Medicare Program Integrity Manual
Chapter 15 - Medicare Enrollment

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(Rev. 423, 06-01-12)

15.1 – Introduction to Provider Enrollment

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10))

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

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

15.1.1 – Definitions

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

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

Accredited provider/supplier means a supplier that has been accredited by a CMS-designated accreditation organization.

Advanced diagnostic imaging service means any of the following diagnostic services:

(i) Magnetic Resonance Imaging (MRI).
(ii) Computed Tomography (CT).
(iii) Nuclear Medicine.
(iv) Positron Emission Tomography (PET).

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

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

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

Billing agency means an entity that furnishes billing and collection services on behalf of a provider or supplier. A billing agency is not enrolled in the Medicare program. A billing agency submits claims to Medicare in the name and billing number of the

provider or supplier that furnished the service or services. In order to receive payment directly from Medicare on behalf of a provider or supplier, a billing agency must meet the conditions described in § 1842(b)(6)(D) of the Social Security Act. (For further information, see CMS Publication 100-04, chapter 1, section 30.2.4.)

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

Change of 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.

CMS-approved accreditation organization means an accreditation organization designated by CMS to perform the accreditation functions specified.

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

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

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges.

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

Enrollment application means a paper CMS-855 enrollment application or the equivalent electronic enrollment process approved by the Office of Management and Budget (OMB).

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

(i) A Medicare-imposed revocation of any Medicare billing privileges;

(ii) Suspension or revocation of a license to provide health care by any State licensing authority;

(iii) Revocation or suspension by an accreditation organization;

(iv) A conviction of a Federal or State felony offense (as defined in §424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or

(v) An exclusion or debarment from participation in a Federal or State health care program.

Immediate family member or member of a physician's immediate family means – under 42 CFR § 411.351 - a husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

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

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

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

Medicare identification number - For Part A providers, the Medicare Identification Number (MIN) is the CMS Certification Number (CCN). For Part B suppliers other than suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), the MIN is the Provider Identification Number (PIN). For DMEPOS suppliers, the MIN is the number issued to the supplier by the NSC**.** (Note that for Part B and DMEPOS suppliers, the Medicare Identification Number may sometimes be referred to as the Provider Transaction Access Number (PTAN).)

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

Operational – under 42 CFR §424.502 – means that the provider or supplier has a qualified physical practice location; is open to the public for the purpose of providing health care related services; is prepared to submit valid Medicare claims; and is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered) to furnish these items or services.

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

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

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Social Security Act.

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

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

Prospective 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, non-physician practitioner, or other supplier has granted a Medicare-enrolled provider or supplier the right to receive payment for the physician's, non-physician practitioner's or other supplier's services.

(For further information, see § 1842(b)(6) of the Social Security Act, the Medicare regulations at 42 CFR §§424.70 - 424.90, and CMS Publication 100-04, chapter 1, sections 30.2 – 30.2.16.)

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

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

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

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

15.1.2 – Medicare Enrollment Application (Form CMS-855)

(Rev. 412, Issued: 03-30-12, Effective: 04- 30-12, Implementation: 04-30-12)

Providers and suppliers, including physicians, may enroll or update their Medicare enrollment record using the:

- Internet-based Provider Enrollment, Chain and Ownership System (PECOS), or
- Paper enrollment application process (e.g., Form CMS-855I).

The Medicare enrollment applications are issued by CMS and approved by the Office of Management and Budget.

The five enrollment applications are distinguished as follows:

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

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

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

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

- CMS-855S – This application should be completed by suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The National Supplier Clearinghouse (NSC) is responsible for processing this type of enrollment application.

A separate application must be submitted for each provider/supplier type.

When a prospective provider or supplier contacts the contractor to obtain a paper enrollment Form CMS-855, the contractor shall encourage the provider or supplier to submit the application using Internet-based PECOS. The contractor shall also notify the provider or supplier of:

- The CMS Web site at which information on Internet-based PECOS can be found and at which the paper applications can be accessed (www.cms.hhs.gov/MedicareProviderSupEnroll).

- Any supporting documentation required for the applicant's provider/supplier type.

- Other required forms, including:

  - The Electronic Funds Transfer Authorization Agreement (Form CMS-588) (Note: The NSC is only required to collect the Form CMS-588 with initial enrollment applications.)

  - The Electronic Data Interchange agreement (Note: This does not apply to the NSC.)

  - The Medicare Participating Physician or Supplier Agreement (Form CMS-460). The contractor shall explain to the provider or supplier the purpose of the agreement and how it differs from the actual enrollment process. (This only applies to suppliers that complete the Forms CMS-855B and CMS-855I.)

- The contractor’s address so that the applicant knows where to return the completed application.

- If the applicant is a certified supplier or certified provider, the need to contact the State agency for any State-specific forms and to begin preparations for a State survey. (This does not apply for those certified entities, such as federally qualified

health centers, that do not receive a State survey.) The notification can be given in any manner the contractor chooses.

