in Medicare,* but are not eligible to do so. If the contractor receives an enrollment application from any of these *individuals or entities*, the contractor *shall deny the application.*

- Acupuncturist
- Assisted Living Facilit*y*
- Birthing Cente*r*
- Certified Alcohol and Drug Counselor
- Certified Social Worker
- Drug and Alcohol Rehabilitation Counselor
- Hearing Aid Center/Dealer
- Licensed Alcoholic and Drug Counselor
- Licensed Massage Therapis*t*
- Licensed Practical Nurs*e*
- Licensed Professional Counselor
- Marriage Family Therapis*t*

- Master of Social Work
- Mental Health Counselor
- National Certified Counselor
- Occupational Therapist Assistant
- Physical Therapist Assistant
- Registered Nurse
- Speech and Hearing Center
- Substance Abuse Facility

15.5.1 – Basic Information (Section 1 of the Form CMS-855)

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

When processing section 1 of the application, the contractor shall ensure that:

- The provider checks one of the "reason" boxes. *If the contractor believes that the provider checked the incorrect box (e.g., "change of ownership" instead of "initial enrollment"), it shall contact the provider for clarification.*

- *The provider's Medicare identification number and National Provider Identifier – if reported in this section - are correct.*

NOTE: That

- If a provider seeks to reestablish itself in the Medicare program after reinstatement from an exclusion, the transaction shall be treated *as an* initial enrollment.

- Hospitals that request enrollment *via the Form CMS-855B* to bill for practitioner services for hospital departments, outpatient locations and/or hospital clinics must submit an initial enrollment application.

- Unless otherwise stated in this chapter, the provider may only check one reason for submittal. Suppose a supplier is changing its *tax identification number via the Form CMS-855B.* It must enroll as a new supplier *and must* terminate its existing *enrollment.* The provider must *therefore* submit two applications: (1) an initial *Form* CMS-855B as a new supplier, and (2) a *Form* CMS-855*B v*oluntary termination. Both transactions cannot be reported on the same applicatio*n*.

15.5.2.2 – Correspondence Address

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. *Background*

The correspondence address must be one where the contractor can directly contact the applicant to resolve any issues once the provider is enrolled in the Medicare program.

It cannot be the address of a billing agency, management services organization, chain home office, or the provider's representative (e.g., attorney, financial advisor). It can, however, be a P.O. Box or, in the case of an individual practitioner, the person's home address.

The contractor shall call the telephone number listed in this section to verify that the contractor can directly contact the applicant. If an answering service appears and the contractor can identify it as the applicant's personal service, it is not necessary to talk directly to the applicant or an official thereof. The contractor only needs to verify that the applicant can be reached at this number.

B. Contact Person

The contractor should use the contact person listed in section 13 of the Form CMS-855 for all communications directly related to the provider's submission of an initial enrollment application, change of information request, etc. All other provider enrollment-oriented matters shall be directed to the correspondence address. For instance, assume a provider submits an initial Form CMS-855 on March 1. The application is approved on April 15. All communications specifically related to the Form CMS-855 submission between March 1 and April 15 should be sent to the contact person (or, if section 13 is blank, to an authorized/delegated official or the individual practitioner). After April 15, all provider enrollment-oriented correspondence shall go to the correspondence address. Assume further that the provider submits a change of information request on August 1, which the contractor approves on August 30. All communications directly related to the change request should go to the designated contact person between August 1 and August 30.

Notwithstanding the above, all approval *(or recommendation for approval) and* denial letters should be sent to the contact person. However, the contractor retains the discretion to send the letter to another address listed on the Form CMS-855 *if circumstances dictate.*

The contractor has the discretion to determine whether a particular communication is "specifically related" to a *Form* CMS-855 submission or whether a particular communication is "provider enrollment-oriented."

