Medicare Program Integrity Manual
Chapter 10 - Medicare Provider/Supplier Enrollment

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1 – Introduction to Provider Enrollment

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

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

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

1.1 – Definitions

(Rev. 269: Issued: 09-19-08; Effective/Implementation Date: 10-20-08)

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

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

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

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

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

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

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

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

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges for Medicare covered items or services provided to Medicare beneficiaries.

Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare covered services and supplies. The process includes:

- Identification of a provider or supplier;

- Validation of the provider or supplier's eligibility to provide items or services to Medicare beneficiaries;

- Identification and confirmation of the provider or supplier's practice locations and owners; and

- Granting the provider or supplier Medicare billing privileges.

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

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

Managing Employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W-2 employee of the provider or supplier.

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

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

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

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

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

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

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

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

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

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

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

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

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

1.2 – CMS-855 Medicare Enrollment Applications

(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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

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

- Help determine the proper amount of Medicare payment.

The five forms are distinguished as follows:

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

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

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

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

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

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

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

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

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

- The Electronic Funds Transfer Authorization Agreement (CMS-588);

- The Electronic Data Interchange (EDI) agreement;

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

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

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

1.3 – Medicare Contractor Duties

(Rev. 214; Issued: 06-29-07; Effective: 07-02-07; Implementation Date: 07-30-07)

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.

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 Administration (GSA) debarment list, in accordance with existing CMS instructions and directives.

- Confirm that enrolled suppliers are reviewed monthly against the MED. This is to ensure that billing privileges are not retained by providers/suppliers that become excluded after enrollment. (This task only applies to carriers.)

- Review and investigate provider/supplier reassignments of Medicare payments to ensure full compliance with operational guidelines.

Coordinate with other Contractors

- The NSC shall maintain a national master file of all durable medical equipment suppliers and share that information with the durable medical equipment regional contractors.

Use of and Establishment of Records in PECOS

Establish, update and close provider and supplier records in PECOS.

2 – Timeliness and Accuracy Standards
(Rev. 269: Issued: 09-19-08; Effective/Implementation Date: 10-20-08)

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.

2.1 – Standards for Initial Applications
(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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.)

2.1.1 - Paper Applications - Timeliness
(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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.

2.1.2 - Paper Applications - Accuracy
(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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.

2.1.3 - Web-Based Applications - Timeliness
(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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.

2.1.4 - Web-Based Applications - Accuracy
(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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.

2.2 – Standards for Changes of Information
(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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

2.2.1 - Paper Applications - Timeliness

(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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.

2.2.2 - Paper Applications - Accuracy

(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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.

2.2.3 - Web-Based Applications - Timeliness
(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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.

2.2.4 - Web-Based Applications - Accuracy
(Rev. 232, Issued: 01-04-08, Effective: 02-04-08, Implementation 02-04-08)

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.

2.3 - General Timeliness Principles
(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

Unless stated otherwise, the principles discussed below apply to all applications discussed in section 2.1 and 2.2 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.

3 – Pre-Screening and Application Returns

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

3.1 – Pre-Screening Process

(Rev. 269: Issued: 09-19-08; Effective/Implementation Date: 10-20-08)

A. Initial 15-Day Review

Within 15 calendar days after the application is received in the contractor's mailroom, the contractor shall complete a "pre-screen" of the application. The purpose of the pre-screening process is to ensure that the provider, at the time the application was originally submitted:

- Completed all required data elements on the application, regardless of the materiality of the data element or whether the information furnished is correct.

- Furnished all required supporting documentation – including, but not limited to, medical or professional licenses, certifications and registrations required by Federal or State law; NPI notification letters from NPPES; business licenses; IRS CP-575 documentation; interim sales agreements; etc. – needed to process the requested enrollment action.

If the provider: (1) files an application with at least one missing required data element, or (2) fails to submit all required supporting documentation, the contractor shall send a letter to the provider – preferably via e-mail or fax - that contains, at a minimum, the elements listed below. (The letter must be sent within the aforementioned 15-day period.)

- A list of all missing data or documentation;

- A request that the provider submit the data within a contractor-specified timeframe (i.e., the contractor can use whatever timeframe it wants, so long as it is within reason);

- The CMS Web site at which the CMS-855 forms can be found. The contractor shall instruct the provider to print out the page(s) containing the missing data; to enter the data on the blank page; to sign and date a new, blank certification statement; and to send it to the contractor. (As an alternative, the contractor can fax the blank page(s) and certification statement to the provider.) The provider need not furnish its initials next to the data element(s) in question.

If the only missing material is documentation (i.e., all data elements have been completed), the contractor can forgo the activities in the previous paragraph. No newly-signed certification statement is required.

- A fax number and mailing address to which the missing data or documentation can be sent.

Note that the pre-screening letter is the only request for missing information or missing documentation that the contractor must make. Obviously, the contractor should respond to any of the provider's telephone calls, e-mails, etc., resulting from the pre-screening letter. However, the contractor need not – on its own volition – make an additional request for the missing data or documentation.

In addition:

- **Missing Information Available Elsewhere** – Even if the provider's application contains missing information that is nevertheless detected elsewhere on the form, in the supporting documentation, or on another enrollment form, the contractor must still send a pre-screening letter requesting the provider to furnish the missing data on the CMS-855. (An example would be if the provider neglected to furnish its ZIP Code but the ZIP Code is clearly indicated on a supporting document; another illustration would be if the provider failed to check the reason why the application was submitted yet it is patently obvious to the contractor that it is an initial enrollment.)

- **Unsolicited Submission of Data** - If the provider later submits the missing data on its own volition (i.e., without being contacted by the contractor) prior to the date the contractor finishes prescreening, the contractor shall include this additional data in its prescreening review.

- **Relationship to the Verification Process –** It is important that the contractor review section 5.3 of this chapter for information on requesting additional (or "clarifying") information and how this is tied to the pre-screening process.

B. Rejection

In accordance with 42 CFR §424.525(a)(1) and (2), respectively, the contractor may reject the provider's application if the provider fails to furnish complete information on the enrollment application, including all supporting documentation, within 30 calendar days from the date of the contractor's request for the missing information or documentation.

The 30-day clock starts on the date the pre-screening letter was sent to the provider. If the contractor makes a follow-up request for information, the 30-day clock does not start anew; rather, it keeps running from the date the pre-screening letter was sent. To illustrate, suppose that the contractor sent out a pre-screening letter on March 1 (thus triggering the 30-day clock) that asked for clarifying information in Sections 4 and 5 of the CMS-855B.

(All supporting documentation was provided.) The provider sent in most, but not all of the requested data. Though not required to make an additional contact beyond the pre-screening letter, the contractor telephoned the provider on March 20 to request the remaining missing data. The provider failed to respond. The contractor can reject the application on March 31, which is 30 days after the initial request.

NOTE: The contractor has the discretion to extend the 30-day time period if it determines that the provider or supplier is actively working with the contractor to resolve any outstanding issues. However, if the contractor elects to extend the 30-day period, this does not stop or restart the 30-day clock; in other words, the clock keeps running from the date the initial request for information was made.

The contractor shall also note the following with respect to rejections:

- **PECOS** – The contractor shall create an L & T record within the 15-day period prescribed in section 2.3 of this chapter. If the contractor rejects the application and was unable to create an L & T record due to missing data, the contractor shall document the provider file accordingly. If the contractor was able to create the L & T record but rejected the application, the contractor shall flip the status to "rejected" in PECOS.

- **Resubmission after Rejection** – If the provider's application is rejected, the provider must complete and submit a new CMS-855 and all supporting documentation.

- **Appeals** – The provider may not appeal a rejection of its enrollment application.

- **Policy Application –** Unless stated otherwise in this manual, the policies contained in this section 3.1 apply to all CMS-855 applications identified in sections 2.1 and 2.2 above (e.g., changes of information, reassignments). Thus, suppose an enrolled provider submits a CMS 588. If any information is missing from the form, the contractor shall send a pre-screening letter to the provider.

- **Incomplete Responses** – The provider must furnish all missing and clarifying data requested by the contractor within the applicable timeframe. Whether the provider indeed furnished all the information is a decision that rests with the contractor. Moreover, if the provider furnishes some, but not all, of the requested data within the applicable time period, the contractor is not required to contact the provider again to request the rest of the information. The contractor has the discretion to wait until the expiration of the applicable timeframe and then reject the application.

- **Notice of Rejection** – If the contractor rejects the application under this section 3.1, it shall notify the provider via letter or e-mail that the application is being rejected, the reason(s) for the rejection, and how to reapply. The contractor is free to keep the original application on file after rejection. If the provider requests a copy of its application, the contractor may fax it to the provider.

- **Documentation** – The contractor shall document in the file the date on which it completed its pre-screening of the application.

- **Commencement of Timeframe** – The 30-day clock identified in 42 CFR §424.525(a) commences when the contractor mails, faxes, or e-mails the pre-screening letter.

- **Acknowledgment of Receipt** – The contractor may, but is not required to, send out acknowledgment letters.

- **"Not Applicable"** - It is unacceptable for the provider to write "N/A" in response to a question that requires a "yes" or "no" answer. This is considered an incomplete reply, thus warranting the issuance of a pre-screening letter based on missing information.

- **"Pending"** – "Pending" is an acceptable response, requiring no further development, in the following situations:

    - **Section 2B2 of the CMS 855** - The license or certification cannot be obtained until after a State survey is performed or RO approval is granted.

    - **Section 4 of the CMS 855** - The license/certification cannot be obtained (or the practice location cannot be considered fully established) until after a State survey is performed or RO approval is granted.

    - **Medicare Identification Number** - New enrollees who have no Medicare billing number can write "pending" in the applicable "Medicare Identification Number" boxes. (This policy, however, does not apply to NPIs.)

- **Licensure** - For certified suppliers and certified providers, there may be instances where a license may not be obtainable until after the State conducts a survey. Since the license is therefore not "required," the contractor shall not consider this to be "missing" information or documentation.

- **Section 6** – If an authorized or delegated official is not listed in section 6 of the CMS-855, this qualifies as an incomplete application and thus triggers the need for a pre-screening letter.

To summarize, if - during the pre-screening process - the contractor finds that data or documentation is missing, it shall send a pre-screening letter to the provider within the 15-day pre-screening period. The provider must furnish all of the missing material or documentation within the applicable timeframe. If the provider fails to do so, the contractor may reject the application.

3.1.1 – Application Rejections
(Rev.)

3.1.2 – Denials for Incomplete Applications
(Rev.)

3.2 – Returning the Application
(Rev. 236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

A. Immediate Returns

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

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

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

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

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

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

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

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

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

B. Procedures for Returning the Application

If the contractor returns the application:

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

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

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

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

C. EFT Agreements

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

4 – Application Review

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

Sections 4.1 through 4.16 below discuss the various provisions of the CMS-855A, CMS-855B, and CMS-855I forms. Unlike previous versions of chapter 10, not every data element on the forms is discussed here. Only those items that warrant additional instructions or policy clarifications are identified. However, contractors shall abide by all instructions in this chapter 10 in terms of the collection, processing, and verification of all data elements on the CMS-855 forms, regardless of whether the data element is specifically discussed in sections 4.1 through 4.16. In other words, the fact that a particular data element is not specifically mentioned in these sections in no way alleviates the contractor from having to collect, process, and validate that data element.

For purposes of brevity, the terms "approval" and "denial," as used in sections 4.1 through 4.16, also include recommendations for approval and recommendations for denial issued for certified providers and certified suppliers.

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

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

When processing section 1 of the application, the contractor shall ensure that the provider checks one of the "reason" boxes. It shall also verify, if reported in this section, that the Medicare identification number and NPI are correct.

Note that:

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

- Hospitals that request enrollment with the carrier to bill for practitioner services for hospital departments, outpatient locations and/or hospital clinics must submit an initial enrollment application.

- Unless otherwise stated in this manual, the provider may only check one reason for submittal. Suppose a supplier is changing its TIN. It must enroll as a new supplier as well as request to terminate its existing billing number. The provider must submit two applications: (1) an initial CMS-855B as a new supplier, and (2) a CMS-855B change request/voluntary termination. Both transactions cannot be reported on the same application.

Further information on the processing of changes of information, changes of ownership (CHOWs), reactivations, deactivations, etc., can be found in the applicable sections of this manual.

4.2 – Identifying Information (Section 2 of the CMS-855)
(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

Unless specifically indicated otherwise, the instructions in sections 4.2.1 through 4.2.4 below apply to the CMS-855A, the CMS-855B, and the CMS-855I.

The instructions in section 4.2.5 apply only to the CMS-855A; the instructions in section 4.2.6 apply only to the CMS-855B; and the instructions in section 4.2.7 only apply to the CMS-855I.

4.2.1 – Employer Identification Numbers and Legal Business Names
(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

A. Employer Identification Numbers

Sections 1124 and 1124A of the Social Security Act require that Medicare applicants furnish their tax identification number (TIN), as well as the TINs of all entities and persons listed in sections 5 and 6, respectively, of the CMS-855. The TIN can either be an employer identification number (EIN) or a social security number (SSN). An application cannot be approved until all TINs (whether EINs or SSNs) have been furnished and properly validated.

The contractor shall validate the applicant's EIN/TIN and legal business name against IRS paperwork, such as a CP-575, a quarterly tax payment coupon, or other IRS correspondence that contains this data. The documentation must be <u>from</u> the IRS. Applications for TINs, such as the SS-4, are not acceptable; provisional TINs are also unacceptable. Moreover, even if the applicant is a sole proprietor, he/she must submit IRS documentation if he/she lists an EIN (as opposed to the SSN) as the TIN.

There may be instances where the applicant cannot obtain the required IRS documentation (e.g., the applicant recently changed its name and the IRS has not sent to it an updated document). In such cases, the applicant must furnish an explanation in a separate attachment and provide evidence that links the legal business name with the TIN listed. One option for the applicant is to request a verification letter (IRS 147c) from the IRS that identifies its TIN and legal business name. The applicant may then submit the old IRS document with the old name, a copy of documentation filed with the State and IRS

concerning the name change, and an accompanying explanation of the situation. If the applicant fails to provide this information or the data otherwise does not match, the contractor shall deny the application.

If the name on the IRS documentation does not match exactly the name on the articles of incorporation, the contractor shall use the name on the IRS documentation as the legal business name. If there is a substantial discrepancy between the names on the two documents, the contractor shall contact the provider for clarification.

As for all other EINs listed on the CMS-855 (e.g., owning and managing organizations), the contractor shall use Qualifier.net as the primary review mechanism. The applicant need not submit IRS documentation for these other organizations, unless the contractor specifically requests it.

B. Qualifier.Net

The contractor must also check each SSN and EIN listed on the application against Qualifier.net, regardless of whether: (1) the SSN was validated by PECOS, or (2) the provider's EIN was verified by IRS documentation. This is to identify any SSNs or EINs that may have been used previously and to spot instances where, for instance, one person may be using multiple SSNs.

If a number is found in Qualifier.net that differs from the number on the application, the contractor shall reconcile this issue. For example, if the executive summary shows a different name associated with the provider's EIN, the contractor shall investigate further.

The contractor shall deny the application if, after investigation, it determines that:

- The person (e.g., applicant, owner, manager, etc.) has used a different SSN in the past or is currently using multiple SSNs, even if PECOS verified the person's SSN that was listed on the application; or

- There is insufficient evidence to link the EIN with the person or entity it is associated with on the form. For instance, suppose an owner lists its EIN in section 5 of the CMS-855. Qualifier.net lists two names next to the EIN, neither of which belongs to the owner. The contractor contacts the applicant for additional information and asks for a copy of IRS documentation verifying the owner's name and associated EIN. The applicant fails to furnish such documentation; as such, the contractor shall deny the application.

(See section 5.2(B) of this manual for more information on the use of Qualifier.net.)

C. Owners and Managers

All instances described in this section 4.2.1 in which the contractor should deny the application also apply to owners, managers, etc., not just the applicant.

D. Certified Providers

There is no prohibition against two or more certified providers having the same TIN (e.g., a company may own four HHAs, all of which are under the company's TIN.) However, each entity must enroll separately.

4.2.2 – Licenses and Certifications

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

The extent to which the applicant must complete the licensure or certification information in section 2 of the CMS-855 depends upon the provider type involved. For instance, some States may require a particular provider to be "certified" but not "licensed," or vice versa.

A. CMS-855B and CMS-855I

The contractor shall verify that the supplier is licensed and/or certified to furnish services in:

- The State where the supplier is enrolling;

- Any other State within the contractor's jurisdiction in which the supplier (per section 4 of the CMS-855) will maintain a practice location.

Verification can be performed by reviewing the licensure documentation submitted by the applicant. If the contractor, in its general review of Qualifier.net, finds inconsistencies between the data on the license and the data in Qualifier.net, the contractor shall request clarifying information. (This may occur if the name on the license does not exactly match the name on the application or the name in Qualifier.net. If the contractor cannot verify that it is the same person, it shall deny the application.)

The only licenses that must be submitted with the application are those required by Medicare or the State to function as the supplier type in question. Licenses and permits that are not of a medical nature are not required, though business licenses needed for the applicant to operate as a health care facility or practice must be submitted. In addition, there may be instances where the supplier is not required to be licensed at all in a particular State; the contractor shall still ensure, however, that the supplier meets all applicable State and Medicare requirements.

The contractor shall also adhere to the following:

- **State Surveys:** Documents that can only be obtained after State surveys or accreditation need not be included as part of the application. (This typically occurs with ambulatory surgical centers (ASCs) and portable x-ray suppliers.) The supplier must, however, furnish those documents that can be submitted prior to the survey/accreditation.

  The contractor need not verify licenses, certifications, and accreditations submitted by ASCs and portable x-ray suppliers. Instead, the contractor shall simply include

such documents, if submitted, as part of the enrollment package that is forwarded to the State and/or RO.

Once the contractor receives the approval letter or tie-in notice from the RO for the ASC or portable x-ray supplier, the contractor is encouraged, but not required, to contact the RO, State agency, or supplier for the applicable licensing and/or certification data and to enter it into PECOS.

- **Notarization:** If the applicant submits a license that is not notarized or "certified true," the contractor shall verify the license with the appropriate State agency. (A notarized copy of an original document has a stamp that says "official seal," along with the name of the notary public, the State, the county, and the date the notary's commission expires. A certified "true copy" of an original document has a raised seal that identifies the State and county in which it originated or is stored.)

- **Temporary Licenses:** If the supplier submits a temporary license, the contractor shall note the expiration date in PECOS. Should the supplier fail to submit the permanent license after the temporary license expiration date, the contractor shall initiate revocation procedures. (A temporary permit – one in which the applicant is not yet fully licensed and must complete a specified number of hours of practice in order to obtain the license – is not acceptable.)

- **Revoked/Suspended Licenses:** If the applicant had a previously revoked or suspended license reinstated, the applicant must submit a copy of the reinstatement notice with the application.

- **Date of Enrollment –** For suppliers other than ASCs and portable x-rays, the date of enrollment is the date the contractor approved the application. The enrollment date cannot be made retroactive. To illustrate, suppose the supplier met all the requirements needed to enroll in Medicare (other than the submission of a CMS-855I) on January 1. He sends his CMS-855I to the contractor on May 1, and the contractor approves the application on June 1. The date of enrollment is June 1, not January 1. (Note that the matter of the date of enrollment is separate from the question of the date from which the supplier may bill.)

B. CMS-855A

Documents that can only be obtained after State surveys or accreditation need not be included as part of the application, nor must the data be provided in section 2 of the CMS-855A. The provider must, however, furnish those documents that can be submitted prior to the survey/accreditation.

The contractor need not verify licenses, certifications, and accreditations that were submitted. It shall simply include such documents as part of the enrollment package that is forwarded to the State and/or RO.

Once the contractor receives the approval letter or tie-in notice from the RO, the contractor is encouraged, but not required, to contact the RO, State agency, or provider for the applicable licensing and/certification data and to enter it into PECOS.

4.2.3 – Correspondence Address

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

A. General

The correspondence address must be one where the contractor can directly contact the applicant to resolve any issues once the provider is enrolled in the Medicare program. It cannot be the address of a billing agency, management services organization, chain home office, or the provider's representative (e.g., attorney, financial advisor). It can, however, be a P.O. Box or, in the case of an individual practitioner, the person's home address.

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

B. Contact Person

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

Notwithstanding the above, all approval/denial letters should be sent to the contact person. However, the contractor retains the discretion to send the letter to another address listed on the CMS-855 if dictated by circumstances.

In short:

- CMS strongly recommends that all communications (e.g., requests for additional information) specifically related to the submission of a CMS-855 (or CMS-588) application be addressed to the contact person in Section 13. However, the contractor retains the discretion to use the correspondence address if circumstances so warrant.

- All provider enrollment-oriented communications/correspondence not specifically related to a CMS-855 (or CMS-588) transaction shall be sent to the correspondence address. The contractor has the discretion to determine whether a particular communication is "specifically related" to a CMS-855 submission or whether a particular communication is "provider enrollment-oriented."

For purposes of this section 4.2.3(B), the term "approved" includes "recommended for approval."

4.2.4 – Accreditation

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

If the provider checks "Yes," the contractor shall ensure that the listed accrediting body is one that CMS recognizes in lieu of a State survey or other certification for the provider type in question. If the accrediting body is not recognized by CMS, the contractor shall advise the provider accordingly. (Note, however, that the provider may not intend to use the listed accreditation in lieu of the State survey and merely furnished the accrediting body in response to the question.)

4.2.5 – Section 2 of the CMS-855A

(Rev. 260, Issued: 06-20-08, Effective: 07-22-08, Implementation: 07-22-08)

A. Home Health Agency (HHA) Branches, Hospital Units, and Outpatient Physical Therapy/Occupational Therapy (OPT/OT) Extension Sites

As explained in section 12.1.6, a branch is a location or site from which an HHA provides services within a portion of the total geographic area served by the parent agency. The branch is part of the HHA and is located sufficiently close to the parent agency such that it shares administration, supervision, and services with the parent. If an existing HHA wishes to add a branch, it is considered a change of information on the CMS-855A. An HHA subunit, meanwhile, is a semi-autonomous organization under the same governing body as the parent HHA and serves patients in a geographic area different from that of the parent. Because of its distance from the subunit, the parent is incapable of sharing administration, supervision and services with the subunit on a daily basis. If the HHA wants to add an HHA subunit, it must complete an initial enrollment application for the subunit. (The subunit also signs a separate provider agreement.)

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

When the provider seeks to add an HHA branch or a hospital unit, the contractor shall make a recommendation for approval or denial and forward the package to the State as described in section 7.2 of this manual. However, the contractor shall emphasize to the provider that a recommendation of approval of the addition of the branch or unit does not signify CMS's approval of the new location. Only the RO can approve the addition.

With respect to PECOS, the contractor shall create a separate enrollment record for the hospital unit. However, a separate enrollment record for each HHA branch and OPT/OT extension site is not required. These locations can simply be listed on the main provider's enrollment record.

B. Critical Access Hospitals

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

C. Transplant Centers

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

4.2.6 – Section 2 of the CMS-855B

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

Any supplier that indicates it is an OT/PT group must complete the questionnaire in section 2E. In doing so:

- If the group indicates that it renders services in patients' homes, the contractor shall verify that the group has an established private practice where it can be contacted directly and where it maintains patients' records.

- If the group answers "yes" to question 2, 3, 4, or 5, it must submit a copy of the lease agreement giving the group exclusive use of the facilities for PT/OT services. If no such lease exists, the contractor shall deny the application.

4.2.7 – Section 2 of the CMS-855I

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

A. Specialties

On the CMS-855I, the physician must indicate his/her supplier specialties, showing "P" for primary and "S" for secondary. Non-physician practitioners must indicate their supplier type.

The contractor shall deny the application if the individual fails to meet the requirements of his/her physician specialty or supplier type.

B. Education for Non-Physician Practitioners

The contractor shall verify all required educational information for non-physician practitioners. The non-physician practitioner must meet all Federal and State requirements and must provide documentation of courses or degrees taken to satisfy Medicare requirements. If the applicant does not meet the educational requirements, the contractor shall deny the application.

Physicians are not required to submit a copy of their degree with their application unless requested to do so by the contractor. If need be, the contractor can verify this information via a State licensure/certification Web site or other mechanism.

C. Resident/Intern Status

If the applicant is a "resident" in an "approved medical residency program" (as these two terms are defined at 42 CFR §413.75(b)), the contractor shall refer to Pub. 100-02, chapter 15, section 30.3 for further instructions. (The contractor may also want to refer to 42 CFR §415.200, which states that services furnished by residents in approved programs are not "physician services.")

Note that an intern cannot enroll in the Medicare program. (For purposes of this requirement, the term "intern" means an individual who is not licensed by the State because he/she is still in post-graduate year (PGY) 1.) Also, an individual in a residency or fellowship program cannot be reimbursed for services performed as part of that program. Thus, if the person indicates that all of his/her services will be furnished within that program, he/she cannot be enrolled.

D. Physician Assistants

As stated in the instructions on page 3 of the CMS-855I, physician assistants (PAs) who are enrolling in Medicare need only complete sections 1, 2, 3, 13, 15, and 17 of the CMS- 855I. The physician assistant must furnish his/her NPI in section 1 of the application, and must list his/her employers in section 2E.

The contractor must verify that the employers listed are: (1) enrolled in Medicare, and (2) not excluded or debarred from the Medicare program. (An employer can only receive payment for a PA's services if both are enrolled in Medicare.) All employers must also have an established record in PECOS. If an employer is excluded or debarred, the contractor shall deny the application.

Since PAs cannot reassign their benefits – even though they are reimbursed through their employer – they should not complete a CMS-855R.

E. Psychologists Billing Independently

The contractor shall ensure that all persons who check "Psychologist Billing Independently" in section 2D2 of the CMS-855I answer all questions in section 2I. If the

supplier answers “no” to question 1, 2, 3, 4a, or 4b, the contractor shall deny the application.

F. Occupational/Physical Therapist in Private Practice (OT/PT)

All OT/PTs in private practice must respond to the questions in section 2J of the CMS-855I. If the OT/PT plans to provide his/her services as: (1) a member of an established OT/PT group, (2) an employee of a physician-directed group, or (3) an employee of a non-professional corporation, and that person wishes to reassign his/her benefits to that group, this section does not apply. Such information will be captured on the group’s CMS-855B application.

If the OT/PT checks that he/she renders all of his/her services in patients' homes, the contractor shall verify that he/she has an established private practice where he/she can be contacted directly and where he/she maintains patient records. (This can be the person’s home address, though all Medicare rules and instructions regarding the maintenance of patient records apply.) In addition, section 4D of the CMS-855I should indicate where services are rendered (e.g., county, State, city of the patients' homes). Post office boxes are not acceptable.

If the OT/PT answers “yes” to question 2, 3, 4, or 5, he/she must submit a copy of the lease agreement that gives him/her exclusive use of the facilities for OT/PT services. If no such lease exists, the contractor shall deny the application.

4.3 – Adverse Legal Actions/Convictions

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

Unless stated otherwise, the instructions in this section 4.3 apply to the following sections of the CMS-855 application:

- Section 3
- Section 4A of the CMS-855I
- Section 5B (Owning and Managing Organizations)
- Section 6B (Owning and Managing Individuals)

If the applicant indicates that a felony or misdemeanor conviction has been imposed against a person or entity listed on the CMS-855, the contractor shall refer the matter to its DPSE contractor liaison for further instructions. (CMS may refer the matter to the OIG or PSC, if necessary.) In its referral to CMS, the contractor shall furnish a brief explanation of the matter along with the applicable section of the CMS-855 (e.g., section 3, section 5). The contractor shall neither approve nor deny the application until DPSE issues a final directive to the contractor.

If the applicant is excluded or debarred, the contractor shall deny the application in accordance with the instructions in this manual; prior approval from DPSE is not necessary. If any other adverse action is listed, the contractor shall refer the matter to its DPSE contractor liaison for instructions.

The applicant shall furnish documentation concerning the type and date of the action, what court(s) and law enforcement authorities were involved, and how the adverse action was resolved. It is extremely important that the contractor obtain such documentation, regardless of whether the adverse action occurred in a State different from that in which the provider currently seeks enrollment. (In other words, all adverse actions must be fully disclosed, irrespective of where the action took place.) In situations where the person or entity in question was excluded but has since been reinstated, the contractor shall verify this through the OIG and ask the applicant to submit written proof (e.g., reinstatement letter) that such reinstatement has in fact taken place.

If the applicant states in section 3, 4A of the CMS-855I, 5, and/or 6 that the person or entity in question has never had an adverse legal action imposed against him/her/it but the contractor's review of Qualifier.Net indicates otherwise, the contractor shall contact DPSE for further instructions. The contractor shall neither approve nor deny the application until DPSE issues a final directive, which could include an instruction to deny the application based on false information furnished by the applicant. (See section 6.2 of this manual for further details on the handling of potentially falsified applications.)

In any situation where CMS directs the contractor to deny an application based on an adverse legal action, the contactor shall notify – via fax or e-mail - all other contractors that have enrolled the applicant. Payment stoppages and recoupment actions may be warranted.

Chain Home Offices, Billing Agencies, and HHA Nursing Registries

If a Qualifier.net search of the entities listed in sections 7, 8, or 12 of the CMS 855 indicate adverse legal history, the contractor shall handle the matter in accordance with the instructions in this section 4.3.

4.4 – Practice Location Information

(Rev. 260, Issued: 06-20-08, Effective: 07-22-08, Implementation: 07-22-08)

Unless specifically indicated otherwise, the instructions in this section 4.4 apply to the CMS-855A, the CMS-855B, and the CMS-855I.

The instructions in section 4.4.1 apply only to the CMS-855A; the instructions in section 4.4.2 apply only to the CMS-855B; and the instructions in section 4.4.3 only apply to the CMS-855I.

