CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 320	Date: December 23, 2009
	Change Request 6645

SUBJECT: Provider Enrollment Revisions

I. SUMMARY OF CHANGES: Consolidated and revised sections 6.2.1 and 12 into section 2 to ensure consistency and flow of information. Minor revisions were made to sections 1.3, 6.1.4, 7.1.2 and 11.8.

NEW / REVISED MATERIAL
EFFECTIVE DATE: *January 25, 2010
IMPLEMENTATION DATE: January 25, 2010

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/1/3/Medicare Contractor Duties
R	10/2/Provider and Supplier Types/Services
R	10/2/1/Intermediary Enrolled Providers and Suppliers
R	10/2/1.1/Community Mental Health Conters (CMHCs)
R	10/2/1.2/Comprehensive Outpatient Rehabilitation Facilities (CORFs)
R	10/2/1.3/End-Stage Renal Disease Facilities (ESRDs)
R	10/2/1.4/Federally Qualified Health Centers (FQHCs)
N	10/2/1.5/Histocompatibility Laboratories
N	10/2/1.6/Reserved
N	10/2/1.7/Hospices
N	10/2/1.8/Hospitals and Hospital Units
N	10/2/1.9/Indian Health Services (IHS) Facilities
N	10/2/1.10/Organ Procurement Organizations (OPOs)
N	10/2/1.11/Outpatient Physical Therapy and Speech Language Pathology (OPT/SLP)
N	10/2/1.12/Religious Non-Medical Health Care Institutions (RNCHIs)

N	10/2/1.13/Rural Health Clinics (RHCs)
N	10/2/1.14/Skilled Nursing Facilities (SNFs)
R	10/2/2/Carrier-Enrolled Organizational Suppliers
R	10/2/2.1/Ambulatory Surgical Centers (ASCs)
R	10/2/2.2/CLIA Labs
R	10/2/2.3/Mammography Screening Centers
R	10/2/2.4/Pharmacies
N	10/2/2.5/Protable X-Ray Suppliers (PXRS)
N	10/2/2.6/Radiation Therapy Centers
N	10/2/2.7/Suppliers of Ambulance Services
R	10/2/3/Medicare Advantage Plans and Other Managed Care Organizations
N	10/2/4/Individual Practitioners
N	10/2/4.1/Anesthesiology Assistants
N	10/2/4.2/Audiologists
N	10/2/4.3/Certified Nurse-Midwives
N	10/2/4.4/Certified Registered Nurse Anesthetists
N	10/2/4.5/Clinical Nurse Specialists (CNS)
N	10/2/4.6/Clinical Psychologists
N	10/2/4.7/Clinical Social Workers
N	10/2/4.8/Nurse Practitioners
N	10/2/4.9/Occupational and Physical Therapists in Private Practice
N	10/2/4.10/Physicians
N	10/2/4.11/Physician Assistants (PAs)
N	10/2/4.12/Psychologists Practicing Independently
N	10/2/4.13/Registered Dietitians
N	10/2/4.14/Speech Language Patholgists in Private Practice
N	10/2/5/Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an ASC
N	10/2.6/Other Part B Services
N	10/2/6.1/Diabetes Self-Management Training (DSMT)
N	10/2/6.2/Mass Immunizers Who Roster Bill
N	10/2/7/Medicaid State Agencies
N	10/2/8/Suppliers Not Eligible to Participate

N	10/2/9/Timeliness and Accuracy Standards
N	10/2/9.1/Standards for Initial Applications
N	10/2/9.1.1/Paper Applications - Timeliness
N	10/2/9.1.2/Paper Applications - Accuracy
N	10/2/9.1.3/Web-Based Applications - Timeliness
N	10/2/9.1.4/Web-Based Applications - Accuracy
N	10/2/9.2/Standards for Changes of Information
N	10/2/9.2.1/Paper Applications - Timeliness
N	10/2/9.2.2/Paper Applications - Accuracy
N	10/2/9.2.3/Web-Based Applications - Timeliness
N	10/2/9.2.4/Web-Based Applications - Accuracy
N	10/2/9.3/General Timeliness Principles
R	10/6/1.4/Effective Billing Date for Physicians, Non-Physician Practitioners, and Physician or Non-Physician Practitioner Organizations
D	10/6/2.1/Suppliers Not Eligible to Participate
R	10/7/1.2/Incomplete or Unverifiable Changes of Information
R	10/11/8/Reserved
R	10/12/Reserved
R	10/12/1/Reserved
R	10/12/1.1/Reserved
R	10/12/1.2/Reserved
R	10/12/1.3/Reserved
R	10/12/1.4/Reserved
R	10/12/1.5/Reserved
D	10/12/1.7/Hospices
D	10/12/1.8/Hospitals and Hospital Units
D	10/12/1.9/Indian Health Services (IHS) Facilities
D	10/12/1.10/Organ Procurement Organizations (OPOs)
D	10/12/1.11/Outpatient Physical Therapy and Speech Language Pathology (OPT/SLP)
D	10/12/1.12/Religious Non-Medical Health Care Institutions (RNCHIs)
D	10/12/1.13/Rural Health Clinics (RHCs)
D	10/12/1.14/Skilled Nursing Facilities (SNFs)