15.5.2.4 – Section 2 of the Form CMS-855A

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. Home Health Agency (HHA) Branches, Hospital Units, and Outpatient Physical Therapy/*Outpatient Speech Pathology* (OPT/*OSP)* Extension Sites

As explained in section 15.4.1.6, a branch is a location or site from which an HHA provides services within a portion of the total geographic area *that the parent company serves*. The branch is part of the HHA and is located sufficiently close to the parent agency such that it shares administration, supervision, and services with the parent. If an existing HHA w*ants* to add a branch, it is considered a change of information on the *Form* CMS-855A. An HHA subunit, meanwhile, is a semi-autonomous organization

under the same governing body as the parent HHA and serves patients in a geographic area different from that of the parent. *Due to* its distance from the subunit, the parent is incapable of sharing administration, supervision and services with the subunit on a daily basis. If the HHA wants to add an HHA subunit, it must complete an initial enrollment application for the subunit. (The subunit also signs a separate provider agreement.)

If an enrolled hospital seeks to add a rehabilitation, psychiatric, or swing-bed unit, it should submit a *Form CMS-855* change of information *request* and not an initial enrollment application. *Similarly, if* an OPT/O*SP* provider *wants* to add an extension site, a *change of information request* should be submitted.

If the contractor makes a recommendation for approval of the provider's request to add an HHA branch or a hospital unit, the contractor *shall forward* the package to the State *agency* as described in this chapter. However, the contractor shall emphasize to the provider that a recommendation *for* approval of *the branch or hospital unit addition* does not signify CMS's approval of the new location. Only the RO can approve the addition.

With respect to the *Provider Enrollment, Chain and Ownership System*, the contractor shall create a separate enrollment record for the hospital unit. However, a separate enrollment record for each HHA branch and OPT/O*SP* extension site is not required. These locations can simply be listed on the main provider's enrollment record.

B. Critical Access Hospitals

Critical access hospitals (CAHs) are not considered to be a hospital sub-type for enrollment purposes. Thus, if an existing hospital wishes to convert to a CAH, it must *submit a Form* CMS-855A as an initial enrollment.

C. Transplant Centers

For purposes of Medicare enrollment, a hospital transplant center is treated similarly to a hospital sub-unit. If the hospital wishes to add a transplant center, it must check the "other" box in section 2A2 of the CMS-855A, write "transplant center" on the space provided, and follow the standard instructions for adding a sub-unit. Unless CMS indicates otherwise, the contractor shall process the application in the same manner it would the addition of a hospital sub-unit; however, no separate enrollment in PECOS need be created for the transplant center.

15.5.4.1 – Section 4 of the Form CMS-855A

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. General Information

A hospital or other provider must list all addresses where *it* - and not a separately enrolled provider *or supplier it owns or operates*, such as a nursing home - furnish*es*

services. The provider's primary practice location should be the first location identified in section 4*A* and the contractor shall treat it as such *– unless there is evidence indicating otherwise -* for purposes of *entry into the Provider Enrollment, Chain and Ownership System (PECOS)*.

NOTE: Hospital departments located at the same address as the main facility need not be listed as practice locations on the *Form* CMS-855A.

If a practice location (e.g., hospital unit) has a *CMS Certification Number (CCN)* that is in any way different from that of the main provider, the contractor shall create a separate enrollment record in PECOS for that location; this does not apply, however, to *home health agency (HHA)* branches, *outpatient physical therapy/outpatient speech pathology (OPT/OSP)* extension sites and transplant centers.

An HHA should complete section 4A with *its* administrative address.

If the provider's address and/or telephone number cannot be verified, the contractor shall request clarifying information from the provider. If the provider states that the facility and its phone number are not yet operational, the contractor may continue processing the application. However, it shall note in its recommendation letter that the address and telephone number of the facility could not be verified. For purposes of PECOS entry, the contractor can temporarily use the date the certification statement was signed as the effective date.

B. Verification of HHA Sites

If the contractor receives an application from an HHA that has the same general practice location address as another enrolled (or enrolling) HHA and the contractor has reason to suspect that the HHAs may be concurrently operating out of the same suite or office, the contractor shall notify *the National Site Visit Contractor of this at the time the contractor orders the required site visit through PECOS.*

15.5.19.5 – Supervising Physicians

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. General Principles

Under 42 CFR § 410.33(b)(1), an *independent diagnostic testing facility (IDTF)* must have one or more supervising physicians who are responsible for:

- The direct and ongoing oversight of the quality of the testing performed;
- The proper operation and calibration of equipment used to perform tests; and
- The qualifications of non-physician IDTF personnel who use the equipment.