A. Practice Location Verification

The contractor shall verify via Qualifier.net that the practice locations listed on the application actually exist; note that the practice location name may be the "doing business

as" name. If a particular location is not shown on the executive summary, the contractor shall request clarifying information. (For instance, the contractor can request that the applicant furnish letterhead showing the appropriate address.)

The contractor shall also verify that the reported telephone number is operational and connects to the practice location/business listed on the application. (The telephone number must be one where patients and/or customers can reach the applicant to ask questions or register complaints.) The contractor shall match the applicant's telephone number with known, in-service telephone numbers, using Qualifier.net to correlate telephone numbers with addresses. If the applicant uses his/her/its cell phone for their business, the contractor shall verify that this is a telephone connected directly to the business. If the contractor cannot verify the telephone number, it shall request clarifying information from the applicant; the inability to confirm a telephone number may indicate that an onsite visit is necessary. In some instances, a 1-800 number or out-of-state number may be acceptable if the applicant's business location is in another State but his/her/its practice locations are within the contractor's jurisdiction.

With respect to individual and organizational suppliers other than ASCs, portable x-ray suppliers, and IDTFs, the contractor shall use the date in section 4A of the CMS-855B or section 4C of the CMS-855I as the date from which the applicant can bill the Medicare program. (This assumes, of course, that the supplier met all of the necessary requirements as of that date.) In situations where the date listed appears to be beyond a reasonable amount of time (e.g., older than 12 months), the contractor shall request clarifying information from the applicant.

In addition:

- If an individual practitioner or group practice: (1) is adding a practice location and (2) is normally required to complete a questionnaire in section 2 of the CMS-855I or CMS-855B specific to its supplier type (e.g., psychologists, physical therapists), the person or entity must submit an updated questionnaire to incorporate services rendered at the new location.

- Any provider submitting a CMS-855A, CMS-855B or CMS-855I application must submit the 9-digit ZIP Code for each practice location listed.

B. Do Not Forward (DNF)

The contractor shall follow the DNF initiative instructions in Pub. 100-04, chapter 1, section 80.5. Returned paper checks, remittance notices, or EFT payments shall be flagged if returned from the post office or banking institution, respectively, as this may indicate that the provider's "special payment" address (section 4 of the CMS-855) or EFT information has changed. The provider should submit a CMS-855 or CMS-588 request to change this address; if the provider does not have an established enrollment record in PECOS, it must complete an entire CMS-855 application and CMS-588 EFT form. The DME MACs are responsible for obtaining, updating and processing CMS-588 changes.

In situations where a provider is closing his/her/its business and has a termination date (e.g., he/she is retiring), the contractor will likely need to make payments for prior services rendered. Since the practice location has been terminated, the contractor may encounter a DNF message. If so, the contractor should request the provider to complete the "special payment" address section of the CMS-855 and to sign the certification statement. The contractor, however, shall not collect any other information unless there is a need to do so.

C. Remittance Notices/Special Payments

For new enrollees, all payments must be made via EFT. The contractor shall thus ensure that the provider has completed and signed the CMS-588, and shall verify that the bank account is in compliance with Pub. 100-04, chapter 1, section 30.2.

If an enrolled provider that currently receives paper checks submits a CMS-855 change request – no matter what the change involves – the provider must also submit:

- A CMS-588 that switches its payment mechanism to EFT. (The change request cannot be processed until the CMS-588 is submitted.) All future payments (excluding special payments) must be made via EFT.

- An updated section 4 that identifies the provider's desired "special payments" address.

The contractor shall also verify that the bank account is in compliance with Pub. 100-04, chapter 1, section 30.2.

(Once a provider changes its method of payment from paper checks to EFT, it must continue using EFT. A provider cannot switch from EFT to paper checks.)

The "special payment" address may only be one of the following:

- One of the provider's practice locations

- A P.O. Box

- The provider's billing agent. The contractor shall request additional information if it has any reason to suspect that the arrangement – at least with respect to any special payments that might be made – may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.

- The chain home office address. Per Pub.100-04, chapter 1, section 30.2, a chain organization may have payments to its providers sent to the chain home office. The legal business name and TIN of the chain home office must be listed on the CMS-588.

- Correspondence address

4.4.1 – Section 4 of the CMS-855A

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

Hospitals and other providers must list all addresses where they (and not a separately enrolled provider/supplier type, such as a nursing home) furnish services. The provider's primary practice location should be the first location identified in section 4 and the contractor shall treat it as such for purposes of PECOS entry, unless there is evidence to the contrary. Note that hospital departments located at the same address as the main facility need not be listed as practice locations on the CMS-855A.

If a practice location (e.g., hospital unit) has a CCN that is in any way different from that of the main provider, the contractor shall create a separate enrollment record in PECOS for that location; this does not apply, however, to HHA branches, OPT/OT extension sites and transplant centers.

The HHAs should complete section 4A with their administrative address.

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

4.4.2 – Section 4 of the CMS-855B

(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

A. Ambulatory Surgical Centers (ASCs) and Portable X-ray Suppliers

If the applicant's address or telephone number cannot be verified via Qualifier.net, the contractor shall contact the applicant for further information. If the supplier states that the facility or its phone number is not yet operational, the contractor shall continue processing the application. However, it shall note in its recommendation letter that the address and telephone number of the facility could not be verified.

For purposes of PECOS entry, the contractor can temporarily use the date the certification statement was signed as the effective date.

B. Reassignment of Benefits

Per Pub. 100-04, chapter 1, section 30.2.7, a contractor may permit a reassignment of benefits to any eligible entity regardless of where the service was rendered or whether the entity owned or leased that location. As such, the contractor need not verify the entity's ownership or leasing arrangement with respect to the reassignment.

C. Ambulance Companies

If an ambulance company will be furnishing all of its services in the same contractor jurisdiction, the supplier should list:

- *Each site at which its vehicles are garaged in section 4A.*
- *Each site from which its personnel are dispatched in section 4A.*
- *Its base of operations – which, for ambulance companies, is their primary headquarters – in section 4E.*

If the supplier will be furnishing services in more than one jurisdiction, it shall follow the applicable instructions in section 4.18 of this chapter.

4.4.3 – Section 4 of the CMS-855I

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

A. Solely-Owned Organizations

The former practice of having solely-owned practitioner organizations (as explained and defined in section 4A of the CMS-855I) complete a CMS-855B, a CMS-855R, and a CMS-855I has been discontinued. All pertinent data for these organizations can be furnished via the CMS-855I alone. The contractor, however, shall require the supplier to submit a CMS-855B, CMS-855I and CMS-855R if, during the verification process, it discovers that the supplier is not a solely-owned organization. Note that a solely-owned supplier type that normally completes the CMS-855B to enroll in Medicare must still do so. For example, a solely-owned LLC that is an ambulance company must complete the CMS-855B, even though section 4A makes mention of solely-owned LLCs. Use of section 4A of CMS-855I is limited to suppliers that perform physician or practitioner services.

Sole proprietorships need not complete section 4A of the CMS-855I. By definition, a sole proprietorship is not a corporation, professional association, etc. Do not confuse a sole proprietor with a physician whose business is that of a corporation, LLC, etc., of which he/she is the sole owner.

In section 4A, the supplier may list a type of business organization other than a professional corporation, a professional association, or a limited liability company (e.g., closely-held corporation). This is acceptable so long as that business type is recognized by the State in which the supplier is located.

The contractor shall verify all data furnished in section 4A (e.g., legal business name, TIN, adverse legal actions). If section 4A is left blank, the contractor may assume that it does not pertain to the applicant.

A solely-owned physician or practitioner organization that utilizes section 4A to enroll in Medicare can generally submit change of information requests to Medicare via the CMS-

855I. However, if the change involves data not captured on the CMS-855I, the change must be made on the applicable CMS form (i.e., CMS-855B, CMS-855R).

B. Individual Affiliations

If the applicant indicates that he/she intends to render all or part of his/her services in a group setting, the contractor shall ensure that the applicant (or the group) has submitted a CMS-855R for each group to which the individual plans to reassign benefits. The contractor shall also verify that the group is enrolled in Medicare. If it is not, the contractor shall enroll the group prior to approving the reassignment.

C. Practice Location Information

A practitioner who only renders services in patients' homes (i.e., house calls) must supply his/her home address in section 4C. In addition, if a practitioner renders services in a retirement or assisted living community, section 4C must include the name and address of that community. In either case, the contractor shall verify that the address is a physical address. Post office boxes and drop boxes are not acceptable.

D. Sole Proprietor Use of EIN

The practitioner must obtain a separate EIN if he/she wants to receive reassigned benefits as a sole proprietor.

E. NPI Information for Groups

If a supplier group/organization is already established in PECOS (i.e., status of "approved), then the physician or non-physician practitioner is not required to submit the NPI in 4B2 of the 855I. In short, if group/organization is already established in PECOS, the group/organization does not need to include an NPI in section 4B2. The only NPI that the physician or non-physician practitioner must supply is the NPI found in section 4C.

NOTE: Physicians and non-physician practitioners are required to supply the NPI in section 4B2 of the CMS-855I for groups/organizations not established in PECOS with a status of "approved."

4.5 – Owning and Managing Organizations

(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

(This section only applies to section 5 of the CMS-855A and CMS-855B. It does not apply to the CMS-855I.)

All organizations that have any of the following must be listed in section 5A of the CMS-855:

1. A 5 percent or greater direct or indirect ownership interest in the provider.

The following illustrates the difference between direct and indirect ownership:

EXAMPLE: The supplier listed in section 2 of the CMS-855B is an ambulance company that is wholly (100 percent) owned by Company A. Company A is considered to be a direct owner of the supplier (the ambulance company), in that it actually owns the assets of the business. Now assume that Company B owns 100 percent of Company A. Company B is considered an indirect owner - but an owner, nevertheless - of the supplier. In other words, a direct owner has an actual ownership interest in the supplier, whereas an indirect owner has an ownership interest in an organization that owns the supplier.

For purposes of enrollment, ownership also includes "financial control." Financial control exists when:

(a) An organization or individual is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the provider or any of the property or assets of the provider, and

(b) The interest is equal to or exceeds 5 percent of the total property and assets of the provider.

2. A partnership interest in the provider, regardless of: (1) the percentage of ownership the partner has, and (2) whether the partnership interest is that of a general partner or limited partner (e.g., all limited partners in a limited partnership must be listed in section 5A).

3. Managing control of the provider.

A managing organization is one that exercises operational or managerial control over the provider, or conducts the day-to-day operations of the provider. The organization need not have an ownership interest in the provider in order to qualify as a managing organization. For instance, the entity could be a management services organization under contract with the provider to furnish management services for one of the provider's practice locations.

Contractors shall also note the following with respect to owning and managing organizations:

- Such organizations generally fall into one of the following categories: (1) corporations (including non-profit corporations); (2) partnerships and limited partnerships; (3) limited liability companies; (4) charitable and religious organizations; (5) governmental/tribal organizations.

- Any entity listed as the applicant in section 2 of the CMS-855 need not be reported in section 5A. The only exception to this involves governmental entities, which must be listed in section 5A even if they are already listed in section 2.

- With respect to governmental organizations, the letter referred to in the CMS-855 form instructions for section 5 must be signed by an appointed or elected official of the

governmental entity who has the authority to legally and financially bind the government to the laws, regulations, and program instructions of Medicare. There is no requirement that this government official also be an authorized official, or vice versa.

- Many non-profit organizations are charitable or religious in nature, and are operated and/or managed by a Board of Trustees or other governing body. The actual name of the Board of Trustees or other governing body should be listed in section 5A of the CMS-855. The applicant should submit a copy of its 501(c)(3) approval notification for non-profit status. If it does not possess such documentation but nevertheless claims it is a non-profit entity, the applicant may submit any other documentation that supports its claim, such as written documentation from the State, etc. This documentation is necessary if the applicant does not list any owners in section 5 or section 6 of the application.

- The contractor shall review all organizations listed in section 5A against Qualifier.net. If an adverse legal action is found, the contractor shall follow the instructions in section 4.3 of this manual.

- Owning/managing organizations need not submit an IRS CP-575 document unless requested by the contractor (e.g., the contractor discovers a potential discrepancy between the organization's legal business name and tax identification number in Qualifier.net.)

4.5.1 - Types of Business Organizations

(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

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

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

A. Corporations

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

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

actions of the corporation because, as stated above, a corporation is separate and distinct from its owners.

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

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

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

Two special types of corporations contractors may encounter are:

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

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

Although PCs and CCs are considered "corporations" for enrollment purposes, State laws governing these entities are often different from those that govern "regular" corporations (i.e., States have separate statutes for "regular" corporations and for PCs/CCs.) In many cases, an entity must specifically elect to be a PC or CC when filing its paperwork with the State.

B. Partnerships

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

- Each partner is liable for all the debts of the partnership. Using the example above, suppose the Y Partnership breached a contract it had with Mr. X, who now sues for

$10,000. Since each partner is liable for all debts, X can collect the entire $10,000 from A, or from B, or $5,000 from each, etc. This is because, unlike a corporation, a partnership is not really a separate and distinct entity from its partners/owners; the partners are the partnership. If Y had been a corporation, the owners (A and B) would likely have been be shielded from liability.

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

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

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

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

C. Limited Liability Companies (LLC)

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

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

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

D. Joint Ventures

A joint venture is when two or more persons/entities combine efforts in a business enterprise and agree to share profits and losses. It is very similar to a partnership, and is

treated as a partnership for tax purposes. The key difference is that a partnership is an ongoing business, while a joint venture is a temporary, one-time business undertaking. A joint venture, therefore, can be classified as a "temporary partnership."

E. Non-Profit Organizations

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

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

F. Sole Proprietorships

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

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

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

G. Government-Owned Entities

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

Note that:

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

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

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

4.6 – Owning and Managing Individuals

(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

(This section applies to section 6 of the CMS-855A, the CMS-855B, and the CMS-855I.)

All individuals who have any of the following must be listed in section 6A:

1. A 5 percent or greater direct or indirect ownership interest in the provider. (See section 4.5 of this manual for information on the distinction between direct and indirect ownership, as well as the definition of "financial control.")

2. A partnership interest in the provider, regardless of: (1) the percentage of ownership the partner has, or (2) whether the partnership interest is that of a general partner or limited partner (e.g., all limited partners in a limited partnership must be listed in section 6A).

3. Managing control of the provider. (For purposes of enrollment, such a person is considered to be a "managing employee." A managing employee is any individual, including a general manager, business manager, office manager or administrator, who exercises operational or managerial control over the provider's business, or who conducts the day-to-day operations of the business. A managing employee also includes any individual who is not an actual W-2 employee but who, either under contract or through some other arrangement, manages the day-to-day operations of the business.)

In addition:

- "Officers" and "directors", as those terms are defined on the CMS-855 form instructions for section 6, need only be reported if the applicant is a corporation. (For-profit and non-profit corporations must list all of their officers and directors; if a non-profit corporation has "trustees" instead of officers or directors, these trustees must be listed in section 6 of the CMS-855.)

- Government entities need only list their managing employees in section 6 of the CMS-855, as they do not have owners, partners, corporate officers, or corporate directors.

- The applicant must list at least one managing employee in section 6 if it is completing the CMS-855A or the CMS-855B. A practitioner completing the CMS-855I need not list a managing employee if he/she does not have one.

- All managing employees at any of the practice locations listed in section 4C of the CMS-855I must be reported in section 6A. However, individuals who: (1) are employed by hospitals, health care facilities, or other organizations shown in section 4C (e.g., the CEO of a hospital listed in section 4C), or (2) are managing employees of any group/organization to which the practitioner will be reassigning his/her benefits, need not be reported.

- The contractor shall review all individuals listed in section 6A of the CMS-855 against Qualifier.net. If an adverse legal action is found, the contractor shall follow the instructions in section 4.3 of this manual.

- Information on processing section 6B (Adverse Legal Actions) of the CMS-855 can be found in section 4.3 of this manual.

- It is not necessary for the contractor to request a copy of the individual's W-2 to confirm that he/she is in fact a W-2 employee (as opposed to a contracted employee).

4.7 – Chain Organizations

(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

(This section only applies to the CMS-855A. It is inapplicable to the CMS-855B and the CMS-855I.)

All providers that are currently part of a chain organization or who are joining a chain organization must complete this section with information about the chain home office. A chain organization exists when multiple providers/suppliers are owned, leased, or through any other devices, controlled by a single business entity. This entity is known as the chain home office.

At the current time, the contractor shall not hold up the processing of the provider's application while awaiting the issuance of a chain home office number (i.e., a determination as to whether a set of entities qualifies as a chain organization). Such an issuance/determination is not presently required prior to the contractor making its recommendation for approval or denial.

The contractor shall ensure that:

- The chain home office is identified in section 5A of the CMS-855A and that adverse legal action data is furnished in section 5B. (For purposes of provider enrollment, a chain home office automatically qualifies as an owning/managing organization.) Note than an NPI is typically not required for a chain home office.

- The chain home office administrator is identified in section 6A of the CMS-855A and that adverse legal action data for the administrator is furnished in section 6B. (For purposes of provider enrollment, a chain home office administrator is automatically deemed to have managing control over the provider.)

The contractor shall review both the chain home office and its administrator against Qualifier.net. If an adverse legal action is found, the contractor shall follow the instructions in section 4.3 of this manual.

For more information on chain organizations, refer to:

- Pub. 100-04, chapter 1, sections 20.3 through 20.3.6.
- 42 CFR §421.404
- CMS change request 5720

4.8 – Billing Agencies

(Rev. 260, Issued: 06-20-08, Effective: 07-22-08, Implementation: 07-22-08)

(This section applies to the CMS-855A, the CMS-855B, and the CMS-855I.)

The provider shall complete this section with information about any and all billing agents that prepare and submit claims on its behalf. As all Medicare payments must be made via EFT, the contractor no longer needs to verify the provider's compliance with the "Payment to Agent" rules in Pub. 100-04, chapter 1, section 30.2. The only exception to this is if the contractor discovers that the "special payments" address in section 4 of the provider's application belongs to the billing agent. In this situation, the contractor may obtain a copy of the billing agreement if it has reason to believe that the arrangement violates the "Payment to Agent" rules.

In all cases, the contractor shall review the billing agency and its TIN against Qualifier.net. (If the billing agent is an individual who does not have an EIN, the person's SSN should be reported in the TIN section.)

If the chain organization listed in section 7 of the CMS-855A also serves as the provider's billing agent, the chain must be listed in section 8 as well.

4.9 – Reserved for Future Use

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

4.10 – Reserved for Future Use

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

4.11 – Reserved for Future Use

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

4.12 – Special Requirements for Home Health Agencies (HHAs)
(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

(This section only applies to the CMS-855A.)

The contractor shall verify that the HHA meets all of the capitalization requirements addressed in 42 CFR §489.28. The contractor may request from the provider any and all documentation deemed necessary to perform this task. Failure to meet the capitalization requirements shall result in a recommendation for denial. For more information on HHA capitalization, review 42 CFR § 489.28 and section 12.1.6 of this manual.

If the HHA checks "yes" in section 12B, the contractor shall review the HHA nursing registry and the tax identification number against Qualifier.net. (A nursing registry is akin to a staffing agency, whereby a private company furnishes nursing personnel to hospitals, clinics, and other medical providers.)

4.13 – Contact Person
(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

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

Notwithstanding the above, all approval/denial letters should be sent to the contact person. However, the contractor retains the discretion to send the letter to another address listed on the CMS-855 if dictated by circumstances.

In short:

- CMS strongly recommends that all communications (e.g., requests for additional information) specifically related to the submission of a CMS-855 (or CMS-588) application be addressed to the contact person in Section 13. However, the contractor retains the discretion to use the correspondence address if circumstances so warrant.

- All provider enrollment-oriented communications/correspondence not specifically related to a CMS-855 (or CMS-588) transaction shall be sent to the correspondence address. The contractor has the discretion to determine whether a particular

communication is “specifically related” to a CMS-855 submission or whether a particular communication is “provider enrollment-oriented.”

- For purposes of this section 4.13, the term “approved” includes “recommended for approval.”

If the contractor discovers that the contact person qualifies as an owning or managing individual, the provider shall list the person in section 6 of the application.

4.14 – Reserved for Future Use

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

4.15 – Certification Statement

(Rev. 246, Issued: 03-14-08, Effective: 04-14-08, Implementation: 04-14-08)

CMS-855I

The individual practitioner is the only person who may sign the CMS-855I. (This applies to initial enrollments, changes of information, reactivations, etc.) This includes solely-owned entities listed in section 4A of the CMS-855I. An individual practitioner may not delegate the authority to sign the CMS-855I on his/her behalf to any other person.

CMS-855A and CMS-855B

For initial enrollment and revalidation, the certification statement must be signed and dated by an authorized official of the provider.

The provider can have an unlimited number of authorized officials, so long as each meets the definition of an authorized official. However, each authorized official must be listed in section 6 of the CMS-855.

If an authorized official is listed as a “Contracted Managing Employee” in section 6 of the CMS-855, he/she cannot be an authorized official. The contractor shall notify the provider accordingly. If the person is listed as anything else in section 6 and the contractor has no reason to suspect that the person does not have the authority to sign the application on the provider’s behalf, no further investigation is required.

Should the contractor have doubts about an authorized official's authority, it shall contact that official or the applicant's contact person to obtain more information about the official's job title and/or authority to bind. If the contractor remains unconvinced about the official's binding authority, it shall notify the provider that the person cannot be an authorized official. If that person was the only authorized official listed and the provider refuses to list a different authorized official, the contractor shall deny the application.

In addition:

- The signature of an authorized official must be original. Faxed, stamped, or photocopied signatures cannot be accepted.

- If an authorized official is being deleted, the contractor need not obtain: (1) that authorized official's signature, nor (2) documentation verifying that the person no longer is or qualifies as an authorized official.

- A change in authorized officials has no bearing on the authority of existing delegated officials to make changes and/or updates to the provider's status in the Medicare program.

- If the provider is submitting a change of information (e.g., new practice location, change of address, new part-owner) and the authorized official signing the form is not on file, the contractor shall ensure that: (1) the person meets the definition of an authorized official, and (2) section 6 of the CMS-855 is completed for that person. The signature of an existing authorized official is not needed in order to add a new authorized official. Note that the original change request and the addition of the new official shall be treated as a single change request (i.e., one change request encompasses two different actions) for purpose of enrollment processing and reporting.

- The effective date in PECOS for section 15 of the CMS-855 should be the date of signature.

- In order to be an authorized official, the person must have and must submit his/her social security number.

- An authorized official must be an authorized official of the provider, not of an owning organization, parent company, or management company. However, the question of "who is the provider?" is not, for purposes of identifying valid authorized officials, determined solely by the provider's TIN. Rather, the organizational structure is the key factor. For instance, suppose that a chain drug store, Company X, wishes to enroll 100 of its pharmacies with the carrier. Each pharmacy has a separate TIN and, therefore, must enroll separately. Yet all of the pharmacies are part of a single corporate entity – X. In other words, there are not 100 separate corporations in our scenario, but merely one corporation whose individual locations have different TINs. Here, an authorized official for Pharmacy #76, can be someone at X's headquarters (assuming that the definition of authorized official is otherwise met), even though this main office might be operating under a TIN that is different from that of #76. This is because headquarters and Pharmacy #76 are part of the same organization/corporation. Conversely, if #76 was a corporation that was separate and distinct from Company X, only individuals that were part of #76 could be authorized officials.

4.16 – Delegated Officials

(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

(This section only applies to the CMS-855A and the CMS-855B.)

A delegated official is an individual who is delegated by an authorized official the authority to report changes and updates to the provider's enrollment record. The delegated official

must be an individual with an ownership or control interest in (as that term is defined in section 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of the provider.

Section 1124(a)(3) defines an individual with an ownership or control interest as:

- A five percent direct or indirect owner of the provider,
- An officer or director of the provider (if the provider is a corporation), or
- A partner of the provider, if the provider is a partnership

The individual must have been delegated the legal authority by an authorized official listed in section 15 of the CMS-855 to make changes and/or updates to the provider's status in the Medicare program, and to commit the provider to fully abide by the laws, regulations, and program instructions of Medicare.

The contractor shall note the following about delegated officials:

- A delegated official has no authority to sign an initial enrollment application or a revalidation application. The primary function of a delegated official is to sign off on changes of information. However, the changes and/or updates that may be made by delegated officials include situations where the provider is contacted by the contractor to clarify or obtain information needed to continue processing the provider's initial CMS-855 application.

- For purposes of section 16 only, the term "managing employee" means any individual, including a general manager, business manager, or administrator, who exercises operational or managerial control over the provider, or who conducts the day-to-day operations of the provider. However, this does <u>not</u> include persons who, either under contract or through some other arrangement, manage the day-to-day operations of the provider but who are not actual W-2 employees. For instance, suppose Joe Smith is hired as an independent contractor by the provider to run its day-to-day-operations. Under the definition of "managing employee" for section 6 of the CMS-855, Smith would have to be listed. However, under the section 16 definition (as described above), Smith cannot be a delegated official because he is not an actual W-2 employee of the provider. Independent contractors are not considered "managing employees" under section 16 of the CMS-855.

  The provider is not required to submit a copy of the owning/managing individual's W-2 to verify an employment relationship, unless requested by the contractor.

- All delegated officials must be reported in section 6 of the CMS-855.

- The provider can have as many delegated officials as it wants. Conversely, the provider is not required to have any delegated officials at all. Should no delegated officials be listed, however, the authorized official(s) remains the only individual(s)

who can make changes and/or updates to the provider's status in the Medicare program.

- The effective date in PECOS for section 16 of the CMS-855 should be the date of signature.

- In order to be a delegated official, the person must have and must submit his/her social security number.

- If a delegated official is being deleted, documentation verifying that the person no longer is or qualifies as a delegated official is not required, nor is the signature of the deleted official needed.

- Delegated officials may not delegate their authority to any other individual. Only an authorized official may delegate the authority to make changes and/or updates to the provider's Medicare status.

- If the provider is submitting a change of information (e.g., new practice location, change of address, new part-owner) and the delegated official signing the form is not on file, the contractor shall ensure that: (1) the person meets the definition of a delegated official, (2) section 6 of the CMS-855 is completed for that person, and (3) an existing authorized official signs off on the addition of the delegated official. Note that the original change request and the addition of the new official shall be treated as a single change request (i.e., one change request encompasses two different actions) for purpose of enrollment processing and reporting.

- The delegated official must be a delegated official of the provider, not of an owning organization, parent company, or management company.

- If the provider submits a CMS-855 change of information, the contractor may accept the signature of a delegated official in Section 15 or 16 of the CMS-855.

4.17 – Reserved for Future Use

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

4.18 – Ambulance Attachment

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

A. Geographic Area

The applicant must list the geographic areas in which it provides services. If the supplier indicates that it provides services in more than one carrier's jurisdiction, it must submit a separate CMS-855B to each carrier.

B. Licensure Information

With respect to licensure:

- The carrier shall ensure that the supplier submits all applicable licenses and certificates.

- If the supplier performs services in multiples States within the same carrier jurisdiction, it must submit all necessary licenses and certificates for each State. Separate full CMS-855Bs are not required for each State; however, the carrier shall create separate enrollment records in PECOS for each.

- An air ambulance supplier that is enrolling in a State to which it flies in order to pick up patients (that is, a State other than where its base of operations is located) is not required to have a practice location or place of business in that State. So long as the air ambulance supplier meets all other criteria for enrollment in Medicare, the carrier for that State may not deny the supplier's enrollment application solely on the grounds that the supplier does not have a practice location in that State. (This policy only applies to air ambulance suppliers.)

C. Paramedic Intercept Information

Paramedic intercept services typically involves an arrangement between a basic life support (BLS) ambulance supplier and an advanced life support (ALS) ambulance supplier, whereby the latter provides the ALS services and the BLS supplier provides the transportation component. (See 42 CFR §410.40 for more information.) If the applicant indicates that it has such an arrangement, it must attach a copy of the agreement/contract.

D. Vehicle Information

Air ambulance suppliers must submit the following:

- A written statement signed by the president, chief executive officer, or chief operating officer that gives the name and address of the facility where the aircraft is hangared; and

- Proof that the air ambulance supplier or its leasing company possesses a valid charter flight license (FAA Part 135 Certificate) for the aircraft being used as an air ambulance. If the air medical transportation company owns the aircraft, the owner's name on the FAA Part 135 certificate must be the same as the supplier's name on the enrollment application. If the air medical transportation company leases the aircraft from another entity, a copy of the lease agreement must accompany the enrollment application. The name of the company leasing the aircraft from that other entity must be the same as the supplier's name on the enrollment application.

E. Hospital-Based Ambulances

An ambulance service that is owned and operated by a hospital need not complete a CMS-855B if:

- The ambulance services will appear on the hospital's cost-report;

- The services will only be billed to the fiscal intermediary (not to the carrier); and

- The hospital possesses all licenses required by the State or locality to operate the ambulance service.

If the hospital decides to divest itself of the ambulance service, the latter will have to complete a CMS-855B if it wishes to bill Medicare.

4.19 – IDTF Attachment

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

Sections 4.19.1 through 4.19.7 of this manual contain provider enrollment instructions regarding entities that must enroll as and bill for the technical component of diagnostic tests as an independent diagnostic testing facility (IDTF).

4.19.1 – IDTF Standards

(Rev. 234; Issued: 01-18-08; Effective: 01-01-08; Implementation: 04-22-08)

A. IDTF Standards

Consistent with 42 CFR §410.33(g), each IDTF must certify on its CMS-855B enrollment application that it meets the following standards and all other requirements:

1. Operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.

- The purpose of this standard is to ensure that suppliers are licensed in the business and specialties being provided to Medicare beneficiaries. Licenses are required by State and/or Federal agencies to make certain that guidelines and regulations are being followed to ensure businesses are furnishing quality services to Medicare beneficiaries.

