CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 289	Date: April 15, 2009
	Change Request 6310

Transmittal 288, dated April 2, 2009, has been rescinded and replaced by Transmittal 289, date April 15, 2009. The word "shall" is changed to "may" in business requirements 6310.5 and 6310.10. In addition, the reference to 42 CFR §424.516(d)(1) (iii), in requirement 6310.10, is removed. All other information remains the same.

SUBJECT: Incorporation of Physician Fee Schedule Regulatory Changes

I. SUMMARY OF CHANGES: This change request incorporates a number of recent regulatory changes related to provider enrollment. Said changes include, but are not limited to: (1) rejections and denials of certain physician and non-physician practitioner CMS-855 applications; (2) effective dates of CMS-855 applications submitted by physicians and certain non-physician practitioners; (3) timeframes for reporting CMS-855 changes of information; (4) licensure and educational requirements for certain types of non-physician practitioners; and (5) revocation effective dates. Also included in this change request are several editorial and technical modifications that are otherwise unrelated to the aforementioned regulatory changes.

NEW / REVISED MATERIAL
EFFECTIVE DATE: JANUARY 1, 2009
IMPLEMENTATION DATE: APRIL 1, 2009
APRIL 22, 2009 for revised business requirements 6310.5 and 6310.10

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/Table of Contents
R	10/1.1/ Definitions
R	10/3.1/Pre-Screening Process
N	10/3.1.1/Application Rejections
N	10/3.1.2/Denials for Incomplete Applications
R	10/3.2/Returning the Application
R	10/4.5.1/Types of Business Organizations
R	10/4.15/Certification Statement

R	10/4.16/Delegated Officials
R	10/4.19.1/IDTF Standards
R	10/5.3/Requesting and Receiving Clarifying Information
R	10/5.5.2.1/Definitions
R	10/5.5.2.2/Determining Whether a CHOW Has Occurred
R	10/5.5.2.3/Processing CHOW Applications
N	10/6.1.4/Effective Billing Date for Physicians, Non-Physician Practitioners, and Physician or Non-Physician Practitioner Organizations
R	10/6.2/Denials
R	10/7.1/General Procedures
R	10/8/Electronic Fund Transfers (EFT)
R	10/12.3/Medicare Advantage and Other Managed Care Organizations
R	10/12.4.5/Clinical Nurse Specialists (CNS)
R	10/12.4.8/Nurse Practitioners
R	10/12.4.10/Physicians
N	10/12.4.14/Speech Language Pathologists in Private Practice
R	10/13.2/Contractor Issued Revocations
R	10/17.3/File Maintenance

III. FUNDING:

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

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

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 289	Date: April 15, 2009	Change Request: 6310

Transmittal 288, dated April 2, 2009, has been rescinded and replaced by Transmittal 289, date April 15, 2009. The word "shall" is changed to "may" in business requirements 6310.5 and 6310.10. In addition, the reference to 42 CFR §424.516(d)(1) (iii), in requirement 6310.10, is removed. All other information remains the same.

SUBJECT: Incorporation of Physician Fee Schedule Regulatory Changes

EFFECTIVE DATE: JANUARY 1, 2009
IMPLEMENTATION DATE: APRIL 1, 2009
APRIL 22, 2009 for revised Business Requirements 6310.5 and 6310.10

I. GENERAL INFORMATION

A. Background: This change request incorporates into chapter 10 of the Program Integrity Manual (PIM) (hereinafter referred to as chapter 10) a number of recent regulatory changes related to provider enrollment. Said changes include, but are not limited to: (1) rejections and denials of certain physician and non-physician practitioner CMS-855 applications; (2) effective dates of CMS-855 applications submitted by physicians and certain non-physician practitioners; (3) timeframes for reporting CMS-855 changes of information; (4) licensure and educational requirements for certain types of non-physician practitioners; and (5) revocation effective dates.

Also included in this change request are several editorial and technical modifications that are otherwise unrelated to the aforementioned regulatory changes.