15.1.3 – Medicare Contractor Duties

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

The contractor must adhere to the processing guidelines established in this chapter 15 (hereinafter generally referred to as "this manual"). In addition, the contractor shall assign the appropriate number of staff to the Medicare enrollment function to meet established processing timeframes.

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

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

- Contractors shall participate in UAT testing for each PECOS release.

- When requested, contractors shall attend scheduled PECOS training.

- Contractors shall report PECOS validation and production processing problems through the designated tracking system for each system release.

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

Conduct Prescreening

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

Conduct Verification, Validation, and Final Processing

- Verify and validate the information collected on the enrollment application (see section 7, of chapter 15 for additional information).

- Coordinate with State survey/certification agencies and regional offices (ROs), as needed

- Collect and maintain the application's certification statement (in house) to verify and validate Electronic Funds Transfer (EFT) changes. The change request signature must be checked against the original signature to determine the validity of any change to EFT information. This check can be made against a digital/photo image kept in-house.

- Confirm that the applicant, all individuals and entities listed on the application, and any names or entities ascertained through the use of an independent verification source, are not presently excluded from the Medicare program by the HHS Office of the Inspector General (OIG). Contractors shall verify eligibility using the Medicare Exclusion Database (MED), and the General Services Excluded Parties List System.

15.2 – Provider and Supplier Business Structures
(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

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

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

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

A. Sole Proprietorships

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

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

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

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

B. Partnerships

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

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

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

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

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

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

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

C. Limited Liability Companies (LLC)

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

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

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

D. Joint Ventures

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

E. Corporations

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

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

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

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

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

Two special types of corporations that contractors may encounter are:

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

applicable State PC statute says). In addition, the title of a PC will usually end in "PC," "PA" (Professional Association) or "Chartered."

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

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

F. Non-Profit Organizations

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

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

G. Government-Owned Entities

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

Note that:

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

- For section 6 of the Form CMS-855, the only people that must be listed are "managing employees." This is because GOEs do not have corporate officers or directors.

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

15.3 – National Provider Identifier (NPI)

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

A. Submission of NPI

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

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

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

B. Additional NPI Information

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

C. Subparts - General

The contractor shall review and become familiar with the principles outlined in the "Medicare Expectations Subpart Paper," the text of which follows below. It was originally issued in January 2006 and has since been slightly updated to reflect certain changes in Medicare terminology.

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

D. Medicare Subparts Paper - Text

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

Purpose of this Paper

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

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

These expectations are based on the NPI Final Rule, on statutory and regulatory requirements with which Medicare must comply, and on policies that are documented in Medicare operating manuals and other directives. These Medicare statutes, regulations and policies pertain to conditions for provider participation in Medicare, enrollment of health care providers in Medicare and assignment of identification

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

numbers for billing and other purposes, submission of cost reports, calculation of payment amounts, and the reimbursement of enrolled providers for services furnished to Medicare beneficiaries.

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

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

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

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

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

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

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

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

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

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

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

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

- Federal statutes or regulations pertaining to requirements for the unique identification of enrolled Medicare providers may relate to entities that could be considered subparts according to the discussion in the NPI Final Rule. Medicare covered organization health care providers must take any such statutes or regulations into account to ensure that, if Medicare providers are uniquely identified now by using Medicare identifiers in HIPAA standard transactions, they obtain NPIs in order to ensure they can continue to be uniquely identified. Medicare is transitioning from the provider identifiers it currently uses in HIPAA standard transactions (for organizations, these could be CCNs, Provider Transaction Access Numbers (PTANs), or NSC Numbers—known as legacy identifiers or legacy numbers) to NPIs. This makes it necessary that Medicare organization health care providers obtain NPIs because the NPIs have replaced the identifiers currently in use in standard transactions with Medicare and with all other health plans. In addition, Medicare organization health care providers must determine if they have subparts that need to be uniquely identified for Medicare purposes (for example, in HIPAA standard transactions conducted with Medicare). If that is the case, the subparts will need to have their own unique NPIs so that they can continue to be uniquely identified in those transactions.

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

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

Medicare Statutes, Regulations, Manuals

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

Medicare Organization Providers and Subparts: Certified Providers and Certified Suppliers

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

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

- Providers apply for Medicare enrollment by completing a Form CMS-855A.
- Most providers are surveyed and certified by the States3 prior to being approved as Medicare providers.
- Providers have in effect an agreement to participate in Medicare.4
- Providers include, but are not limited to: skilled nursing facilities, hospitals5, critical access hospitals, home health agencies, rehabilitation agencies (outpatient physical therapy, speech therapy), comprehensive outpatient rehabilitation facilities, hospices, community mental health centers, religious non-medical health care institutions.
- Providers are assigned CCNs to identify themselves in Medicare claims and other transactions, including cost reports for those providers that are required to file Medicare cost reports.