- The responsibility for determining what licenses are required to operate a supplier's business is the sole responsibility of the supplier. The contractor is not responsible for notifying any supplier of what licenses are required or that any changes have occurred in the licensure requirements. No exemptions to applicable State licensing requirements are permitted, except when granted by the State.

- The contractor shall not grant billing privileges to any business not appropriately licensed as required by the appropriate State or Federal agency. If a supplier is found providing services for which it is not properly licensed, billing privileges may be revoked and appropriate recoupment actions taken.

2. Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment

application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

(**NOTE:** This 30-day requirement takes precedence over the certification in section 15 of the CMS-855B whereby the supplier agrees to notify Medicare of any changes to its enrollment data within 90 days of the effective date of the change. By signing the certification statement, the IDTF agrees to abide by all Medicare rules for its supplier type, including the 30-day rule in 42 CFR §410.33(g)(2)).

3. Maintain a physical facility on an appropriate site. For the purposes of this standard, a post office box, commercial mailbox, hotel, or motel is not considered an appropriate site. The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.

- IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.

- The requirements in 42 CFR §410.33(g)(3) take precedence over the guidelines in sections 4.4(A) and 4.4.2 of this manual pertaining to the supplier's practice location requirements.

- The physical location must have an address, including the suite identifier, which is recognized by the United States Postal Service (USPS).

4. Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—

(i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;

(ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request; and

(iii) Maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers, and provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days.

5. Maintain a primary business phone under the name of the designated business. The IDTF must have its--

(i) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.

(ii) Telephone or toll free telephone numbers available in a local directory and through directory assistance.

The requirements in 42 CFR §410.33(g)(5) take precedence over the guidelines in sections 4.4(A) and 4.4.2 of this manual pertaining to the supplier's telephone requirements.

IDTFs may not use "call forwarding" or an answering service as their primary method of receiving calls from beneficiaries during posted operating hours.

6. Have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must--

(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident; and

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations.

7. Agree not to directly solicit patients, which includes - but is not limited to - a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician, who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Nonphysician practitioners may order tests as set forth in §410.32(a)(3).

- By the signature of the authorized official in section 15 of the CMS-855B, the IDTF agrees to comply with 42 CFR §410.33(g)(7).

- The supplier is prohibited from directly contacting any individual beneficiary for the purposes of soliciting business for the IDTF. This includes contacting the individual beneficiary by telephone or via door-to-door sales.

- There is no prohibition on television, radio or Internet advertisements, mass mailings, or similar efforts to attract potential clients to an IDTF.

- If the contractor determines that an IDTF is violating this standard, the contractor should notify its DPSE contractor liaison immediately.

8. Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) The date the complaint was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

9. Openly post these standards for review by patients and the public.

10. Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.

11. Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

12. Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.

13. Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days.

14. Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must---

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours.

The IDTF must meet all of the standards in 42 CFR §410.33 – as well as all other Federal and State statutory and regulatory requirements – in order to be enrolled in, and to maintain its enrollment in, the Medicare program. Failure to meet any of the standards in 42 CFR §410.33 or any other applicable requirements will result in the denial of the supplier's CMS-855 application or, if the supplier is already enrolled in Medicare, the revocation of its Medicare billing privileges.

B. Sharing of Space and Equipment

Effective January 1, 2008, with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF does not: (i) share a practice location with another Medicare-enrolled individual or organization; (ii) lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization; or (iii) share diagnostic testing equipment

used in the initial diagnostic test with another Medicare-enrolled individual or organization. (See 42 CFR §410.33(g)(15).)

Effective January 1, 2008, if the contractor determines that an IDTF is leasing or subleasing its operations to another organization or individual, the contractor shall revoke the supplier's Medicare billing privileges.

Note that while the prohibition against the sharing of space at a practice location is effective on January 1, 2008, for newly-enrolling IDTFs (including those with applications that are still pending as of January 1, 2008), the space-sharing provision in 42 CFR §410.33(g)(15)(i) for IDTFs that are currently occupying a practice location with another Medicare-enrolled individual or organization will not become effective until January 1, 2009.

C. One Enrollment per Practice Location

The IDTFs must separately enroll each of their practice locations (with the exception of locations that are used solely as warehouses or repair facilities). This means that each enrolling IDTF can only have one practice location on its CMS-855B enrollment application; thus, if an IDTF is adding a practice location to its existing enrollment, it must submit a new, complete CMS-855B application for that location and have that location undergo a separate site visit. Also, each of the IDTF's mobile units must enroll separately. Consequently, if a fixed IDTF site also contains a mobile unit, the mobile unit must enroll separately from the fixed location.

For those IDTFs with multiple practice locations that were enrolled prior to the implementation date of this instruction, each practice location of the IDTF must meet all of applicable IDTF requirements, including those listed in this manual. Failure to comply with any of these requirements at any practice location represent the supplier's noncompliance with 42 CFR §410.33 as a whole, and will result in the revocation of its Medicare billing privileges.

D. Effective Date of Billing Privileges

Effective January 1, 2008, the filing date of the Medicare enrollment application is the date that the Medicare contractor receives a signed provider enrollment application that it is able to process to approval. (See 42 CFR 410.33(i).) The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

(1) The filing date of the Medicare enrollment application that was subsequently approved by a Medicare fee-for-service contractor; or

(2) The date the IDTF first started furnishing services at its new practice location.

A newly-enrolled IDTF, therefore, may not receive reimbursement for services furnished before the effective date of billing privileges.

The contractor shall note that if it rejects an IDTF application on or after January 1, 2008, and a new application is later submitted, the date of filing is the date the contractor receives the new enrollment application.

4.19.2 – Multi-State IDTF Entities

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

As stated in 42 CFR § 410.33(e)(1), an IDTF that operates across State boundaries must:

- Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it operates; and

- Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.

The point of the actual delivery of service means the place of service on the claim form. When the IDTF performs or administers an entire diagnostic test at the beneficiary's location, the beneficiary's location is the place of service. When one or more aspects of the diagnostic testing are performed at the IDTF, the IDTF is the place of service.

4.19.3 – Interpreting Physicians

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

The applicant shall list all physicians for whose diagnostic test interpretations it will bill. This includes physicians who are providing purchased interpretations to the IDTF (in accordance with Pub. 100-04, chapter 1, section 30.2), as well as physicians who are reassigning their benefits to the IDTF.

The carrier shall ensure and document that:

- All listed physicians are enrolled in Medicare.

- All interpreting physicians who are reassigning their benefits to the IDTF have the right to do so.

- All required CMS-855R forms have been submitted.

- The interpreting physicians listed are qualified to interpret the types of tests (codes) listed. (The carrier may need to contact another carrier to obtain this information). If the applicant does not list any interpreting physicians, the carrier need not request additional information because the applicant may not be billing for the interpretations; that is, the physicians may be billing for the interpretation themselves. However, the applicant cannot bill globally for interpreting physicians not listed.

If an interpreting physician has been recently added or changed, the new interpreting physician must have met all of the interpreting physician requirements at the time any tests were performed.

4.19.4 – Technicians

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

Each non-physician who performs the IDTF diagnostic tests must be listed. These persons are often referred to as technicians.

A. Licensure and Certification

All technicians must meet the standards of a State license or State certification at the time of the IDTF's enrollment. Carriers may not grant temporary exemptions from such requirements. Also, the IDTF must attach a copy of each technician's license or certification with its application.

B. Changes of Technicians

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

If the carrier receives notification from a technician that he/she is no longer performing tests at the IDTF, the carrier shall request from the supplier a CMS-855B change of information. If the provider did not have another technician qualified to perform the tests listed on the current application, the supplier must submit significant documentation in the form of payroll records, etc. to substantiate the performance of the test by a properly qualified technician after the date the original technician was no longer performing procedures at the IDTF.

4.19.5 – Supervising Physicians

(Rev. 234; Issued: 01-18-08; Effective: 01-01-08; Implementation: 04-22-08)

A. General Principles

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

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

Of course, not every supervising physician has to be responsible for all of these functions. For instance, one supervising physician can be responsible for the operation and calibration of equipment, while other supervising physicians can be responsible for test supervision and the qualifications of non-physician personnel. The basic requirement, however, is that all the supervisory physician functions must be properly met at each location, regardless of

the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervisory physicians at different locations. They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

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

B. Information about the Supervising Physicians

The carrier shall check and document that each supervisory physician: (1) is licensed to practice in the State(s) where the diagnostic tests he or she supervises will be performed, and (2) is Medicare enrolled. The physician(s) need not necessarily be Medicare enrolled in the State where the IDTF is enrolled.

In addition:

- The carrier shall verify the licensure for the State where the IDTF is being enrolled for each supervisory physician enrolled with another carrier, based upon the physician's license submission and discussions with the carrier where they are enrolled.

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

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

- If the carrier knows that a listed supervisory physician has been listed with several other IDTFs, the carrier shall check with the physician to determine whether the physician is still acting as supervisory physician for the previously enrolled IDTFs.

C. General, Direct, and Personal Supervision

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

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

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

D. Attestation Statement for Supervising Physicians

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

With respect to physician verification, the carrier shall:

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

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

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

4.19.6 – Desk and Site Reviews

(Rev. 246, Issued: 03-14-08, Effective: 04-14-08, Implementation: 04-14-08)

All new IDTF applications shall receive: (1) a thorough desk review, and (2) a mandatory site review prior to the carrier's enrollment of the applicant and issuance of a billing number. The general purpose of both reviews is to determine whether the information listed on Attachment 2 of the CMS-855B is correct, verifiable, and in accordance with all IDTF regulatory and manual requirements.

The contractor shall record the results of each IDTF site visit it performs on the CMS-10221 form.

A. The General Site Review Process

The site visit shall be performed by qualified employees of either the contractor or an individual or organization with which the contractor has contracted for the performance of this function.

B. Mobile Units

Mobile units are required to list their geographic service areas in section 4 of the CMS-855B. Based on the information furnished therein, the carrier shall perform a site visit via the following methods: (1) the mobile unit may visit the office of the site reviewer, or (2) the site reviewer may obtain an advance schedule of the locations the IDTF will be visiting and conduct the site visit at one of those locations.

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

- How they will perform these types of supervision on a mobile basis;

- What their responsibilities are;

- That a patient's physician who is performing direct or personal supervision for the IDTF on their patient should be aware of the prohibition concerning physician self-referral for testing (in particular this concerns potentially illegal compensation to the supervisory physician from the IDTF).

C. Changes of Information

Addition of Codes

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

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

If the enrolled IDTF originally listed only general supervision codes and was only reviewed for only general supervision tests, and now wants to perform tests that require direct or personal supervision, the carrier shall promptly suspend all payments for all codes other than those requiring general supervision. A new site visit is required. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment), and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

4.19.7 – Special Procedures and Supplier Types

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

A. Diagnostic Mammography

If an IDTF performs diagnostic mammography services, it must have a Food and Drug Administration (FDA) certification to perform the mammography. However, an entity that only performs diagnostic mammography services should not be enrolled as an IDTF. Rather, it should be separately enrolled as a mammography center.

B. CLIA Tests

An IDTF may not perform or bill for CLIA tests. However, an entity with one tax identification number (TIN) may own both an IDTF and an independent CLIA laboratory. In such a situation, they should be separately enrolled and advised to bill separately. The carrier shall also advise its claims unit to ensure that the CLIA codes are not being billed under the IDTF provider number.

4.20 – Processing CMS-855R Applications

(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

A CMS-855R application must be completed for any individual who will: (1) reassign his/her benefits to an eligible entity, or (2) terminate an existing reassignment.

If the individual who wants to reassign his or her benefits is not enrolled in Medicare, the person must complete a CMS-855I as well as the CMS-855R. (The CMS-855I and CMS-855R can be submitted concurrently.) Moreover, if the entity to which the person's benefits will be reassigned is not enrolled in Medicare, the organization must complete a CMS-855B. (See section 5.4 for additional instructions regarding the joint processing of CMS-855Rs, CMS-855Bs, and CMS-855Is.)

Note that benefits are reassigned to a supplier, not to the practice location(s) of the supplier. As such, the carrier shall not require each practitioner in a group to submit a CMS-855R each time the group adds a practice location.

In addition:

- An individual can receive reassigned benefits. The most common example of this is a physician or practitioner who reassigns his/her benefits to a physician who is either: (1) a sole proprietor, or (2) the sole owner of an entity listed in section 4A of the CMS-855I. Here, the only forms that will be required are the CMS-855R, and separate CMS-855Is from the reassignor and the reassignee. (No CMS-855B is implicated.) The reassignee himself/herself must sign section 4B of the CMS-855R, as there is no authorized or delegated official involved.

- The carrier shall follow the instructions in Pub. 100-04, chapter 1, section 30.2 to ensure that a group or person is eligible to receive reassigned benefits.

- If the individual is initiating a reassignment, both he/she and the group's authorized or delegated official must sign section 4 of the CMS-855R. If either of the two signatures is missing, the carrier may return the application per section 3.2 of this manual.

- If the person (or group) is terminating a reassignment, either party may sign section 4 of the CMS-855R; obtaining both signatures is not required. If no signatures are present, the carrier may return the application per section 3.2 of this manual.

- A CMS-855R is required to terminate a reassignment. The termination cannot be done via the CMS-855I.

- The authorized or delegated official who signs section 4 of the CMS-855R must be someone who is currently on file with the carrier as such. If this is a new enrollment, with a joint submission of the CMS-855B, CMS-855I, and CMS-855R, the person must be listed on the CMS-855B as an authorized or delegated official.

- The effective date of a reassignment is the date on which the individual began or will begin rendering services with the reassignee.

- The carrier need not verify whether the reassigning individual is a W-2 employee or a 1099 contractor.

- There may be situations where a CMS-855R is submitted and the group practice is already enrolled in Medicare. However, the authorized official is not on file. In this case, the carrier shall return the CMS-855R, with a request that the group submit a CMS-855B change request adding the new authorized official.

- In situations where the supplier is both adding and terminating a reassignment, each transaction must be reported on a separate CMS-855R. The same CMS-855R cannot be used for both transactions.

- In situations where an individual is reassigning benefits to a person/entity, both the reassignor and the reassignee must be enrolled with the same carrier.

4.21 – National Provider Identifier (NPI)

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

A. Submission of NPI

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

notification, and providers may be able to furnish NPI Registry Details Pages more quickly than copies of their NPI notifications.

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

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

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

B. Additional NPI Information

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

C. Subparts - General

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

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

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

D. Medicare Subparts Paper - Text

MEDICARE EXPECTATIONS ON DETERMINATION OF SUBPARTS

BY MEDICARE ORGANIZATION HEALTH CARE PROVIDERS WHO ARE COVERED ENTITIES UNDER HIPAA

January 2006

Purpose of this Paper

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

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

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

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

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

This paper is not intended to serve as official HHS guidance to the industry in determining subparts for any covered health care providers other than those who are organizations and are enrolled in the Medicare program. This paper does not address health care providers who are enrolled in Medicare as individual practitioners. These practitioners are Individuals (such as physicians, physician assistants, nurse practitioners, and others, including health care providers who are sole proprietors). In terms of NPI assignment, an Individual is an Entity Type 1 (Individual) and is eligible for a single NPI. As Individuals,

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

these health care providers cannot be subparts and cannot designate subparts. A sole proprietorship is a form of business in which one person owns all of the assets of the business and the sole proprietor is solely liable for all of the debts of the business. There is no difference between a sole proprietor and a sole proprietorship. In terms of NPI assignment, a sole proprietor/sole proprietorship is an Entity Type 1 (Individual) and is eligible for a single NPI. As an Individual, a sole proprietor/sole proprietorship cannot have subparts and cannot designate subparts.

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

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

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

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

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

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

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

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

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

- Federal statutes or regulations pertaining to requirements for the unique identification of enrolled Medicare providers may relate to entities that could be considered subparts according to the discussion in the NPI Final Rule. Medicare

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

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

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

Medicare Statutes, Regulations, Manuals

The Social Security Act (sections 1814, 1815, 1819, 1834, 1861, 1865, 1866, and 1891) and Federal regulations (including those at 42 CFR 400.202, 400.203, 403.720, 405.2100, 409.100, 410.2, 412.20, 416.1, 418.1, 424, 482.1, 482.60, 482.66, 483, 484, 485, 486, 489, 491, and 493.12) establish, among other things, the Conditions for Participation for Medicare providers and set requirements by which Medicare enrolls providers, requires cost reports, calculates reimbursement, and makes payments to its providers. These Medicare statutory and regulatory requirements are further clarified in various Medicare operating manuals, such as the State Operations Manual and the Program Integrity Manual, in which requirements and policies concerning the assignment of unique identification numbers, for billing and other purposes, are stated.

Medicare Organization Providers and Subparts: Certified Providers and Suppliers

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

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

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

- Providers apply for Medicare enrollment by completing a CMS-855A.
- Most providers are surveyed and certified by the States3 prior to being approved as Medicare providers.
- Providers have in effect an agreement to participate in Medicare.4
- Providers include, but are not limited to: skilled nursing facilities, hospitals5, critical access hospitals, home health agencies, rehabilitation agencies (outpatient physical therapy, speech therapy), comprehensive outpatient rehabilitation facilities, hospices, community mental health centers, religious non-medical health care institutions.
- Providers are assigned OSCAR numbers to use to identify themselves in Medicare claims and other transactions, including cost reports for those providers that are required to file Medicare cost reports.
- In general, each entity that is surveyed and certified by a State is separately enrolled in Medicare and is considered a Medicare provider. (An exception involves home health agency branches. The branches are not separately enrolled Medicare providers.) In many cases, the enrolled provider is not itself a separate legal entity; i.e., it is an entity that is a part of an enrolled provider that is a legal entity and is, for purposes of the NPI Final Rule, considered to be a subpart.

Certified Suppliers, most of which bill Medicare carriers:

- Certified suppliers apply for Medicare enrollment by completing a CMS-855B.
- Certified suppliers include ambulatory surgical centers, portable x-ray suppliers, independent clinical labs (CLIA labs), rural health centers, and federally qualified health centers.
- Most certified suppliers bill the carriers; however, rural health centers and federally qualified health centers bill the fiscal intermediaries.
- Certified suppliers are typically surveyed and certified by the States prior to being approved for enrollment as Medicare certified suppliers. (For CLIA labs, each practice location at which lab tests are performed must obtain a separate CLIA Certificate for that location, though there are a few exceptions to this.)
- Certified suppliers may have in effect an agreement to participate in Medicare.
- Certified suppliers are assigned OSCAR numbers for purposes of identification within Medicare processes. However, the carriers assign unique identification numbers to certified suppliers for billing purposes. (For CLIA labs, a CLIA Number is typically assigned to each practice location for which a CLIA certificate is issued. A CLIA Number may not be used to identify a clinical laboratory as a "health care provider" in HIPAA standard transactions. The CLIA Number has no relation to the Medicare billing number.)

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

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

5 Hospitals bill carriers for certain types of services.

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

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

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

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

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

Medicare Organization Providers and Subparts: Supplier Groups and Supplier Organizations

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

- Supplier groups and supplier organizations apply for Medicare enrollment by completing a CMS-855B.
- Supplier groups and supplier organizations bill Medicare Part B carriers.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Final Notes About NPIs

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

Enrolled organization health care providers or subparts who bill more than one type of Medicare contractor: Generally, the type of service being reported on a Medicare claim determines the type of Medicare contractor who processes the claim. Medicare will expect an enrolled organization health care provider or subpart to use a single (the same) NPI when billing more than one type (fiscal intermediary, carrier, RHHI, DMERC) of Medicare contractor. However, in certain situations, Medicare requires that the organization health care provider (or possibly even a subpart) enroll in Medicare as more

than one type of provider. For example, an ambulatory surgical center enrolls in Medicare as a certified supplier and bills a carrier. If the ambulatory surgical center also sells durable medical equipment, it must also enroll in Medicare as a Supplier of DME and bill a DMERC. This ambulatory surgical center would obtain a single NPI and use it to bill the fiscal intermediary and the DMERC. Medicare expects that this ambulatory surgical center would report two different Taxonomies when it applies for its NPI: (1) that of ambulatory health care facility—clinic/center--ambulatory surgical (261QA1903X) and (2) that of suppliers—durable medical equipment & medical supplies (332B00000X) **or** the appropriate sub-specialization under the 332B00000X specialization.

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

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

Medicare will, of course, use NPIs to identify health care providers and subparts in HIPAA standard transactions. (NPI Final Rule, page 3469: section 162.412(a): "A health plan must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.") Medicare will ensure that the NPIs it receives in HIPAA standard transactions are valid6. Medicare will reject HIPAA standard transactions that contain invalid NPIs. Valid NPIs, however, like the provider identifiers used today, must be "known" to Medicare. Medicare is not permitted to make payments for services rendered by non-Medicare providers7, nor is it permitted to reimburse providers who are not enrolled in the Medicare program. Medicare will return, with appropriate messages, any HIPAA standard transactions containing valid but unrecognizable NPIs.

5 – Verification and Validation

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

Unless stated otherwise in this manual, the instructions in sections 5 through 5.3 apply to the CMS-855A, the CMS-855B and the CMS-855I. These instructions are in addition to, and not in lieu of, all other instructions in this manual.

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

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

5.1 – General Verification Principles

(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

Unless stated otherwise in this manual, the contractor shall comply with the following principles when processing CMS-855 enrollment applications:

- **Completeness:** The contractor shall ensure that the provider completed all required data elements on the CMS-855 (including all effective dates) and that all supporting documentation has been furnished. The contractor shall also ensure that the provider completed the application in accordance with the instructions on the CMS-855 form. (Note that the instructions on the CMS-855 shall be read and applied in addition to, and not in lieu of, the instructions in this manual.)

- **Written Data Elements:** Unless stated otherwise in this manual or other CMS directive, the provider shall complete all required data elements on the CMS-855 via the application itself. The contractor shall not accept any required information captured on the CMS-855 via telephone, letterhead, e-mail, etc., regardless of the relative materiality of the data element in question.

- **Validation:** The contractor shall verify and validate all information furnished by the provider on the CMS-855. (See section 5.2 below for more information.)

- **Photocopying Pages -** The contractor may accept photocopied pages in any CMS-855 application it receives so long as the application contains an original signature. For example, suppose a corporation wants to enroll five medical clinics it owns. The section 5 data on the CMS-855B is exactly the same for all five clinics. The contractor may accept photocopied section 5 pages for these providers. However, original signatures must be furnished in section 15 of each application.

- **White-Out & Highlighting** - The contractor shall not write on, or highlight any part of, the original CMS-855 application or any supplementary pages the applicant submits. Provider usage of white-out is acceptable, although the contractor should contact the applicant to resolve any ambiguities. In addition, the contractor must determine whether the amount of white-out used on a particular application is within reason. For instance, if an entire application page is whited-out, the contractor should request that the page be resubmitted.

5.2 – Verification of Data

(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

The general purpose of the verification process is to determine if any of the data furnished on the CMS-855 conflicts with Qualifier.net, supporting documentation, or any other information. The contractor may begin the verification process at any time, including during the prescreening phase.

A. Concurrent Reviews

If the contractor receives multiple CMS-855s for related entities, it can perform concurrent reviews of similar data. For instance, suppose a chain home office submits initial CMS-855A applications for four of its chain providers. The ownership information (sections 5 and 6) and chain home office data (section 7) is the same for all four providers. The contractor need only verify the ownership and home office data once; it need not do it four times – once for each provider. However, the contractor shall document in each provider's file that a single verification check was made for all four applications.

For purposes of this requirement: (1) there must be some sort of organizational, employment, or other business relationship between the entities, and (2) the applications must have been submitted simultaneously – or at least within a few weeks of each other. As an illustration, assume that Group Practice A submits an initial CMS-855B on January 1. Group Practice B submits one on October 1. Section 6 indicates that Joe Smith is a co-owner of both practices, though both entities have many other owners that are not similar. In this case, the contractor must verify Mr. Smith's data in both January and October. It cannot use the January verification and apply it to Group B's application because: (1) the applications were submitted nine months apart, and (2) there is no evidence that the entities are related. (On the other hand, a CMS-855I, CMS-855B, and CMS-855R enrollment package would probably meet the two criteria above.)

B. Qualifier.net

Unless stated otherwise in this manual or in other CMS directives (e.g., JSMs), the contractor shall verify all data furnished on the CMS-855 using Qualifier.net. Such data includes, but is not limited to:

- Adverse legal history of the provider and all entities and persons listed in sections 5 and 6 of the CMS-855.

- For non-certified suppliers (e.g., physician clinics), all practice locations and phone numbers listed in section 4 of the CMS-855.

- Legal business names and employer identification numbers of all entities listed in section 5 of the CMS-855. (Social security numbers and dates of birth are validated by PECOS – and reviewed against Qualifier.net for discrepancies – via the procedures outlined in section 4.2.1 of this manual.)

- Billing agency information (e.g., legal business name) listed in section 8 of the CMS-855.

- HHA staffing agencies (e.g., legal business name) listed in section 12 of the CMS-855A.

If there is a discrepancy between the information furnished by the applicant and the information on Qualifier.net, the contractor shall use alternative means to confirm the data in question. Examples of such other means include, but are not limited to:

- **Phone number of provider's practice location or billing agency** - Calling the number listed on the application directly; checking the Yellow Pages.

- **Provider's practice location** - Checking the Yellow Pages; conducting a site visit.

- **Provider's "doing business as" name** - Reviewing the IRS CP-575, articles of incorporation, State Web site, etc.

- **Legal business name or tax identification number of an entity listed in section 5 of the CMS-855** – Asking for a copy of the entity's CP-575.

If the discrepancy still cannot be resolved, the contractor shall request clarifying information from the provider to help resolve the unverifiable data.

Any information on the CMS-855 that is verified via supporting documentation (e.g., certifications, licenses) need not also be verified through Qualifier.net. For instance, suppose a nurse practitioner furnishes her licensure information in section 2 of the CMS-855I and includes a copy of the license as supporting documentation. The carrier need not verify the licensure data against Qualifier.net, as it has already been verified via the documentation. Other examples of data verifiable via documentation include:

- National Provider Identifier (NPI)

- Organization type listed in section 2 of the CMS-855 (e.g., corporation, limited liability company, non-profit status)

- Legal business name and tax identification number of the provider (e.g., IRS CP-575)

- Education listed in section 2 of the CMS-855I

In short, all information furnished on the CMS-855 must be verified via Qualifier.net, unless it is data: (1) exempted from this requirement in this manual or other CMS directive, or (2) that is verifiable via documentation submitted by the provider.

In addition:

- All Qualifier.net executive summaries are valid for 120 days.

- The contractor is not required to run additional Qualifier.net searches on "AKA" names that appear on Qualifier.net.

- There may be instances where CMS directs contractors to verify certain data via the Medicare Exclusion Database and/or the GSA Excluded Parties List System, rather than through Qualifier.net. If a potential hit is found on the GSA List and the contractor needs to make a positive identity, it shall contact the agency that took the action for further information; based on this data, the contractor shall determine

whether it is the same person. If a positive match still cannot be made, the contractor may approve the application.

- The contractor is not required to use the Fraud Investigation Database (FID) when processing incoming enrollment applications, including changes of information. If the contractor chooses to use the FID on a particular provider, owner, etc., and the person/entity appears on the FID, the contractor should continue to process the application. However, it should refer the matter to the PSC for guidance.

- In some instances, a contractor may need to contact another Medicare contractor for information regarding the provider. The latter contractor shall respond to the former contractor's request within three business days absent extenuating circumstances.

5.3 – Requesting and Receiving Clarifying Information

(Rev. 269: Issued: 09-19-08; Effective/Implementation Date: 10-20-08)

A. Requesting Clarifying Data

After the completion of the pre-screening phase, if the contractor determines that it needs clarifying information from the provider, the contractor shall send a letter to the provider – preferably via e-mail or fax - that contains, at a minimum, the elements listed below:

1. A list of all data to be clarified and documentation to be submitted;

2. A request that the provider submit the clarifying data within a contractor-specified timeframe (i.e., the contractor can use whatever timeframe it wants, so long as it is within reason);

3. The name and phone number of a contact person at the contractor site;

4. The CMS Web site at which the CMS-855 forms can be found. The contractor shall instruct the provider to: (1) print out the page(s) containing the data in question; (2) enter the data on the blank page; (3) sign and date a new, blank certification statement; and (4) send it to the contractor. (As an alternative, the contractor can fax the blank page(s) and certification statement to the provider.) The provider need not furnish its initials next to the data element(s) in question.

5. A fax number and mailing address to which the data or documentation can be sent.

(The contractor can forgo items 4 and 5 above if resolution of the issue will not involve changes to the CMS-855.)

If the provider fails to furnish <u>all</u> of the requested clarifications and documentation within the timeframes specified in 42 CFR §424.525(a) and section 3.1 of this chapter, the contractor may reject the application. It shall notify the provider via letter or e-mail that the application is being rejected, the reason(s) for the rejection, and how to reapply. The

contractor is free to keep the original application on file after the rejection. If the provider requests a copy of its application, the contractor may fax it to the provider.

In addition:

- **Only One Request Needed** - The "clarification letter" is the only request for clarification that the contractor must make. Obviously, the contractor should respond to any of the provider's telephone calls, e-mails, etc., resulting from the clarification letter. However, the contractor need not – on its own volition – make an additional request for clarification unless it uncovers missing information that it failed to previously spot.

  To the maximum extent possible, the contractor should avoid contacting a provider for clarifying information until it has attempted to verify all of the data on the application. This will obviate the need to contact the provider each time the contractor discovers a discrepancy.

- **Resubmission after Rejection** – If the provider's application is rejected, the provider must complete and submit a new CMS-855 and all supporting documentation.