D	10/12/2/Carrier-Enrolled Organizational Suppliers
D	10/12/2.1/Ambulatory Surgical Centers (ASCs)
D	10/12/2.2/CLIA Labs
D	10/12/2.3/Mammography Screening Centers
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D	10/12/2.5/Protable X-Ray Suppliers (PXRS)
D	10/12/2.6/Radiation Therapy Centers
D	10/12/2.7/Slide Preparation Facilities
D	10/12/2.8/Suppliers of Ambulance Services
D	10/12/3/Medicare Advantage Plans and Other Managed Care Organizations
D	10/12/4/Individual Practitioners
D	10/12/4.1/Anesthesiology Assistants
D	10/12/4.2/Audiologists
D	10/12/4.3/Certified Nurse-Midwives
D	10/12/4.4/Certified Registered Nurse Anesthetists
D	10/12/4.5/Clinical Nurse Specialists (CNS)
D	10/12/4.6/Clinical Psychologists
D	10/12/4.7/Clinical Social Workers
D	10/12/4.8/Nurse Practitioners
D	10/12/4.9/Occupational and Physical Therapists in Private Practice
D	10/12/4.10/Physicians
D	10/12/4.11/Physician Assistants (PAs)
D	10/12/4.12/Psychologists Practicing Independently
D	10/12/4.13/Registered Dietitians
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D	10/12/5/Manufacturers of Replacement parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an ASC
D	10/12/5.1/Other Part B Services
D	10/12/5.2/Diabetes Self-Management Training (DSMT)
D	10/12/5.3/Mass Immunizers Who Roster Bill
D	10/12/6/Medicaid State Agencies

III. FUNDING:

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

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

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 320	Date: December 23, 2009	Change Request: 6645

SUBJECT: Provider Enrollment Revisions

EFFECTIVE DATE: January 25, 2010
IMPLEMENTATION DATE: January 25, 2010

I. GENERAL INFORMATION

Background: Consolidated and revised sections 6.2.1 and 12 into section 2 to ensure consistency and flow of information. Minor revisions were made to sections 1.3, 6.1.4, 7.1.2 and 11.8.

B. Policy: Reorganized Pub. 100-08, PIM, chapter 10, section 2,. Consolidated and revised sections 6.2.1 and 12 into section 2 to ensure consistency and flow of information. Minor revisions were made to sections 1.3, 6.1.4, 7.1.2 and 11.8.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6645.1	Due to the removal of the UPIN, contractors shall use DC instead of CH for doctors of chiropractic medicine - PECOS has been systematically updated to reflect the chiropractor's credentials from CH to DC.	X			X						
6645.2	The contractor shall process all enrollment actions (i.e., initials, changes, revalidations and reactivations) through PECOS.	X			X						
6645.3	The contractor shall deactivate or revoke in FISS only if the provider or supplier is not in PECOS. Deactivations for providers who have not submitted claims after 12 consecutive months are excluded from this requirement. The MCS does deactivate providers and creates an extract for PECOS in this situation.	X			X						
6645.4	The contractor shall close or delete any aged logging and trackings (L & Ts) that exceed 120 days for which there is not an associated enrollment application.	X			X						
6645.5	Medicare contractors shall interpret the phrase "circumstances precluded enrollment," to mean that the physician, non-physician practitioner or physician or non-physician practitioner organization meets all program requirements, including State licensure, during the 30	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	
	days before an application was submitted and no final adverse action, as identified in 42 CFR § 424.502 and in Pub. 100-08, PIM, chapter 10, section 1.1, precluded enrollment.										
6645.6	If a final adverse action precluded enrollment during the 30 day period prior to date of filing, the Medicare contractor shall establish an effective billing date the day after the date the final adverse action was resolved as long as it is not more than 30 days prior to the date the application was submitted.	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:
Use "Should" to denote a recommendation.

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

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

V. CONTACTS

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

VI. FUNDING

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

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*:

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

Medicare Program Integrity Manual

Chapter 10 - Medicare Provider/Supplier Enrollment

Table of Contents
(Rev.320, 12-23-09)

1.3 – Medicare Contractor Duties

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

The contractor must adhere to the processing guidelines established in this chapter 10 (hereinafter generally referred to as "this manual"). In addition, the contractor shall assign the appropriate number of staff to the Medicare enrollment function to meet established processing timeframes.

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

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

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

Conduct Prescreening

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

Conduct Verification, Validation, and Final Processing

- Verify and validate the information collected on the enrollment application.
- Coordinate with State survey/certification agencies and regional offices (ROs), as needed.
- Collect and maintain the application's certification statement (in house) to verify and validate Electronic Funds Transfer (EFT) changes. The change request signature must be checked against the original signature to determine the validity of any change to EFT information. This check can be made against a digital/photo image kept in-house. (See section 8 of this manual for more information.)
- Confirm that the applicant, all individuals and entities listed on the application, and any names or entities ascertained through the use of an independent verification source, are not presently excluded from the Medicare program by the HHS Office of the Inspector General (OIG). Contractors shall confirm and validate data through Qualifier.net, the Medicare Exclusion Database (MED), and the General Services

2 - *Provider and Supplier Types/Services*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

Sections 12.1 through 12.3 contain general background information on various provider and supplier types that may enroll in Medicare. Contractors shall consult other Medicare manuals for more information on how these providers and suppliers bill Medicare, their conditions of coverage and conditions of participation, etc.

2.1 - *Intermediary-Enrolled Providers and Suppliers*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

2.1.1 - *Community Mental Health Centers (CMHCs)*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. General Background Information

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

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

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

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

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

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

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

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

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

- *There is a written agreement between the two entities.*

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

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

B. Enrollment and Certification

Once it is determined whether the CMHC complies with Federal, State, and local laws, the RO will either approve or deny the CMHC's enrollment. This is the same process that virtually all

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

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

Prior to making a recommendation for approval or denial, the intermediary shall ensure that the provider has submitted a completed and signed CMHC attestation statement. If the CMHC does not submit one, the intermediary shall recommend denial. (The attestation requirement also applies to new owners in a CHOW.) The CMHC attestation statement typically serves as the provider agreement.