B. Policy: The purpose of this change request is to incorporate a number of recent regulatory revisions into chapter 10.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6310.1	The contractor shall note that the concept of "rejection" is no longer applicable to those individuals and organizations identified in section 3.1.2, of chapter 10, who/that are submitting an initial enrollment application, a reassignment, or a change request.	X			X						
6310.2	The contractor shall note that, in accordance with 42 CFR §424.520(d), the effective date of billing privileges for the individuals and organizations identified in section 6.1.4, of chapter 10, is the later of the date of filing or the date the supplier first began	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	furnishing services at a new practice location.										
6310.2.1	If the effective date of billing privileges for the individuals and organizations identified in section 6.1.4, of chapter 10, is established prior to the date of filing or the date the person or organization first began furnishing services, the contractor shall verify that the individual or organization was in compliance with all applicable requirements (e.g., State licensure) during the period (e.g., 30-day period) prior to the effective date.	X			X						
6310.2.2	The contractor shall note that the date of filing for Internet-based Provider Enrollment, Chain and Ownership System (PECOS) applications submitted by the individuals and organizations identified in section 6.1.4, of chapter 10, is the date that the contractor received an electronic version of the enrollment application and a signed certification statement.	X			X						
6310.2.3	The contractor shall note that the individuals and organizations identified in section 6.1.4, of chapter 10, may retrospectively bill for services when the supplier has met all program requirements (including State licensure requirements) and the services were provided at the enrolled practice location for up to: (1) 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or (2) 90 days prior to their effective date if a Presidential-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§5121-5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.	X			X						
6310.3	When denying an application on the grounds articulated in section 3.1.2, of chapter 10, the contractor shall use Denial Reason 1 in section 13.2, of chapter 10 (42 CFR §424.530(a) (1)).	X			X						
6310.4	The contractor shall note that, per 42 CFR §424.516(d)(1), the individuals and organizations identified in section 7.1(A), of chapter 10, must report the following changes within 30 days: (1) a change of	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	ownership; (2) a final adverse action; and (3) a change in practice location.										
6310.5	In accordance with 42 CFR §424.565, if an individual or organization identified in section 7.1(A) of chapter 10 fails to comply with the reporting requirements specified in 42 CFR §424.516(d) (1) (ii) or (iii) (relating to, respectively, final legal actions and practice location changes), the contractor may assess an overpayment back to the date of the final adverse action or change in practice location, though said date shall be no earlier than January 1, 2009.	X			X						
6310.6	This requirement intentionally deleted by CMS.										
6310.7	The contractor shall note that, effective January 1, 2009, a doctor of nursing practice (DNP) doctoral degree will satisfy the educational requirements for clinical nurse specialists as described in 42 CFR §410.76(a)(2).	X			X						
6310.8	The contractor shall note that, effective January 1, 2009, in order to bill Medicare a nurse practitioner must meet the revised requirements identified in 42 CFR §410.75(b).	X			X						
6310.9	The contractor shall note the requirements for enrolling as a speech language pathologist in private practice in section 12.4.14, of chapter 10.	X			X						
6310.10	In accordance with 42 CFR §424.535(a)(9)), the contractor may revoke the billing privileges of any individual or organization identified in section 7.1(A) that fails to comply with the reporting requirements specified in 42 CFR §424.516(d)(1)(ii).	X			X						
6310.11	The contractor shall note that, per 42 CFR §424.535(g), a revocation based on a: (1) Federal exclusion or debarment, (2) felony conviction, (3) license suspension or revocation, or (4) determination that the provider or supplier is no longer operational, is effective with the date of the exclusion, debarment, felony conviction, license suspension or revocation, or the date that CMS or the contractor determined that the provider or supplier is no longer operational.	X		X	X	X					
6310.12	The contractor shall note that, in accordance with 42 CFR §424.535(g), any physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, registered	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	dietitian or nutrition professional, organization (e.g., group practices) consisting of the individuals previously identified, or IDTF who/that is revoked from the Medicare program must, within 60 calendar of the effective date of the revocation, submit all claims for items and services furnished.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6310.13	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X	X					

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact: Frank Whelan, frank.whelan@cms.hhs.gov, (410) 786-1302.
Post-Implementation Contact: Frank Whelan, frank.whelan@cms.hhs.gov, (410) 786-1302.