- **Appeals** – The provider may not appeal a rejection of its enrollment application.

- **Policy Application –** Unless stated otherwise in this manual, the policies enunciated in this section 5.3 apply to all CMS-855 applications identified in sections 2.1 and 2.2 of this chapter (e.g., changes of information, reassignments).

- **Good-Faith Effort by Provider** – If the provider fails to submit the requested clarification within the timeframes specified in 42 CFR §424.525(a) and section 3.1 of this chapter but appears to be making a good-faith effort to do so, the contractor may at its discretion continue processing the application.

- **Incomplete Responses** – The provider must furnish <u>all</u> clarifying data requested by the contractor within the applicable timeframes. Whether the provider indeed furnished all the information is a decision resting solely with the contractor.

  Moreover, if the provider furnishes some, but not all, of the requested data within the applicable time period, the contractor is not required to contact the provider again to request the rest of the information. For instance, suppose the contractor requested clarification of certain items in Sections 3, 4 and 5 of the CMS-855A. Clarification was only furnished with respect to the Section 3 information. The contractor has the discretion to wait until the expiration of the 30-day period and then reject the application; however, as stated above, it should take into account any good-faith efforts of the provider to furnish the information.

- **Rejections vs. Denials** – If the provider failed to fully comply with the contractor's request for additional or clarifying information, there are two possible outcomes:

- Rejection of the application under 42 CFR § 424.525(a), due to the provider's failure to furnish the missing data or documentation, or

- Denial of the application if one of the denial reasons in section 6.2 of this chapter is implicated.

  If the contractor is faced with this situation, it is free to contact its DPSE contractor liaison for guidance prior to making its decision to reject or deny.

- **Commencement of Timeframe** – For information requests under 42 CFR §424.525(a)(1), the 30-day clock described above commences when the contractor mails, faxes, or e-mails the letter.

B. Relationship to the Pre-Screening Process

The contractor may begin the verification process during the pre-screening phase described in section 3.1 of this chapter. If the contractor, in doing so, uncovers data requiring further development (e.g., problems verifying the SSN of a managing employee; Qualifier.net indicates that a person may be using two SSNs), the contractor may include this request for clarifying information within the pre-screening letter. This, in turn, means that the provider must furnish: (1) all missing data and documentation requested in the pre-screening letter within the applicable timeframe specified in 42 CFR §424.525(a), and (2) all clarifications asked for in the contractor's request for clarifying information within the applicable timeframe specified in 42 CFR § 424.525(a).

EXAMPLE 1: The provider submits a CMS-855B on March 1. The contractor pre-screens the application and finds that all data elements have been completed and all required documentation submitted. Hence, no pre-screening letter is needed. Since several SSN discrepancies were found during the validation process, however, the contractor sent a request for clarifying information to the provider on March 20. In this scenario, the provider must furnish all of the requested data/clarifications by April 19.

EXAMPLE 2: The provider submits a CMS-855B on March 1. The contractor completed its pre-screening of the application on March 7 and found that three relatively minor data elements were missing, thus triggering the need for a pre-screening letter to be sent no later than March 16. The contractor decides to begin the verification process on March 8 and completes validation on March 13, finding two SSN discrepancies. The contractor thus sends out a single letter on March 14 addressing both the missing data elements (pre-screening) and the SSN issues (request for clarifying information). In this situation, the provider must furnish both the missing data elements and the requested clarification by April 13.

Now suppose that the contractor had not completed the entire verification process by March 16. In its pre-screening letter, the contractor identified the missing information and requested clarification of the two SSN discrepancies. The contractor completed the validation process on April 2; that same day, the contractor sent a request for additional

information to the provider regarding two EIN discrepancies. In this scenario, the provider must furnish the missing information and SSN clarifications by April 13. Even if it does so, it must still provide the EIN clarifications by May 1 (or 30 days after the April 2 letter was sent). If the provider fails to comply with the March 14 letter, the contractor may reject the application on April 13 without waiting to see if the provider can furnish the requested EIN clarifications.

C. Receiving Clarifying Information

Unless stated otherwise in this manual, any data collected on the CMS-855 for which the contractor requested clarification must be furnished by the provider on the applicable page(s) of the CMS-855. A newly-signed and dated certification statement must also be submitted. Note that this certification statement must be separate and distinct from the previous certification statement; that is, the provider cannot simply add its signature to the existing statement. It must sign a separate one.

The contractor can receive the clarifying information, including the new certification statement, via fax. Upon receipt, the contractor shall verify the new data. (The contractor need not re-verify the existing data on the application.)

D. Unsolicited Submission of Clarifying Information

Any new or changed information submitted by an applicant prior to the date the contractor finishes processing the application is considered to be an update to the original application. (It is immaterial whether the data was requested by the contractor.) The data is not considered to be a separate change of information. For instance, suppose the provider submitted an initial enrollment application to the fiscal intermediary. On the 58th day – one day before the intermediary planned to make its recommendation for approval – the provider on its own volition submitted updates to its section 6 data. The intermediary must process this information prior to making its recommendation, even if it takes the application beyond the 30-day limit. The contractor cannot make its recommendation as planned on the 59th day and simply process the section 6 data as a change of information after the fact. Of course, if the late-arriving data takes the timeframe over 60 days, the contractor should document the file and explain the special circumstances involved.

E. Site Visits

In addition to the site visits required for all IDTF, DME and CMHC applicants (which have their own site visit instructions), the contractor may conduct site visits: (1) of other applicants seeking enrollment in the Medicare program, or (2) to verify the status of currently enrolled providers. Such site visits should be unannounced; the contractor representatives shall always conduct themselves in a professional manner, disclosing to the provider appropriate identifying credentials and explaining the purpose of the visit. The contractor shall maintain records of all site visits to support decisions regarding the denial or revocation of a Medicare billing number.

5.4 - Special Verification Procedures for CMS-855B, CMS-855I and CMS-855R Applications

(Rev. 230; Issued: 12-14-07; Effective: 01-01-08; Implementation: 01-07-08)

A. Reassignment Packages

In situations where an entity wants to simultaneously enroll a group practice, the individual practitioners therein, and to reassign benefits accordingly, the contractor shall adhere to the instructions contained in the scenarios below. During the pre-screening process, the contractor shall examine the incoming forms to see if a reassignment may be involved.

- Only the CMS-855Rs are submitted - If a brand new group with new practitioners is attempting to enroll but submits only the CMS-855Rs for its group members (i.e., neither the initial CMS-855B nor the initial CMS-855Is were submitted), the contractor may return the applications if the group fails to submit all of the other forms necessary to process the enrollment package within 15 calendar days after receipt of the CMS-855Rs.

- Only the CMS-855B is submitted - If a brand new group wants to enroll but submits only the CMS-855B without attaching the CMS-855Is and CMS-855Rs for its group members (i.e., the CMS-855B arrives alone, without the other forms), the contractor may return the application if the group fails to submit all of the other forms necessary to process the enrollment package within 15 calendar days after receipt of the CMS-855B.

  - Only the CMS-855I is submitted – Suppose an individual: (1) submits only the CMS-855I without attaching the CMS-855B and CMS-855R (i.e., the CMS-855I arrives alone, without the other forms), and (2) indicates on the CMS-855I that he/she will be reassigning all of his/her benefits to the group practice. In this scenario, the contractor may return the application if the applicant fails to submit all of the other forms necessary to process the enrollment package within 15 calendar days after receipt of the CMS-855I.

In each of the aforementioned situations, the contractor can also return all other forms that were submitted as part of the incomplete enrollment package. For instance, suppose an individual reassigning all of his/her benefits to a group submits his/her CMS-855I on Day 1. The CMS-855B is submitted on Day 15, but no CMS-855R arrives. The contractor can return both the CMS-855B and the CMS-855I. (Note also that the 15-day clock described above begins when the contractor first received part of the reassignment package; in our example above, the clock started when the contractor received the CMS-855I.)

When applications are returned as described in this section 5.4, the contractor shall follow the provisions of section 3.2 of this manual in terms of notification to the provider, no creation of an L & T record in PECOS, etc. The timeliness clocks for these applications only begin when and if the entire enrollment package is submitted within the initial 15-day period.

In situations where an individual will be reassigning part (but not all) of his/her benefits to a group, the contractor shall not return the CMS-855I application if the CMS-855R and the CMS-855B do not arrive. Rather, the contractor shall begin processing the individual's CMS-855I with respect to the practice location for the individual's practice.

B. Other Items

The contractor shall note the following:

- If an individual is joining a group that was enrolled prior to the CMS-855B (i.e., the group never completed a CMS-855), the contractor shall obtain a CMS-855B from the group. During this timeframe, the contractor shall not withhold any payment from the group. Once the group's application is received, the contractor shall add the new reassignment; if the CMS-855R was not submitted, the contractor shall secure it from the supplier.

- If a supplier is changing its tax identification number, the transaction shall be treated as a brand new enrollment as opposed to a change of information. Consequently, the supplier must complete a full CMS-855 application and a new enrollment record must be created in PECOS. (This does not apply to ASCs and portable x-ray suppliers. These entities can submit a TIN change as a change of information unless a CHOW is involved. If the latter is the case, the instructions in subsection (C) of section 5.6 of this manual should be followed.)

- If the supplier is adding or changing a practice location and the new location is in another State within the contractor's jurisdiction, the contractor shall ensure that the supplier furnishes all applicable licenses, certifications, etc., for that State. A complete CMS-855 application for the new State is not required, though the contractor shall create a new enrollment record in PECOS for the new State.

- All members of a group practice must be entered into PECOS.

5.5 – Special Verification Procedures for CMS-855A Applications
(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

Unless otherwise stated:

- All references to the "RO" in sections 5.5.1 through 5.5.4 of this manual refer to the RO's survey & certification staff.

- For purposes of sections 5.5.1 through 5.5.7 of this manual, the term "intermediary" includes Medicare Administrative Contractors (MACs).

5.5.1 - Jurisdictional Issues
(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

A. Audit and Claims Intermediaries

For purposes of enrollment, there are generally two categories of intermediaries: audit intermediaries and claims intermediaries. The audit intermediary enrolls the provider, conducts audits, etc. The claims intermediary pays the provider's claims. In most cases, the provider's audit intermediary and claims intermediary will be the same. On occasion, however, they will be different; this often happens with provider-based entities, whereby the provider's enrollment application will be processed by the parent provider's intermediary (audit intermediary) and its claims will be paid by a different intermediary (claims intermediary).

In situations where the audit and claims intermediaries differ, the audit intermediary shall process all changes of information, including all EFT changes. The audit intermediary shall notify the applicant during the initial enrollment process that all future changes of information must be sent to the audit intermediary, not the claims intermediary. (Quite often, a provider will submit an EFT change request to the claims intermediary because the latter processes the provider's claims.) If the provider inadvertently sends a change of information request (or, for that matter, an initial enrollment) to the claims intermediary, the latter shall return the application per section 3.2 of this manual.

Once the audit intermediary finishes processing the initial enrollment application, it shall fax a copy of the application to the claims intermediary. It shall also fax copies of any future changes of information involving payment issues (e.g., EFT) to the claims intermediary once it has finished processing said change.

Moreover, in situations where the audit intermediary is different from the claims intermediary, the audit intermediary shall fax a copy of all tie-in and tie-out notices it receives to the claims intermediary. For instance, if the audit intermediary receives a tie-in notice signifying that a provider's request for Medicare participation has been approved, the audit intermediary shall send a copy to the claims intermediary. This is to ensure that the claims intermediary is fully aware of the RO's action, as some ROs may only send copies of tie-in and tie-out notices to the audit intermediary. If the audit intermediary chooses, it can simply contact the claims intermediary by phone or e-mail and ask if the latter received the tie-in notice.

Again, it is imperative that audit and claims intermediaries effectively communicate and coordinate with each other in all payment-related and program integrity matters involving the provider.

B. Provider Nomination

With respect to issues regarding provider nomination and changes of intermediaries, the contractor shall adhere to the instructions in Publication 100-04, chapter 1, sections 20 through 20.5.1, and CMS change request 5720.

If an intermediary receives a request from a provider to change its existing intermediary, it shall refer the provider to the RO contact person responsible for intermediary assignments.

5.5.2 - Changes of Ownership (CHOWs)
(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

Unless specified otherwise, the term "CHOW" - as used in sections 5.5.2 through 5.5.2.5 of this manual - includes CHOWs, acquisitions/mergers and consolidations.

Changes of ownership (CHOWs) are officially defined and governed by 42 CFR §489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). The ROs make the final determination as to whether a CHOW has occurred (unless this function has been delegated).

5.5.2.1 - Definitions
(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

For purposes of provider enrollment only, there are three main categories of CHOWs captured on the CMS-855A application:

- **"Standard" CHOW** – This occurs when the CCN number and provider agreement of a provider are transferred to another entity as a result of the latter's purchase of the provider. To illustrate, suppose Entity A is enrolled in Medicare, but Entity B is not. B acquires A. Assuming all regulatory requirements are met, A's provider agreement and CCN number will transfer to B.

This is the most frequently encountered change of ownership scenario. Even though it is technically an acquisition (i.e., B bought/acquired A) under §489.18, this situation falls under the "CHOW" category – as opposed to the "Acquisition/Merger" category – on the CMS-855A.

- **Acquisition/Merger** - In general, this occurs when two or more Medicare-enrolled entities combine, leaving only one remaining CCN number and provider agreement. For instance, Entity A and Entity B are both enrolled in Medicare, each with its own CCN number and provider agreement. The two entities decide to merge. Since Entity B's CCN number and provider agreement will be eliminated (leaving only Entity A's CCN number and provider agreement), a §489.18 merger has occurred.

If the acquisition results in an existing provider having new owners but keeping its existing provider number, the applicant should check the CHOW box in section 1A of the CMS-855A.

Unlike the new owner in a CHOW or consolidation, the new owner in an acquisition/merger need not complete the entire CMS-855A. This is because the new owner is already enrolled in Medicare; as such, the provider being acquired should simply be reported as a practice location in section 4 of the new owner's CMS-855A.

- **Consolidations** - This occurs when the merger of two or more Medicare-enrolled entities results in the creation of a brand new entity. To illustrate, if Entities A and B decide to combine and, in the process, create a new entity (Entity C), the CCN numbers and provider agreements of both A and B will be eliminated; Entity C will have its own CCN number and provider agreement.

  Note the difference between acquisitions/mergers and consolidations. In an acquisition/merger, when A and B combine there is one surviving entity. In a consolidation, however, when A and B combine there are no surviving entities; rather, a new entity is created – Entity C.

5.5.2.2 - Determining Whether a CHOW Has Occurred

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

In examining whether: (1) a CHOW has occurred, and/or (2) the new owner will be accepting assignment of the Medicare assets and liabilities of the old owner, the intermediary shall perform all necessary research – including reviewing the sales agreement, contacting the provider(s) to request clarification of the sales agreement, etc. – before referring the matter to the RO for guidance. Such referrals to the RO should only be made if the intermediary is truly unsure as to whether a CHOW has taken place and should not be made as a matter of course. (An RO CHOW determination is usually not required prior to the intermediary making its recommendation.) Note that a provider may undergo a financial or administrative change that it considers to be a CHOW, but does not meet the regulatory definition identified in §489.18.

While a CHOW is usually accompanied by a TIN change, this is not always the case. There may be a few instances where the TIN will remain the same. Conversely, there may be some cases where a provider is changing its TIN but not its ownership. In short, while a change of TIN (or lack thereof) is evidence that a CHOW has or has not occurred, it is not the most important factor; rather, the change in the provider's ownership arrangement is. Hence, it is imperative that the intermediary review the sales agreement closely, as this will give the best indication as to whether a CHOW has occurred.

If the provider claims that the transaction in question is a stock transfer and not a CHOW, the intermediary reserves the right to request any information from the provider to verify this (e.g., copy of the stock transfer agreement).

With respect to PECOS, suppose a request for a CHOW comes in and the intermediary enters the data into PECOS as a CHOW. It turns out, after additional research, that the transaction was not a CHOW (e.g., was a stock transfer; was an initial enrollment because the new owner refused to accept the Medicare liabilities). If the intermediary cannot change the transaction type in PECOS, it can leave the record in CHOW status but should note in the provider's file that the transaction was not a CHOW.

5.5.2.3 - Processing CHOW Applications

(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

Unless stated otherwise in this *chapter*, the intermediary shall ensure that all applicable sections of the CMS-855A for both the old and new owners are completed in accordance with the instructions on the CMS-855A.

A. Old Owners

The old owner's CMS-855A CHOW application does not require a recommendation for approval or denial; any recommendations will be based upon the CHOW application received from the new owner.

If the old owner's CMS-855A is available at the time of review, the intermediary shall examine the information thereon against the new owner's CMS-855A to ensure consistency (e.g., same names). If the old owner's CMS-855A has not been received, the intermediary shall contact the old owner and request it. However, the intermediary may begin processing the new owner's application without waiting for the arrival of the old owner's application; it may also make its recommendation to the State agency without having received the old owner's CMS-855A. The intermediary, of course, shall not make a recommendation for approval unless the new owner has checked on the form that it will assume the provider agreement and that the terms of the sales agreement indicate as such.

If a certification statement is not on file for the old owner, the intermediary shall request that section 6 be completed for the individual who is signing the certification statement. The intermediary shall review this individual against all applicable databases, including Qualifier.net.

Note that an old owner's CMS-855A CHOW application is essentially the equivalent of a CMS-855 voluntary termination submission, as the seller is voluntarily leaving the Medicare program. As such, the contractor shall not require the seller to submit a separate CMS-855 voluntary termination along with its CMS-855A CHOW application.

B. New Owners

If a CMS-855A is not received from the new owner within 14 calendar days of receipt of the old owner's CMS-855A, the intermediary shall contact the new owner. If the new owner fails to: (1) submit a CMS-855A and (2) indicate that it accepts assignment of the provider agreement, within 30 calendar days after the intermediary contacted it, the latter shall stop payments unless the sale has not yet taken place per the terms of the sales agreement. Payments to the provider can resume once this information is received and the intermediary ascertains that the provider accepts assignment.

C. Order of Processing

To the maximum extent practicable, CMS-855A applications from the old and new owners in a CHOW should be processed as they come in. The intermediary should not wait for applications from both the old and new owner to arrive before processing them. However, unless the instructions in this *chapter* indicate otherwise, the intermediary should attempt to send the old and new applications to the State simultaneously, rather than as soon as they

are processed. For instance, suppose the old owner submits an application on March 1. The intermediary should begin processing the application immediately, without waiting for the arrival of the new owner's application. Yet it should avoid sending the old owner's application to the State until the new owner's application comes in. (For acquisition/mergers and consolidations, the intermediary may send in the applications separately, since one number is going away.)

D. Sales Agreements

The intermediary shall abide by the following:

- **Verification of Terms** - The intermediary shall determine: (1) whether the information contained in the sales agreement is consistent with that reported on the new owner's CMS-855A (e.g., same names), and (2) whether the terms of the contract indicate that the new owner will assume the provider agreement. In many cases, the sales agreement will not specifically refer to the Medicare provider agreement. Clearly, if the box in section 2F is checked "yes" and the sales agreement either confirms that the new owner will assume the agreement or is relatively silent on the matter, the intermediary can proceed as normal. (The RO will obviously make the final decision.) Conversely, if the agreement indicates that the assets and liabilities will not be accepted, the contractor should recommend denial. As discussed above, such matters can be referred to the RO if needed.

- **Form of Sales Agreement** - There may be instances where the parties in a CHOW did not sign a "sales agreement" in the conventional sense of the term; the parties, for example, may have documented their agreement via a "bill of sale." The contractor may accept this alternative documentation in lieu of a sales agreement so long as the document furnishes clear verification of the terms of the transaction.

- **Submission of Final Sales Agreement** - The intermediary shall not forward a copy of the application to the State agency until it has received and reviewed the final sales agreement. It need not revalidate the information on the CMS-855A even if the data therein may be somewhat outdated by the time the final sales agreement is received.

  If a final sales agreement is not submitted within 90 days after the intermediary's receipt of the new owner's application, the intermediary shall reject the application. Though the intermediary must wait until the 90th day to reject the application, the intermediary may do so regardless of how many times it contacted the new owner or what type of responses (short of the actual receipt of the sales agreement) were obtained.

Unless otherwise specified in this manual or other CMS directive, both the old and new owners must submit separate CMS-855A applications as well as copies of the interim and final sales agreements.

E. CHOWs Involving Subunits and Subtypes

Any subunit that has a separate provider agreement (e.g., HHA subunits) must report its CHOW on a separate CMS-855A. They cannot report the CHOW via the main provider's CMS-855A. If the subunit has a separate CCN number but not a separate provider agreement (e.g., hospital psychiatric unit, HHA branch), the CHOW can be disclosed on the main provider's CMS-855A. This is because the subunit is a practice location of the main provider and not a separately enrolled entity.

On occasion, a CHOW may occur in conjunction with a change to the facility's provider subtype. This most frequently happens when a hospital undergoes a CHOW and changes from a general hospital to another type of hospital, such as a psychiatric hospital. Although a change in hospital type is considered a change of information, it is not necessary for the provider to submit separate applications – one for the COI and one for the CHOW. Instead, all information (including the change of hospital type) should be reported on the CHOW application; the entire application should then be processed as a CHOW. However, if the facility is changing from one main provider type to another (e.g., hospital converting to a SNF) and also undergoing a CHOW, the provider must submit its application as an initial enrollment.

NOTE: For Medicare purposes, a critical access hospital (CAH) is a separately-recognized provider type. Thus, a general hospital that undergoes a CHOW while converting to a CAH must submit its CMS-855A as an initial enrollment, not as a CHOW.

F. Early Submission of CHOW Application

The CMS-855A CHOW applications may be accepted by the intermediary up to 90 calendar days prior to the anticipated date of the proposed ownership change. Any application received more than 3 months in advance of the projected sale date can be returned under section 3.2 of this *chapter*.

G. Unreported CHOW

If the intermediary ascertains by any means that an enrolled provider has: (1) been purchased by another entity or (2) purchased another Medicare enrolled provider, the intermediary shall immediately request CMS-855A applications from both the old and new owners. If the new owner fails to submit the CMS-855A within the latter of: (1) the date of acquisition or (2) thirty (30) days after the request, the intermediary shall stop payments to the provider. Payments may be resumed upon receipt of the completed CMS-855A.

If the contractor learns of the transaction via the receipt of a tie-in notice from the RO, it shall follow the instructions under "Receipt of Tie-In When CMS-855A Not Completed" in section 5.5.3*E* of this *chapter*.

H. Relocation of Entity

A new owner may propose to relocate the provider concurrent with the CHOW. If the relocation is to a site in a different geographic area serving different clients than previously served and employing different personnel to serve those clients, the contractor shall notify

the RO immediately. Unless the RO dictates otherwise, the provider shall - per Pub. 100-07, chapter 3, section 3210.1(B)(5), treat the transaction as an initial enrollment (and the provider as a new applicant), rather than as an address change of the existing provider.

5.5.2.4 - Intervening CHOWs

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

In situations where: (1) the provider submits a CMS-855A initial application or CHOW application and (2) a CMS-855A CHOW application is later submitted but before the contractor has finished processing the first application, the contractor shall notify its DPSE liaison immediately. To illustrate, suppose that the seller (X) and the buyer (Y) in a CHOW submit their respective CMS-855A applications on March 1. On March 30, Y and Z submit CHOW applications as the old and new owners, respectively, in a subsequent CHOW. Assuming that it has not yet finished processing the March 1 applications, the contractor shall immediately refer the matter to its DPSE liaison.

5.5.2.5 - EFT Payments and CHOWs

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

In a CHOW, the intermediary shall continue to pay the old owner until it receives the tie-in notice from the RO. Hence, any request from the old or new owner to change the EFT account to that of the new owner shall be denied. It is ultimately the responsibility of the old and new owners to work out any payment arrangements between themselves while the CHOW is being processed by the intermediary and the RO.

5.5.2.5.1 – Pre-Approved Informational Changes

(Rev.)

5.5.3 - Tie-In Notices

(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

A. General Principles for Tie-In/Tie-out Issuances

Tie-in and tie-out notices *(CMS-2007)* are generally issued in the following circumstances:

1. Initial enrollments;

2. CHOWs;

3. Voluntary terminations;

4. Involuntary terminations (e.g., provider no longer meets conditions of participation or coverage) prompted by the State/RO

With the exception of voluntary and involuntary terminations, each of the transactions described above require a referral and recommendation to the State/RO.

B. CMS-855 Changes of Information

(i). Referrals to State/RO

The following is a list of CMS-855A changes of information that require a recommendation and referral to the State/RO:

- *Addition of OPT extension site;*
- *Addition of hospice satellite*
- *Addition of HHA branch;*
- *Change in type of PPS-exempt unit;*
- *Conversion of a hospital from one type to another (e.g., acute care to psychiatric);*
- *Change in practice location or subunit address in cases where a survey of the new site is required;*
- *Stock transfers*

In these situations, the PECOS record should not be switched to "approved" until the contractor receives notice from the RO that the latter has indeed authorized the change/addition.

(ii). Post-Approval RO Contact Required

Changes that do not mandate a recommendation to the State/RO but do require post-approval correspondence with the RO include:

- *Deletions/Voluntary Terminations of practice locations or subunits;*
- *LBN, TIN, or DBA name changes that do not involve a CHOW;*
- *Address changes that do not require a survey of the new location;*
- *Addition of hospital practice location*

For these transactions, the contractor shall notify the provider via letter, e-mail, or telephone that the change has been made and shall switch the PECOS record to "approved." The contractor shall also notify the State and RO of the changed information (via any mechanism it chooses, including copying the State/RO on the notification letter or e-mail) no later than 10 calendar days after it has completed processing the transaction. Such notice to the State/RO should specify the type information that is changing.

(iii). All Other Changes of Information

For all CMS-855A change requests not identified in (B)(i) or (B)(ii) above, the contractor shall notify the provider via letter, e-mail, or telephone that the change has been made and shall switch the PECOS record to "approved." The State and RO need not be notified of the change.

(iv). Revalidations, Reactivations and Complete CMS-855 Applications

In situations where the provider submits a: (1) CMS-855A reactivation, (2) CMS-855A revalidation, or (3) full CMS-855A as part of a change of information (i.e., the provider does not have a complete enrollment record in PECOS), the contractor shall make a recommendation to the State/RO and switch the PECOS record to "approval recommended" only if the application contains new/changed data falling within the category of items in (B)(i) above. For instance, if a revalidation application reveals a new hospital psychiatric unit that has never been previously reported to CMS via the CMS-855A, the contractor shall make a recommendation to the State/RO and await the RO's approval before switching the record to "approved." In this situation, the contractor should forward the whole application to the State with a note explaining that the only matter the State/RO needs to consider is the new hospital unit.

If the application contains new/changed data falling within the category of items in (B)(ii) above, the contractor can switch the PECOS record to "approved." It shall also notify the State and RO of the changed information (via any mechanism it chooses, including copying the State/RO on the notification letter or e-mail) no later than 10 calendar days after it has completed processing the transaction.

C. Provider-Specific, Non-CMS-855 Changes

If the contractor receives a tie-in notice for a transaction/change regarding information that is not collected on the CMS-855 application, the contractor obviously need not request the provider to submit a CMS-855 change of information.

D. Involuntary Termination Prompted by State/RO

If the contractor receives a tie-out notice from the RO that involuntarily terminates the provider's participation in the Medicare program on the grounds that the provider no longer meets the conditions of participation, the contractor need not send a letter to the provider notifying the latter that its participation/enrollment in Medicare has been terminated. (The RO will issue such a letter and afford appeal rights.)

E. Miscellaneous Information

Items 1 through 6 below address special procedures related to the contractor's handling of tie-in and tie-out notices.

1. **Receipt of Tie-In When CMS-855A Not Completed** - If the contractor receives a tie-in notice from the RO but the provider never completed the necessary CMS-855A paperwork, the contractor shall have the provider complete and submit said paperwork.

This applies to initial applications, CHOWs, practice location additions, etc.*, but does not apply to the cases described in subsection C above.*

2. Delegation to State Agency – *There may* be instances when the RO delegates the task of issuing tie-in or tie-out notices to the State agency. The *contractor* may accept such notices from the State in lieu of those from the RO. However, the *contractor* should first contact the applicable RO to confirm: (1) that the latter has indeed delegated this function to the State, and (2) the specific transactions (e.g., CHOWs, HHA branch additions) for which this function has been delegated.

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

4. **Creation of New L & T Record Unnecessary** - The *contractor* is not required to create a new L & T record in PECOS when the tie-in notice comes in, as the existing record should not be in a final status and can therefore be modified. Simply changing the L & T status is sufficient.

5. Provider Inquiries – *Once the contractor has made its recommendation for approval to the State/RO, any inquiry the contractor receives from the provider regarding the status of its request for Medicare participation shall be referred to the State or RO.*

6. Timeframes - *So as not to keep the PECOS record in "approval recommended" status interminably, if the contractor does not receive notification of approval from the RO after what it deems to be an excessive amount of time, it may contact the RO to see if such approval is forthcoming.*

5.5.3.1 –Prcessing Tie-In Notices
(Rev.)

5.5.4 - Out-of-State Practice Locations for Certified Providers
(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

As a general rule, the question of whether a CMS-855A needs to be completed for each State in which the provider performs services depends on three things: (1) State law, (2) the fiscal intermediary jurisdictions involved, and (3) how the RO(s) wants to handle the situation. Consider the following scenario:

A provider is enrolled in State X and now wants to perform services in State Y.

1. Assume that X & Y are in the same intermediary jurisdiction. If State Y requires an entity performing services in Y to be surveyed or the RO says that the provider must sign a separate provider agreement and obtain a separate CCN for its State Y services, the provider must submit an initial CMS-855A application for State Y in order to be a

provider in that state. If a separate enrollment is not required, the provider would simply submit a CMS-855A change of information request that adds the out-of-state location.