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

C. Practice Locations/Alternative Sites

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

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

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

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

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

D. Additional CMHC Information

For more information on CMHCs, refer to the following:

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

2.1.2 - *Comprehensive Outpatient Rehabilitation Facilities (CORFs)*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. General Background Information

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

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

* *Services that the CORF must provide*

In addition:

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

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

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

B. CORF Enrollment

Notwithstanding the "single fixed location" language cited in subsection A above, there may be isolated cases where the RO permits a CORF to have an offsite location. This typically arises if the CORF wants to provide physical therapy (PT), occupational therapy (OT), or speech language pathology (SLP) services away from the primary location. (This is permitted under 42 CFR §485.58(e)(2)). The offsite location would not necessarily be separately surveyed, but would be listed as a practice location on the CORF's Form CMS-855A.

For more information on CORFs, refer to:

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

2.1.3 - *End-Stage Renal Disease Facilities (ESRDs)*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. Types of ESRDs

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

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

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

    - *The RDC need not furnish transplantation services;*

    - *An RTC can also be an RDC;*

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

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

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

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

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

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

B. ESRD Survey and Certification

The standard CMS survey and certification form used for ESRDs is the Form CMS-3427. Part I of this form must be completed, as must the Form CMS-855A, when the ESRD is initially enrolling, changing or adding a location, or undergoing a CHOW. Part I must also be completed for: (1) a change in service and (2) an expansion or addition of ESRD stations.

However, the Form CMS-855A need not be furnished in these two latter instances (e.g., an ESRD station does not qualify as a practice location on the Form CMS-855A), though the RO may issue a tie-in notice to the intermediary as notification of the change. Also, because the "End-Stage Renal Disease Facility" category on the Form CMS-855A encompasses all five ESRD categories, it is not necessary for the facility to submit a Form CMS-855A if it is changing from one ESRD type to another, though it must complete the Form CMS-3427. (See Pub. 100-07, SOM, chapter 2, sections 2274 – 2276 and 2278 – 227, for more information on the Form CMS-3427 requirement.)

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

C. Miscellaneous ESRD Policies

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

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

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

D. ESRD Enrollment

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

- *If an enrolled RTC also wants to become an RDC, the provider must submit a new, complete Form CMS-855A for the RDC. For enrollment purposes, the RTC and the RDC will be treated as two separate ESRD facilities.*
- *If an enrolled ESRD wants to change to another type of ESRD, the provider need not submit a Form CMS-855A change of information (assuming that this is the only change to the provider's enrollment data).*

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

E. Additional Information on ESRD Facilities

For further data on ESRD facilities, refer to:

- *Section §1881 of the Social Security Act;*
- *42 CFR Part 405, Subpart U;*
- *Pub. 100-07, chapter 2, section 2270 – 2287B (State Operations Manual);*
- *Pub. 100-02, chapter 11 (Benefit Policy Manual); and*
- *Pub. 100-04, chapter 8 (Claims Processing Manual).*

2.1.4 - *Federally Qualified Health Centers (FQHCs)*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

The FQHCs are not required to obtain a State survey; there is little State agency involvement with FQHCs. As such, the intermediary will make its recommendation for approval or denial and forward it directly the RO. The RO will then make the final decision as to whether the supplier qualifies as a FQHC. Generally, in order to so qualify the facility must be receiving, or be eligible to receive, certain types of Federal grants (sometimes referred to as "grant status"), or must be an outpatient facility operated by an Indian tribal organization. The Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (DHHS) may assist the RO in determining whether a particular supplier meets FQHC standards, since HRSA maintains a list of suppliers that met certain grant requirements. (See Pub. 100-07, SOM, chapter 2, sections 2825-2826D for more information.)

A few other notes about FQHCs:

- *As stated above, there is no State agency involvement with FQHCs. However, FQHCs still must meet all applicable State and local requirements and submit all applicable licenses. Typically, HRSA will verify such State/local compliance by asking the FQHC to attest that it meets all State/local laws.*
- *The FQHCs can be based in a rural or urban area.*

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

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

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

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

For additional general information on FQHCs, refer to:

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

- *42 CFR Part 491;*

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

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

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

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

- *Pub. 100-04, chapter 1, section 20;*

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

- *CMS Change Request 6207.*

2.1.5 - Histocompatability Laboratories

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

2.1.6 - Reserved

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

2.1.7 - Hospices

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

For more information on hospices, refer to:

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

2.1.8 - Hospitals and Hospital Units

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

- ***Swing-Bed Designation*** *- A "swing-bed" hospital is one that is approved by CMS to furnish post-hospital SNF services. That is, hospital (or critical access hospital (CAH)) patients' beds can "swing" from furnishing hospital services to providing SNF care*

without the patient necessarily being moved to another part of the building. It receives a separate survey and certification from that of the hospital; thus, if swing-bed designation is terminated, the hospital still maintains its certification. In addition, the hospital is given an additional OSCAR number to bill for swing-bed services. (The third digit of the number will be the letter U, W, Y or Z.)

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

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

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

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

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

2.1.9 - Indian Health Services (IHS) Facilities

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

hospital is involved, the provider may check "Indian Health Services Facility" or "Hospital" on the application - or perhaps both. Even if it only checked "Hospital," the LBN or DBA Name will typically contain some type of reference to Indian Health Services; as such, the intermediary will know it is dealing with an IHS facility.