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2 Clinical laboratory certification is handled by the Food and Drug Administration.
3 Religious non-medical health care institutions are handled differently.
4 Community mental health centers attest to such an agreement. Religious non-medical health care institutions are handled differently.
5 Hospitals bill *Medicare Part B* for certain types of services.

- In general, each entity that is surveyed and certified by a State is separately enrolled in Medicare and is considered a Medicare provider. (One exception involves home health agency branches. The branches are not separately enrolled Medicare providers.) In many cases, the enrolled provider is not itself a separate legal entity; i.e., it is an entity that is a part of an enrolled provider that is a legal entity and is, for purposes of the NPI Final Rule, considered to be a subpart.

Certified Suppliers, which bill Medicare Part B:

- Certified suppliers apply for Medicare enrollment by completing a Form CMS-855A or CMS-855B, depending on the supplier type.

- Certified suppliers include ambulatory surgical centers, portable x-ray suppliers, independent clinical labs (CLIA labs), rural health centers, and federally qualified health centers.

- Certified suppliers are typically surveyed and certified by the States prior to being approved for enrollment as Medicare certified suppliers. (For CLIA labs, each practice location at which lab tests are performed must obtain a separate CLIA Certificate for that location, though there are a few exceptions to this.)

- Certified suppliers may have in effect an agreement to participate in Medicare.

- Certified suppliers are assigned CCNs for purposes of identification within Medicare processes. However, the contractors assign unique identification numbers to certain certified suppliers for billing purposes. (For CLIA labs, a CLIA number is typically assigned to each practice location for which a CLIA certificate is issued. A CLIA number may not be used to identify a clinical laboratory as a "health care provider" in HIPAA standard transactions. The CLIA number has no relation to the Medicare PTAN.)

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

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

Medicare Expectations for NPI Assignments for Providers and Certified

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

- Obtain its own unique NPI.

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

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

Medicare Organization Providers and Subparts: Supplier Groups and Supplier Organizations

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

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

- Supplier groups and supplier organizations bill Medicare Part B.

- Certain supplier organizations are certified by the States, certified by the Food and Drug Administration (FDA), or must undergo an on-site inspection by the contractor. These requirements vary by type of supplier organization.

- Supplier groups are primarily group practices, such as a group of physicians or other practitioners.

- Supplier organizations include ambulance companies, mammography facilities, and independent diagnostic testing facilities (IDTFs).

Medicare enrolls supplier groups/supplier organizations based on TINs. A supplier

group or supplier organization may have multiple locations; however, if each location operates under the same single TIN, Medicare does not separately enroll each location. There are exceptions:

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

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

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

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

- Obtain its own unique NPI.

- Determine if it has any subparts that are themselves enrolled Medicare providers. If there are subparts, ensure that they obtain their own unique NPIs, or obtain the NPIs for them.

EXAMPLE: An enrolled IDTF has four different locations, and each one must be separately inspected by the contractor. All four locations operate under a single TIN. Because each location is separately inspected in order to enroll in Medicare, a total of four unique NPIs should be obtained: one for each location.

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

Medicare Organization Providers and Subparts:

DMEPOS Suppliers

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

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

- Suppliers of DMEPOS bill Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

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

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

Final Notes About NPIs

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

Enrolled organization health care providers or subparts that bill more than one type of Medicare contractor: Generally, the type of service being reported on a Medicare claim determines the type of Medicare contractor that processes the claim. Medicare will expect an enrolled organization health care provider or subpart to use a single (the same) NPI when billing more than one type of Medicare contractor. However, in certain situations, Medicare requires that the organization health care provider (or possibly even a subpart) enroll in Medicare as more than one type of provider. For example, an ambulatory surgical center enrolls in Medicare as a certified supplier and bills a Part A/B Medicare Administrative Contractor (A/B MAC). If the ambulatory surgical center also sells durable medical equipment, it must also enroll in Medicare as a Supplier of DME and bill a DME MAC. This ambulatory surgical center would obtain a single NPI and use it to bill the A/B MAC and the DME MAC. Medicare expects that this ambulatory surgical center would report two different

Taxonomies when it applies for its NPI: (1) that of ambulatory health care facility—clinic/center--ambulatory surgical (261QA1903X) and (2) that of suppliers—durable medical equipment & medical supplies (332B00000X) **or** the appropriate sub-specialization under the 332B00000X specialization.

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

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

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

15.3.1 – NPI-Legacy Combinations

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

If the contractor determines that a provider is having claim payment issues due solely to an incorrect NPI-Provider Transaction Access Number (PTAN) combination or NPI-CMS Certification Number (CCN) combination entered into the Provider Enrollment, Chain and Ownership System (PECOS), the contractor shall request that the provider submit the correct NPI-legacy combination via a Form CMS-855 change of information. The change request can be faxed, although the contractor shall verify the faxed signature against the provider's or authorized official's signature on file before any changes are made in PECOS.