VI. FUNDING

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

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

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

Table of Contents
(Rev.289, 04-15-09)

1.1 – Definitions

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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.*

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

Enrollment Application means a *paper CMS-855* enrollment application or an electronic

enrollment process approved by the Office of Management and Budget (OMB).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.1 – Pre-Screening Process

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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 <u>only</u> 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.*

- ***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.)*

NOTE: *"Pending" as an acceptable response does not apply to DMEPOS supplier applicants.*

- ***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. (This policy does not apply to DMEPOS suppliers.)*

- ***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.*

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

- ***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.*

3.1.1 – Application Rejections

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

(This section 3.1.1 does not apply to the following individuals and organizations that are submitting an initial application, a change request, or a reassignment:

1. *Physicians*
2. *Physician assistants*
3. *Nurse practitioners*
4. *Clinical nurse specialists*
5. *Certified registered nurse anesthetist*
6. *Certified nurse-midwife*
7. *Clinical social worker*
8. *Clinical psychologist*
9. *Registered dietitian or nutrition professional*
10. *Physician or non-physician practitioner organizations (e.g., group practices) consisting of the individuals identified in 1 through 9 above (e.g., physician clinic).)*

In accordance with 42 CFR §424.525(a)(1) and (2), respectively, the contractor (Including the NSC) 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 identified in 42 CFR §424.525(a) starts on the date that the contractor mails, faxes, or e-mails the pre-screening letter 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.

***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.*

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

- ***PECOS** – The contractor (with the exception of the NSC) shall create an L & T record within the 15-day period prescribed in sections 2.3 and 15 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 chapter, 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.*

NOTE: *The NSC only collects the CMS-588 for initial DMEPOS supplier enrollment applications (CMS-855S). The NSC does not have to include the CMS-588 in any prescreening letter to a DMEPOS supplier that is not initially applying for a Medicare billing number.*

- ***Incomplete Responses*** *– The provider must furnish all missing and clarifying data requested by the contractor within the applicable timeframe. 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.*

- ***Notice of Rejection*** *– If the contractor rejects the application under this section 3.1.1, 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.*

To summarize, if - during the pre-screening process - the contractor finds that data or documentation is missing, it shall send a pre-screening letter 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.

3.1.2 – Denials for Incomplete Applications

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

(This section 3.1.2 only applies to the following individuals and organizations that are submitting an initial application, a change request, or a reassignment:

1. *Physicians*
2. *Physician assistants*
3. *Nurse practitioners*
4. *Clinical nurse specialists*
5. *Certified registered nurse anesthetist*
6. *Certified nurse-midwife*
7. *Clinical social worker*
8. *Clinical psychologist*
9. *Registered dietitian or nutrition professional*
10. *Physician and Non-Physician Practitioner Organizations (e.g., group practices) consisting of the individuals identified in 1 through 9 above (e.g., physician clinic).)*

In accordance with 42 CFR §424.530(a)(1), the contractor may deny 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 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.

Note that the concept of "rejection" is no longer applicable to an initial application, reassignment, or change request that is submitted by any of the individuals or organizations identified in 1 through 10 above. Such applications must be denied, not rejected.

The contractor shall also note the following with respect to denials for the submission of incomplete applications:

- ***PECOS** – The contractor shall create an L & T record within the 15-day period prescribed in sections 2.3 and 15 of this chapter. If the contractor denies 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 denied the application, the contractor shall flip the status to "denied" in PECOS.*

- ***Incomplete Responses** – The provider must furnish all missing and clarifying data requested by the contractor within the applicable timeframe. 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.*

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

To summarize, if - during the pre-screening process - the contractor finds that data or documentation is missing, it shall send a pre-screening letter 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 must deny the application.

3.2 – Returning the Application

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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 *2006 paper* 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 circumstances in sections 5.5.2.5, 5.5.2.5.1, or 5.6.2.1.2 of this manual apply.

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.)

4.5.1 - Types of Business Organizations

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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

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

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

A. Sole Proprietorships

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

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

<u>A sole proprietorship is not a corporation</u>. Suppose a physician operates his/her business as a home health agency. If he/she incorporates his/her business, the business becomes a corporation (even though the physician is the only stockholder). Thus, the frequently-used term "unincorporated sole proprietorship" is a misnomer, because sole proprietorships by definition are unincorporated. In addition, merely because the sole proprietor hires employees does not mean that the business is no longer a sole

proprietorship. Assume W is a sole proprietor and he hires X, Y, and Z as employees. W's business is still a sole proprietorship because he remains the 100% owner of the business. On the other hand, if W had sold parts of his sole proprietorship to X, Y, and Z the business would no longer be a sole proprietorship, as there is now more than one owner.