The overwhelming majority of IHS facilities on the Part A side are either hospitals, SNFs, CAHs, or ESRD facilities. The contractor processes IHS applications in the same manner (and via the same procedures) as it would with a hospital, SNF, etc. (This also applies to procedures for PECOS entry.)

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

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

2.1.10 - Organ Procurement Organizations (OPOs)

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

There can be only <u>one</u> designated OPO per geographic service area. When an OPO is de-certified and its service area is opened for competition, the applicable CMS RO publishes a notice in local newspapers. CMS then selects an OPO to take over the service area, using the process at 42 CFR §486.316. As stated above, the OPO that CMS selects must first have been certified by CMS and the OPO must also meet the qualifications for designation at 42 CFR §486.304. The OPO must sign a provider agreement (Form CMS-576A) and participate in the

Organ Procurement and Transplantation Network (OPTN). (See Pub. 100-07, chapter 2, sections 2810 and 2811.) Note that OPOs do not receive a State survey.

For more information on OPOs, refer to:

- *Section 1138 of the Social Security Act;*
- *42 CFR § 486.301 - § 486.348; and*

- *Pub. 100-07, chapter 2, sections 2810 – 2819 (State Operations Manual).*

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

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

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. General Background Information

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

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

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

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

Note further that:

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

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

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

B. Extension Locations

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

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

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

C. Additional OPT/OSP Information

For more information on OPT/SLP providers refer to:

- *Section 1861(p) of the Social Security Act;*

- *42 CFR Part 485, subpart H;*

- *Pub. 100-07, chapter 2, sections 2290 – 2306 (State Operations Manual); and*
- *Pub. 100-07, Appendix E (State Operations Manual).*

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

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

RNHCIs furnish only nonmedical nursing services and items to people who choose to rely solely on obtaining a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious views. Such nonmedical services are performed by nonmedical nursing personnel and include activities like assistance in moving, comfort and support measures, and general assistance in performing day-to-day activities. (Of course, the nonmedical nursing personnel must be experienced in caring for the physical needs of nonmedical patients.) RNHCIs do not perform any medical screenings, examinations, diagnoses, or treatments, including the administration of drugs. It should also be noted that each beneficiary who wishes to receive services in an RNHCI must make a valid and formal written statement (or "election") to do so. (The specific election requirements are discussed in 42 CFR §403.724 and Pub. 100-07, SOM, chapter 2, section 2054.1B.)

The Boston RO, has primary responsibility over the approval and certification of RNHCIs. RNHCIs are not certified by the State, but must meet all of the conditions of coverage outlined in 42 CFR §403.720, as well as all conditions of participation outlined in 42 CFR §403.730 through 746. For purposes of provider enrollment, the two most important conditions are:

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

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

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

For more information on RNCHIs, refer to:

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

- *42 CFR Part 403, subpart G;*

- *Pub. 100-07, SOM, chapter 2, sections 2054, 2054.1, 20541A and 2054.1 (State Operations Manual);*
- *Pub. 100-04, chapter 3, sections 170 - 180 (Claims Processing Manual); and*

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

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

2.1.13 - Rural Health Clinics (RHCs)

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. General Background Information

Rural health clinics (RHCs):

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

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

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

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

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

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

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

- *FQHCs furnish preventive services while RHCs do not.*

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

B. Additional RHC Information

For more information on RHCs, refer to:

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

- *42 CFR Part 491, subpart A;*

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

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

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

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

- *Pub. 100-04, chapter 1, section 20;*

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

- *CMS Change Request 6207.*

2.1.14 - Skilled Nursing Facilities (SNFs)

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. General Background Information

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

- *Is primarily engaged in providing to residents skilled nursing care and related services for residents who require medical or nursing care; or*

- *Is primarily engaged in providing to residents skilled rehabilitation services for the rehabilitation of injured, disabled, or sick persons and is not primarily for the care and treatment of mental diseases;*

- *Has in effect a transfer agreement (meeting the requirements of §1861(1) of the Social Security Act with one or more hospitals having agreements in effect under §1866 of the Social Security Act); and*

- *Meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of §1819 of the Social Security Act.*

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

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

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

B. SNF Distinct Parts

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

- *A hospital is permitted to have only one SNF distinct part.*
- *The hospital will typically submit to the State a diagram/floor plan outlining the distinct part's area.*
- *"Distinct part" designation is not the same thing as being "provider-based." (A provider-based SNF, like a distinct part SNF, receives an OSCAR number separate from that of the hospital.)*

A SNF distinct part unit must enroll separately (it cannot be listed as a practice location on the hospital's Form CMS-855A), be separately surveyed and sign a separate provider agreement. (Note how this is different from "swing-bed" units, which do not enroll separately and do not sign separate provider agreements.)

(See Pub. 100-07, chapter 2, section 2762B, subsection 4, for more information on SNF distinct parts.)

C. Additional Information

For more information on SNFs, refer to:

- *Section 1819(a) of the Social Security Act;*
- *42 CFR Part 488, subpart E;*
- *Pub. 100-07, chapter 7 (State Operations Manual);*
- *Pub. 100-02, chapter 8 (Benefit Policy Manual); and*
- *Pub. 100-04, chapter 6 (Part A) and chapter 7 (Part B) (Claims Processing Manual).*

2.2 - *Carrier-Enrolled Organizational Suppliers*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

2.2.1 - *Ambulatory Surgical Centers (ASCs)*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. General Background Information

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

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

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

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

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

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

B. ASCs and Hospitals

There are three main enrollment situations involving ASCs and hospitals:

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

2. Hospital outpatient department *– If the ASC is treated as a hospital outpatient department, it will not independently enroll with the carrier as an ASC. It will simply be considered part of the*

hospital, and the services furnished therein will be billed to the fiscal intermediary. (See Pub. 100-04, chapter 14, section 10.1.)