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

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

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

15.4 – Provider and Supplier Types/Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Contractors shall consult other Medicare manuals for more information on how these providers and suppliers bill Medicare, their conditions of coverage and conditions of participation, etc.

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

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

15.4.1.1 - Community Mental Health Centers (CMHCs)

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

A. General Background Information

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

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

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

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

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

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

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

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

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

- There is a written agreement between the two entities.

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

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

B. Initial Enrollment and Certification

1. Initial Site Visit

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

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

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

typically serves as the provider agreement.

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

2. Post-Tie-In Notice Site Visit

In addition to the site visit discussed in (B)(1), the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the CMHC. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

C. Revalidations

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

D. Practice Locations/Alternative Sites

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

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

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

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

- RO approvals of such alternative sites should be very limited because (1) CMHCs must serve a distinct and definable community, and (2) CMS has not limited the number of CMHCs an entity may submit for Medicare approval as long as these proposed CMHCs serve different communities.

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

E. Additional Information

For more information on CMHCs, refer to:

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

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

15.4.1.2 - Comprehensive Outpatient Rehabilitation Facilities (CORFs)

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

A. General Background Information

A CORF is a facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients

by or under the supervision of a physician. Specific examples of such services include:

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

(* Services that the CORF must provide)

In addition:

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

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

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

B. Enrollment

1. Offsite Locations

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

2. Site Visits

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

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

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

For more information on CORFs, refer to:

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

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

15.4.1.3 - End-Stage Renal Disease Facilities (ESRDs)

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

A. Types of ESRD Facilities

ESRD facilities are entities that perform renal services for patients with irreversible and

permanent kidney failure. There are several types of ESRD facilities:

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

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

    - The RDC need not furnish transplantation services.

    - An RTC can also be an RDC.

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

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

- Renal Dialysis Facility (RDF) – This is a unit (but not necessarily a hospital unit) approved to furnish dialysis services directly to ESRD patients. A hospital (whether enrolled or not) can be an RDF if it is an outpatient provider of dialysis services that will not be furnishing inpatient dialysis services. Note that a hospital-based RDF "satellite" is one that is hospital-owned and administered but is not located on the hospital's premises. A hospital can have multiple RDF satellites.

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

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

B. ESRD Survey and Certification

The standard CMS survey and certification form used for ESRDs is the Form CMS-3427. Part I of this form must be completed, as must the Form CMS-855A, when the ESRD is initially enrolling, changing or adding a location, or undergoing a change of

ownership (CHOW). Part I must also be completed for: (1) a change in service and (2) an expansion or addition of ESRD stations. However, the Form CMS-855A need not be furnished in these two latter instances (e.g., an ESRD station does not qualify as a practice location on the Form CMS-855A), though the RO may issue a tie-in notice or approval letter to the contractor as notification of the change. Also, because the "End-Stage Renal Disease Facility" category on the Form CMS-855A encompasses all five ESRD categories, it is not necessary for the facility to submit a Form CMS-855A if it is changing from one ESRD type to another, though it must complete the Form CMS-3427. (See Pub. 100-07, chapter 2, sections 2274 – 2276 and 2278 – 227, for more information on the Form CMS-3427 requirement.)

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

C. Miscellaneous ESRD Policies

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

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

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

D. ESRD Enrollment

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

- If an enrolled RTC also wants to become an RDC, the provider must submit a new, complete Form CMS-855A for the RDC. For enrollment purposes, the RTC and the RDC will be treated as two separate ESRD facilities.

- If an enrolled ESRD wants to change to another type of ESRD, the provider need not submit a Form CMS-855A change of information (assuming that this is the only change to the provider's enrollment data).

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

E. Additional Information on ESRD Facilities

For further data on ESRD facilities, refer to:

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

15.4.1.4 - Federally Qualified Health Centers (FQHCs)

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

FQHCs furnish services such as those performed by physicians, nurse practitioners, physician assistants, clinical psychologists, and clinical social workers. This also includes certain preventive services like prenatal services, immunizations, blood pressure checks, hearing screenings and cholesterol screenings. (See CMS Publication 100-02, chapter 13, for more information). Even though they complete the Form CMS-855A application, FQHCs are considered Part B certified suppliers.

FQHCs are not required to obtain a State survey; there is no State agency involvement with FQHCs. As such, the contractor will either deny the application or make a recommendation for approval and forward it directly the RO. The RO will then make the final decision as to whether the entity qualifies as a FQHC. Generally, in order to so qualify, the facility must be receiving, or be eligible to receive, certain types of Federal grants (sometimes referred to as "grant status"), or must be an outpatient facility operated by an Indian tribal organization. The Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services (DHHS) may assist the RO in determining whether a particular supplier meets FQHC standards, since HRSA maintains a list of suppliers that met certain grant requirements. (See CMS Pub. 100-07, chapter 2, sections 2825-2826D for more information.)