Not every supervising physician has to be responsible for all of these functions. For

instance, one supervising physician can be responsible for the operation and calibration of equipment, while another supervising physician can be responsible for test supervision and the qualifications of non-physician personnel. The basic requirement, however, is that all supervising physician functions must be properly met at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervising physicians at different locations. They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

Under 42 CFR § 410.33(b)(1), each supervising physician must be limited to providing supervision at no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

B. Information about Supervising Physicians

The contractor shall ensure and document that each supervising physician is: (1) licensed to practice in the State(s) where the diagnostic tests he or she supervises will be performed, (2) Medicare-enrolled, and (3) not currently excluded or debarred. The physician(s) need not necessarily be Medicare-enrolled in the State where the IDTF is enrolled. If the physician is enrolled in another State or with another contractor, however, the contractor shall ensure that he or she is appropriately licensed in that State.

In addition:

- Each physician of the group who actually performs an IDTF supervisory function must be listed.

- If a supervising physician has been recently added or changed, the updated information must be reported via a Form CMS-855B change request. The new physician must have met all of the supervising physician requirements at the time any tests were performed.

- If the contractor knows that a listed supervising physician has been listed with several other IDTFs, the contractor shall check with the physician to determine whether he or she is still acting as supervising physician for these other IDTFs.

C. General, Direct, and Personal Supervision

Under 42 CFR § 410.33(b)(2), if a procedure requires the direct or personal supervision of a physician as set forth in 42 CFR § 410.32(b)(3), the contractor shall ensure that the IDTF's supervising physician furnishes this level of supervision.

The contractor's enrollment staff shall be familiar with the definitions of personal, direct and general supervision set forth at 42 CFR § 410.32(b)(3), and shall ensure that the applicant has checked the highest required level of supervision for the tests being

performed.

Each box that begins with "Assumes responsibility," must be checked. However, as indicated previously, the boxes can be checked through the use of more than one physician.

D. Attestation Statement for Supervising Physicians

A separate attestation statement must be completed and signed by each supervis*ing* physician listed. If Question E2 is not completed, the contractor may assume *– unless it has reason to suspect otherwise -* that the supervis*ing* physician in question supervises for all codes listed in section 2 of the IDTF attachment*. If* Question E2 is completed, the contractor shall ensure that all codes listed in section 2 are covered through the use of multiple supervis*ing* physicians.

With respect to physician verification, the contractor shall:

- Check the signature on the attestation against that of the enrolled physician.

- Contact each supervisory physician by *telephone to* verify that the physician: (1) actually exists (e.g., is not using a phony or inactive physician number); (2) indeed signed the attestation; and (3) is aware of his or her responsibilities.

If the physician is enrolled with a different contractor, the contractor shall contact the latter contractor and obtain the listed telephone number of the physician.

15.5.19.6 – Desk and Site Reviews

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

All *initial and revalidating independent diagnostic testing facility (IDTF)* applica*nts* shall receive: (1) a thorough desk review, and (2) a mandatory site *visit* prior to the contractor's *approval of the application.* The general purpose*s of these reviews* are to determine whether:

- The information listed on Attachment 2 of the *Form* CMS-855B is correct, verifiable, *and* in accordance with all IDTF regulatory and *enrollment* requirements.

- *To the extent applicable, the IDTF meets the criteria outlined in section 15.19.2.2(B) of this chapter.*

- *The IDTF meets the supplier standards in 42 CFR § 410.33.*

The contractor shall order the site visit through the Provider Enrollment, Chain and Ownership System. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

A. Mobile Units

Mobile units are required to list their geographic service areas in section 4 of the *Form* CMS-855B. Based on the information furnished therein, the *NSVC will generally* perform *the* site visit *via one of the* following methods: (1) the mobile unit *visits* the office of *the NSVC (or some other agreed-to location) for inspection, (2) the NSVC visits the mobile unit's base of operations to inspect the unit, or (3) the NSVC obtains* an advance schedule of the locations *at which the IDTF will be performing services* and conduct*s* the site visit at one of those locations.