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

In short, if an ASC is hospital-operated, it has the option of being covered under Medicare as an ASC, or of being treated as a hospital-affiliated outpatient surgery department. (See Pub. 100-02, chapter 15, section 260.1.) If a hospital-based facility decides not to become a certified ASC, it bills the fiscal intermediary via the Form CMS-1450.

C. Additional Information

For more information on ASCs, refer to:

- *Section 5.6 of this manual;*
- *Section 1832(a)(2)(F) of the Social Security Act;*
- *42 CFR Part 416;*
- *Pub. 100-07, chapter 2, section 2210 and Appendix L (State Operations Manual);*
- *Pub. 100-02, chapter 15, sections 260 – 260.5.3 (Benefit Policy Manual); and*
- *Pub. 100-04, chapter 14 (Claims Processing Manual).*

Also, see Pub. 100-07, chapter 2, section 2210, for information regarding the sharing of space between ASCs and other providers.

2.2.2 - CLIA Labs

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. General Background Information

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

part; laboratories are subject to CLIA- unless an exemption applies - regardless of the complexity or amount of testing that the laboratory will perform.

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

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

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

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

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

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

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

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

- *Facilities which serve only as collection stations.*

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

B. Form CMS-116 and CLIA Certificates

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

- *CLIA certificate being requested;*

- *Type of laboratory (e.g., hospital, physician office, ASC);*

- *Hours during which laboratory testing will take place;*

- *Sites where testing will occur; and*

- *Type of tests that will be performed.*

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

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

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

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

There are several types of CLIA certificates, including:

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

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

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

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

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

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

C. CLIA Enrollment

Note the following on CLIA Medicare enrollment:

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

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

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

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

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

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

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

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

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

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

D. Additional Information

For additional data on CLIA laboratories, refer to:

- *42 CFR Part 493;*

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

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

- *Form CMS-116 (CLIA Application for Certification).*

2.2.3 - *Mammography Screening Centers*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

For more information on mammography screening centers, refer to:

- *§1834(c) of the Social Security Act*
- *21 CFR Part 900*
- *42 CFR §410.34*
- *Pub. 100-04, chapter 18, sections 20 through 20.8 (Claims Processing Manual)*
- *Pub. 100-02, chapter 15, section 280.3 (Benefit Policy Manual)*

2.2.4 - *Pharmacies*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

2.2.5 - Portable X-Ray Suppliers (PXRSs)

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. General Background Information

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Enrollment of PXRS

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

- *Whether it furnishes services from a "mobile facility" or "portable unit." The former term typically describes a vehicle that travels from place to place to perform services 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(s).*

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

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

As stated in Pub. 100-07, chapter 2, section 2422, the "residence used as the patient's home" can include a SNF or hospital that does not provide x-ray services for its patients and arranges for these services through a PXRS, such as a mobile unit. However, the mobile unit can neither be fixed at any one location nor permanently located in a SNF or a hospital.

C. Additional Information

For more information on PXRSs, refer to:

- *Sections 5.6 and 7.2 of this manual;*

- *Section 1861(s)(3) of the Social Security Act;*

- *42 CFR Parts 486.100 – 486.110;*

- *Pub. 100-07, chapter 2, sections 2420 – 2424B (State Operations Manual);*

- *Pub. 100-02, chapter 15, sections 80.4 – 80.4.4 (Benefit Policy Manual); and*

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

2.2.6 - Radiation Therapy Centers

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

For additional background on radiation therapy services, see:

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

- *42 CFR §410.35;*

- *Pub. 100-04, chapter 13; and*

- *Pub. 100-02, chapter 15, section 90.*

2.2.7 - Suppliers of Ambulance Services

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

A. Types of Ambulance Services

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

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

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

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

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

*4. **Basic Life Support** (BLS) - Transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by an individual who is qualified in accordance with State and local laws as an emergency medical technician-basic (EMT-Basic).*

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

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

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

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

- *Furnish services only at the BLS level.*

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

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

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

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

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

B. Ambulance Qualifications

1. Vehicle Design and Equipment

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

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

- *Be equipped with emergency warning lights and sirens, as required by State or local laws.*

- *Be equipped with telecommunications equipment as required by State or local law to include, at a minimum, one two-way voice radio or wireless telephone.*

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

2. Vehicle Personnel

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

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

C. Ambulance Claims Jurisdiction

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

D. Completion of the CMS-855B

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

E. Miscellaneous Information

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

2. ***Non-Emergency Transport*** *- As stated in 42CFR §410.40(d), non-emergency transportation by ambulance is appropriate if either: (1) the beneficiary is bed-confined, and it is*

documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or (2) if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required.

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

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

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

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

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

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

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

(See Pub. 100-02, chapter 10, section 10.3.2 for information on "institution-to-institution" ambulance services; as stated therein, there may be instances where the institution to which the patient is initially taken is found to have inadequate or unavailable facilities to provide the required care, and the patient is then transported to a second institution having appropriate facilities. Also see Pub. 100-02, chapter 10, section 10.4.4, for information on hospital-to-hospital air ambulance transport; the air transport of a patient from one hospital to another may be covered if the medical appropriateness criteria are met - that is, transportation by ground ambulance would endanger the beneficiary's health and the transferring hospital does not have adequate facilities to provide the medical services needed by the patient.)