2. Assume that X & Y are not in the same intermediary jurisdiction. In this case, the provider must submit an initial CMS-855A application to the State Y intermediary - regardless of whether a separate survey, agreement, or CCN number is needed.

In short, if a provider in one State wishes to perform services in another State and the latter State is serviced by a different intermediary, a new enrollment is required with that intermediary. If both States are in the same intermediary jurisdiction, a CMS-855 initial application or a CMS-855 change of information is necessary; whether an initial application or a change request is required will depend on State law and what the RO says. In either case, the intermediary must create a new enrollment record in PECOS – one for each State. (See section 7.2 of this manual for additional guidance.)

5.5.5 - State Surveys and the CMS-855A

(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

In general, information on the CMS-855A is still considered to be valid notwithstanding a delay in the State survey. However, the provider will be required to submit an updated CMS-855A application to the contractor if:

- The contractor becomes aware of such a delay;
- The delay is the fault of the provider; and
- At least 6 months have passed since the contractor sent its recommendation for approval to the State.

If these criteria are met, the contractor shall send a letter to the provider requesting an updated CMS-855A. The application must contain, at a minimum, any information that is new or has changed since the recommendation for approval was made, as well as a newly-signed certification statement. If no information has changed, the provider may instead submit: (1) a letter on its business letterhead stating as such, and (2) a newly-signed CMS-855A certification statement.

NOTE: If the applicant is an HHA, it must resubmit capitalization data as required by section 12 of the CMS-855A irrespective of whether any of the provider's other CMS-855A information has changed. To illustrate, if no CMS-855A data has changed, the HHA must submit the letter, capitalization data and the signed certification statement.

If the provider fails to furnish the requested information within 60 days, the contractor shall submit a revised letter to the State that recommends denial of the provider's application.

5.5.6 - Sole Proprietorships

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

If the provider indicates in section 2B1 of the CMS-855A that he/she is a sole proprietor, the contractor shall note the following:

- The LBN in section 2B1 should list the person's (the sole proprietor's) legal name;

- The TIN in section 2B1 should list the person's SSN;

- Section 3 of the CMS-855A must be completed with information about the individual's adverse legal history;

- Section 5 of the CMS-855A will not apply unless the person has hired an entity to exercise managerial control over the business (i.e., no owners will be listed in section 5, as the sole owner has already reported his/her personal information in sections 2 and 3).

- No owners, partners, or directors/officers need be reported in section 6. However, all managing employees (whether W-2 or not) must be listed.

- The sole proprietor may list multiple authorized or delegated officials in section 15 and 16.

Since most sole proprietorships that complete the CMS-855A will also have an EIN, the contractor shall request from the provider a copy of its CP-575.

5.5.7 - Additional CMS-855A Processing Instructions

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

- **Non-Enrollment Functions and Timeliness** – There may be instances where the contractor cannot forward an application to the State until it performs certain non-enrollment functions pertaining to that application (e.g., the reimbursement unit needs to examine patient listing data). The intermediary may flip the PECOS status to "approval recommended" prior to the conclusion of this non-enrollment activity, but only if this is the lone remaining activity to be completed. In other words, all enrollment tasks required to be performed under this chapter 10 must have been completed prior to the intermediary making its determination.

- **Multiple Providers under a Single TIN** - It is acceptable for multiple providers to have the same TIN. However, each provider must submit a separate CMS-855A application, and the intermediary must create a separate enrollment record for each.

Future Effective Dates – In situations where the contractor cannot enter effective dates into PECOS because the provider, practice location, etc., is not yet established, the contractor may use the authorized official's date of signature as the temporary effective date. Once the actual effective date is established (e.g., the tie-in notice is received), the contractor shall go into PECOS and change the effective date.

5.6 – Special Verification Procedures for Enrolling Independent CLIA

Labs, Ambulatory Surgical Centers (ASCs), and Portable X-ray Suppliers

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

Unless otherwise stated, all references to the "RO" in sections 5.6.2 through 5.6.2.3 of this manual refer to the RO's survey & certification staff.

5.6.1 - CLIA Labs

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

Labs that are "integrated" into an existing provider or supplier do not require a separate CMS-855B enrollment. "Integrated" labs are typically those that have exactly the same ownership and physical location as another enrolled supplier or provider. (Common examples include: (1) hospital labs and (2) a lab at a physician's office.) If a lab is deemed as "integrated," the parent provider shall identity the lab as a practice location in section 4 of its CMS-855.

If the lab is not "integrated," the lab must enroll as an independent CLIA lab via the CMS-855B application. The contractor shall advise the lab that it must contact the applicable CLIA office; the lab cannot be enrolled until it receives a CLIA number. The contractor shall also ensure that the lab has furnished a notarized or certified true copy of the CLIA certificate or State license.

Labs that do not plan to participate in the Medicare program must be directed to the applicable CLIA office.

For more information on the enrollment of CLIA labs, refer to section 12.2.3 of this manual.

5.6.2 - ASCs and Portable X-ray Suppliers (PXRS)

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

Unlike other supplier types whose applications are processed by contractors, ASCs and PXRSs must receive a State survey and formal RO approval before they can be enrolled in Medicare. As such, once it finishes reviewing the supplier's application the contractor can only make a recommendation for approval or denial to the State. The contractor shall not enroll the supplier unless and until it receives a document or other notification from the RO stating that the supplier has met all of the qualifications needed to obtain Medicare billing privileges. (This document is usually an approval letter or "tie-in notice.") Upon receipt of the tie-in notice or approval letter from the RO, the contractor shall enroll the ASC or PXRS effective on the date shown on the notice. This is the date from which the supplier can bill for services.

5.6.2.1 - ASC/PXRS Changes of Ownership (CHOWs)

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

Though ASCs and PXRSs are not specifically mentioned in 42 CFR §489.18, CMS generally applies the change of ownership (CHOW) provisions of said regulation to these two supplier types. CHOWs involving ASCs and PXRSs are therefore handled in accordance with the principles of 42 CFR §489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). Note that the ROs make the final determination as to whether a CHOW has occurred (unless this function has been delegated).

As discussed in more detail in sections 12.2.1 and 12.2.2 of this manual, an ASC must sign a supplier agreement with Medicare prior to enrollment; PXRSs have no such requirement. The ROs may therefore handle CHOWs involving ASCs and PXRSs differently. To alleviate confusion and to ensure consistency, however, contractors will – unless stated otherwise – handle the CMS-855B processing of ASC CHOWs in the same manner as PXRS CHOWs.

5.6.2.1.1 - Determining Whether a CHOW Has Occurred

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

A. Review of Sales Agreement

If the "Change of Ownership" box in section 1B of the CMS-855B is checked, the contractor shall ensure that the entire application is completed and that the supplier submits a copy of the sales agreement. The contractor shall review the sales agreement to determine whether:

1. The ownership change qualifies as a CHOW under the principles of 42 CFR §489.18 and Pub. 100-07, chapter 3, section 3210.1D;

2. Its terms indicate that the new owner will be accepting assignment of the Medicare assets and liabilities of the old owner;

3. The information contained in the agreement is consistent with that reported on the new owner's CMS-855B (e.g., same names)

If the sales agreement is unclear as to issues 1 and 2 above, the contractor shall request clarifying information from the supplier. (Note that some sales agreements may fail to specifically refer to Medicare supplier agreements, assets, and/or liabilities, therefore requiring a close review of the sales agreement in its totality.) The information shall be in the form of additional legal documentation or a letter. If the clarification – for whatever reason - requires an update to the supplier's CMS-855B application, the contractor shall request the submission of said update. In addition, if the contractor discovers discrepancies between the data in the sales agreement and that on the CMS-855B (issue 3 above), the contractor shall seek clarifying information and, if necessary, obtain an updated CMS-855B.

In reviewing the application and the sales agreement, the contractor shall keep in mind the following:

- There may be instances where the parties in a CHOW did not sign a "sales agreement" in the conventional sense of the term; the parties, for example, may have documented their agreement in a "bill of sale." The contractor may accept this alternative documentation in lieu of a sales agreement so long as the document furnishes clear verification of the terms of the transaction.

- While a CHOW is usually accompanied by a TIN change, this is not always the case; there may be a few instances where the TIN remains the same. Conversely, there may be cases where a supplier is changing its TIN but not its ownership. So while a change of TIN (or lack thereof) is evidence that a CHOW has or has not occurred, it is not the most important factor; rather, the change in the provider's ownership structure is.

- CMS-855B CHOW applications may be accepted by the contractor up to 90 calendar days prior to the anticipated date of the proposed ownership change. Any application received more than 3 months in advance of the projected sale date shall be returned under section 3.2 of this manual.

- On occasion, an ASC or PXRS may submit a CMS-855B change of information to report a large-scale stock transfer or other significant ownership change that the supplier does not believe qualifies as a CHOW. If the contractor has any reason to suspect that the transaction in question may indeed be a CHOW, it shall request clarifying information (e.g., copy of the stock transfer agreement).

If – after performing the necessary research – the contractor remains unsure as to whether a CHOW has occurred and/or whether the new owner is accepting assignment, the contractor may refer the matter to the RO for guidance. Such referrals to the RO should only be made if the contractor is truly uncertain as to whether a CHOW and/or acceptance of assignment has taken place and should not be made as a matter of course. A RO CHOW determination is usually not required prior to the contractor making its recommendation.

B. Processing Steps

After performing the steps identified in subsection (A) above, the contractor shall abide by the following:

1. If the contractor believes that a CHOW has occurred but the new owner is not accepting the assets and liabilities of the old owner, the contractor shall treat the ASC/PXRS as a brand new supplier. It shall notify the ASC/PXRS that it must submit: (1) a CMS-855B voluntary termination to terminate the "old" facility, and (2) a CMS-855B initial enrollment for the "new" facility.

2. If the contractor believes that a CHOW has taken place and that the new owner is accepting the old owner's assets and liabilities, it shall process the application normally and make a recommendation for approval/denial to the State (with a cc: to the RO). If the valid CHOW/acceptance of assignment was accompanied by a change in TIN, the transaction must be treated as a CHOW notwithstanding the general rule that a TIN

change constitutes an initial enrollment. In other words, the reporting rules regarding CHOWs/assignments in this particular situation take precedence over the "change of TIN" principle.

3. If the contractor believes that a CHOW has not occurred and that the transaction merely represents an ownership change (e.g., minor stock transfer) that does not qualify as a 42 CFR §489.18-type CHOW, the transaction must be reported as a change of information. The only exception to this is if the change of information was accompanied by a change of TIN, in which case the supplier must enroll as a new entity.

   Note that it is not uncommon for a supplier to undergo a financial or administrative change that it considers to be a CHOW but in actuality does not meet the regulatory definition identified in §489.18.

In scenario 2 above, the contractor shall not forward a copy of the CHOW application to the State agency until it has received and reviewed the final sales agreement. (In some cases, the supplier may submit an interim sales agreement with its application; this is acceptable, so long as it submits the final agreement in accordance with these instructions.) If the final sales agreement is not submitted within 90 days after the contractor's receipt of the new owner's application, the contractor shall reject the application. Though the contractor must wait until the 90th day to reject the application, the contractor may do so regardless of how many times it contacted the new owner or what type of responses (short of the actual receipt of the sales agreement) were obtained.

C. CHOWs and Address Changes

A new owner may propose to relocate the supplier concurrent with a CHOW. If the relocation is to a site in a different geographic area serving different clients than previously served and employing different personnel to serve those clients, the contractor shall notify the RO immediately. Unless the RO dictates otherwise, the supplier shall - per Pub. 100-7, chapter 3, section 3210.1(B)(5) - treat the transaction as an initial enrollment (and the supplier as a new applicant), rather than as an address change of the existing supplier.

5.6.2.1.2 - EFT Payments and CHOWs

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

In a CHOW, the contractor shall continue to pay the old owner until it receives the tie-in/approval notice from the RO. Hence, any request from the old or new owner to change the EFT account to that of the new owner shall be denied. It is ultimately the responsibility of the old and new owners to work out any payment arrangements between themselves while the CHOW is being processed by the contractor and the RO.

If – pursuant to the CHOW – the seller submits a CMS-855B voluntary termination, the contractor shall contact and explain to the seller that the ASC/PXRS will not receive any payments until the RO approves the CHOW. (This is because, as explained above, payments must be sent to the seller until the tie-in/approval letter is sent). If the seller insists that its application be processed, the contractor shall process said termination;

however, it shall first notify the facility/new owner and explain that payments will cease once the seller's termination is effective. In fact, it is highly recommended that, upon receipt of a CMS-855B CHOW application, the contractor contact the supplier to notify it of the payment rule identified in the previous paragraph.

5.6.3 - ASC/PXRS Tie-in Notices

(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

(For purposes of this section 5.6.3, the terms "tie-in notices" and approval letters will be collectively referred to as tie-in notices. "Tie-out notices" are notices from the RO to the contractor that, in effect, state that the supplier's billing number, Medicare enrollment, practice location, etc., should be terminated.)

A. General Principles for Tie-in/Tie-out Issuances

*T*ie-in and tie-out notices are generally issued in the following circumstances:

1. Initial enrollments;

2. CHOWs;

3. Voluntary terminations;

4. Involuntary terminations (e.g., supplier no longer meets conditions of coverage) prompted by the State/RO.

With the exception of voluntary and involuntary terminations, each of the transactions described above require a referral and recommendation to the State/RO.

B. CMS-855B Changes of Information

(i). Referrals to State/RO

The following is a list of transactions that require a recommendation and referral to the State/RO:

- *Addition of practice location;*

- *Stock transfers;*

- *Change in practice location or subunit address in cases where a survey of the new site is required*

In these situations, the PECOS record should not be switched to "approved" until the contractor receives notice from the RO that the latter has indeed authorized the change/addition.

(ii). Post-Approval RO Contact Required

Changes that do not mandate a recommendation to the State/RO but do require post-approval correspondence with the RO include:

- *Deletions/voluntary terminations of practice locations or subunits;*
- *LBN, TIN, or DBA name changes that do not involve a CHOW;*
- *Address changes that do not require a survey of the new location;*

For these transactions, the contractor shall notify the supplier via letter, e-mail, or telephone that the change has been made and shall switch the PECOS record to "approved." The contractor shall also notify the State and RO of the changed information (via any mechanism it chooses, including copying the State/RO on the notification letter or e-mail) no later than 10 calendar days after it has completed processing the transaction. Such notice to the State/RO should specify the type of information that is changing.

(iii). All Other Changes of Information

For all CMS-855B change requests not identified in (i) or (ii) above, the contractor shall notify the supplier via letter, e-mail, or telephone that the change has been made and shall switch the PECOS record to "approved." The State and RO need not be notified of the change.

(iv). Revalidations, Reactivations and Complete CMS-855 Applications

In situations where the provider submits a: (1) CMS-855B reactivation, (2) CMS-855B revalidation, or (3) full CMS-855B as part of a change of information (i.e., the supplier does not have a complete enrollment record in PECOS), the contractor shall make a recommendation to the State/RO and switch the record to "approval recommended" only if the application contains new/changed data falling within the category of items in (i) above. For instance, if a revalidation application reveals a new practice location that has never been previously reported to CMS via the CMS-855B, the contractor shall make a recommendation to the State/RO and await the RO's approval before switching the record to "approved." In this situation, the contractor should forward the whole application to the State with a note explaining that the only matter the State/RO needs to consider is the new location.

If the application contains changed data falling within the category of items in (ii) above, the contractor can switch the PECOS record to "approved." The contractor shall also notify the State and RO of the changed information (via any mechanism it chooses, including copying the State/RO on the notification letter or e-mail) no later than 10 days after it has completed processing the transaction.

C. Supplier-Specific, Non-CMS-855 Changes

If the contractor receives a tie-in notice for a transaction/change regarding information that is not collected on the CMS-855B application, the contractor obviously need not request the supplier to submit a CMS-855B change of information.

D. Involuntary Termination Prompted by State/RO

If the contractor receives a tie-out notice from the RO that involuntarily terminates the supplier's participation in the Medicare program on the grounds that the supplier no longer meets the conditions of coverage, the contractor need not send a letter to the supplier notifying the latter that its participation/enrollment in Medicare has been terminated. The RO will issue such a letter and afford appeal rights.

E. Miscellaneous Information

Items 1 through 6 below address special procedures related to the contractor's handling of tie-in and tie-out notices.

1. **Receipt of Tie-In When CMS-855B Not Completed** - If the contractor receives a tie-in notice from the RO but the supplier never completed the necessary CMS-855B paperwork, the contractor shall have the supplier complete and submit said paperwork. This applies to initial applications, CHOWs, practice location additions, etc., *but does not apply to the cases described in subsection C above.*

2. Delegation to State Agency – *There may be* instances when the RO delegates the task of issuing tie-in or tie-out notices to the State agency. The contractor may accept such notices from the State in lieu of those from the RO. However, the contractor should first contact the applicable RO to confirm: (1) that the latter has indeed delegated this function to the State, and (2) the specific transactions (e.g., CHOWs, site additions) for which this function has been delegated.

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

4. **Creation of New L & T Record Unnecessary** - The contractor is not required to create a new L & T record in PECOS when the tie-in notice comes in, as the existing record should not be in a final status and can therefore be modified. Simply changing the L & T status is sufficient.

5. Provider Inquiries - *Once the contractor has made its recommendation for approval to the State/RO, any inquiry the contractor receives from the provider regarding the status of its request for Medicare participation shall be referred to the State or RO.*

6. Timeframes - *So as not to keep the PECOS record in "approval recommended" status interminably, if the contractor does not receive notification of approval from the RO after*

what it deems to be an excessive amount of time, it may contact the RO to see if such approval is forthcoming.

5.6.3.1 – Processing Tie-In Notices
(Rev.)

5.6.4 - Out-of-State Practice Locations for Certified Suppliers
(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

As a general rule, the question of whether a CMS-855B needs to be completed for each State in which the certified supplier performs services depends on three things: (1) State law, (2) the contractor jurisdictions involved, and (3) how the RO(s) wants to handle the situation. Consider the following scenario:

A supplier is enrolled in State X and now wants to perform services in State Y:

1. Assume that X & Y are in the same contractor jurisdiction. If State Y requires an entity performing services in Y to be surveyed or if the RO says that the supplier must sign a separate supplier agreement, the supplier must submit an initial CMS-855B application for State Y in order to be a provider in that state. If a separate enrollment is not required, the supplier can simply submit a CMS-855B change of information request that adds the out-of-state location.

2. Assume that States X & Y are not in the same contractor jurisdiction. Here, the supplier must submit an initial CMS-855B application to the State Y contractor - irrespective of whether a separate survey or agreement is needed.

In short, if a certified supplier wants to perform services in another State that is serviced by another contractor, a new enrollment with that contractor is required. If both States are in the same contractor jurisdiction, a CMS-855B initial application or a CMS-855B change of information will be necessary; whether an initial enrollment or a change request is required will depend on State law and what the RO says. In either case, the contractor must create a new enrollment record in PECOS – one for each State. (See section 7.2 of this manual for additional guidance.)

5.6.5 - State Surveys and the CMS-855B
(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

A. *Delay in State Survey*

In general, information on the CMS-855B is still considered to be valid notwithstanding a delay in the State survey. However, the supplier will be required to submit an updated CMS-855B application to the contractor if:

- The contractor becomes aware of such a delay;

- The delay is the fault of the supplier; and

- At least 6 months have passed since the contractor sent its recommendation for approval to the State.

If these criteria are met, the contractor shall send a letter to the supplier requesting an updated CMS-855B. The application must contain, at a minimum, any information that is new or has changed since the recommendation for approval was made, as well as a newly-signed certification statement. If no information has changed, the supplier may instead submit: (1) a letter on its business letterhead stating as such, and (2) a newly-signed CMS-855*B* certification statement.

If the supplier fails to furnish the requested information within 60 calendar days, the contractor shall submit a revised letter to the State that recommends denial of the supplier's application.

B. Future Effective Dates

In situations where the contractor cannot enter effective dates into PECOS because the supplier, its practice location, etc., is not yet established, the contractor may use the authorized official's date of signature as the temporary effective date. Once the provider and actual effective date is established (e.g., the tie-in notice is received), the contractor shall go into PECOS and change the effective date.

5.7 – Special Program Integrity Procedures
(Rev.)

5.7.1 – Special Procedures for Physicians and Non-Physician Practitioners
(Rev.)

6 – Final Application Actions
(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

6.1 - Approvals
(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

6.1.1 - Non-Certified Suppliers and Individual Practitioners
(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

Medicare carriers, including A/B MACs and the NSC, shall notify all suppliers regarding the disposition of their CMS-855 enrollment application. If the contractor approves a supplier's enrollment (except for ASCs and PXRSs), it shall notify the applicant via letter that the enrollment has been approved. The letter shall include the NPI by which the

supplier will bill the Medicare program and the Provider Transaction Access Number (PTAN) that has been assigned to the supplier as an identifier for inquiries.

The approval letter should provide instructions on how suppliers should use the assigned PTAN whenever they use the contractor interactive voice response (IVR) system for inquires concerning claims status, beneficiary eligibility, check status or other supplier-related IVR transactions. CR 5061 and CR 5089 provide further guidance on the issuance and use of the PTAN.

In addition to instructing suppliers to use their NPI on electronic claim submissions, the contractor shall include language reminding suppliers to update their NPPES record whenever their information changes.

For claims submitted by physicians and non-physicians prior to the date of enrollment, the contractor shall follow the instructions in Pub. 100-04, chapter 1, section 70, with respect to the claim filing limit. Payments cannot be made for services furnished prior to the date the applicant is appropriately licensed. For initial enrollment, the contractor should use the date that the supplier started practicing at the practice location as the date it can begin submitting claims.

6.1.2 - Certified Providers and Certified Suppliers

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

(This section only applies to: (1) fiscal intermediaries when processing initial CMS-855A applications or CHOW, acquisition/merger, or consolidation applications submitted by the new owner; and (2) carriers when processing initial ASCs and PXRs applications.)

Once the contractor has completed its review of the provider or supplier's application and has decided to recommend approval, the contractor shall send a letter of recommendation for approval to the applicable State agency, with a copy going to the RO's survey and certification unit. (For those provider types that do not require a State survey, such as FQHCs, the letter can be sent directly to the RO.) The recommendation letter shall be written (not e-mailed) and, at a minimum, contain the following information:

- Supplier/Provider NPI Number;
- CCN Number (if available);
- Type of enrollment transaction (CHOW, initial enrollment, branch addition, etc.);
- Contractor Number;
- Contractor Contact Name;
- Contractor Contact Phone Number;

- Date Application Recommended for Approval;

- An explanation of any special circumstances, findings, or other information that either the State or the RO should know about.

The contractor shall also:

- Send a photocopy (not the original) of the final completed CMS-855 to the State agency, along with all updated CMS-855 pages, explanatory data, documentation, correspondence, final sales agreements, etc. The photocopied CMS-855 should be sent in the same package as the recommendation letter.

The contractor shall not send a copy of the CMS-855 to the RO unless the latter specifically requests it or if the transaction in question is one for which State involvement is unnecessary.

- Notify the applicant that the contractor has completed its initial review of the application. The notification can be furnished orally or in writing, and shall advise the applicant of the next steps in the enrollment process (e.g., site visit, survey). The contractor may, but is by no means required to, send a copy of its recommendation letter to the provider as a means of satisfying this requirement. However, the contractor should not send a copy to the provider if the recommendation letter contains sensitive information. In addition, when notifying the provider that the review is finished, the contractor is under no obligation to inform the provider as to the contents of the recommendation (i.e., approval or denial).

- Inform the applicant that it could take 6 to 9 months (or longer) for the provider or supplier to obtain its billing number. (In the case of a CHOW, the contractor shall specify that CMS cannot send payments to the new owner until the tie-in notice is issued.) This can be done at any time prior to, or in conjunction with, the notification to the provider of the completion of its review of the application. The contractor may notify the applicant of the phone numbers and e-mail addresses of the applicable State agency and RO that will be handling the survey and certification process from that point forward; the applicant shall also be instructed that all questions related to this process shall be directed to the State agency and/or RO.

6.1.3 - Approval of DMEPOS Suppliers

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

As stated in 42 CFR §424.57(b), a DMEPOS supplier must, among other things, meet the following conditions to be eligible to receive payment for a Medicare-covered item:

- The supplier has submitted a completed CMS-855S, including all supporting documentation, to the NSC; and

- The item was furnished on or after the date the NSC issued to the supplier a DMEPOS supplier number conveying Medicare billing privileges.

The date identified in the previous bullet represents the "date of approval."

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

6.2 – Denials
(Rev. 269: Issued: 09-19-08; Effective/Implementation Date: 10-20-08)

A. Denial Reasons

Per 42 CFR §424.530(a), contractors must deny an enrollment application if any of the situations described below are present, and must provide appeal rights.

When issuing a denial, the contractor shall insert the appropriate regulatory basis (e.g., 42 CFR §424.530(a)(1)) into its determination letter. The contractor shall not use provisions from this chapter 10 as the basis for denial.

Note that if the applicant is a certified provider or certified supplier and one of the denial reasons listed below is implicated, the contractor need not submit a recommendation for denial to the State/RO. The contractor can simply: (1) deny the application, (2) close out the PECOS record, and (3) send a denial letter to the provider in a format similar to that which is used for carrier denials of non-certified supplier applications (see sections 14 and 19 of this chapter). The contractor shall copy the State and the RO on said letter.

Denial Reason 1 (42 CFR §424.530(a)(1))

The provider or supplier is determined not to be in compliance with the Medicare enrollment requirements described in this section or on the enrollment application applicable to its provider or supplier type, and has not submitted a plan of corrective action as outlined in 42CFR part 488.

Denial Reason 2 (42 CFR §424.530(a)(2))

The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier who is required to be reported on the CMS-855 is—

- Excluded from Medicare, Medicaid, or any other Federal health care program, as defined in 42 CFR §1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Social Security Act, or

- Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with section 2455 of the Federal Acquisition Streamlining Act.

Denial Reason 3 (42 CFR §424.530(a)(3))

The provider, supplier, or any owner of the provider or supplier was, within the 10 years preceding enrollment or revalidation of enrollment, convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. Offenses include--

- Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

- Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

- Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

- Any felonies outlined in section 1128 of the Social Security Act.

Denial Reason 4 (42 CFR §424.530(a)(4))

The provider or supplier submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program. (The contractor shall contact its DPSE contractor liaison prior to issuing or recommending denial of an application on this ground.)

Denial Reason 5 (42 CFR §424.530(a)(5))

The CMS determines, upon onsite review or other reliable evidence, that the provider or supplier is not operational to furnish Medicare covered items or services, or does not meet Medicare enrollment requirements to furnish Medicare covered items or services. This includes, but is not limited to, the following situations:

- The applicant does not have a license(s) or is not authorized by the Federal/State/local government to perform the services for which it intends to render. (In its denial letter, the contractor shall cite the appropriate statute and/or regulations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the denial letter the exact provision within said statute/regulation that the provider/supplier has failed to comply with.)

- The applicant does not have a physical business address or mobile unit where services can be rendered and/or does not have a place where patient records are stored to determine the amounts due such provider or other person (as set forth in §1833(e) of the Social Security Act.)

- The applicant does not meet CMS regulatory requirements for the specialty. (In its denial letter, the contractor shall cite the appropriate statutory and/or regulatory citations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the denial letter the exact provision within said statute/regulation that the provider/supplier is not in compliance with.)

- The applicant does not qualify as a provider of services or a supplier of medical and health services. An entity seeking Medicare payment must be able to receive reassigned benefits from physicians in accordance with the Medicare reassignment provisions in §1842(b)(6) of the Act (42 U.S.C. 1395u(b)).

NOTE: This denial provision should be used in cases where the applicant is not recognized by any Federal statute as a Medicare provider or supplier (e.g., marriage counselors).

- The applicant does not provide a valid SSN/EIN for the applicant, owner, partner, managing organization/employee, officer, director, medical director, and/or delegated or authorized official.

- A home health agency (HHA) does not meet the capitalization requirements outlined in 42 CFR §489.28.

B. Denial Letters

When a decision to deny is made, the carrier shall send a letter to the supplier by certified mail identifying the reason(s) for denial and furnishing appeal rights. The letter shall follow the format of that shown in section 14 of this chapter.

As previously indicated, and in accordance with 42 CFR § 405.874(a), all denial (or recommendation for denial) letters shall contain sufficient factual and background information so that the reader understands exactly why the denial occurred. It is not enough to simply list one of the denial reasons. All applicable regulations, as well as a detailed factual rationale for the contractor's decision, must be identified in the letter. For instance, if an application is denied based on falsification, the carrier must identify in its letter the falsified information, how and why the carrier determined it was false, the regulation in question, etc. If there were multiple reasons for denial, the letter shall state as such and shall furnish all of the aforementioned statutes, regulations, facts, etc. applicable to each reason. The notice must also identify the provider's right to appeal under 42 CFR Part 498 and the address to which the written appeal must be mailed. For more detailed information on the appropriate composition of denial letters, see sections 14 and 19 of this chapter.

C. Post-Denial Submission of Enrollment Application

A provider or supplier that is denied enrollment in the Medicare program cannot submit a new enrollment application until the following has occurred:

- If the denial was not appealed, the provider or supplier may reapply after its appeal rights have lapsed.

- If the denial was appealed, the provider or supplier may reapply after it received notification that the determination was upheld.

D. 30-Day Effective Date of Denial

A denial is effective 30 calendar days after the contractor sends its denial notice to the provider.

As stated in 42 CFR §424.530(c), if the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare services, the denial may be reversed if the provider or supplier submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification. The contractor, however:

- Need not solicit or ask for such proof in its denial letter. It is up to the provider to furnish this data on its own volition.