Units that are performing CPT-4 or HCPCS code procedures that require direct or personal supervision *mandate* special attention. To this end, the contractor shall maintain a listing of all mobile IDTFs that perform procedure codes that require such levels of supervision. The contractor shall also discuss with the applicant and all supervis*ing* physicians listed:

- How they will perform these types of supervision on a mobile basis;
- What their responsibilities are; *and*
- That a patient's physician who is performing direct or personal supervision for the IDTF on their patient should be aware of the prohibition concerning physician self-referral for testing (in particular, this concerns potentially illegal compensation to the supervisory physician from the IDTF).

B. Addition of Codes

An enrolled IDTF that wants to perform additional CPT-4 or HCPCS codes must submit a *Form* CMS-855B change request. If the additional procedures are of a type and supervision level similar to those previously reported (e.g., an IDTF that performs MRIs for shoulders wants to perform MRIs for hips), a new site visit is typically not required, though the contractor *reserves the right to request that the NSVC perform one.*

If, however, the enrolled IDTF wants to perform additional procedures that are not similar to those previously reported (e.g., an IDTF that conducts sleep studies wants to perform ultrasound tests or skeletal x-rays), *the contractor shall order an NVSC* site visit *through PECOS*. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment), and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

If the enrolled IDTF originally listed only general supervision *codes, was* only reviewed for only general supervision tests, and now wants to perform tests that require direct or personal supervision, the contractor shall promptly suspend all payments for all codes other than those requiring general supervision. *The contractor shall order an NSVC site visit through PECOS.* All IDTF claims for the additional procedures shall

be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment), and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

In the situations described in the two previous paragraphs, the contractor shall not approve the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

15.19.2.1 – Background

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Consistent with 42 CFR § 424.518, newly-enrolling and existing providers and suppliers will, beginning on March 25, 2011, be placed into one of three levels of categorical screening: limited, moderate, or high. The risk levels denote the level of the contractor's screening of the provider when it initially enrolls in Medicare, adds a new practice location, or revalidates its enrollment information.

The contractor shall utilize the screening procedures outlined below for applications it receives on or after March 25, 2011.

A. Limited

The "limited" level of categorical screening consists of the following provider and supplier types:

- Physicians
- Non-physician practitioners other than physical therapists
- Physician group practices
- Non-physician group practices other than physical therapist group practices
- Ambulatory surgical centers
- Competitive Acquisition Program/Part B Vendors
- End-stage renal disease facilities
- Federally qualified health centers
- Histocompatibility laboratories
- Hospitals (including critical access hospitals, Department of Veterans Affairs hospitals, and other federally-owned hospital facilities.
- Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act
- Mammography screening centers

- Mass immunization roster billers
- Organ procurement organizations
- *Outpatient physical therapy/outpatient speech pathology providers enrolling via the Form CMS-855A*
- Pharmacies that are newly enrolling or revalidating via the Form CMS-855B application
- Radiation therapy centers
- Religious non-medical health care institutions
- Rural health clinics
- Skilled nursing facilities

For providers and suppliers in the "limited" category, the contractor shall (unless section 19.2.5 of this *c*hapter applies) process initial, revalidation, and new location applications in accordance with existing instructions.