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

B. Partnerships

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

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

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

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

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

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

An alternative type of partnership is a limited partnership (as opposed to a "general partnership," described above). While possessing many of the characteristics of a general partnership, there are some key differences. First, a limited partnership (LP) must file formal documents with the State. Second, a LP has two types of partners –general and limited. The general partner(s) runs the business, yet is personally responsible for all of

the LP's debts. Conversely, the limited partner(s) have limited liability yet cannot participate in the management of the business.

C. Limited Liability Companies (LLC)

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

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

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

D. Joint Ventures

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

E. Corporations

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

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

  Despite the concept of limited liability, there may be instances where a corporation's owners/stockholders can be held personally liable for the

corporation's debts. This is known as "piercing the corporate veil" (PCV), whereby one tries to get past the brick wall of the corporation in order to collect money from the owners behind that wall. However, PCV is a difficult thing to do and many courts are unwilling to allow it, meaning that plaintiffs can only collect from the corporation itself.

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

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

Two special types of corporations contractors may encounter are:

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

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

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

F. Non-Profit Organizations

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

NPO status is important for enrollment purposes because NPOs generally do not have

owners. Thus, a NPO need not list any owners in sections 5 or 6 of the CMS-855.

G. Government-Owned Entities

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

Note that:

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

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

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

4.15 – Certification Statement

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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, *chain home office,* 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.

In short, an authorized official must be a 5 percent direct owner, chairman of the board, etc., of the enrolling provider. One cannot use his/her status as the CEO, CFO, etc., of the provider's parent company, management company, or chain home office as a basis for his or her role as an authorized official of the provider.

4.16 – Delegated Officials

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

(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 not 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, *chain home office*, or management company. *One cannot use his/her status as a W-2 managing employee of the provider's parent company, management company, or chain home office as a basis for his or her role as a delegated official of the provider.*

- 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.

4.19.1 – IDTF Standards

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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. 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 Maintain a physical facility on an appropriate site. For the purposes of this standard, 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.

15. Enrolls in Medicare for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location.

16. Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act. (Section 1861(w)(1) states that the term

"arrangements" is limited to arrangements under which receipt of payments by the hospital, critical access hospital, skilled nursing facility, home health agency or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.)

If the IDTF claims that it is furnishing services under arrangement as described in section 1861(w)(1), the IDTF must provide documentation of such with its initial or revalidation CMS-855 application.

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.

E. Leasing and Staffing

For purposes of the provisions in 42 CFR §410.33, a "mobile IDTF" does not include entities that lease or contract with a Medicare enrolled provider or supplier to provide: a) diagnostic testing equipment; b) non-physician personnel described in 42 CFR 410.33(c); or c) diagnostic testing equipment and non-physician personnel described in 42 CFR 410.33(c). This is because the provider/supplier is responsible for providing the appropriate level of physician supervision for the diagnostic testing.

5.3 – Requesting and Receiving Clarifying Information

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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 cont ains, 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.)

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.

- **Policy Application –** Unless stated otherwise in this *chapter*, 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).

- **Incomplete Responses** – The provider must furnish all clarifying data requested by the contractor within the applicable timeframe*s*. 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** – *For providers and suppliers covered by section 3.1.1, of this chapter that are submitting an initial application or a change request to add a practice location:* 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; indications* 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-855*A* 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-855*A* 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.

5.5.2.1 - Definitions

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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.

Note that under 42 CFR §489.18(a)(4), the lease of all or part of a provider facility constitutes a change of ownership of the leased portion. If only part of the provider is leased, the original provider agreement remains in effect only with respect to the un-leased portion. (See Pub. 100-07, chapter 3, section 3210.1D (4) for more information.)

5.5.2.2 - Determining Whether a CHOW Has Occurred

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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, *lease 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*/lease* 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.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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.*
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 and *Lease* Agreements

The intermediary shall abide by the following:

- **Verification of Terms** - The intermediary shall determine: (1) whether the information contained in the sales*/lease* 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/lease* agreement will not specifically refer to the Medicare provider agreement. Clearly, if the box in section 2F is checked "yes" and the *sales/lease* 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*/Lease* Agreement** - There may be instances where the parties in a CHOW did not sign a *"sales" or "lease" 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*/lease* agreement so long as the document furnishes clear verification of the terms of the transaction.

- **Submission of Final Sales*/Lease* Agreement** - The intermediary shall not forward a copy of the application to the State agency until it has received and reviewed the final sales*/lease* 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 agreement* is received.

If a final *sales/lease* 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 agreement*) were obtained.