- Has the ultimate discretion to determine whether sufficient "proof" exists.

See section 19 of this chapter for information on Corrective Active Plans (CAP).

6.2.1 - Suppliers Not Eligible to Participate

(Rev.260, Issued: 06-20-08, Effective: 07-22-08, Implementation: 07-22-08)

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
- Speech Language Pathologist
- Substance Abuse Facility

7 – Changes of Information

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

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

7.1 – General Procedures

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

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

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

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

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

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

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

7.1.1 – Changes of Information and Complete CMS 855 Applications

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

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

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

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

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

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

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

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

7.1.2 - Incomplete or Unverifiable Changes of Information

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

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

A. Provider is in PECOS

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

B. Provider is Not in PECOS

As stated in sections 7.1.1 and 8 of this manual, if a provider does not have an established enrollment record in PECOS and wants to change any of its existing enrollment of EFT

information, it must submit a complete CMS-855 form before the contractor can effectuate the change. If the provider refuses to or otherwise fails to submit the completed form within the applicable 60 day period, the contractor shall request that the provider revalidate its Medicare enrollment information per 42 CFR § 424.515.

7.2 - Special Instructions for Certified Providers, ASCs, and Portable X-ray Suppliers

(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

A. Timeframe for RO Approval

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

B. Post-Recommendation Changes

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

In entering the change request into PECOS, the contractor shall use the date it received the change request in its mailroom as the actual receipt date in PECOS; the date the tie-in notice was issued shall not be used. The contractor shall explain the situation in the "Comments" section in PECOS and in the provider file.

C. Hospital Addition of Practice Location

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

7.3 – Voluntary Terminations

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

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

If the termination involves a certified provider, ASC, or PXRSs, the contractor may terminate the entity without making a recommendation to the State and RO. No later than 3 business days after the contractor has finished processing the termination, however, it

shall notify the State and RO thereof; said notification can be made via letter, e-mail, or fax.

Upon receipt of a voluntary termination, the contractor may ask the provider to complete the "Special Payments" portion of section 4 so that future payments can be sent thereto. If the provider has no special payments address already on file, the addition should be included in the same transaction as the termination (i.e., one transaction incorporating both items). If the provider wants to change its existing special payments address, the transaction should be treated as a separate change request (i.e., one termination and one change request). The provider is not required to submit a CMS-588 in conjunction with a termination.

8 – Electronic Fund Transfers (EFT)

(Rev. 269: Issued: 09-19-08; Effective/Implementation Date: 10-20-08)

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

As stated in 42 CFR §424.510(d)(2)(iv) and §424.510(e), all providers (including Federal, State and local governments) entering the Medicare program for the first time must use EFT in order to receive payments. Moreover, any provider not currently on EFT that: (1) submits any change to its existing enrollment data or (2) submits a revalidation application, must also submit a CMS-588 form and thereafter receive payments via EFT.

Under 42 CFR §424.510(d)(2)(iv) and §424.510(e), if a provider is already receiving payments via EFT and is located in a jurisdiction that is undergoing a change of Medicare contractors (e.g., fiscal intermediary to an A/B MAC), the provider must continue to receive EFT payments and, to this end, must also submit a new CMS-588 form that authorizes the new contractor to make payments to the provider's EFT account. The contractor shall process the CMS-588 in this situation as it would in any other scenario.

In addition:

- **Banking Institutions** - All payments must be made to a banking institution. EFT payments to non-banking institutions (e.g., brokerage houses, mutual fund families) are not permitted.

  If the provider's bank of choice does not or will not participate in the provider's proposed EFT transaction, the provider must select another financial institution.

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

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

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

- **Comparing Signatures** - If the contractor receives an EFT change request, it shall compare the signature thereon with the same official's signature on file to ensure that it is indeed the same person. (See also Pub. 100-04, chapter 24, section 40.7) If the person's signature is not already on file, the contractor shall request that he/she complete section 6 of the CMS-855 and furnish his/her signature in section 15 or 16 of the CMS-855. (This shall be treated as part of the EFT change request for purposes of timeliness and reporting.)

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

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

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

- **Final Payments** - In situations where a non-certified supplier (e.g., physician, ambulance company) voluntarily withdraws from Medicare and needs to obtain its

final payments, the contractor shall send said payments to the provider's EFT account of record. If the account is defunct, the contractor can send payments to the provider's "special payments" address or, if none is on file, to any of the provider's practice locations on record. If neither the EFT account nor the addresses discussed above are in existence, the provider shall submit a CMS-855 or CMS-588 request identifying where it wants payments to be sent.

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

- **Audit and Claims Intermediaries –** In cases where the provider's audit and claims intermediaries differ, the contractor shall not reject the provider's CMS-588 form if the provider listed the claims intermediary – rather than the audit intermediary – thereon.

9 - Revalidation

(Rev. 173; Issued: 11-13-06; Effective/Implementation Dates: 11-15-06)

Per 42 CFR § 424.515, Medicare providers and suppliers (other than DMEPOS suppliers) must resubmit and recertify the accuracy of their enrollment information every five years in order to maintain Medicare billing privileges. Contractors may initiate revalidation activities at any time during the fiscal year.

The following principles apply to revalidation:

- The processing times for "initial" applications – outlined in section 2.1 of this manual – apply to revalidation applications.

- Per 42 CFR § 424.515, a provider whom the contractor requested to furnish all requested information (as part of the revalidation) must do so within 60 calendar days after the date the contractor notified the provider of the need to revalidate. If the provider fails to do so, the contractor shall revoke the provider's billing privileges using existing revocation procedures.

- The provider must submit all required documentation with its application, even if such documentation is already on file with the contractor.

The contractor shall verify all data furnished on the application – just as it would with an initial enrollment – using the procedures identified in this manual (e.g., section 5.2)

9.1 – Supplementary Revalidation Activities
(Rev.)

10 - Documentation

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

To ensure that proper internal controls are maintained and that important information is recorded in case of potential litigation, the contractor shall maintain documentation as outlined in this section 10. CMS cannot stress enough how crucial it is for contractors to document their actions as carefully and thoroughly as possible.

Note that these requirements are in addition to, and not in lieu of, all other documentation or document maintenance requirements that CMS has mandated.

A. Written and Telephonic Communications

(For purposes of this section 10, "written correspondence" includes faxes and e-mails.)

The contractor shall:

- Retain copies of all written correspondence pertaining to the provider, regardless of whether the correspondence was initiated by the contractor, the provider, CMS, State officials, etc.

- Document when it sends written letters and faxes to providers. For instance, if the carrier crafts an approval letter to the supplier dated March 1 but sends it out on March 3, the contractor shall note this in the file.

- Document all referrals to CMS, the PSC, or the OIG.

- Document any and all actual or attempted telephonic or face-to-face contacts with the provider, any representative thereof, or any other person regarding a provider. This includes, but is not limited to, the following situations:

  - Telephoning a provider about its application. (Even if the provider official was unavailable and a voice mail message was left, this must be documented.)

  - Requesting information from the State or another contractor concerning the applicant or enrollee;

  - Contacting the PSC for an update concerning an application sent to them;

  - Phone calls from the provider;

  - Conducting a meeting at the contractor's headquarters/offices with officials from a hospital concerning problems with its application;

- Contacting CO or the RO's survey and certification staff – and receiving instructions there from - about a problem the contractor is having with an applicant or an existing provider;

- Contacting the provider's billing department with a question about the provider.

When documenting oral communications, the contractor shall indicate: (1) the time and date of the call or contact; (2) who initiated contact; (3) who was spoken with; and (4) what the conversation pertained to. Concerning the last requirement, the contractor need not write down every word that was said during the conversation. Rather, the documentation should merely be adequate to reflect the contents of the conversation. The documentation can be stored electronically, if the contractor can provide access within 24 hours upon request.

Note that the documentation requirements in this subsection (A) only apply to enrolled providers and to providers that have already submitted an enrollment application. In other words, these documentation requirements go into effect only after the provider submits an initial application. To illustrate, if a hospital contacts the contractor requesting information concerning how it should enroll in the Medicare program, this need not be documented because the hospital has not yet submitted an enrollment application.

If an application is returned per section 3.2 of this manual, the contractor shall document this. The manner of documentation lies within the contractor's discretion.

B. Verification of Data Elements

Once the contractor has completed its review of the CMS-855 (e.g., approved/denied application, approved change request), it shall provide a written statement asserting that it has: (1) verified all data elements on the application, and (2) reviewed all applicable names on the CMS-855 against Qualifier.net, the MED, and the GSA debarment list. The statement must be signed and dated. It can be drafted in any manner the contractor chooses so long as it certifies that the above-mentioned activities were completed. The record can be stored electronically.

For each person or entity that appeared on the MED or GSA lists, the contractor shall document the finding via a screen printout. In all other situations, the contractor is not encouraged to document their reviews via screen printouts. Simply using the verification statement described above is sufficient. Although the contractor has the discretion to use screen prints if it so chooses, the verification statement is still required.

11 – Special Processing Situations

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

11.1 – Non-CMS-855 Enrollment Activities

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

There are instances where the contractor processes non-CMS-855 forms and other documentation relating to provider enrollment. Such activities include:

- EFT agreements (CMS-588) submitted alone;
- "Do Not Forward" issues;
- Par agreements (CMS-460);
- Returned remittance notices;
- Informational letters received from other contractors;
- Diabetes self-management notices;
- Verification of new billing services;
- Paramedic intercept contracts;
- 1099 issues that need to be resolved.

Unless specifically stated otherwise in this manual, the contractor shall not create an L & T record for any non-CMS-855 document or activity other than the processing of par agreements. The contractor should track and record all other activities internally.

11.2 – Contractor Communications

(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

Medicare contractors (carriers and fiscal intermediaries) create Associate and Enrollment Records in the Provider Enrollment, Chain and Ownership System (PECOS). Ownership of an Associate or an Enrollment Record belongs to the contractor within whose jurisdiction the provider/supplier is located. PECOS permits only the contractor who created the Associate or the Enrollment Record (known as the owning contractor) to make any updates, changes, or corrections to those records. (In other words, the owning contractor is the only contractor that can make changes to the associate record.)

On occasion, the updates, changes, or corrections do not come to the attention of the owning contractor, but instead go to a different carrier or fiscal intermediary. In those situations, the contractor that has been notified of the update/change/correction (the "requesting" contractor) must convey the update/change/correction information to the owning contractor so that the latter can access the record in PECOS and make the update/change/correction.

The requesting contractor may notify the owning contractor via fax of the need to update/change/correct information in a provider's PECOS record. When the requesting

contractor notifies the owning contractor of the needed update/change/correction, the following information must be furnished:

1. The legal business name of the provider;
2. The provider's Medicare identification number;
3. The provider's NPI (by including a copy of the provider's NPI notification); and
4. The updated/changed/corrected data (by including a copy of the appropriate section of the CMS-855).

The owning contractor, within 7 calendar days of receiving the requesting contractor's request for a change to a PECOS record, shall make the change in the PECOS record and notify the requesting contractor that the change has been made. Notification may occur by fax, e-mail, or telephone.

If the owning contractor – for whatever reason - feels uncomfortable about making the change, it shall contact its CO DPSE contractor liaison for guidance. Note that the owning contractor may ask the requesting contractor for any additional information about the provider it deems necessary (e.g., IRS documentation, licenses, Qualifier.net data). However, the former should not be overly obstructionist about the matter.

It is not necessary for the contractor to ask the provider for a CMS-855 change of information in associate profile situations. That is, if another intermediary asks the contractor/record holder to make a change to the record, the record holder need not ask the provider to submit a CMS-855 change request to it. It can simply work off of the CMS-855 copy that the requesting intermediary or carrier sent/faxed to the contractor. For instance, suppose Provider X is enrolled in two different intermediary jurisdictions – A and B. The provider enrolled with "A" first; its legal business name was listed as "John Brian Smith Hospital." It later enrolls with "B" as "John Bryan Smith Hospital." "B" has verified that "John Bryan Smith Hospital" is the correct name and sends a request to "A" to fix the name. "A" is not required to ask the provider to submit a CMS-855A change of information. It can simply use the CMS-855A copy that it received from "B."

11.3 – Provider-Based

(Rev. 173; Issued: 11-13-06; Effective/Implementation Dates: 11-15-06)

The contractor shall adhere to the following rules regarding the enrollment of provider-based entities:

- **Certified Provider Initially Enrolling –** Suppose an HHA or other entity wishes to enroll and become provider-based to a hospital. The provider must enroll with the intermediary as a separate entity. It cannot be listed as a practice location on the hospital's CMS-855A.

- **Certified Provider Changing its Provider-Based Status –** If a certified provider is changing its status from provider-based to freestanding or vice versa, it need not submit any updates to its CMS-855A enrollment.

- **Group Practice Initially Enrolling –** If a group practice is enrolling in Medicare and will become provider-based to a hospital, the group generally must enroll with the carrier if it wants to bill for practitioner services. The group would also need to be listed or added as a practice location on the hospital's CMS 855A.

- **Group Practice Changing from Provider-Based to Freestanding** – In this situation, the hospital should submit a CMS-855A change request that deletes the clinic as a practice location. The group may also need to change the type of clinic it is enrolled as; this may require a brand new CMS 855B.

- **Group Practice Changing from Freestanding to Provider-Based** – Here, the hospital shall submit a CMS-855A change request adding the group as a practice location. The group may also need to change the type of clinic it is enrolled as; this may require a brand new CMS 855B.

Unless the RO specifically dictates otherwise, the intermediary shall not delay the processing of any additional practice locations pending receipt of provider-based attestations or RO concurrence of provider-based status.

11.4 – Non-Participating Emergency Hospitals, Veterans Administration (VA) Hospitals, and Department of Defense (DOD) Hospitals

(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

A non-participating emergency hospital, VA hospital, or DOD hospital must complete and submit a CMS-855A enrollment application and CMS-588 EFT form if it wishes to bill Medicare for any services performed.

When creating a PECOS enrollment record for one of these providers, the contractor shall select a Provider Type of "Other" and then enter the type of hospital in question.

11.5 – Carrier Processing of Hospital Applications

(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

A. Group Practices

The carrier shall review all CMS-855B applications for hospital-owned clinics/physician practices and department billings. The carrier shall contact the applicant to determine if the latter will be billing any of these locations as provider-based. If the applicant will not be billing as provider-based, the carrier shall process the application normally. If, however, the applicant will bill as provider-based, the carrier shall notify the applicant that the hospital must report any changed practice locations to its intermediary via the CMS-855A.

If the supplier is enrolling as a hospital department (under the "Clinic/Group Practice" category on the CMS-855B) or an existing hospital department is undergoing a change of ownership (CHOW), the *contractor* shall only issue the necessary billing numbers upon notification that a provider agreement has been issued *– or, in the case of a CHOW,* the

provider agreement has been transferred to the new owner. *If, however, the supplier is enrolling as a group practice that is merely owned by a hospital (as opposed to being a hospital department), it is not necessary for the contractor to wait until the provider agreement is issued before conveying billing privileges to the group.*

B. Individual Billings

Assume an individual physician works for a hospital and will be billing for services as an individual (i.e., not as part of the hospital service/payment). However, he/she wants to reassign these benefits to the hospital. In this case, the hospital needs to enroll with the *contractor* via the CMS-855B (e.g., as a hospital department, outpatient location).

11.6 – Participation (Par) Agreements and the Acceptance of Assignment

(Rev. 173; Issued: 11-13-06; Effective/Implementation Dates: 11-15-06)

Carriers shall abide by the instructions in Pub. 100-04, chapter 1, sections 30 through 30.3.12.3 when handling matters related to par agreements and assignment. Queries related to the interpretation of such instructions shall be referred to the responsible CMS component.

11.6.1 – General Information

(Rev.)

11.6.2 – Initial Enrollments and PECOS

(Rev.)

11.6.3 – PECOS Information

(Rev.)

11.7 – Opt-Out

(Rev. 173; Issued: 11-13-06; Effective/Implementation Dates: 11-15-06)

There are physicians and other individual practitioners who do not wish to enroll in the Medicare program. Physicians and practitioners (but not organizations) can "opt-out" of Medicare. This means that neither the physician nor the beneficiary submits the bill to Medicare for services performed. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. In fact, a private contract is signed between the physician and the beneficiary that states, in essence, that neither one can receive payment from Medicare for the services that were performed. (The contract, of course, must be signed before the services are provided so the beneficiary is fully aware of the physician's opt-out status.) Moreover, the supplier must submit an affidavit to Medicare expressing his/her decision to opt-out of the program. The provider enrollment unit must process these affidavits.

The difference between opting-out and not accepting assignment is relatively straightforward. If the practitioner opts-out, neither he/she nor the beneficiary can bill Medicare. If the practitioner chooses not to accept assignment, he/she must still enroll in Medicare and must submit the bill to the carrier.

(For additional information on "opt-out," see Pub. 100-02, chapter 15, section 40.)

In an emergency care or urgent care situation, a physician or practitioner who opts out may treat a Medicare beneficiary with whom he or she does not have a private contract. In those circumstances, the physician or practitioner must complete a CMS-855 application after the emergency services were provided.

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

(Rev. 173; Issued: 11-13-06; Effective/Implementation Dates: 11-15-06)

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.

11.9 – Carrier Assignment of Provider Transaction Access Numbers (PTANs)

(Rev.260, Issued: 06-20-08, Effective: 07-22-08, Implementation: 07-22-08)

The contractor shall only assign the minimum number of PTANs necessary to ensure that proper payments are made. The contractor shall not assign an additional PTAN(s) to a physician, non-physician practitioner, or other supplier merely because the individual or entity requests one, the only exception being for hospitals that request separate billing numbers for their hospital departments in section 2C of the CMS-855B enrollment application. However, a hospital requesting an additional PTAN must associate the new PTAN with an NPI in section 4 of the CMS-855.

11.10 – Reciprocal Billing, Locum Tenens and the Provider Enrollment Process

(Rev.)

12 - Provider and Supplier Types/Services

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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.

12.1 - Intermediary-Enrolled Providers and Suppliers

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

12.1.1 - Community Mental Health Centers (CMHCs)

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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, chapter 2, section 2250F 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, chapter 2, section 2252I 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).

12.1.2 - Comprehensive Outpatient Rehabilitation Facilities (CORFs)

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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).

12.1.3 - End-Stage Renal Disease Facilities (ESRDs)
(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

A. Types of ESRDs

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, 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, chapter 2, sections 2274 – 2276 and 2278D – 2278F 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).

12.1.4 - Federally Qualified Health Centers (FQHCs)

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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, chapter 2, sections 2825-2826D for more information.)

A few other notes about FQHCs:

- All new FQHC applications nationwide are handled by a single intermediary, United Government Services (UGS) – regardless of whether the facility is provider-based.

- 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.

- 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.

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

For more 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)

12.1.5 - Histocompatability Laboratories

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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.

All histocompatibility laboratory Form CMS-855A applications are processed by a single fiscal intermediary –Riverbend.

12.1.6 - Home Health Agencies (HHAs)

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

A. General Background Information

An HHA is an entity that provides skilled nursing services and at least one of the following therapeutic services: speech therapy, physical therapy, occupational therapy, home health aide services, and medical social services. The services must be furnished in a place of residence used as the patient's home.

Like most certified providers, HHAs receive a State survey or survey from an approved accrediting organization to determine compliance with Federal, State, and local laws, and must also sign a provider agreement. All HHA services, moreover, must be part of a plan of care established by a physician, accompanied by a certification from the doctor that the patient needs home health services. HHA services can be covered even if the patient lives with someone who might ordinarily be able to perform such services himself/herself.

B. Capitalization Requirements

To ensure that each HHA has sufficient operating funds, 42 CFR §489.28 requires that each HHA furnish written documentation verifying that it has sufficient operating funds for the first 3 months of its Medicare operations. This is informally known as the "capitalization requirement" and is addressed in Section 12 of the Form CMS-855A. The question of what constitutes "sufficient" funds is usually left to the intermediary's discretion. Factors that the intermediary considers in its determination include: the number of home visits the HHA plans to make in its first3 months and first 12 months of operation; the geographic area involved; and the capitalization figures for comparable HHAs in the same jurisdiction. To illustrate, suppose HHA #1 will be performing hundreds of visits in its first 90 days, while HHA #2 will be doing just a few dozen. Higher capitalization may be required of HHA #1 than HHA #2 since far more Medicare funds will be going to #1, thus increasing the risk to Medicare if #1 ceases operations.

In addition:

- The documentation of funds typically must include some sort of financial statement accompanied by an attestation from the bank certifying the availability of funds.

- A certain percentage of the available funds cannot have been borrowed.

- Per 42 CFR § 489.28(a), the new owner in an HHA CHOW, acquisition/merger, or consolidation must meet the capitalization requirements if the ownership change results in the issuance of a new provider number (e.g., the new owner will not assume the provider agreement and is therefore enrolling as a new provider).

(For more information on HHA capitalization requirements, see section 4.12 of this manual.)

C. HHA Components

There are three potential "components" of an HHA organization:

Parent – The parent HHA is the entity that maintains overall administrative control of its location(s).

Sub-unit – A sub-unit is associated with the parent HHA, but services a different geographic area. It is thus considered a semi-autonomous HHA since it is too far away from the parent HHA to share administration/supervision on a day-to-day basis. This means that HHA sub-units must separately enroll in Medicare, obtain a separate State survey, and sign a separate provider agreement. As with parent HHAs, sub-units receive their own 6-digit CCN.

Branch – Is a location or site that services patients in the same geographic area as the parent and shares administration with the parent on a daily basis. Consequently, unlike sub-units, branches need not enroll separately. They can be listed as practice locations on the main provider's (or sub-unit's) Form CMS-855A. Though the branch receives a 10-digit CCN identifier, it bills under the parent HHA's or sub-unit's CCN number.

The question of whether a particular location qualifies as a branch or a sub-unit – and hence requires a separate Form CMS-855A enrollment – is resolved by the RO.

Consider the following scenario:

PARENT HHA

owns owns owns

BRANCH A **SUB-UNIT B** **BRANCH C**

operates

BRANCH D

Here, the parent HHA has two branches (A and C) and one sub-unit (B). B also has a branch (D). They will be enrolled as follows:

- The parent HHA must complete a Form CMS-855A, undergo a State survey, and sign a provider agreement;

- Branches A and C would be listed as practice locations on the parent's Form CMS-855A because a branch is sufficiently "attached" to the parent to be considered part of it;

- Sub-unit B would enroll separately from the parent and would complete its own Form CMS-855A, undergo its own survey, and sign its own agreement. For purposes of enrollment, it is considered an entity separate and distinct from the parent, henceforth requiring a separate enrollment. (This also means that Sub-unit B would not have to be listed on the parent's Form CMS 855A as a practice location.)

- Because sub-units can have branches just like parents can, Branch D would be listed as a practice location on Sub-unit B's application.

- See Pub. 100-07, Chapter 2, section 2182 for discussion of branches.

D. Out-of-State HHA Branches

In general, an HHA can only have a branch in another State (and treat it as a branch, rather than a separate HHA) if there is a reciprocity agreement between the two States. If none exists, the out-of-state location must enroll as a new provider by submitting a new Form CMS-855A and signing a separate provider agreement. It cannot be treated as a branch/practice location of the main HHA. (See Pub. 100-07, chapter 2, section 2184 for specific provisions regarding HHAs that cross State lines.)

E. Additional Data

For more information on HHAs, refer to:

- Sections 1861(o) and 1891 of the Social Security Act;

- 42 CFR Part 484l

- 42 CFR §489.28 (capitalization);

- Pub. 100-07, chapter 2, sections 2180 – 2198C (State Operations Manual);

- Pub. 100-04, chapter 10 (Claims Processing Manual); and

- Pub. 100-02, chapter 7 (Benefit Policy Manual)

12.1.7 - Hospices

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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, 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)

12.1.8 - Hospitals and Hospital Units

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

- **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, 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.

12.1.9 - Indian Health Services (IHS) Facilities

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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 Form CMS-855A - 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. All Part A IHS facility applications are processed by a single intermediary - TrailBlazer Health Enterprises. The intermediary 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.) TrailBlazer will also receive tie-in notices from the RO.

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

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

12.1.10 - Organ Procurement Organizations (OPOs)

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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 one 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.

All independent OPOs' applications are processed by a single intermediary – Riverbend Government Benefits Administrator. A hospital-based OPO must enroll separately, be separately certified, and sign its own provider agreement. However, the hospital's intermediary will service the OPO; the OPO will not receive its own OSCAR number.

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).

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

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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, 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, chapter 2, section 2292A.)

B. Extension Locations

As discussed in Pub. 100-07, 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, 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, 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).

12.1.12 - Religious Non-Medical Health Care Institutions (RNCHIs)
(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

The 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, chapter 2, section 2054.1B.)

The CMS's Boston RO has primary responsibility over the approval and certification of RNHCIs. All RNCHI applications are handled by a single intermediary – Riverbend. 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©); and

- The provider must be a non-profit organization per subsection ©(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 Form 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, chapter 2, sections 2054, 2054.1, 20541A and 2054.1B (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).

12.1.13 - Rural Health Clinics (RHCs)

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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.

- Have special intermediaries. However, provider-based RHCs enroll with the parent provider's intermediary, which will also act as the RHC's claims intermediary.

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).

12.1.14 - Skilled Nursing Facilities (SNFs)

(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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).

12.2 - Carrier-Enrolled Organizational Suppliers
(Rev. 236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

12.2.1 - Ambulatory Surgical Centers (ASCs)
(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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.

12.2.2 - CLIA Labs

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

A. General Background Information

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

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

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

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

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

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

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

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

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

- Facilities which serve only as collection stations.

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

B. Form CMS-116 and CLIA Certificates

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

- CLIA certificate being requested;

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

- Hours during which laboratory testing will take place;

- Sites where testing will occur; and

- Type of tests that will be performed.

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

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

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

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

There are several types of CLIA certificates, including:

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

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

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

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

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

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

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).

12.2.3 - Mammography Screening Centers

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

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

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

For more information on mammography screening centers, refer to:

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

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

12.2.4 - Pharmacies

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

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

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

12.2.5 - Portable X-Ray Suppliers (PXRSs)

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

A. General Background Information

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Enrollment of PXRS

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

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

12.2.6 - Radiation Therapy Centers
(Rev. 236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

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

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

12.2.7 - Slide Preparation Facilities
(Rev. 236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

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

12.2.8 - Suppliers of Ambulance Services
(Rev.261, Issued: 06-27-08, Effective: 07-01-08, Implementation: 07-28-08)

Per 42CFR §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.

12.3 - Medicare Advantage and Other Managed Care Organizations
(Rev. 190, Issued: 02-23-07; Effective: 04-01-07; Implementation: 04-02-07)

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.)

The MA organizations and other MCOs undergo a stringent application process and are scrutinized closely by CMS regional and central office staffs before admission. If the organization does not have an indirect billing number, the contractor shall return the application and advise them to contact the CMS's Health Plan Payment Operations Support Team, which may issue the indirect billing number. When the number is received, the applicant may resubmit the enrollment package.

Whenever there is a reduction in a geographic area or an entire contract is terminated, the applicable CMS central office organization will provide a termination letter. Upon receipt of a termination notice, the MA/MCOs lose all Medicare billing privileges, effective December 31 of that year. The plan that leaves the MA/MCO arrangement will have to complete a new Form CMS-855B in order to qualify for Medicare billing privileges.

Durable Medical Equipment—If a MA/MCO wants to bill for durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) related to the care it has given an enrollee and which falls under the indirect payment procedure, it must contact the National Supplier Clearinghouse (NSC.) The Form CMS-855S shall be returned to the NSC with a copy of the letter conveying the indirect billing number issued by CMS central office. The above termination instructions apply for DMEPOS also.

12.4 - Individual Practitioners

(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

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.

12.4.1 - Anesthesiology Assistants

(Rev.195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

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)

12.4.2 - Audiologists

(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

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

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

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

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

OR

- Successfully completed a minimum of 350 clock-hours of supervised clinical practicum (or is in the process of accumulating that supervised clinical experience under the supervision of a qualified master or doctoral-level audiologist); and
- Performed at least 9 months of full-time audiology services under the supervision of a qualified master or doctoral-level audiologist after obtaining a master's or doctoral degree in audiology, or a related field; and
- Successfully completed a national examination in audiology approved by the Secretary. (42 CFR §440.110(c)(3)(ii)(B))

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

For more information on audiologists, refer to:

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

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

12.4.3 - Certified Nurse-Midwives
(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

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)

12.4.4 - Certified Registered Nurse Anesthetists (CRNAs)
(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

As stated in Pub. 100-04, chapter 12, section 140.1, a certified registered nurse anesthetist (CRNA) is a registered nurse who is licensed as such by the State in which the nurse practices and who:

- Is currently certified by the Council on Certification of Nurse Anesthetists or the Council on Recertification of Nurse Anesthetists, or

- Has graduated within the past 18 months from a nurse anesthesia program that meets the standards of the Council of Accreditation of Nurse Anesthesia Educational Programs and is awaiting initial certification.

For more information on CRNAs, refer to:

- Section 1861(bb) of the Social Security Act

- 42 CFR §410.69(b)

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

12.4.5 - Clinical Nurse Specialists (CNS)
(Rev. 219, Issued: 08-17-07, Effective: 11-19-07, Implementation: 11-19-07)

Per Pub. 100-02, chapter 15, section 210, a clinical nurse specialist must:

- 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; and

- 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)

12.4.6 - Clinical Psychologists

(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

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).

12.4.7 - Clinical Social Workers
(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

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)

12.4.8 - Nurse Practitioners
(Rev. 219, Issued: 08-17-07, Effective: 11-19-07, Implementation: 11-19-07)

Under 42 CFR §410.75(b), in order to bill Medicare a nurse practitioner must meet the following conditions:

- 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 be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; or

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner by December 31, 2000.