A few other notes about FQHCs:

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

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

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

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

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

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

For additional general information on FQHCs, refer to:

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

- 42 CFR Part 491

- Pub. 100-07, chapter 2, sections 2825 – 2826H

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

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

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

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

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

- CMS Change Request 6207

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

A histocompatibility laboratory does "matching" tests in preparation for procedures such as kidney transplants, bone marrow transplants, and blood platelet transfusions. It is the only type of laboratory that must submit a Form CMS-855A application. Each histocompatibility lab must meet all applicable requirements in 42 CFR Part 493 (see 42 CFR §493.1278 in particular) and undergo a State survey.

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

15.4.1.6 - Home Health Agencies (HHAs)
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. General Background Information

An HHA is an entity that provides skilled nursing services and at least one of the following therapeutic services: speech therapy, physical therapy, occupational therapy, home health aide services, and medical social services. The services must be furnished in a place of residence used as the patient's home.

Like most certified providers, HHAs receive a State survey (or a survey from an approved accrediting organization to determine compliance with Federal, State, and local laws), and must sign a provider agreement. All HHA services, moreover, must be part of a plan of care established by a physician, accompanied by a certification from the physician that the patient needs home health services. HHA services can be covered even if the patient lives with someone who might ordinarily be able to perform such services himself/herself.

B. Capitalization and Site Visit Requirements

See section 15.26.2 of this chapter for more information on HHA capitalization requirements. See sections 15.19.2 through 15.19.2.5 for more information on HHA site visit requirements.

C. HHA Components

There are three potential "components" of an HHA organization:

Parent – The parent HHA is the entity that maintains overall administrative control of its location(s).

Sub-unit – A sub-unit is associated with the parent HHA but services a different

geographic area. It is thus considered a semi-autonomous HHA, since it is too far away from the parent HHA to share administration/supervision on a day-to-day basis. This means that HHA sub-units must separately enroll in Medicare, obtain a separate State survey, and sign a separate provider agreement. As with parent HHAs, sub-units receive their own 6-digit CMS Certification Number (CCN).

Branch – A branch is a location or site that services patients in the same geographic area as the parent and shares administration with the parent on a daily basis. Consequently, unlike sub-units, branches need not enroll separately. They can be listed as practice locations on the main provider's (or sub-unit's) Form CMS-855A. Though the branch receives a 10-digit CCN identifier, it bills under the parent HHA's or sub-unit's CCN number.

The question of whether a particular location qualifies as a branch or a sub-unit – which will determine whether a separate Form CMS-855A enrollment is needed – is resolved by the RO.

Consider the following scenario:

PARENT HHA

owns owns owns

BRANCH A **SUB-UNIT B** **BRANCH C**

operates

BRANCH D

Here, the parent HHA has two branches (A and C) and one sub-unit (B). B also has a branch (D). They will be enrolled as follows:

- The parent HHA must complete a Form CMS-855A, undergo a State survey, and sign a provider agreement.

- Branches A and C must be listed as practice locations on the parent's Form CMS-855A because a branch is sufficiently "attached" to the parent to be considered part of it.

- Sub-unit B must: (1) enroll separately from the parent, (2) complete its own Form CMS-855A, (3) undergo its own survey, and (4) sign its own provider agreement. For enrollment purposes, it is considered a separate and distinct entity from the parent, hence requiring a separate enrollment. (This also means that Sub-unit B would not have to be listed on the parent's Form CMS-855A as a practice location.)

- Because sub-units, like parents, can have branches, Branch D would be listed as a practice location on Sub-unit B's application.

See Pub. 100-07, chapter 2, section 2182, for more information on branches.

D. Out-of-State HHA Branches

In general, an HHA can only have a branch in another State (and treat it as a branch, rather than a separate HHA) if there is a reciprocity agreement between the two States. If none exists, the out-of-state location must enroll as a new provider by submitting a new Form CMS-855A and signing a separate provider agreement. It cannot be treated as a branch/practice location of the main HHA. (See Pub. 100-07, chapter 2, section 2184 for specific provisions regarding HHAs that cross State lines.)