Unless otherwise specified in this *chapter* 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*/lease* 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.

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

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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

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

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

- *The supplier has met all program requirements, including State licensure requirements, and*
- *The services were provided at the enrolled practice location for up to—*
    1. *30 days prior to their effective date if circumstances precluded enrollment in*

advance of providing services to Medicare beneficiaries, or

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

The effective date of billing for a physician/non-physician practitioner and physician/non-physician practitioner's organization is the later of the date of filing or the date the physician or non-physician practitioner began furnishing services at the practice location.

***EXAMPLE 1:** Dr. Joe is establishing a new practice location on July 1, 2009, and submits his enrollment application on June 10, 2009. The effective date is July 1, 2009. Obviously, there is no period of retrospective payment, since Dr. Joe submitted his CMS-855 application prior to the start date.*

***EXAMPLE 2:** Dr. Joe started working at his new practice location on August 15, 2009 and filed his enrollment application on September 1, 2009. While September 1, 2009 is the later of these two dates and is therefore the effective date of filing, the effective date for billing purposes (and for retrospective payment) is August 15, 2009.*

***EXAMPLE:** Dr. Joe started working on January 2, 2009 and submits his enrollment application on March 1, 2009. Dr. Joe's effective date of filing is March 1, 2009, but his effective date for billing purposes is limited to the 30 days prior to March 1, 2009. In this case, Dr. Joe's effective billing date is January 31, 2009.*

***NOTE:** This calculation includes 28 days for February.*

***EXAMPLE 4:** Dr. Joe's Medicare billing privileges were deactivated due to 12 consecutive months of non-billing on October 1, 2009. Dr. Joe submits an enrollment application on December 15, 2009 to reactivate his billing privileges. In this case, Dr. Joe's enrollment application indicates that he started seeing patients at this location on January 1, 1998. Dr. Joe's effective date of filing is December 15, 2009, while his effective date of billing is November 16, 2009. Dr. Joe is precluded from receiving payment for services rendered between October 1, 2009 and November 15, 2009.*

In each scenario described above, the contractor shall enter the effective date of billing into sections 1 and 4 of PECOS.

Note that for purposes of 42 CFR §424.520(d) and §424.521(a), a CMS-855 reactivation application is treated as an initial enrollment application. This means that a reactivated provider will have a new effective date (i.e., the later of the date of filing or the date it first began furnishing services at a new practice location) and, per §424.521(a), limited ability to bill retrospectively.

6.2 - Denials

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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 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 42 CFR part 488.

Note that this denial reason shall be used in the situations described in section 3.1.2, of this chapter.

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.

While, as discussed in section 13.2(D), of this chapter, the contractor will establish an enrollment bar for providers and suppliers whose billing privileges are revoked, this in no way precludes the contractor from denying re-enrollment to a provider or supplier who was convicted of a felony within the preceding 10-year period or who otherwise does not meet all criteria necessary to enroll in Medicare.

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 containing the licensure/certification/authorization requirements for that its denial letter, the contractor shall cite the appropriate statutory and/or regulatory citations 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.*

No reenrollment bar shall be established for denied applications. Reenrollment bars apply only to revocations.

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.*

E. Provider Enrollment Appeals Process

For more information regarding the provider enrollment appeals process, see section 19, of this chapter.

7.1 – General Procedures

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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 accordance with 42 CFR §424.516(d) and (e), the timeframes for providers to report changes in their CMS-855 information are as follows:*

A. For physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives; clinical social workers; clinical psychologists; registered dietitians or nutrition professionals; and organizations (e.g., group practices) consisting of any of the categories of individuals identified in this paragraph.): The following changes must be reported within 30 days:

- *A change of ownership*
- *A final adverse action*
- *A change in practice location*

All other informational changes involving the providers listed in this section 7.1(A) must be reported within 90 days.

B. All providers and suppliers other than: (1) those listed in section 7.1(A); (2) DMEPOS suppliers; and (3) IDTFs: Any change of ownership, including a change in an authorized or delegated official, must be reported within 30 days. All other informational changes involving the providers listed in this section 7.1(B) must be reported within 90 days.

The reporting requirements for IDTFs can be found in 42 CFR 410.33(g)(2) and in section 4.19.1(A)(2) of this chapter. Reporting requirements for DMEPOS suppliers can be found at 42 CFR 424.57(c)(2))

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 *all applicable databases* 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.