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

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

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

For additional information on ambulance services, refer to:

- *Section 1834(l) of the Social Security Act*
- *42CFR410.40, 410.41, and 414.605.*
- *Pub. 100-02, chapter 10*
- *Pub. 100-04, chapter 15*
- *Section 4.18 of this manual.*

2.3 - *Medicare Advantage and Other Managed Care Organizations*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

NOTE: *Specialty code 88 should be used.*

2.4 - Individual Practitioners

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

2.4.1 - Anesthesiology Assistants

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

- Is permitted by State law to administer anesthesia; and

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

For more information on anesthesiology assistants, refer to:

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

2.4.2 - Audiologists

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

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

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

OR

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

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

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

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

For more information on audiologists, refer to:

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

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

2.4.3 - Certified Nurse-Midwives

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

(2) Meet one of the following requirements:

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

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

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

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

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

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

For more information on certified nurse midwives, refer to:

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

2.4.4 - Certified Registered Nurse Anesthetists (CRNAs)

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

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

(4) Meets the following criteria:

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

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

For more information on CRNAs, refer to:

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

2.4.5 - Clinical Nurse Specialists (CNS)

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

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

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

- *American Academy of Nurse Practitioners;*

- *American Nurses Credentialing Center;*

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

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

- *Oncology Nurses Certification Corporation;*

- *AACN Certification Corporation; and*

- *National Board on Certification of Hospice and Palliative Nurses.*

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

within the scope of the CNS's professional expertise, with medical direction and appropriate supervision as required by the law of the State in which the services are furnished.

For more information on clinical nurse specialists, refer to:

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

2.4.6 - Clinical Psychologists

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

- *Hold a doctoral degree in psychology; and*

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

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

For more information on clinical psychologists, refer to:

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

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

2.4.7 - Clinical Social Workers

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

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

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

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

For more information on clinical social workers, refer to:

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

2.4.8 - Nurse Practitioners

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

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

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

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

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

- *American Academy of Nurse Practitioners;*
- *American Nurses Credentialing Center;*
- *National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;*
- *Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);*
- *Oncology Nurses Certification Corporation;*
- *AACN Certification Corporation; and*
- *National Board on Certification of Hospice and Palliative Nurses.*

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

For more information on nurse practitioners, refer to:

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

2.4.9 - Occupational and Physical Therapists in Private Practice

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. Occupational Therapists (OTs)

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

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

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

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

B. Physical Therapists (PTs)

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

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

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

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

- *Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of*

physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

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

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

- *42 CFR §410.59(c) (occupational therapists)*
- *42 CFR §410.60(c) (physical therapists)*
- *Pub. 100-02, chapter 15, sections 230.2 and 230.4 (Benefit Policy Manual) (occupational therapists)*
- *Pub. 100-02, chapter 15, sections 230.1 and 230.4 (Benefit Policy Manual) (physical therapists)*
- *Sections 4.2.6 and 4.2.7(H) of chapter 10 of this manual*

2.4.10 - Physicians

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

1. Doctors of:

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

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

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

2.4.11 - Physician Assistants (PAs)

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

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

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

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

- *The PA's employer can be either an individual or an organization. If the employer is a professional corporation or other duly qualified legal entity (e.g., LLC, LLP) in a State that permits PA ownership in the entity (e.g., as a stockholder, member), the entity may bill for PA services even if a PA is a stockholder or officer of the entity – so long as the entity is eligible to enroll as a provider or supplier in the Medicare program. PAs may not otherwise organize or incorporate and bill for their services directly to the Medicare program, including as, but not limited to, sole proprietorships or general partnerships. Accordingly, a qualified employer is not a group of PAs that incorporate to bill for their services. Moreover, leasing agencies and staffing companies do not qualify under the Medicare program as "providers of services" or suppliers of services.*

For more information on physician assistants, refer to:

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

2.4.12 - Psychologists Practicing Independently

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

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

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

For more information on independently practicing psychologists, refer to:

- *Section 4.2.7 of this manual*

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

2.4.13 - Registered Dietitians

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

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

There are two caveats to these requirements:

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

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

For more information on registered dietitians, refer to:

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

- *42 CFR §410.130 through §410.134*

2.4.14 – Speech Language Pathologists in Private Practice
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

(A) An unincorporated solo practice.

(B) An unincorporated partnership or unincorporated group practice.

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

(D) An employee of a physician group.

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

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

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

2.5 - Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an ASC
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

Since carriers make payments for implantable prosthetics and DME to hospitals, physicians or ASCs, carriers shall not enroll manufacturers of implantable or non-implantable and prosthetics DME into the Medicare program. Manufacturers of non-implantable prosthetics and DME and replacement parts and supplies for prosthetic implants and surgically implantable DME may

enroll in the Medicare program as a supplier with the NSC if they meet the definition of a supplier as well as the requirements set forth in 42 CFR § 424.57.

2.6 - Other Part B Services

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

2.6.1 - Diabetes Self-Management Training (DSMT)

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

A. General Background Information

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

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

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

For more information on DSMT, refer to:

- *Section 1861(qq) of the Social Security Act*
- *42 CFR Part 410 (subpart H)*

- *Pub. 100-02, chapter 15, sections 300 – 300.5.1 (Benefit Policy Manual)*

2.6.2 - Mass Immunizers Who Roster Bill

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

- *They may not bill Medicare for any services other than pneumococcal pneumonia vaccines (PPVs), influenza virus vaccines, and their administration.*

- *They must submit claims through the roster billing process.*

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

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

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

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

- *Pub. 100-04, chapter 18, sections 10 through 10.3.2.3 (Claims Processing Manual) (**NOTE:** Section 10.3.1 outlines the requirements for submitting roster bills.)*

2.7 - Medicaid State Agencies

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

2.8 - Suppliers Not Eligible to Participate

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

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

- *Speech and Hearing Center*
- *Substance Abuse Facility*

2.9 – Timeliness and Accuracy Standards

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

Sections 2.1 through 2.3 of this chapter address the timeliness and accuracy standards applicable to the processing of CMS-855 applications. Even though the provisions of 42 CFR §405.874(h) contain processing timeframes that are longer than those in sections 2.1 through 2.3, the contractor shall adhere to the standards specified in sections 2.1 through section 2.3.