E. Additional Data

For more information on HHAs, refer to:

- Sections 1861(o) and 1891 of the Social Security Act
- 42 CFR Part 484
- 42 CFR § 489.28 (capitalization)
- Pub. 100-07, chapter 2, sections 2180 – 2198C (State Operations Manual)
- Pub. 100-04, chapter 10 (Claims Processing Manual)
- Pub. 100-02, chapter 7 (Benefit Policy Manual)

15.4.1.7 - Hospices

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

A. Multiple Practice Locations

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

B. Site Visits

- Initial application – If a hospice submits an initial application, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) after the contractor receives the tie-in notice (or approval letter) from the RO

but before the contractor conveys Medicare billing privileges to the hospice. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

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

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

For more information on hospices, refer to:

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

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

15.4.1.8 - Hospitals and Hospital Units

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

A. Swing-Bed Designation

A "swing-bed" hospital is one that is approved by CMS to furnish post-hospital skilled nursing facility (SNF) services. That is, hospital (or critical access hospital (CAH)) patients' beds can "swing" from furnishing hospital services to providing SNF care without the patient necessarily being moved to another part of the building. It receives a separate survey and certification from that of the hospital. Thus, if swing-bed

designation is terminated, the hospital still maintains its certification. In addition, the hospital is given an additional CMS Certification Number (CCN) to bill for swing-bed services. (The third digit of the CCN will be the letter U, W, Y or Z.)

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

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

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

B. Psychiatric and Rehabilitation Units

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

C. Multi-Campus Hospitals

A multi-campus hospital (MCH) has two or more hospital campuses operating under one CCN number. The MCH would report its various units/campuses as practice locations on the Form CMS-855A. A hospital that has its own main campus but also occupies space in another hospital has a "satellite facility" in that other hospital.

For additional information on multi-campus hospitals, see Pub. 100-07, chapter 2, section 2024.

D. Physician-Owned Hospitals

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

Section 2(A)(4) of the Form CMS-855A asks the applicant to identify whether it is a physician-owned hospital. If the applicant indicates in section 2(A)(2) that it is a

hospital, it must complete section 2(A)(4). Applicants that are not hospitals need not complete section 2(A)(4).

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

15.4.1.9 - Indian Health Services (IHS) Facilities

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

A. General Background Information

For purposes of provider enrollment only, there are several types of IHS facilities: (1) those that are wholly owned and operated by the IHS, (2) facilities owned by the IHS but tribally operated, and (3) facilities wholly owned and operated by a tribe, though under the general IHS umbrella. When an IHS facility wishes to enroll with the Part A contractor, it may check either: (a) "Indian Health Services Facility," or (b) the specific provider type it is. For instance, if an IHS hospital is involved, the provider may check "Indian Health Services Facility" or "Hospital" on the application - or perhaps both. Even if it only checked "Hospital," the LBN or DBA Name will typically contain some type of reference to Indian Health Services. The contractor will therefore know that it is dealing with an IHS facility.

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

As for CCN numbers, the IHS facility uses the same series that its concomitant provider type does. That is, an IHS hospital uses the same CCN series as a "regular" hospital, an IHS CAH utilizes the same series as a regular CAH, and so forth.

B. IHS Enrollment

Effective September 1, 2010, IHS facilities and tribal providers seeking to initially enroll in Medicare or submit a change of information may utilize Internet-based PECOS or use the paper form CMS-855 enrollment application.

If an IHS facility or tribal provider chooses to use Internet-based PECOS, it will be responsible for mailing to TrailBlazer Health Enterprises, LLC (TrailBlazer), the designated Medicare contractor, the following:

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

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

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

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

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

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

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

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

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

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

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

15.4.1.10 - Organ Procurement Organizations (OPOs)

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

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

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

There can be only one designated OPO per geographic service area. When an OPO is de-certified and its service area is opened for competition, the applicable CMS regional office publishes a notice in local newspapers. CMS then selects an OPO to take over the service area, using the process at 42 CFR §486.316. The OPO that CMS selects must first have been certified by CMS and must meet the qualifications for designation at 42 CFR §486.304. The OPO must also sign a provider agreement (Form CMS-576A) and participate in the Organ Procurement and Transplantation Network. (See CMS Pub. 100-07, chapter 2, sections 2810 and 2811.) Note that OPOs do not receive a State survey.

For more information on OPOs, refer to:

- Section 1138 of the Social Security Act
- 42 CFR §486.301 - §486.348
- Pub. 100-07, chapter 2, sections 2810 – 2819 (State Operations Manual).

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

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

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

A. General Background Information

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

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

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

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

Note that:

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

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

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

B. Extension Locations

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

An OPT/OSP provider may also furnish therapy services in a patient's home or in a patient's room in a SNF. Because they are not considered extension locations, neither

the home nor the patient's room need be listed as a practice location on the provider's Form CMS-855A. (See Pub. 100-07, chapter 2, section 2298B.)

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

C. Additional OPT/OSP Information

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

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

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

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

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

CMS's Boston regional office has primary responsibility over the approval and certification of RNHCIs. RNHCIs are not certified by the State, but must meet all of the conditions of coverage outlined in 42 CFR §403.720, as well as all conditions of participation outlined in 42 CFR §403.730 through 403.746. For purposes of provider enrollment, the three most important conditions are that the provider:

1. Must not be owned by, under common ownership with, or have an ownership interest of 5 percent or more in, a provider of medical treatment or services.

2. Must not be affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in a provider of medical treatment or services. (Permissible affiliations are described in 42 CFR §403.738(c)).