Nurse practitioners applying for a Medicare billing number for the first time on or after January 1, 2001, must meet the following requirements:

- 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

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

Nurse practitioners applying for a Medicare billing number for the first time on or after January 1, 2003, must meet the following requirements:

- 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

- Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; and

- Possess a master's degree in nursing.

Thus, any nurse practitioner applying for a Medicare billing number for the first time on or after January 1, 2003, must meet the post-January 1, 2003 requirements.

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)

12.4.9 - Occupational and Physical Therapists in Private Practice
(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

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

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

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

1. Doctors of:

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

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

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

12.4.11 - Physician Assistants (PAs)
(Rev. 236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

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

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

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

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

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

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

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

For more information on physician assistants, refer to:

- 42 CFR §410.74

- Pub. 100-04, chapter 12, sections 110 through 110.3 (Claims Processing Manual)

12.4.12 - Psychologists Practicing Independently

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

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

- They render services on their own responsibility, free of the administrative and professional control of an employer such as a physician, institution or agency;

- The persons they treat are their own patients;

- They have the right to bill directly, collect and retain the fee for their services; and

- The psychologist is State-licensed or certified.

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

- The office is confined to a separately-identified part of the facility which is used solely as the psychologist's office and cannot be construed as extending throughout the entire institution; and

- The psychologist conducts a private practice (i.e., services are rendered to patients from outside the institution as well as to institutional patients).

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

For more information on independently practicing psychologists, refer to:

- Section 4.2.7 of this manual

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

12.4.13 - Registered Dietitians

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

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

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

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

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

There are two caveats to these requirements:

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

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

For more information on registered dietitians, refer to:

- Sections 1861(vv) of the Social Security Act

- 42 CFR §410.130 through §410.134

12.4.14 – Speech Language Pathologists in Private Practice
(Rev.)

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

12.5.1 - Other Part B Services
(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

12.5.2 - Diabetes Self-Management Training (DSMT)
(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

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)

12.5.3 - Mass Immunizers Who Roster Bill

(Rev. 195, Issued: 03-30-07, Effective: 04-30-07, Implementation: 04-30-07)

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.)

12.6 - Medicaid State Agencies

(Rev. 182, Issued: 01-12-07; Effective: 01-26-07; Implementation: 03-01-07)

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.

13 – Provider Enrollment Disenrollment Actions

(Rev. 158, Issued: 09-15-06; Effective: 10-01-06; Implementation: 10-02-06)

If circumstances warrant, a fee-for-service contractor shall deactivate or revoke a provider or supplier's Medicare billing privileges under certain circumstances. Deactivation or revocation of Medicare billing privileges will not impact a provider or supplier's ability to submit claims to non-Medicare payers using their National Provider Identifier.

13.1 – CMS or Contractor Issued Deactivations

(Rev. 272; Issued: 11-07-08; Effective/Implementation Date: 12-08-08)

A. General Instructions

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

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

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

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

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

Providers and suppliers deactivated for non-submission of a claim are required to complete and submit a Medicare enrollment application to recertify that the enrollment information currently on file with Medicare is correct and must furnish any missing information as

appropriate. The provider or supplier must meet all current Medicare requirements in place at the time of reactivation, and be prepared to submit a valid Medicare claim.

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

Each contractor shall forward a copy of the Deactivation Summary Report provided by the Multi-Carrier System to its designated DPSE contractor liaison *no later than the last calendar day of each month.*

B. Certified Suppliers and Providers

If a certified supplier's or provider's billing privileges are deactivated or reactivated, the contractor shall notify the RO thereof no later than 10 calendar days after the deactivation or reactivation became effective. The notification can be done in any manner the contractor chooses, including copying the RO on any reactivation/deactivation letter sent to the supplier or provider.

13.2 – Contractor Issued Revocations

(Rev. 269: Issued: 09-19-08; Effective/Implementation Date: 10-20-08)

A. Revocation Reasons

The contractor may issue a revocation (or recommend a revocation) using revocation reasons 1 through 10 below without prior approval from CMS. Section 13.3 lists an additional revocation reason that requires DPSE review and approval.

When issuing a revocation, the contractor shall insert the appropriate regulatory basis (e.g., 42 CFR §424.535(a)(1)) into its determination letter. The contractor shall not use provisions from this chapter 10 as the basis for revocation.

Revocations based on non-compliance:

Revocation 1 (42 CFR §424.535(a)(1))

The provider or supplier is determined not to be in compliance with the enrollment requirements described in this section or in the enrollment application applicable to its provider or supplier type, and has not submitted a plan of corrective action as outlined in 42 CFR Part 488.

Noncompliance includes, but is not limited to the provider or supplier no longer having a physical business address or mobile unit where services can be rendered and/or does not have a place where patient records are stored to determine the amounts due such provider

or other person and/or the provider or supplier no longer meets or maintains general enrollment requirements.

Revocation 2

The provider or supplier has lost its license(s) or is not authorized by the Federal/state/local government to perform the services for which it intends to render. (In its revocation letter, the contractor shall cite the appropriate statutory and/or regulatory citations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the revocation letter the exact provision within said statute/regulation that the provider/supplier has failed to comply with.)

Revocation 3

The provider or supplier no longer meets CMS regulatory requirements for the specialty for which it has been enrolled. (In its revocation letter, the contractor shall cite the appropriate statutory and/or regulatory citations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the revocation letter the exact provision within said statute/regulation that the provider/supplier is not in compliance with.)

Revocation 4 (42 CFR §424.535(a)(1))

The provider or supplier (upon discovery) does not have a valid SSN/employer identification number for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or delegated or authorized official.

Revocations based on provider or supplier conduct:

Revocation 5 (42 CFR §424.535(a)(2))

The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is:

(i) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in 42CFR §1001.2 , in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) Is debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 C.F.R. part 76.

If an excluded party is found, notify DPSE immediately. DPSE will notify the Government Task Leader (GTL) for the appropriate PSC. The GTL will, in turn, contact the Office of Inspector General's office with the findings for further investigation.

Revocations based on felony:

Revocation 6 (42 CFR §424.535(a)(2))

The provider, supplier, or any owner of the provider or supplier, within the 10 years preceding enrollment or revalidation of enrollment, was convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries to continue enrollment.

(i) Offenses include—

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(ii) Revocations based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

Revocations based on false or misleading information:

Revocation 7 (42 CFR §424.535(a)(4))

The provider or supplier certified as ‘‘true’’ misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current law and regulations.)

If it is discovered that the provider or supplier deliberately falsified, misrepresented, or omitted information contained in the application or deliberately altered text on the application form, issue a revocation or recommendation for revocation.

Revocations based on misuse of billing number

Revocation 8 (42 CFR §424.535(a)(7))

The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers who enter into a valid reassignment of benefits as specified in 42CFR §424.80 or a change of ownership as outlined in 42CFR §489.18.

Additional revocation reasons:

Revocation 9 (42 CFR §424.535(a)(5))

CMS determines, upon on-site review, that the provider or supplier is no longer operational to furnish Medicare covered items or services, or is not meeting Medicare enrollment requirements under statute or regulation to supervise treatment of, or to provide Medicare covered items or services for, Medicare patients. Upon on-site review, CMS determines that—

(i) A Medicare Part A provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) A Medicare Part B supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

Revocation 10 (42 CFR §424.535(a)(6))

The provider or supplier fails to furnish complete and accurate information and all supporting documentation within 30 calendar days of the provider or supplier's notification from CMS to submit an enrollment application and supporting documentation.

B. Revocation Letters

In accordance with 42 CFR § 405.874(b), all revocation letters shall be sent by certified mail and shall contain sufficient factual and background information so that the reader understands exactly why the revocation occurred. It is not enough to simply list one of the revocation reasons. All applicable regulations, as well as a detailed factual rationale for the contractor's decision, must be identified in the letter. For instance, if a provider is revoked based on the submission of false information, the contractor must identify in its letter the falsified information, how and why the contractor determined it was false, the regulation in question, etc. If there were multiple reasons for revocation, the letter shall state as such and shall furnish all of the aforementioned statutes, regulations, facts, etc. applicable to each reason. The notice must also identify the provider's right to appeal under 42 CFR Part 498 and the address to which the written appeal must be mailed. For more detailed information on the appropriate composition of revocation letters, see sections 14 and 19 of this chapter.

When a provider or supplier number is revoked, the contractor must maintain documentation as required by section 10 of this chapter. In addition, when a provider's or

supplier's billing privileges are revoked, the provider agreement in effect at the time of revocation is also terminated.

Prior to issuing a revocation for a Part A provider or a certified Part B supplier, the contractor shall notify DPSE.

C. Effective Date of Revocations

Per 42 CFR §405.874(b)(2), a revocation is effective 30 days after CMS or the CMS contractor mails the notice of its determination to the provider or supplier. However, a revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment. In addition, if the revocation was due to the revocation or suspension of the provider/supplier's license or certification to perform Medicare services, said revocation can be made retroactive to the date of the license suspension/revocation.

As stated in 42 CFR §424.535(d), if the revocation was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare services, the revocation may be reversed if the provider or supplier submits proof that it has terminated its business relationship with that individual or organization within 30 days of the revocation notification. The contractor, however:

- Need not solicit or ask for such proof in its recommendation letter. It is up to the provider to furnish this data on its own volition.

- Has the ultimate discretion to determine whether sufficient "proof" exists.

D. Payment

Per 42 CFR §405.874(b)(3),Medicare does not pay and a CMS contractor rejects claims for items or services submitted with a service date on or after the effective date of a provider's or supplier's revocation.

E. Corrective Action

Per 42 CFR §405.874(e), if a provider or supplier completes a corrective action plan and provides sufficient evidence to the contractor that it has complied fully with the Medicare requirements, the contractor may reinstate the provider's or supplier's billing privileges. The contractor may pay for services furnished on or after the effective date of the reinstatement. The effective date is based on the date the provider or supplier is in compliance with all Medicare requirements.

A contractor's refusal to reinstate the provider or supplier's billing privileges based on a corrective action plan is not an initial determination under 42CFR part 498.

F. Reapplying After Revocation

As stated in 42 CFR §424.535(c), after a provider, supplier, delegated official, or authorizing official that has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation. For instance, a revocation on the grounds that the provider is no longer operational will generally warrant a 2 year bar; a revocation based on a felony conviction or the submission of false information will typically result in a 3 year bar.

Prior to sending out the revocation letter, the contractor shall refer the matter to DPSE, which will make the determination as to the appropriate length of the re-enrollment bar.

13.2.1 - Revocations Involving Certified Suppliers and Providers

(Rev. 260, Issued: 06-20-08, Effective: 07-22-08, Implementation: 07-22-08)

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

In revoking the provider or supplier, the contractor shall:

- Issue the revocation letter in accordance with section 13.2; the contractor shall copy the RO and/or the State on said letter;

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

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

13.3 - DPSE Issued Revocations

(Rev. 175; Issued: 11-24-06; Effective/Implementation Dates: 12-26-06)

Based on information from a Program Safeguard Contractor (PSC), CMS Satellite Office, or other CMS component, including a Regional Office, DPSE may request that fee-for-service contractors revoke a provider or supplier's Medicare billing privileges using revocation 11. Fee-for-service contractors shall only issue a revocation using Revocation 11 when they receive a properly executed Joint Signature Memorandum from CMS Central Office.

13.3.1 - PSC Identified Revocations

(Rev. 214; Issued: 06-29-07; Effective: 07-02-07; Implementation Date: 07-30-07)

If a PSC believes that the use of revocation 11 is appropriate, the PSC will develop a case file, including their reason(s) for revocation, and submit the case file and all supporting documentation to their respective government task leader (GTL) within Division of Benefit Integrity Management Operations (DBIMO). The PSC will provide the GTL with the name, all known billing numbers, including the NPI and associated Medicare billing numbers, and locations of the provider or supplier in question as well as detailed information to substantiate the revocation action.

The GTL will review the PSC case file and:

- Return the case file to PSC for additional development, or
- Recommend that DPSE consider approval the PSC recommendation for revocation.

If DPSE concurs with GTL's revocation recommendation, DPSE will instruct the applicable fee-for-service contractor to revoke a billing number through a Joint Signature Memorandum and notify the DBIMO of the action taken.

13.3.2 - CMS Satellite Office or Regional Office Identified Revocations
(Rev. 269: Issued: 09-19-08; Effective/Implementation Date: 10-20-08)

If a CMS satellite office or regional office believes that the use of revocation 11 (see 42 CFR §424.535(a)(8) and section 13.2 of this chapter) is appropriate, the CMS satellite office or regional office will develop a case file, including the reason(s) for revocation, and submit the case file and all supporting documentation to DPSE. The CMS satellite office or regional office will provide the DPSE with the name, all known billing numbers, including the NPI and associated Medicare billing numbers, and locations of the provider or supplier in question as well as detailed information to substantiate the revocation action.

If DPSE concurs with revocation recommendation, DPSE will instruct the applicable contractor to revoke the billing number and notify DBIMO of the action taken.

Revocation 11 (42 CFR §424.535(a)(8))

The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

13.4 - External Reporting Requirements
(Rev. 233; Issued: 01-18-08; Effective/Implementation: 02-20-08)

No later than the last day of January, April, July and October of each year, the contractor shall furnish to its DPSE liaison via e-mail the following information for the previous quarter:

A. Fiscal Intermediaries (includes A/B MACs)

- Number of recommendations for denial of initial CMS-855A applications (including new owner CHOWs) and the three most frequent reasons for said recommendations;

- Number of revocations (or recommendations for revocations) and the three most frequent reasons for said actions.

B. Carriers (includes A/B MACs)

- Number of denials of initial CMS-855 applications (this includes denial recommendations for ASCs and PXRS) and the three most frequent reasons for said denials. (CMS-855B and CMS-855I denials shall be listed separately.)

- Number of revocations and the three most frequent reasons therefore. (CMS-855B and CMS-855I revocations shall be listed separately.)

The contractor need not submit this data to CMS via any sort of spreadsheet. A simple e-mail is sufficient. The first report is due by January 31, 2008, and shall cover actions taken in October, November and December of 2007.

14 – Model Correspondence Letters

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

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

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

14.1 – Model Acknowledgement Letter

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

CMS alpha representation
Contractor

[Month Day & Year]

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

Dear [Insert Provider/Supplier name]:

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

[Insert this language if a reference number is provided: Your application reference number is: (insert reference number)]

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

Sincerely,

[Your Name]
[Title]

14.2 – Model Development Letter

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

See section 3.1 of this manual for information on the requirements for the development letter.

CMS alpha representation
Contractor

[Month Day & Year]

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

[Insert application reference number]

Dear [Insert Provider/Suppler name]:

We have received your Medicare enrollment application [insert application type]. In order to complete processing your application we are requesting the following revisions and or supporting documentation. Consistent with regulations found at 42 CFR §424.525, we may reject this application if you do not furnish complete information within 60 calendar days of the postmark date of this letter.

Requested Revisions:

(The following are examples)

- [Insert section number and subsection letter (if applicable)]
    - [Insert a brief description of revision needed. Try to limit descriptions to two sentences or less. (See examples below.)]
- Section 1A
    - National Provider Identifier (NPI)
- Section 6 and 16
    - Complete these sections for each Delegated Official
- Section 15
    - Print, sign, and date this section to approve the changes requested
- Section 17
    - Completed Form CMS 460, Medicare Participating Physician or Supplier Agreement (PAR)

Medicare enrollment application(s) [insert application type] must be downloaded from the Centers for Medicare & Medicaid Services (CMS) Web site at www.cms.hhs.gov/MedicareProviderSupEnroll. You should return the complete application(s) to the address listed below:

[Insert contact address]

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

Sincerely,

[Your Name]
[Title]
[Enclosure]

14.3 – Model Rejection Letter

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

See section 3.1 of this manual for specific reasons when a contractor shall reject the provider or suppliers enrollment application(s). This policy applies to all applications identified in sections 2.1 and 2.2 of this manual.

CMS alpha representation
Contractor

[Month Day & Year]

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

Dear [Insert Provider/Suppler name]:

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

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

(Repeat for multiple, if necessary)

In compliance with Federal regulations found at 42 CFR §424.525, providers and suppliers are required to submit complete and all supporting documentation within 60 calendar days from the postmark date of the contractor request for missing/incomplete information. If you would like to resubmit an application, you must complete a new Medicare enrollment application(s) [insert application type(s)]. Please make sure to address the issues stated above as well as sign and date the new certification statement page on your resubmitted application.

Medicare enrollment application(s) [insert application type] must be downloaded from the Centers for Medicare & Medicaid Services (CMS) Web site at www.cms.hhs.gov/MedicareProviderSupEnroll. You should return the complete application(s) to the address listed below:

[Insert contact address]

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

Sincerely,

[Your Name]
[Title]

14.4 – Model Returned Application Letter

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

See section 3.2 of this manual for information on when a contractor shall return the enrollment application(s) to the provider or supplier. This policy applies to all applications identified in sections 2.1 and 2.2 of this manual.

CMS alpha representation
Contractor

[Month Day & Year]

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

[Insert application reference number]

Dear [Insert Provider/Suppler name]:

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

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

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

Medicare enrollment application(s) [insert application type] must be downloaded from the Centers for Medicare & Medicaid Services (CMS) Web site at www.cms.hhs.gov/MedicareProviderSupEnroll. You should return the complete application(s) to the address listed below:

[Insert contact address]

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

Sincerely,

[Your Name]
[Title]

14.5 – Model Revalidation Letter

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

See section 9 of this manual for information regarding revalidation.

CMS alpha representation
Contractor

[Month Day & Year]

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

Dear [Insert Provider/Suppler name]:

Consistent with Medicare regulations found at 42 CFR §424.515, [insert contractor name], a Medicare contractor, requires that you submit a Medicare enrollment application [insert application type] and all applicable supporting documentation, including the National Provider Identifier (NPI) and the Authorization Agreement Electronic Funds Transfer (CMS-588) within 60 calendar days of the postmark date of this letter.

Enclosed is the appropriate [insert application type] enrollment application for your provider or supplier type. Additional copies of the Medicare enrollment application(s) [insert application type] must be downloaded from the Centers for Medicare & Medicaid Services (CMS) Web site at www.cms.hhs.gov/MedicareProviderSupEnroll.

While the submission of this application will start your 5-year revalidation cycle, you are required by regulations found at 42 CFR §424.520 to submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) doing business as (DBA) name, (3) practice location, (4) ownership, (5) authorized/delegated officials and (6) changes in payment information such as changes in electronic funds transfer information. In addition, you are required to report any adverse legal actions, including felony convictions, license suspensions and debarments and exclusions.

Failure to submit a complete [insert application type] and all supporting documentation within 60 calendar days of the postmark date of this letter may result in your Medicare billing privileges being revoked.

Please return the completed application(s) to:

[Insert application return address]

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

Sincerely,

[Your Name]
[Title]
[Enclosure]

14.6 – Model Approval Recommended Letter for Part A Providers & Certified Suppliers

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

CMS alpha representation
Contractor

[Month Day & Year]

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

Dear [Insert Provider/Suppler name]:

[Name of contractor] has processed your Medicare enrollment application [insert application type] to enroll in the Medicare Program and forwarded a recommendation to the CMS regional office for review. The next step of the enrollment process involves a site visit or survey conducted by the State Survey Agency or an accrediting organization to ensure compliance with the Conditions of Participation for your provider or supplier type.

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

Sincerely,

[Your Name]
[Title]
Enclosure
cc:

14.7 – Model Approval Letter for Initial Enrollment

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]

[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

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

Now that we have issued your PTAN, you can start billing the Medicare program using your NPI. You must use your NPI on all Medicare claim submissions. Your PTAN is also activated for use and is required to access the interactive voice response (IVR) system for inquires concerning claims status, beneficiary eligibility, check status or other supplier related transactions. Because the PTAN is not considered your Medicare legacy identifier, do not report it to the National Plan and Provider Enumeration System (NPPES) as an "other" provider identification number.

Medicare Enrollment Information

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

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

Finally, you are required by regulations found at 42 CFR §424.520 to submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) doing business as (DBA) name, (3) practice location, (4) ownership, (5) authorized/delegated officials and (6) changes in payment information such as changes in electronic funds transfer information. In addition, you are required to report any adverse legal actions, including felony convictions, license suspensions and debarments and exclusions.

Additional information about the Medicare program, including billing, fee schedules, and Medicare polices and regulations can be found at our Web site at [insert Web site address] or the Centers for Medicare & Medicaid Services' (CMS) Web site at www.cms.hhs.gov/home/medicare.asp. Please verify the accuracy of your enrollment information, if changes are necessary or if you have any questions, please call [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

14.8 – Model Approval Letter for Change of Information
(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

CMS alpha representation
Contractor

[Month Day & Year]

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

Dear [Insert Provider/Suppler name]:

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

Medicare Enrollment Information

Provider \ Supplier name:	[Insert name]
[Insert revised item on the application]:	[Insert updated or changed item on the application]
National Provider Identifier (NPI):	[Insert issued NPI]
[Insert active or terminated here] Provider Transaction Access Number (PTAN):	[Insert active or inactive PTAN]
Specialty:	[Insert provider/supplier specialty]
You are a:	[Insert participating or nonparticipating]

Effective date [Insert "of termination" if the applicant is voluntarily terminating Medicare participation]	[Insert effective date or effective date of termination]

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

ADDITIONAL INFORMATION

The provider/supplier's PTAN will be the required authentication element for all inquiries to Interactive Voice Response (IVR) systems, customer service representatives (CSRs), and written inquiry units, therefore keep your PTAN secure.

If you are an existing Medicare provider and currently submit claims electronically, or are new to the Medicare program and plan on filing claims electronically, please contact our EDI department at [insert phone number].

To maintain an active enrollment status in the Medicare Program, regulations found at 42 CFR §424.520 require that you submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) doing business as (DBA) name, (3) practice location, (4) ownership, (5) authorized/delegated officials and (6) changes in payment information such as changes in electronic funds transfer information. In addition, you are required to report any adverse legal actions, including felony convictions, license suspensions and debarments and exclusions.

As a Medicare health provider or supplier, you must also obtain or update your National Provider Identifier (NPI) maintained with the National Plan and Provider Enumeration System (NPPES). To make changes to an NPI, please contact the NPI Enumerator at https://NPPES.cms.hhs.gov or call the Enumerator at 1-800-465-3203 or TTY 1-800-692-2326. For more information about NPI enumeration, visit www.cms.hhs.gov/NationalProvIdentStand.

Please verify the accuracy of your enrollment information, if additional changes are necessary or if you have any questions, please call [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

14.9 – Model Revalidation Approval Letter

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

CMS alpha representation
Contractor

[Month Day & Year]

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

Dear [Insert Provider/Suppler name]:

We have processed your Medicare enrollment application [insert application type] to revalidate your Medicare enrollment information.

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

Medicare Enrollment Information:

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

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

Please verify the accuracy of your enrollment information, if additional changes are necessary or if you have any questions, feel free to contact our office at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

14.10 – Model Denial Letter for Part B, Non-IDTF

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

See section 6.2 of this manual and/or 42 CFR §424.530 for information regarding denial reasons.

CMS alpha representation
Contractor

[Month Day & Year]

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

RE: [insert decision]

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application [insert application type], it was determined that you do not meet the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., Doctor of Medicine, Physicians Assistant, Nurse Practitioner, etc.]

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

(Repeat for multiple, if necessary)

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

[Insert contact address]

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

[Insert contact address]

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

Sincerely,

[Your Name]
[Title]

14.11 – Model Denial Letter for IDTFs

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

See section 4.19 of this manual and/or CFR §410.33 for the IDTF performance standards and requirements.

CMS alpha representation
Contractor

[Month Day & Year]

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

Re: [Subject]

Dear [Insert Provider/Suppler Name]:

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

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

STANDARDS: [List ALL performance standards not met].

FACTS: [List ALL applicable regulatory authority that corresponds to the performance standards not met. For example, 42 CFR §410.33(c), 42 CFR §410.33(g)(4)(i) and 42 CFR §410.33(g)(5)(ii)].

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within

30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Contractor address]

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

[Contractor Address]

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

Sincerely,

[Your Name]
[Title]

14.12 – Model Revocation Letter

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

See section 13 of this manual to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges.

CMS alpha representation
Contractor

[Month Day & Year]

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

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare Provider Transaction Access Number (PTAN) [insert PTAN] that is associated to the National Provider Identifier (NPI) [insert NPI] is being revoked effective [insert date 30 days from date of letter].

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

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

[Insert contract address]

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

[Insert contact address]

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

Sincerely,

[Your Name]
[Title]

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

14.13 – Model Reconsideration Letter

(Rev. 266; Issued: 09-05-08; Effective/Implementation Dates: 10-06-08)

See section 19 of this manual for information on the appeals process.

CMS alpha representation
Contractor

[Month Day & Year]

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

[Reference number]

Dear [Insert Provider/Suppler name]:

This decision letter is in response to your request received by [insert contractor name]. This request is based on the above referenced providers [revocation or denial] of your [insert Medicare number or application type]. The initial determination letter was dated [insert date of initial determination letter] and thus, this appeal is timely submitted. This letter contains the decision.

The decision is based on Medicare laws, regulations and guidelines. This decision is based on the evidence in the file, and any information that you may have sent with or since the time of your hearing request.

FACTS: [Insert Regulation]

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

(Repeat for multiple, if necessary)

DECISION:

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

This decision is an UNFAVORABLE DECISION. Please see below for additional appeal rights.

FURTHER APPEAL RIGHTS: ADMINISTRATIVE LAW JUDGE (ALJ)

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

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

Appeal rights can be found at 42 CFR §498 of the Medicare regulations. The regulation explains the appeal rights following the determinations by The Centers for Medicare & Medicaid Services as to whether such entities [meet and/or continue to meet] the requirements for enrollment in the Medicare Program.

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

Sincerely,

[Your Name]
[Title]

14.14 – Model Identity Theft Prevention Letter
(Rev.)

15 – Internet-based PECOS Applications
(Rev. 271; Issued: 10-24-08; Effective/Implementation Date: 11-24-08)

This section furnishes guidance to contractors on the proper handling and processing of CMS-855 applications submitted via the Internet (hereinafter referred to as "Internet-based PECOS" applications). Unless otherwise stated, the instructions in this section 15 apply only to Internet-based PECOS applications.

Contractors shall begin processing such applications as soon as the Internet-based capability is effective for their respective A/M MAC jurisdiction or State/processing area.

A. General Background Information

The principal logging and tracking (L & T) statuses for PECOS Internet applications that are not in a final status are:

- Received;
- In Review;
- Returned for Corrections;
- Corrections Received;
- Review Complete; and

- Application in Process.

The submission of a PECOS Internet application will immediately place the L & T record into a "Received" status.

B. Certification Statement

If the provider fails to submit a signed and dated certification statement to the contractor within 15 calendar days of the date on which it submitted its Internet-based PECOS application to the contractor, the contractor may – but is not required to - reject the application. (For purposes of this policy, the certification statement must be received by the contractor's provider enrollment unit by the 15th day.) The 15-day rule applies to all CMS-855 PECOS Internet applications, regardless of the transaction involved.

For initial PECOS Internet applications (as the term "initial" is defined in section 2.1 of this manual), it is only necessary that the dated signature of at least one of the provider's authorized officials be on the certification statement that must be sent in by the 15th day; obtaining the signatures of the other authorized and delegated officials shall be done through the normal application development process. For PECOS Internet changes of information (as the term "changes of information" is defined in section 2.2 of this manual), if the certification statement is signed by an individual who is not on file with the contractor as being an authorized or delegated official of the provider, the contractor may accept the certification statement but shall develop for information on the person in question in accordance with sections 4.15 and 4.16 of this manual.

If the provider submits: (1) an undated certification statement, or (2) a certification statement on which the Web Tracking ID does not match that in PECOS, the contractor shall treat it as a non-submission; while it is recommended that the contractor contact the provider to request a signed/correct certification statement, it is not required. (This requirement applies to any CMS-855 transaction, including requests for additional/clarifying information.)

If the contractor elects to contact the provider to request a dated/valid certification statement, the contractor may give the provider an additional 15 days (or, for that matter, any additional time beyond the initial 15-day period) to submit the new certification statement. In determining whether to accept an untimely certification statement, the contractor shall take into account factors such as: (1) the degree of the provider's cooperation, (2) the time it took for the certification statement to be transferred from the contractor's main mailroom to the provider enrollment department, and (3) the number of days by which the provider missed the 15-day deadline.

C. Pre-Screening

The contractor shall prescreen all PECOS Internet applications, as the term "prescreen" is defined in section 3.1 of this manual.

If the contractor can determine (without actively processing the application) that an application can be returned under section 3.2 of this manual (e.g., was submitted more than 30 days prior to the effective date), the contractor shall return the application without waiting for the arrival of the certification statement.

D. Switch to "In Review" Status

After – and only after - it receives and accepts the provider's certification statement, the contractor shall: (1) enter the date of signature into the "Certification Date" box in the L & T record, and (2) change the L & T status to "In Review." The contractor, in other words, shall not initiate any application verification activities prior to its receipt and acceptance of the certification statement and its completion of tasks (1) and (2) in the previous sentence.

After changing the L & T status to "In Review," the contractor shall review the Application Data Report (ADR), and shall commence all applicable validation activities identified in this manual. Note that the ADR is only available for printing when the L & T record is in one of the following statuses: "In Review," "Returned for Corrections," or "Corrections Received."