8 – Electronic Fund Transfers (EFT)

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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:

1. **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.

2. **Verification** - The contractor shall verify that all initial EFT applications and EFT changes comply with Pub. 100-04, chapter 1, section 30.2.5.

3. **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.

4. **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 *chapter*, the contractor shall create an L & T record using the "Other" button in PECOS.

5. **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.)

6. **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.)

7. **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.

8. **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.

9. **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.

10. **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.

11. **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.

12.3 - Medicare Advantage and Other Managed Care Organizations

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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.*

12.4.5 - Clinical Nurse Specialists (CNS)

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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

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

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

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

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

- American Academy of Nurse Practitioners;

- American Nurses Credentialing Center;

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

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

- Oncology Nurses Certification Corporation;
- AACN Certification Corporation; and
- National Board on Certification of Hospice and Palliative Nurses.

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

For more information on clinical nurse specialists, refer to:

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

12.4.8 – Nurse Practitioners

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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

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

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

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

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

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

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

- American Academy of Nurse Practitioners;

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

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

For more information on nurse practitioners, refer to:

- Pub. 100-02, chapter 15, section 200 (Benefit Policy Manual)
- Pub. 100-04, chapter 12, sections 120 and 120.1 (Claims Processing Manual)

12.4.10 - Physicians

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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

1. Doctors of:

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

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

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

12.4.14 – Speech Language Pathologists in Private Practice
(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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

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

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

(A) An unincorporated solo practice.
(B) An unincorporated partnership or unincorporated group practice.
(C) An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated speech-language pathology practice.
(D) An employee of a physician group.
(E) An employee of a group that is not a professional corporation.

For more information on speech language pathologists in private practice, see Pub. 100-02, chapter 15, section 230.

13.2 – Contractor Issued Revocations
(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

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 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. *Noncompliance also includes situations when the provider or supplier has failed to pay any user fees as assessed under 42 CFR Part 488.*

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 42 CFR §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.
The Centers for Medicare & Medicaid Services (CMS) stresses, however, that an enrollment bar issued pursuant to 42 CFR § 424.535(c) does not preclude CMS or its contractors from denying re-enrollment to a provider or supplier who was convicted of a felony within the preceding 10-year period or who otherwise does not meet all criteria necessary to enroll in Medicare.

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.)

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 42 CFR §424.80 or a change of ownership as outlined in 42 CFR § 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.

Revocation 11 (42 CFR §424.535(a)(9))

The physician, non-physician practitioner, physician organization or non-physician organization failed to comply with the reporting requirement specified in 42 CFR §424.516(d)(1)(ii), which pertains to the reporting of changes in adverse actions, within 30 days of the reportable event.

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

B. Effective Date of Revocations

Per 42 CFR §405.874(b)(2), a revocation is effective 30 days after CMS or the CMS contractor *(including the NSC)* mails the notice of its determination to the provider or supplier. *However, per 42 CFR §424.535(g) a revocation based on a: (1) Federal exclusion or debarment, (2) felony conviction as described in 42 CFR §424.535(a)(3), (3) license suspension or revocation, or (4) determination that the provider or supplier is no longer operational, is effective with the date of the exclusion, debarment, felony conviction, license suspension or revocation, or the date that CMS or the contractor determined that the provider or supplier is no longer operational.*

Note that in accordance with CFR §424.565, if an individual or organization identified in this section 7.1(A) of this chapter fails to comply with the reporting requirements specified in 42 CFR §424.516(d)(1)(ii), said supplier is assessed an overpayment back to the date of the final adverse action, though said date shall be no earlier than January 1, 2009. Moreover, no later than 10 calendar days after the contractor assesses the overpayment, the contractor shall notify its DPSE liaison of the amount assessed.

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 *and/or supplies,* 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*/supplier* to furnish this data on its own volition.

- Has the ultimate discretion to determine whether sufficient “proof” exists.

C. 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.

D. 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.

Unless stated otherwise in this section 13.2, 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. The contractor shall establish the re-enrollment bar in accordance with the following:

1 year – License revocation/suspension that a deactivated provider (i.e., is enrolled, but is not actively billing) failed to timely report to CMS; provider failed to respond to revalidation request.

2 years – The provider is no longer operational.

3 years – Medical license revocation/suspension and the practitioner continued to bill Medicare after the license revocation/suspension; felony conviction and the practitioner continued to bill Medicare after the date of the conviction; falsification of information. For all other revocation reasons, the contractor shall contact its DPSE liaison; DPSE will establish the appropriate enrollment bar for that particular case.