B. Moderate

The "moderate" level of categorical screening consists of the following provider and supplier types:

- Ambulance service suppliers
- Community mental health centers (CMHCs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Hospice organizations
- Independent clinical laboratories
- Independent diagnostic testing facilities
- Physical therapists enrolling as individuals or as group practices
- Portable x-ray suppliers (PXRSs)
- Revalidating home health agencies (HHAs)
- Revalidating DMEPOS suppliers

For providers and suppliers in the "moderate" level of categorical screening, the contractor shall (unless section *15.*19.2.2 of this *c*hapter *or another CMS directive* applies):

1. Process initial, revalidation, and new location applications in accordance with existing instructions; and

2. *Except for revalidating DMEPOS suppliers, order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) in accordance with sections 2(a) through (e) below. The site visit, which the National Site Visit Contractor (NVSC) will perform, is to ensure that the supplier is in compliance with CMS's enrollment requirements. Unless stated otherwise in this chapter, the scope of the site visit will be consistent with section 15.19.2.2.*

a. Ambulance suppliers, independent clinical laboratories, physical therapists, and physical therapist groups

- *Initial application – If the supplier submits an initial application, the contractor shall order a site visit. The contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- *Revalidation – If the supplier submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- *New location - The contractor shall order a site visit of the location. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

b. CMHCs

- *Initial application - In addition to the site visit discussed in section 15.4.1.1(B)(1) of this chapter, the contractor shall order a site visit after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the CMHC. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- *Revalidation - If the CMHC submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- *New location - The contractor shall order a site visit of the location after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

c. CORFs, hospices and PXRSs

- *Initial application – If the provider/supplier submits an initial application, the contractor shall order a site visit after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the provider/supplier. The contractor shall not convey Medicare billing privileges to the provider/supplier prior to the*

completion of the NSVC's site visit and the contractor's review of the results.

- *Revalidation – If the provider/supplier submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- *New location - The contractor shall order a site visit of the location after the contractor receives notice of approval from the RO but before the contractor switches the provider/supplier's enrollment record to "Approved." The contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

d. IDTFs

- Initial applications – The *NSVC wi*ll conduct site visits of initially enrolling IDTFs *consistent with section 15.4.19.6 of this chapter.*

- Revalidations - The *NVSC wi*ll conduct site visits of revalidating IDTFs (prior to *the contractor's* final decision regarding the revalidation application) *consistent with section 15.4.19.6 of this chapter.*

- *Code Changes – The NSVC will conduct site visits for IDTF code changes as specified in section 15.4.19.6(B) of this chapter.*

e. Revalidating HHAs – *If an HHA submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.*

f. Revalidating DMEPOS suppliers – The *National Supplier Clearinghouse (NSC)* shall conduct a site visit of the DMEPOS supplier prior to making a final decision regarding the revalidation application.

C. High

The "high" level of categorical screening consists of the following provider and supplier types:

- Newly enrolling DMEPOS suppliers
- Newly enrolling HHAs

For providers and suppliers in the "high" level of categorical screening*:*

1. The *contractor shall* process the application in accordance with existing instructions; and

2. The *NSVC will p*erform a site visit *for newly enrolling HHAs. (The NSC will perform a site visit for newly enrolling DMEPOS suppliers.) For initially enrolling HHAs, the contractor shall order a site visit via PECOS after the contractor receives the tie-in notice or approval letter from the RO but before the contractor switches the provider's enrollment record to "Approved." The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

Note: Also, the following:

- Enrolled DMEPOS suppliers that are adding another location will be classified as "high" for screening purposes. (See section 19.2.3 below for information regarding DMEPOS changes of ownership and tax identification number (TIN) changes.)

- Newly-enrolling HHA sub-units fall within the "high" level of categorical screening.

- The addition of a new HHA branch falls within the "moderate" level of categorical screening. *The contractor shall order a site visit of the location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." This is to ensure that the provider is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

  This is the only site visit of the new HHA branch that *must be performed* prior *to t*he record *being switched* to "Approved."

15.19.2.2 - Scope of Site Visit

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. DMEPOS Suppliers and IDTFs

*The scope of s*ite visits of DMEPOS suppliers and IDTFs shall continue to be conducted in accordance with existing CMS instructions and guidance.