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

To this end, the contractor shall: (1) examine Sections 5 and 6 of the CMS-855A, and (2) verify the provider's non-profit status to ensure that the aforementioned conditions are met.

For more information on RNCHIs, refer to:

- Section 1861(ss)(1) of the Social Security Act
- 42 CFR Part 403, subpart G
- Pub. 100-07, chapter 2, sections 2054, 2054.1, 20541A and 2054.1 (State Operations Manual)
- Pub. 100-04, chapter 3, sections 170 - 180 (Claims Processing Manual)
- Pub. 100-02, chapter 1, sections 130 – 130.4.2 (Benefit Policy Manual)

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

15.4.1.13 - Rural Health Clinics (RHCs)

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

A. General Background Information

Rural health clinics (RHCs):

- Are considered to be Part B certified suppliers, even though they enroll in Medicare via the Form CMS-855A.
- Must be primarily engaged in furnishing outpatient services. However, the services can, in certain instances, be performed in locations outside of the four walls of the clinic. (See CMS Pub. 100-02, chapter 13 for more information.)

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

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

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

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

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

- FQHCs furnish preventive services. RHCs do not.

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

B. Additional RHC Information

For more information on RHCs, refer to:

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

- 42 CFR Part 491, subpart A

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

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

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

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

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

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

15.4.1.14 - Skilled Nursing Facilities (SNFs)

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

A. General Background Information

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

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

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

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

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

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

As indicated above, a SNF must have a "transfer agreement" with a Medicare-enrolled hospital. The agreement must provide for the transfer of patients between the hospital and the SNF, as well as the interchange of patient information. This requirement is

needed since patients that are discharged from hospitals may then go to a SNF for follow-up or additional nursing care. The transfer agreement need not be submitted with the SNF's Form CMS-855A enrollment application; the State and/or CMS regional office (RO) will verify that the agreement exists.

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

B. SNF Distinct Parts

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

each receive a separate CMS Certification Number (CCN). Also:

- A hospital may have only one SNF distinct part.

- The hospital will typically submit to the State a diagram/floor plan outlining the distinct part's area.

- "Distinct part" designation is not equivalent to being "provider-based." (A provider-based SNF, like a distinct part SNF, receives a CCN that is separate from that of the hospital.)

A SNF distinct part unit must enroll separately (i.e., it cannot be listed as a practice location on the hospital's Form CMS-855A), be separately surveyed, and sign a separate provider agreement. (Note how this is different from "swing-bed" units, which do not enroll separately and do not sign separate provider agreements.) (See Pub. 100-07, chapter 2, section 2762B, subsection 4, for more information on SNF distinct parts.)

C. Additional Information

For more information on SNFs, refer to:

- Section 1819(a) of the Social Security Act;

- 42 CFR Part 488, subpart E;

- Pub. 100-07, chapter 7 (State Operations Manual);

- Pub. 100-02, chapter 8 (Benefit Policy Manual); and

- Pub. 100-04, chapter 6 (Part A) and chapter 7 (Part B) (Claims Processing Manual).

15.4.2 – Certified Suppliers That Enroll Via the Form CMS-855B
(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

15.4.2.1 - Ambulatory Surgical Centers (ASCs)
(Rev. 404, Issued: 01-20-12, Effective: 04-22-12, Implementation: 04-22-12)

A. General Background Information

An ASC is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients. The ASC signs a supplier agreement (Form CMS-370) with CMS and enrolls via the Form CMS-855B; the supplier agreement is very similar to provider agreements signed by Part A providers. Note that ASCs can be fixed locations or mobile in nature.

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

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

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

- Authorizes the release to CMS, of the findings of the accreditation survey.

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

B. ASCs and Hospitals

There are three main enrollment situations involving ASCs and hospitals:

1. The ASC is operated by a hospital – If the ASC is operated by a hospital, the ASC enrolls, participates and is paid only as an ASC. It must independently enroll via the Form CMS-855B and cannot be paid as a hospital outpatient department. The ASC agreement (Form CMS-370) will be made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC.

2. Hospital outpatient department – If the ASC is treated as a hospital outpatient department, it will not independently enroll via the Form CMS-855B as an ASC. It will be considered part of the hospital. (See Pub. 100-04, chapter 14, section 10.1.)

3. The ASC is not hospital-operated (i.e., not a part of a provider of services or any other facility) – In this case, the ASC simply enrolls via the Form CMS-855B.

In short, if an ASC is hospital-operated, it has the option of being covered under Medicare as an ASC, or of being treated as a hospital-affiliated outpatient surgery department. (See Pub. 100-02, chapter 15, section 260.1.)