The contractor shall update PECOS to reflect that the individual is prohibited from participating in Medicare for the 1, 2 or 3-year period reflected by the enrollment bar in question.

Note also that reenrollment bars apply only to revocations. The contractor shall not impose a reenrollment bar following a denial of an application.

E. Submission of Claims for Services Furnished Before Revocation

Per 42 CFR §424.535(g), any physician, physician assistants, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, registered dietitian or nutrition professional, organization (e.g., group practices) consisting of any of the categories of individuals identified in this paragraph, or IDTF who/that is revoked from the Medicare program must, within 60 calendar of the effective date of the revocation, submit all claims for items and services furnished.

F. Voluntary Reporting of Final Adverse Action

Notwithstanding any instructions to the contrary in this chapter, if a physician or non-physician practitioner reports the imposition of a final adverse action (other than felony

convictions) against him or her within the reporting timeframes specified in 42 CFR §424.516, and if the final adverse action is one for which the provider's billing privileges would typically be revoked, the contractor shall:

- *Treat the submission as a voluntary withdrawal, rather than a revocation*
- *Establish an overpayment back to the date of the reportable event*

By reporting final adverse actions in a timely manner (i.e., 30 days), physicians and non-physician practitioners can avoid the imposition of an enrollment bar.

(As alluded to above, this policy does not apply to felony convictions. The contractor must revoke the provider's billing privileges in such cases even if the provider timely reported the conviction.)

(For purposes of this section 13.2(F), the term non-physician practitioner only includes physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives; clinical social workers; clinical psychologists; and registered dietitians or nutrition professionals.)

G. Provider Enrollment Appeals Process

For more information regarding the provider enrollment appeals process, see section 19 of this chapter.

H. Summary

In sum, if the contractor determines that a provider's billing privileges should be revoked, it shall undertake the activities described in this section 13.2, which include, but are not limited to:

- *Revoking the provider's billing privileges back to the appropriate date;*
- *Establishment of the applicable reenrollment bar;*
- *Updating PECOS to show the length of the reenrollment bar;*
- *Assessment of an overpayment, as applicable;*
- *Providing DPSE with the amount of the assessed overpayment within 10 days of the overpayment assessment; and*
- *Affording appeal rights;*

17.3 – File Maintenance

(Rev.289, Issued: 04-15-09, Effective: 01-01-09, Implementation: 04-01-09)

Contractors shall maintain and store all documents relating to the enrollment of a provider into the Medicare program. These documents include, but are not limited to, Medicare enrollment applications and all supporting documents, attachments, correspondence, and appeals submitted in conjunction with an initial enrollment,

reassignment, change of enrollment, revalidation, etc.

Supporting documentation includes, but is not limited to:

- Copies of Federal, State and/or local (city/county) professional licenses, certifications and/or registrations;

- Copies of Federal, State, and/or local (city/county) business licenses, certifications and/or registrations;

- Copies of professional school degrees or certificates or evidence of qualifying course work; and

- Copies of CLIA certificates and FDA mammography certificates.

Medicare contractors shall dispose of the aforementioned records as described below:

1) Provider/Supplier and Durable Medical Equipment Supplier Application

a. Rejected applications as a result of provider failing to provide additional information

Disposition: Destroy when 7 years old.

b. Approved applications of provider/supplier

Disposition: Destroy 15 years after the provider/supplier's enrollment has ended.

c. Denied applications of provider/supplier.

Disposition: Destroy 15 years after the date of denial.

d. Approved application of provider/supplier, but the billing number was subsequently revoked.

Disposition: Destroy 15 years after the billing number is revoked.

e. Voluntary deactivation of billing number

Disposition: Destroy 15 years after deactivation.

f. Provider/Supplier dies

Disposition: Destroy 7 years after date of death.

2) Electronic Mail and Word Processing System Copies

a. Copies that have no further administrative value after the recordkeeping copy is made. These include copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories on hard disk or network drives, and copies on shared network drives that are used only to produce the recordkeeping copy.

Disposition: Delete within 180 days after the recordkeeping copy has been produced.

b. Copies used for dissemination, revision or updating that are maintained in addition to the recordkeeping copy.

Disposition: Delete when dissemination, revision, or updating is complete.