B. Other Provider and Supplier Types

For all provider and supplier types – other than DMEPOS suppliers and IDTFs – that

are subject to a site visit in accordance with this section, the *SVC wi*ll perform such visits *consistent with* the procedures outlined in sections 20 and 20.1 of this *c*hapter. This includes the following:

- Documenting the date and time of the visit, and including the name of the individual attempting the visit;
- Photographing the provider or supplier's business for inclusion in the provider/supplier's file. All photographs *will* be date/time stamped;
- Fully documenting observations made at the facility, which could include facts such as: (a) the facility was vacant and free of all furniture; (b) a notice of eviction or similar documentation is posted at the facility, and (c) the space is now occupied by another company;
- Writing a report of the findings regarding each site verification; and
- Including a signed declaration stating the facts and verifying the completion of the site verification. (The sample declaration identified in section 20.1 of this *c*hapter is recommended.)

In terms of the extent of the visit, the *SVC wi*ll determine whether the following criteria are met:

- The facility is open
- Personnel are at the facility
- Customers are at the facility (if applicable to that provider or supplier type)
- The facility appears to be operational

This will require the site visitor(s) to enter the provider or supplier's practice location/site, rather than simply conducting an external review.

If any of the 4 elements listed above are not met, the enrollment contractor will, as applicable - and using the procedures outlined *in this chapter and in existing CMS instructions -* deny the provider's enrollment application pursuant to §424.530(a)(5)(i) or (ii), or revoke the provider's Medicare billing privileges under §424.535(a)(5)(i) or (ii).

15.19.2.3 – Changes of Information *and Ownership*

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. Limited

Changes of information (including additions of practice locations) submitted by

providers and suppliers in the “limited” level of categorical screening shall be processed in accordance with existing instructions.

B. Moderate *and High*

Unless otherwise specified in this chapter or in another CMS directive, this section 15.19.2.3(B) applies to providers and suppliers in the "moderate" or "high" level of categorical screening.

1. Addition of Practice Location

With the exception of *suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS)*, if a provider or *supplier submits* a Form CMS-855 request to add a practice location (including *a home health agency (HHA)* branch*):*

- *T*he contractor shall process the application in accordance with existing instructions, and

- *A site visit shall be performed consistent with section 15.19.2.1 above*.

(As explained earlier, a DMEPOS supplier that is adding a new practice location falls within the "high" screening category.)

2. Change of Location

a. DMEPOS Suppliers

If a DMEPOS supplier reports a change in the physical location of an existing practice location, the National Supplier Clearinghouse shall perform a site visit in accordance with existing instructions.

b. Non-DMEPOS Suppliers

If a provider or non-DMEPOS supplier reports a change in the physical location of an existing practice location, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) in accordance with the following:

i. Ambulance service suppliers, independent clinical laboratories, independent diagnostic testing facilities, physical therapists enrolling as individuals or group practices – The contractor shall order a site visit of the changed location prior to the contractor's final decision regarding the application. This is to ensure that the location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2 of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not make its final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

ii. Community mental health centers, comprehensive outpatient rehabilitation facilities, hospices, portable x-ray suppliers, HHAs - The contractor shall order a site visit of the changed location after the contractor receives notice of approval

from the RO but before the contractor switches the provider/supplier's enrollment record to "Approved." This is to ensure that the location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2 of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

For purposes of this requirement:

- *A change of location includes situations in which the provider/supplier is switching suite numbers or floors within a building. A site visit is required.*

- *If the provider/supplier's physical location is not changing (e.g., the provider's street name is changing but its actual office space is not), no site visit is required.*

3. Change of Ownership

With the exception of DMEPOS suppliers and HHAs, if a provider or supplier undergoes a change of ownership resulting in a new tax identification number (TIN), the contractor shall:

(1) Process the application in accordance with existing instructions, and

(2) *Order a site visit through PECOS* in accordance with the following:

- For ownership changes that must be approved by the *RO* under current CMS instructions, the site visit shall be *ordered and* performed after the contractor receives *notice of approval from the RO but before the contractor switches the provider/supplier's enrollment record to an "Approved" status. The contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

- For ownership changes that do not require *RO* approval under current CMS instructions, the site visit shall be *ordered and* performed prior to the contractor's final decision regarding the application.