2.9.1 – Standards for Initial Applications

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

For purposes of sections 2.1.1 through 2.1.4 of this manual, the term "initial applications" also includes:

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

2. "Complete" CMS-855 applications submitted by enrolled providers: (a) voluntarily, (b) as part of any change request if the provider does not have an established enrollment record in PECOS, (c) as part of a reactivation, or (d) as part of a revalidation. (See section 7.1.1 of this manual for more information on the processing of "complete" applications.)

2.9.1.1 - Paper Applications - Timeliness

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

The contractor shall process 80 percent of paper CMS-855 initial applications within 60 calendar days of receipt, process 90 percent of paper CMS-855 initial applications within 120 calendar days of receipt, and process 99 percent of paper CMS-855 initial applications within 180 calendar days of receipt. This process generally includes, but is not limited to:
Receipt of the application in the contractor's mailroom and forwarding it to the appropriate office for review;

- *Prescreening the application in accordance with section 3.1 of this manual;*
- *Creating an L & T record and an enrollment record in PECOS;*

- *Verification of the application in accordance with sections 5.1 through 5.6 of this manual;*

- *Requesting and receiving clarifying information in accordance with section 5.3 of this manual;*

- *Supplier site visit (if necessary);*

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

2.9.1.2 - Paper Applications – Accuracy
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

The contractor shall process 98 percent of paper CMS-855 initial applications in full accordance with all of the instructions in chapter 10 (with the exception of the timeliness standards identified in section 2.1.1 above) and all other applicable CMS directives.

2.9.1.3 - Web-Based Applications - Timeliness
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

The contractor shall process 90 percent of CMS-855 Web-based initial applications within 45 calendar days of receipt, process 95 percent of CMS-855 Web-based initial applications within 60 calendar days of receipt, and process 99 percent of CMS-855 Web-based initial applications within 90 calendar days of receipt. This process generally includes, but is not limited to: Receipt of the provider's certification statement in the contractor's mailroom and forwarding it to the appropriate office for review;

- *Verification of the application in accordance with sections 5.1 through 5.6 of this manual;*

- *Requesting and receiving clarifying information in accordance with section 5.3 of this manual;*

- *Supplier site visit (if necessary);*

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

2.9.1.4 - Web-Based Applications - Accuracy
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

The contractor shall process 98 percent of CMS-855 Web-based initial applications in full accordance with all of the instructions in chapter 10 (with the exception of the timeliness standards identified in section 2.1.3 above) and all other applicable CMS directives.

2.9.2 – Standards for Changes of Information
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

For purposes of timeliness, the term "changes of information" also includes:

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

2. *CMS-588 changes submitted without a need for an accompanying complete CMS-855 application;*

3. *CMS-855R applications submitted independently (i.e., without being part of a CMS-855I or CMS-855B package);*

4. *CMS-855 voluntary terminations*

2.9.2.1 - Paper Applications - Timeliness
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

The contractor shall process 80 percent of paper CMS-855 changes of information within 45 calendar days of receipt, process 90 percent of paper CMS-855 changes of information within 60 calendar days of receipt, and process 99 percent of paper CMS-855 changes of information within 90 calendar days of receipt. This process generally includes, but is not limited to:

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

- *Prescreening the change request in accordance with section 3.1 of this manual;*

- *Creating an L & T record and, if applicable, tying it to an enrollment record in PECOS; Verification of the change request in accordance with sections 5.1 through 5.6 of this manual, as well as the applicable instructions in sections 7.1 and 7.2 of this manual;*

- *Requesting and receiving clarifying information in accordance with section 5.3 of this manual;*

- *Supplier site visit (if necessary);*

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

2.9.2.2 - Paper Applications - Accuracy
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

The contractor shall process 98 percent of paper CMS-855 changes of information in full accordance with all of the instructions in chapter 10 (with the exception of the timeliness standards identified in section 2.2.1 above) and all other applicable CMS directives.

2.9.2.3 - Web-Based Applications - Timeliness
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

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

- *Verification of the change request in accordance with sections 5.1 through 5.6 of this manual, as well as the applicable instructions in sections 7.1 and 7.2 of this manual;*

- *Requesting and receiving clarifying information in accordance with section 5.3 of this manual;*

- *Supplier site visit (if necessary);*

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

2.9.2.4 - Web-Based Applications – Accuracy
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

The contractor shall process 98 percent of CMS-855 Web-based change of information applications in full accordance with all of the instructions in chapter 10 (with the exception of the timeliness standards identified in section 2.2.3 above) and all other applicable CMS directives.

2.9.3 - General Timeliness Principles
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

Unless stated otherwise, the principles discussed below apply to all applications discussed in sections 2.9 through 2.9.2.4 above (e.g., CHOW applications submitted by old and new owners, CMS-588 forms).