E. Request for Additional/Clarifying Information

If, when performing verification activities, the contractor determines that additional or clarifying information is needed, the contractor shall – after switching the L & T status to "Returned for Corrections" - send an e-mail (via PECOS Internet) to the provider:

- Requesting said data along with, as necessary, a signed and dated certification statement; and

- Listing a date(s) by which the information and certification statement, respectively, must be submitted to the contractor. (The establishment of this submission due date shall be done in accordance with section 5.3(A)(2) of this manual.)

(In accordance with section 5.1 of chapter 10 – and to avoid multiple contacts with the provider - the contractor shall attempt to validate <u>all</u> of the data on the ADR prior to requesting additional/clarifying information from the provider.)

The contractor shall not attempt to contact the provider for additional/clarifying information prior to sending the e-mail referenced above, though the contractor is free to make a follow-up contact with the provider after sending the e-mail. Note that this e-mail is the only contact that the contractor is required to make per section 5.3 of this manual.

The provider must submit all applicable supporting documentation (e.g., licenses, CMS-588) with its PECOS Internet application. It is not necessary, however, for the provider to submit the supporting documentation: (1) in the same package as the certification statement, or (2) prior to its submission of the certification statement. Regardless, if the provider fails to submit all applicable supporting documentation, the contractor shall develop for it.

F. Submission of Additional/Clarifying Information

The contractor shall note that a provider may submit requested additional/clarifying data via PECOS Internet or any other mechanism permitted under chapter 10 (e.g., paper, fax).

If the provider fails to submit the requested additional/clarifying information and the accompanying certification statement within 30 calendar days from the date the contractor sent the e-mail referred to above, the contractor shall follow the procedures in section 3.1 of this manual. If, however, the contractor receives the additional/clarifying information from the provider, the contractor shall not recommence its processing of the application until the accompanying certification statement is received in the contractor's provider enrollment department. Once the contractor accepts the newly signed and dated certification statement, it shall enter the certification statement date into the L & T record.

If, after receiving the additional/clarifying information and certification statement from the provider, the contractor determines that further information is needed and elects to request this data from the provider (i.e., elects to waive the "one contact" threshold described in section 5.3 of this manual), the contractor shall do so in accordance with the instructions in this section 15.

G. Transferal of Data into PECOS

Once the contractor ties the L & T record to the enrollment record, the contractor shall begin the process of transferring the data into PECOS by accepting or rejecting the various data elements. The contractor shall note that: (1) it cannot undo any transfer of information into PECOS, and (2) once the L & T is tied to the enrollment record, the application cannot be returned to the provider for corrections.

H. Miscellaneous Instructions

The contractor shall note the following:

- **Deletion of Erroneous Record** - The contractor shall only delete an erroneously created L & T record by: (1) moving the L & T record to a status of "Rejected," and (2) using an L & T status reason of "Deleted."

- **Gatekeeper/Enrollment Screens** - The Gatekeeper and Enrollment screens are only used in the case of CMS-855 initial enrollment PECOS Internet submissions.

- **Post-Processing Recordkeeping** - After processing a particular PECOS Internet transaction, the contractor shall maintain in the provider's file: (1) a copy of the final version of the ADR, (2) all submitted certification statements and applicable supporting documents, and (3) documentation of all contacts with the provider (e.g., phone calls, e-mails) per section 10 of this manual.

State Agencies - In situations described in this manual in which the contractor is required to submit a copy of the provider's paper CMS-855 to the State agency, the contractor shall send a copy of the ADR in lieu of the CMS-855 if the provider sent in its application via the Internet.

16 – Reserved for Future Use

(Rev. 173; Issued: 11-13-06; Effective/Implementation Dates: 11-15-06)

17 – Maintenance and Release of CMS-855 Data

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

17.1 – Security

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

The contractor shall ensure that the highest level of security is maintained for all systems and its physical and operational processes, in accordance with the CMS/Business Partners Systems Security Manual (BPSSM) and the Program Integrity Manual.

Applications shall never be removed from the controlled area to be worked on at home or in a non-secure location. Additionally, provider enrollment staff must control and monitor all applications accessed by other contractor personnel.

All contractor staff shall be trained on security procedures as well as relevant aspects of the Privacy Act and the Freedom of Information Act. This applies to all management, users, system owners/managers, system maintainers, system developers, operators and administrators, including contractors and third parties, of CMS information systems, facilities, communication networks and information.

Note that these instructions are in addition to, and not in lieu of, all other instructions issued by CMS regarding security.

17.2 - Release of Information

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

Once the provider has submitted an enrollment application (as well as after it has been enrolled), the contractor may not release – either orally or in writing - any information about the provider's enrollment status (unless specifically authorized in some other CMS instruction) to any person in the provider's organization other than an authorized or delegated official of the provider, or the provider's contact person listed in section 13 of the CMS-855. It is recommended that the contractor notify the provider of this as early in the enrollment process as possible to avoid later problems.

In addition:

- When sending e-mails, the contractor shall not transmit sensitive data, such as SSNs or EINs.

- The contractor may not send PECOS screen printouts to the provider.

- If the provider requests a copy of the CMS-855 it has on file, the contractor shall ask an authorized or delegated official on file to submit a signed letter on the provider's letterhead formally requesting the CMS-855. If he/she sends it in and the contractor has no reason to question its authenticity, it may furnish the provider one copy of its CMS-855.

- Carriers shall not send Medicare provider numbers (PINs) to groups or organizations, including the group's authorized or delegated official. If a group/organization needs to know the PIN number of an individual provider, it must contact the provider directly for this information or have the individual provider request this information in writing from the carrier. If the individual provider requests its PIN number, the carrier can mail it to the provider's practice location. The contractor should never give this information over the phone.

17.3 – File Maintenance

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

Contractors shall maintain and store all documents relating to the enrollment of a provider into the Medicare program. These documents include, but are not limited to, Medicare enrollment applications and all supporting documents, attachments, correspondence, and appeals submitted in conjunction with an initial enrollment, reassignment, change of enrollment, revalidation, etc.

Supporting documentation includes, but is not limited to:

- Copies of Federal, State and/or local (city/county) professional licenses, certifications and/or registrations;

- Copies of Federal, State, and/or local (city/county) business licenses, certifications and/or registrations;

- Copies of professional school degrees or certificates or evidence of qualifying course work;

- Copies of CLIA certificates and FDA mammography certificates;

Medicare contractors shall dispose of the aforementioned records as described below:

1) Provider/Supplier and Durable Medical Equipment Supplier Application

a. Rejected applications as a result of provider failing to provide additional information

Disposition: Destroy when 7 years old.

b. Approved applications of provider/supplier

Disposition: Destroy 15 years after the provider/supplier's enrollment has ended.

c. Denied applications of provider/supplier.

Disposition: Destroy 15 years after the date of denial.

d. Approved application of provider/supplier, but the billing number was subsequently revoked.

Disposition: Destroy 15 years after the billing number is revoked.

e. Voluntary deactivation of billing number

Disposition: Destroy 15 years after deactivation.

f. Provider/Supplier dies

Disposition: Destroy 7 years after date of death.

2) Electronic Mail and Word Processing System Copies

a) Copies that have no further administrative value after the recordkeeping copy is made. These include copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories on hard disk or network drives, and copies on shared network drives that are used only to produce the recordkeeping copy.

Disposition: Delete within 180 days after the recordkeeping copy has been produced.

b) Copies used for dissemination, revision or updating that are maintained in addition to the recordkeeping copy.

Disposition: Delete when dissemination, revision, or updating is complete.

18 – Customer Service

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

18.1 - Web Sites

(Rev. 150, Issued: 06-30-06, Effective: 07-03-06, Implementation: 07-03-06)

Contractors must provide a link to CMS' provider/supplier enrollment Web site located at http: www.cms.hhs.gov/MedicareProviderSupEnroll. The link shall be available on the contractor's existing provider outreach Web site (which should be an established subdomain of the contractor's current commercial Web site) and it must comply with the

guidelines stated in the Provider/Supplier Information and Education Web site section (Activity Code 14101) under the Provider Communications (PCOM) Budget and Performance Requirements (BPRs). Bulletins, newsletters, seminars/workshops and other information concerning provider enrollment issues shall also be made available on the existing provider outreach Web site. All contractor Web sites must comply with section 508 of the Rehabilitation Act of 1973 in accordance with, 36 CFR §1194, and must comply with CMS' Contractor Web site Standards and Guidelines posted on CMS's Web site.

The CMS Provider/Supplier Enrollment Web site, http://www.cms.hhs.gov/MedicareProviderSupEnroll, furnishes the user with access to provider/supplier enrollment forms, specific requirements for provider/supplier types, manual instructions, frequently asked questions (FAQs), contact information, hot topics, and other pertinent provider/supplier information. The contractor shall not duplicate content already provided at the CMS provider/supplier enrollment Web site, and shall not reproduce the forms or establish the contractor's own links to forms. It shall, however, have a link on its Web site that goes directly to the forms section of the CMS provider/supplier enrollment site.

On a quarterly basis, each contractor shall review and provide updates regarding their information that we show at URL: http://www.cms.hhs.gov/MedicareProviderSupEnroll/PSEC. If the contractor services several States with a universal address and telephone number, the contractor shall report that information. In situations where no actions are required, a response from the contractor is still required (i.e., the contact information is accurate). In addition, only information that pertains to provider enrollment activity for the contractor's jurisdiction is to be reported. All updates shall be sent directly via e-mail to the DPSE Policy Mailbox.

18.2 - Provider Enrollment Inquiries

(Rev. 218, Issued: 08-10-07, Effective: 10-01-07, Implementation: 10-01-07)

The contractor's customer service unit may handle provider enrollment inquiries that do not involve complex enrollment issues. Examples of inquiries that can be processed by customer service units include:

- Application status checks (e.g., "Has the contractor finished processing my application?");

- Furnishing information on where to access the CMS-855 forms (and other general enrollment information) on-line;

- Explaining to providers/suppliers which CMS-855 forms should be completed.

- Contractors may wish to consider establishing electronic mechanisms by which providers can obtain updates on the status of their enrollment applications via the contractor's Web site or via automated voice response (AVR).

Contractors are strongly encouraged to establish e-mail "listserves" with the provider community to disseminate important information thereto, such as contractor address

changes, new CMS enrollment policies or internal contractor procedures, reminders about existing policies, etc. By being proactive in distributing information to their providers on a regular basis (e.g., weekly, bi-weekly), contractors can reduce the number of policy inquiries they receive and help facilitate the submission of complete and accurate CMS-855 applications.

18.3 – Mailing Annual "Supplier Responsibilities" Letter

(Rev.)

18.3.1 – Mailing Annual Material to Physicians

(Rev.)

18.3.2 – Mailing Annual Material to Non-physician Sole Pract*itioners*

(Rev.)

18.3.3 – Mailing Annual Material to Physicians and Non-physician Practitioner Organizations

(Rev.)

19 - Administrative Appeals

(Rev. 251, Issued: 04-11-08; Effective/Implementation Date: 05-12-08)

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

Denial/Revocation of Medicare Billing Privileges

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

If a contractor reviews an initial enrollment application for a provider or supplier and finds a basis for denying the application pursuant to 42 CFR §424.530, such as; the provider or supplier does not meet one or more of the Federal or State requirements, the contractor

shall deny the application and send a denial letter to the provider or supplier. The denial letter shall contain:

- a clear explanation of why the application is being denied,
- the regulatory basis to support each reason or reasons for the denial,
- an explanation of how the provider or supplier does not meet the enrollment criteria or requirements to enroll,
- how to submit a corrective action plan (CAP) and
- information regarding appeal rights including the procedures for requesting a contractor reconsideration.

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

- a clear explanation of why Medicare billing privileges are being revoked,
- the regulatory basis to support each reason or reasons for the revocation,
- an explanation of how the provider or supplier no longer meets the enrollment criteria or requirements for billing privileges,
- the effective date of the revocation (30 days from the date the notice is mailed, or 15 days from the date the notice is mailed for DMEPOS suppliers),
- how to submit a CAP, and
- information about appeal rights including the procedures for requesting a contractor reconsideration.

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

The contractor, including the NSC, shall accept, for review, the submission of a CAP for denied or revoked billing privileges if the CAP is submitted within 30 days from the date of the notice for providers and suppliers or 15 days from the date of the notice for DMEPOS suppliers. Submission of a CAP shall contain, at a minimum, verifiable evidence of provider or supplier compliance with enrollment requirements. If a CAP for a denied application is approved by a contractor, billing privileges can be issued and be made retroactive to the date the provider or supplier came into compliance with enrollment requirements or as of the date it is awarded by the NSC. If a CAP for revoked billing privileges is approved, billing privileges can be restored and made retroactive to the date the provider or supplier came into compliance with enrollment requirements. CMS's approval is required prior to restoring billing privileges.

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

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

Request for Reconsideration (formerly Contractor Hearing)

A provider or supplier that wishes to request a reconsideration must file its request, in writing, with the contractor within 60 days after the postmark of the notice to be considered timely filed. A DMEPOS supplier must file its request within 90 days after the postmark of the notice to be considered timely filed. Contractors shall extend the filing period an additional 5 days to allow for mail time. Reconsideration requests submitted on the 65th day or the 95th day of which falls on a weekend or holiday should still be considered timely filed and not rejected. The date the request is received by the contractor is treated as the date of filing. The request must be signed by the physician, non-physician practitioner, or any responsible authorized official within the entity. For DMEPOS suppliers, the request must be signed by the authorized representative, delegated official, owner or partner. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

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

NOTE: The NSC reconsiderations only are conducted by a HO.

Upon receipt of the reconsideration, the contractor/HO shall send a letter to the provider or supplier to acknowledge receipt of their request. In its acknowledgment letter, the contractor/HO shall advise the requesting party that the reconsideration will be conducted and a determination issued as soon as possible, but no later than 90 days from the date of the request. The contractor/HO shall include a copy of its acknowledgment letter in the reconsideration file. A model acknowledgment letter can be found in §19.1. The language therein may need to be modified, depending upon: (1) whether it is the contractor/HO assigned to the case that is sending out the acknowledgment, and (2) any special circumstances involved in the case.

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

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

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

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

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

The contractor/HO shall issue a written decision as soon as practicable, but no later than 90 days from the date of the request and forward the decision to the contractor and by certified mail to the provider, supplier or the authorized representative. The reconsideration letter should include: (i) the re-stated facts and findings, including the regulatory basis for the action as determined by the contractor in their initial determination; (ii) a clear explanation of why the contractor/HO is upholding or overturning the denial or revocation action; (iii) if applicable, the regulatory basis to support each reason or reasons for the denial (iv) an explanation of how the provider or supplier does not meet the enrollment criteria or requirements to enroll; (v) the information about the provider or supplier's further right to appeal the denial or revocation; (vi) the address to which the written appeal must be mailed; (vii) the date by which the appeal must be filed; and (viii) the information the appellant must include with their appeal (that is, their name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision.)

A request for reconsideration may be withdrawn at any time prior to the mailing of the reconsideration decision either by the party that filed the appeal request or their authorized

representative. The request for withdrawal must be in writing, signed, and filed with the contractor.

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

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

Request for Administrative Law Judge (ALJ) Hearing

If the provider or supplier is not in agreement with the reconsidered determination, a further appeal can be filed with an ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

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

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

Upon receipt of the request to file an ALJ hearing, an ALJ at the DAB will issue a letter by certified mail to the provider or supplier, CMS and the regional office of General Counsel (OGC) acknowledging receipt of an appeals request and detailing a scheduled pre-hearing conference. The OGC will assign an attorney that will represent CMS during the appeal's process and also will serve as the DAB point of contact. CMS nor the contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the pre-hearing conference to discuss any issues. The contractors shall work with and provide the OGC attorney with all necessary documentation. Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS.

Request for Departmental Appeals Board (DAB) Hearing

If a provider or supplier is dissatisfied with the ALJ decision, then that party may request a review by the DAB. A provider or supplier that wishes to request a review by the DAB must file its request within 60 days after the date of receipt of the ALJ's decision. Failure

to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

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

Request for Judicial Review

Any provider or supplier dissatisfied with a DAB decision has a right to seek judicial review by timely filing a civil action in a United States District Court. The time limit for filing is 60 days from receipt of the notice of the DAB's decision.

B. Fiscal Intermediary (including A/B MACs)

If a contractor reviews an initial enrollment application for a provider or certified supplier and finds that the application should be denied pursuant to 42 CFR §424.530, such as; a facility's failure to meet one or more of the Federal or State requirements, then the contractor sends a recommendation for denial to the RO. If the RO finds that the contractor's recommendation is consistent with the applicable rules and regulations, a denial letter is sent to the provider or certified supplier by the RO. The denial letter shall contain:

- a clear explanation of why the application is being denied,
- a regulatory basis to support each reason or reasons for the denial,
- an explanation of how the provider or certified supplier does not meet the enrollment criteria or requirements to enroll,
- how to submit a corrective action plan (CAP), and
- information regarding appeal rights including the procedures for requesting RO reconsideration.

Similarly, when a contractor discovers that there is a basis for revoking a provider or certified supplier's billing privileges, such as; a provider or certified supplier that no longer meets one of the requirements for billing privileges, the provider or certified supplier's billing privileges is revoked and a revocation letter is sent to the provider or certified supplier by the contractor with a cc to the RO and the CMS contractor liaison. The revocation letter must contain:

- a clear explanation of why Medicare billing privileges are being revoked,
- the regulatory basis to support each reason or reasons for the revocation,

- an explanation of how the provider or certified supplier no longer meets the enrollment criteria or requirements for billing privileges,
- the effective date of the revocation (30 days from the date the notice is mailed)
- how to submit a CAP, and
- information about appeal rights including the procedures for requesting an RO reconsideration.

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

The contractor or the RO shall accept, for review, the submission of a CAP for denied or revoked billing privileges if the CAP is submitted within 30 days from the date of the notice. Submission of a CAP shall contain, at a minimum, verifiable evidence of the provider or certified supplier's compliance with enrollment requirements. If a CAP for a denied application is approved by the RO, billing privileges can be issued once the provider or certified supplier has passed the state survey and been issued a certification date. If a CAP for revoked billing privileges is approved, billing privileges can be restored and made retroactive to the date the provider or certified supplier came into compliance with enrollment requirements. CMS approval is required prior to restoring billing privileges.

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

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

Request for RO Reconsideration

A provider or certified supplier that wishes to request a reconsideration must file its request, in writing, with the RO within 60 days after the postmark of the notice to be considered timely filed. The RO shall extend the filing period an additional 5 days to allow for mail time. Reconsideration requests submitted on the 65th day of which falls on a weekend or holiday shall still be considered timely filed and not rejected. The date the request is received by the RO is treated as the date of filing. The request may be signed by

the authorized official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

Upon receipt of the reconsideration, the RO shall send a letter to the provider or certified supplier to acknowledge receipt of their request. In its acknowledgment letter, the RO shall advise the requesting party that the reconsideration will be conducted and a determination issued as soon as possible, but no later than 90 days from the date of the request. The RO shall include a copy of its acknowledgment letter in the reconsideration file. A model acknowledgment letter can be found in §19.1.

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

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

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

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

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

The RO shall issue a written decision as soon as practicable, but no later than 90 days from the date of the request and forwards the decision by certified mail to the contractor, the provider, certified supplier or the authorized representative. The reconsideration letter should include: (i) the re-stated facts and findings, including regulatory basis for the action as, determined by the RO in their initial determination; (ii) a clear explanation of why the RO is upholding or overturning the denial or revocation action; (iii) if applicable, the regulatory basis to support each reason or reasons for the denial or revocation; (iv) an explanation of how the provider or certified supplier does not meet the enrollment criteria

or requirements to enroll; (v) the information about the provider or certified supplier's further right to appeal the denial or revocation; (vi) the address to which the written appeal must be mailed; (vii) the date by which the appeal must be filed; and (viii) the information the appellant must include with their appeal (that is, their name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision.)

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

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

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

Request for ALJ Hearing

If the provider or certified supplier is not in agreement with the reconsidered determination a further appeal can be filed with an ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such appeal must be filed, in writing, within 60 days from the receipt of the reconsideration decision. ALJ requests should be sent to:

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Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

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

Upon receipt of the request to file an ALJ hearing, an ALJ at the Departmental Appeals Board (DAB) will issue a letter by certified mail to the provider or certified supplier, CMS, the RO and the OGC acknowledging receipt of an appeals request and detailing a scheduled prehearing conference. The OGC will assign an attorney that will represent CMS during the appeal's process and also will serve as the DAB point of contact. CMS, the RO, nor the contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the pre-hearing

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

Request for DAB Hearing

If a provider or certified supplier is dissatisfied with the ALJ's decision, then that party may request review by the DAB. A provider or certified supplier that wishes to request a review by the DAB must file its request within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

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

Request for Judicial Review

Any provider or certified supplier dissatisfied with DAB review has a right to seek judicial review by timely filing a civil action in a United States District Court. The time limit for filing is 60 days from receipt of the notice of the DAB's decision.

20 - Provider Enrollment Fraud Detection Program for High Risk Areas

(Rev. 217, Issued: 07-13-07, Effective: 07-01-07, Implementation: 08-13-07)

The PSCs shall identify an area as a potential high risk for provider/supplier enrollment and shall notify the A/B MACs and ACs, excluding the NSC, through the JOA process. High risk areas may be identified by emerging or widespread anomalies that may lead to potential fraud and abuse in, for example, claim type, provider type and geographic area. (See PIM, chapter 4, §§4.32 and 4.32.1 for additional information concerning the responsibilities of the PSC.)

After receiving and reviewing the information on the potential high risk areas the AC or the A/B MAC shall determine if the information is a high risk for provider/ supplier enrollment and, if so, provide a written request to the Director of the Division of Provider and Supplier Enrollment (DPSE), requesting approval that the area be designated as high risk. The request should include the name of the AC or the A/B MAC, a contact name, phone number and a justification for designating an area as high risk for fraud and abuse.

The A/B MAC shall notify its project officer of the request for designation as a high risk fraud and abuse area concurrent with the A/B MAC's request for approval to the Director of DPSE.

20.1 – Submission of Proposed Implementation Plan for High Risk Areas
(Rev. 217, Issued: 07-13-07, Effective: 07-01-07, Implementation: 08-13-07)

Upon obtaining approval from the Director of the DPSE within the Program Integrity Group regarding the designation of a high risk area, the A/B MAC or AC shall submit, for approval, an implementation plan that addresses the problems identified in the high risk areas. The request shall include the name of the A/B MAC or AC, a contact name, phone number, and a description of the proposed action plan.

The A/B MAC or AC shall propose an implementation plan that includes, but is not limited to the following actions to remediate the identified problems in the high areas:

- Conduct revalidation activities;
- Conduct unannounced site visits;
- Expand verification and validation activities to include felony searches for individuals, owners, managing officials, and delegated officials;
- Establish a risk assessment for newly enrolled providers/suppliers.

The A/B shall work with it project officer in coordination with DPSE to determine the specific support functions needed for ongoing and proposed project activities.

If the A/B MAC or AC determines that a provider or supplier no longer meets Medicare enrollment standards, the MAC or AC shall follow the procedures set forth in section 13 of this chapter.

21 – Special Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Instructions
(Rev. 236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

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

21.1 – DMEPOS Supplier Accreditation
(Rev. 236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Provider Education for IHS Facilities

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

4. Specialty Codes

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

21.3 - Special Situations Concerning Accreditation and Enrollment

(Rev. 261, Issued: 06-27-08, Effective: 07-01-08, Implementation: 07-28-08)

1. A change of ownership application for an existing supplier location submitted by a new owner company with a new tax identification number (TIN) shall be rejected (consistent with 42CFR §424.525) if the new owner does not have an accreditation that covers all of its locations. If the old owner does have such an accreditation, the new owner could be enrolled as of the date of sale if the accreditor determines that the accreditation should remain in effect as of the date of sale. (This, however, is only applicable when the new owner also meets all other enrollment criteria found at 42CFR §424.57). If the new owner submits an application without evidence that the accreditation is still in effect for the new owner, the application should be rejected.

2. Some ownership changes do not result in a complete change of ownership, since the business entity remains the same with no change in TIN. However, in cases where more than 5 percent of the ownership has changed, the following principles apply:

- If the change in ownership has not been reported to the NSC within the required 30-day period, the NSC shall proceed with revocation action.

- If the change has been received within the required 30-day period and the supplier has been accredited, the NSC shall immediately notify the accreditor of the ownership change and request that the latter advise the NSC if the accreditation should still remain in effect.

3. A DMEPOS supplier requesting reactivation after a deactivation for non-billing shall be required to be accredited on or after March 1, 2008.

4. A revoked DMEPOS supplier that has submitted an acceptable corrective action plan can be reinstated without accreditation unless the accreditation was already required prior to revocation.

5. A DMEPOS supplier that has been deactivated for failing to respond to a reenrollment request shall obtain accreditation if the reenrollment occurs after February 29, 2008.

6. DMEPOS suppliers with 25 or more enrolled locations prior to March 1, 2008, may enroll additional locations without accreditation until September 30, 2009.

21.4 – Development and Use of Fraud Level Indicators

(Rev.)

21.4.1 – Fraud Prevention and Detection

(Rev.)

21.5 – Alert Codes

(Rev.)

21.6 - Accreditation

(Rev.)

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R272PI	11/07/2008	Clarification of Provider Enrollment Procedures Involving Certified Suppliers and Providers	12/08/2008	6151
R271PI	10/24/2008	Instructions for the Implementation of the Internet-Based Provider Enrollment, Chain and Ownership System (PECOS)	11/24/2008	6231
R269PI	09/19/2008	Incorporation of Recent Regulatory Revisions into Chapter 10 of the Program Integrity Manual	10/20/2008	6178
R266PI	09/05/2008	Model Letters	10/06/2008	6051
R261PI	06/27/2008	Update to Section 12 of Chapter 10 of the Program Integrity Manual	07/28/2008	6071
R260PI	06/20/2008	Clarification of Chapter 10	07/22/2008	6065
R251PI	04/11/2008	Administrative Appeals for Provider Enrollment	05/12/2008	5826
R246PI	03/14/2008	Clarification of Items in Chapter 10	04/14/2008	5952
R236PI	02/01/2008	Update to Chapter 10	03/03/2008	5892
R234PI	01/18/2008	Revision to Instructions Relating to Compliance Standards for Independent Diagnostic Testing Facilities (IDTFs)	04/22/2008	5856
R233PI	01/18/2008	Update to Chapter 10	02/20/2008	5862
R232PI	01/04/2008	Clarification of Standards for Processing CMS-855 Enrollment Applications	02/04/2008	5854
R230PI	12/14/2007	Update to Chapter 10	01/07/2008	5802
R227PI	11/02/2007	Update to Requirement to Submit National Provider Identifier (NPI) Notification	01/07/2008	5795
R221PI	09/06/2007	Administrative Appeals for Provider Enrollment	10/01/2007	5467
R219PI	08/17/2007	Nurse Practitioner (NP) Services and Clinical Nurse Specialist (CNS) Services	11/19/2007	5639
R218PI	08/10/2007	Provider Enrollment Manual Update	10/01/2007	5671
R217PI	07/13/2007	Provider Enrollment Fraud Detection Program for High Risk Areas	08/13/2007	5633
R216PI	07/13/2007	Implementation of New Compliance Standards for Independent Diagnostic Testing Facilities (IDTFs)	10/01/2007	5672
R214PI	06/29/2007	Clarification of Provider Enrollment	07/30/2007	5504

Rev #	Issue Date	Subject	Impl Date	CR#
		Revocations		
R212PI	06/29/2007	Administrative Appeals for Provider Enrollment - Replaced by Transmittal 221	10/01/2007	5467
R195PI	03/30/2007	General Background Information on Individual Practitioners and Certain Part B Services	04/30/2007	5503
R191PI	03/23/2007	Provider/Supplier Enrollment Approval Letters	05/23/2007	5285
R190PI	02/23/2007	General Background Information on Certified Providers and Certified Suppliers	04/02/2007	5401
R182PI	01/12/2007	Medicaid State Agencies	03/01/2007	5284
R175PI	11/24/2006	Division of Provider and Supplier Enrollment Issued Revocations	12/26/2006	5340
R173PI	11/13/2006	Update to Chapter 10-Medicare Provider/Supplier Enrollment	11/15/2006	5338
R158PI	09/15/2006	Provider Enrollment Disenrollment Actions	10/02/2006	5076
R151PI	07/14/2006	Provider Enrollment Appeals Process	08/14/2006	4354
R150PI	06/30/2006	Re-issuance of Chapter 10	07/03/2006	5139
R146PI	04/28/2006	Provider Enrollment Update	05/30/2006	4340
R137PI	02/10/2006	Provider Enrollment Workload and Timeliness Reports	04/15/2006	4214
R134PI	12/30/2005	Change in Provider Enrollment Timeliness Standards	03/01/2006	4213
R133PI	11/18/2005	Enrolling Indian Health Service (IHS) Facilities as Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers	04/03/2006	3845
R132PI	11/18/2005	New Process for Web Maintenance of Provider Enrollment Contractor Contact Information	12/19/2005	4141
R095PI	01/14/2005	Change in Provider Enrollment Appeals Process	02/14/2005	3601
R088PI	11/26/2004	Timeframes for Processing 855 Enrollment Applications	12/27/2004	3528
R069PI	03/26/2004	Streamlining Enrollment Requirements	04/26/2004	3159
R060PI	11/28/2003	Establishing an Enrollment Record in PECOS	12/29/2003	2855
R058PI	11/28/2003	Tracking with PECOS Instead of CROWD	12/10/2003	2939
R041PI	05/23/2003	General Revision	05/23/2003	2595
R029PIM	07/24/2002	Enrollment Process for New Medicare Providers/Suppliers	07/26/2002	2114
R007PIM	05/31/2001	Physician Identification and Registration	07/01/2001	1550

Rev #	Issue Date	Subject	Impl Date	CR#
		Instructions		