A DMEPOS supplier that is:

- Undergoing a change of ownership with a change in TIN falls within the "high" screening category.

- Undergoing a change of ownership with no change in TIN falls within the "moderate" screening category.

- Undergoing a change in TIN with no change in ownership falls within the "moderate screening category.

With respect to HHAs:

- For HHAs undergoing a change in majority ownership, the contractor shall – consistent with section 15.26.1 of this *c*hapter – determine whether the provisions of 42 CFR §424.550(b)(1) and (2) apply. If the contractor determines that a change in majority ownership has occurred and that none of the exceptions in §424.550(b)(2) apply, the HHA must enroll as a new entity, in which case the newly-enrolling HHA will be placed into the "high" level of categorical screening. If the contractor determines that an exception does apply, the transaction will be subject to the "moderate" level of categorical screening; a site visit will be necessary.

  In addition, if: (1) the contractor determines that one of the exceptions to the 36-month rule applies, and (2) the ownership change is one that requires a recommendation for approval to the RO, the contractor shall ensure that its recommendation letter specifies:

  - *That the transaction qualifies as a change in majority ownership*
  - *The particular exception that applies.*

- For HHAs reporting an ownership change that is not a change in majority ownership as that term is defined in §424.502, the contractor shall process the change in accordance with existing instructions. A site visit is not necessary.

- For HHAs seeking to reactivate their Medicare billing privileges, the transaction shall be processed under the "moderate" level of categorical screening. A site visit will be necessary prior to the reactivation of the provider's billing privileges.

4. All Other Changes of Information

All other changes of information for providers and suppliers in the moderate *or high* level of categorical screening shall be processed in accordance with existing instructions.

15.19.2.4 – Reactivations

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. Limited

Reactivation applications submitted by providers and suppliers in the "limited" level of categorical screening shall be processed in accordance with existing instructions.

B. Moderate

Reactivation applications submitted by providers and suppliers in the "moderate" level of categorical screening *– including existing home health agencies and suppliers of durable medical equipment, prosthetics, orthotics and suppliers (DMEPOS)* – shall be processed in accordance with the screening procedures for this category. A site visit will therefore be necessary prior to the contractor's final decision regarding the application.

C. High

Reactivation applications submitted by providers and suppliers in the "high" level of categorical screening shall be processed in accordance with the screening procedures for this category. A site visit will therefore be necessary prior to the contractor's final decision regarding the application.

15.19.2.5 – Movement of Providers and Suppliers into the High Level

(Rev. .414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Under §424.518*(c)(*3), CMS may adjust a particular provider or supplier's screening level from "limited" or "moderate" to "high" if any of the following occur:

1. CMS imposes a payment suspension on a provider or supplier at any time within the last 10 years;

2. The provider or supplier:

   a. Has been excluded from Medicare by the Office of Inspector General; or

   b. Had *its* billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by:

      i. Enrolling as a new provider or supplier; or
      ii. Obtaining billing privileges for a new practice location

   c. Has been terminated or is otherwise precluded from billing Medicaid

   d. Has been excluded from any Federal health care program

   e. Has been subject to any final adverse action (as defined in §424.502) within the previous 10 years.

3. CMS lifts a temporary moratorium for a particular provider or supplier type, and a provider or supplier that was prevented from enrolling based on the

moratorium applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

CMS sends to the contractor on a bi-monthly basis a list of current and former Medicare providers and suppliers within the contractor's jurisdiction that meet any of the criteria in subsection (1) or (2) above. Upon receipt of an *initial or revalidation* application from a provider or supplier that otherwise falls within the limited or moderate screening category (and after the appropriate fee has been paid, etc.), the contractor shall determine whether the provider or supplier is on the bi-monthly "high" screening list. If the provider or supplier is, the contractor shall process the application using the procedures in the "high" screening category. If the provider or supplier is not on said list, the contractor shall process the application in accordance with existing instructions.

With respect to subsection (3) above, if the contractor receives an initial or new location application from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the procedures in the "high" screening category.