A. Clock Stoppages

The processing time clocks identified in sections 2.1 and 2.2 of this manual cannot be stopped or suspended for any reason. This includes, but is not limited to, the following situations:

- *Referring an application to the OIG or the Payment Safeguard Contractor (PSC);*
- *Waiting for the final sales agreement (e.g., CHOW, acquisition/merger);*
- *Waiting for the RO to make a provider-based, HHA capitalization, or CHOW determination;*
- *Referring a provider to the Social Security Administration (SSA) to resolve a discrepancy involving a social security number (SSN), as explained in section 4.2.1 of this manual.*
- *Contacting CO (e.g., DPSE) or an RO's survey/certification staff with a question regarding the application in question or CMS policy.*

Despite the prohibition on clock stoppages and suspensions, the contractor should always document any delays by identifying when the referral to CMS, the OIG, etc., was made, the reason for the referral, and when a response was received. By doing so, the contractor will be able to furnish explanatory documentation to CMS should applicable time limits be exceeded. To

illustrate, assume a contractor received an initial CMS-855B application on March 1. On March 30, the contractor sent an adverse legal action question to CMS, and received a reply on April 7. The processing time clock did not stop from March 31 to April 7. However, the contractor should document its files to explain that it forwarded the question to CMS, the dates involved, and the reason for the referral.

B. Calendar Days

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

C. Date-Stamping

As a general rule, all incoming correspondence must be date-stamped on the date it was received in the contractor's mailroom. This includes, but is not limited to:
Any CMS-855 application, including initials, changes, CHOWs, etc. (The first page of the application must be date-stamped.)

- *Letters from providers. (The first page of the letter must be date-stamped.)*
- *Supporting documentation, such as licenses, certifications, articles of incorporation, and billing agreements. (The first page of the document or the envelope must be date-stamped.)*
- *Data furnished by the provider (via mail or fax) per the contractor's request for additional information. (All submitted pages must be date-stamped. This is because many contractors interleaf the new/changed pages within the original application; hence, it is necessary to determine the sequence in which the application and the additional pages were received.)*

The timeliness clocks discussed in sections 2.1 and 2.2 above start on the date the application/envelope is date-stamped in the contractor's mailroom, not when the application is date-stamped or received by the provider enrollment unit. As such, the date-stamping activities described in the aforementioned bullets must be performed in the contractor's mailroom. In cases where the mailroom staff fails to date-stamp a particular document, the provider enrollment unit may date-stamp the page in question. However, there shall not be long lapses between the time it was received in the mailroom and the time the provider enrollment unit date-stamped the pages.

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

D. When the Processing Cycle Ends

For: (1) fiscal intermediaries, and (2) carriers processing ASC or portable x-ray applications, the processing cycle ends on the date the contractor sends its recommendation for approval or denial to the State agency. In situations involving a change request that does not require a recommendation (i.e., it need not be forwarded to and approved by the State or RO), the cycle ends on the date the contractor sends notification to the provider that the change has been processed. If notification to the provider is made via telephone, the cycle ends on the date the telephone call is made (e.g., the date the voice mail message is left).

For carriers processing applications other than those from ASCs and portable x-ray suppliers, the processing cycle ends on the date the carrier sends its approval/denial letter to the supplier. For change request approval/denial notifications made via telephone, the cycle ends on the date the telephone call is made (e.g., the date the voice mail message is left).

For any application that is rejected per section 3.1 or 5.3 of this manual, the processing time clock ends on the date the contractor sends notification to the provider that the application has been rejected.

E. PECOS

Unless stated otherwise in this manual, the contractor must create an L & T record in PECOS no later than 15 calendar days after its receipt of the provider's application in the contractor's mailroom. Moreover, the contractor must establish a complete enrollment record in PECOS – if applicable - prior to its approval or denial of (or recommendation of approval or denial of) the provider's application; to the maximum extent possible, the contractor shall establish the enrollment record at one time, rather than on a piecemeal basis.

The L & T and enrollment record requirements in the previous paragraph apply to all applications identified in sections 2.1 and 2.2 above (e.g., reassignments, CHOW applications submitted by old and new owners).

In situations where the contractor cannot create an L & T record within 15 days due to missing information (e.g., no NPI was furnished), the contractor shall document the provider file accordingly.

6.1.4 – Effective Billing Date for Physicians, Non-Physician Practitioners, and Physician or Non-Physician Practitioner Organizations

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

(This section 6.1.4 only applies to the following individuals and organizations: physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives; clinical social workers; clinical psychologists; registered dietitians or nutrition professionals; and physician and non-physician practitioner organizations (e.g., group practices) consisting of any of the categories of individuals identified in this paragraph.)

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

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

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

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

1. 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or

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

Medicare contractors shall interpret the phase "circumstances precluded enrollment" shown above to mean that that the physician, non-physician practitioner or physician or non-physician practitioner organization meets all program requirements, including State licensure, during the 30 days before an application was submitted and no final adverse action, as identified in 42 CFR § 424.502 and in section 1.1 of chapter 10 of the PIM precluded enrollment. If a final adverse action precluded enrollment during the 30 day period prior to date of filing, the Medicare contractor shall only establish an effective billing date the day after the date the final adverse action was resolved as long as it is not more than 30 days prior to the date the application was submitted.

7.1.2 - Incomplete or Unverifiable Changes of Information

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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

A. Provider is in PECOS

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

B. Provider is Not in PECOS

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

12 – *Reserved*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

12.1 – *Reserved*

(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

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12.1.2 – *Reserved*
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

12.1.3 – *Reserved*
(Rev.320, Issued: 12-23-09, Effective: 01-25-10, Implementation: 01-25-10)

12.1.4 – *Reserved*
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12.1.5 – *Reserved*
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