C. Additional Information

For more information on ASCs, refer to:

- Section 1832(a)(2)(F) of the Social Security Act

- 42 CFR Part 416

- Pub. 100-07, chapter 2, section 2210 and Appendix L (State Operations Manual)

- Pub. 100-02, chapter 15, sections 260 – 260.5.3 (Benefit Policy Manual)

- Pub. 100-04, chapter 14 (Claims Processing Manual)

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

15.4.2.2 - CLIA Labs

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

A. General Background Information

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

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

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

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

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

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

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

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

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

- Facilities that serve only as collection stations.

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

B. Form CMS-116 and CLIA Certificates

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

- CLIA certificate being requested;

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

- Hours during which laboratory testing will take place;

- Sites where testing will occur; and

- Types of tests that will be performed.

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

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

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

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

There are several types of CLIA certificates, including:

- Certificate of Waiver (COW) – There are certain laboratory tests that are "waived," meaning that the laboratory is not subject to routine CLIA inspections. In

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

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

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

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

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

C. CLIA Enrollment

NOTE: The following:

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

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

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

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

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

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

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

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

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

- The CLIA number is a 10-digit number.

D. Site Visits of Independent CLIA Labs

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

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

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

E. Additional Information

For additional data on CLIA laboratories, refer to:

- 42 CFR Part 493
- Publication 100-07, chapter 6 (State Operations Manual)
- Publication 100-04, chapter 16 (Claims Processing Manual)
- Form CMS-116 (CLIA Application for Certification
- See sections 15.19.2.2 through 15.19.2.4 of this chapter for additional lab site visit information.

15.4.2.3 - Mammography Screening Centers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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

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

For more information on mammography screening centers, refer to:

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

15.4.2.4 - Pharmacies

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

Pharmacies typically enroll with the National Supplier Clearinghouse. However, there are certain covered drugs that are billed through the physician fee schedule and not the

schedule for durable medical equipment, prosthetics, orthotics and supplies. These drugs must be billed to the Part A/B Medicare Administrative Contractor (A/B MAC), meaning that the pharmacy must enroll with the A/B MAC via the Form CMS-855B.

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

15.4.2.5 - Portable X-Ray Suppliers (PXRSs)

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

A. General Background Information

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

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

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

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

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

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

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

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

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

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

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

A PXRS can be simultaneously enrolled as a mobile IDTF, though they cannot bill for the same service.

NOTE: The PXRSs requires a State survey, while mobile IDTFs do not (although IDTFs do require a site visit). Moreover, PXRSs can bill for transportation and set-up, while mobile IDTFs cannot.

PXRSs do not have a supplier agreement.

B. Enrollment of PXRSs

1. Section 4 of the Application

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

- Whether it furnishes services from a "mobile facility" or "portable unit." The former term typically describes a vehicle that travels from place to place to perform services inside the vehicle. Examples of such vehicles include mobile homes or trailers. A "portable unit" exists when a supplier transports medical equipment to a particular location. Unlike with mobile facilities, the equipment on a portable unit is separate from and unattached to the vehicle.

- A PXRS can be either a mobile facility or portable unit, although it usually is the latter. A mobile IDTF, on the other hand, while it too can be either, is typically a mobile facility.

- Its base of operations. This is where personnel are dispatched from and where equipment is stored. It may or may not be the same address as the practice location.

- All geographic locations at which services will be rendered.

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

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

2. Site Visits

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

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

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

D. Additional Information

For more information on PXRSs, refer to:

- Section 1861(s)(3) of the Social Security Act
- 42 CFR Parts 486.100 – 486.110
- Pub. 100-07, chapter 2, sections 2420 – 2424B (State Operations Manual)
- Pub. 100-02, chapter 15, sections 80.4 – 80.4.4 (Benefit Policy Manual)
- Pub. 100-04, chapter 13, sections 90 – 90.5 (Claims Processing Manual)

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

15.4.2.6 - Radiation Therapy Centers

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

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

For additional background on radiation therapy services, see:

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

15.4.2.7 - Suppliers of Ambulance Services

(Rev. 408 Issued: 02-22-12, Effective: 02-03-12, Implementation: 02-03-12 For Business Requirement 7363.6, the implementation date is March 9, 2012)

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

A. Types of Ambulance Services

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

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

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

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

and the provision of at least one of the seven ALS procedures specified in 42CFR §414.605.

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

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

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

- Be furnished in an area that is designated as a rural area;
- Be furnished under contract with one or more volunteer ambulance services that meet the following conditions:
- Are certified to furnish ambulance services as required under 42CFR §410.41.
- Furnish services only at the BLS level.
- Be prohibited by State law from billing for any service.
- Be furnished by a paramedic ALS intercept supplier that meets the following conditions
- Is certified to furnish ALS services as required in 42CFR §410.41(b)(2).
- Bills of all the recipients who receive ALS intercept services from the entity, regardless of whether or not those recipients are Medicare beneficiaries.

6. **Specialty Care Transport** (SCT) - Inter-facility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary

supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area (e.g., nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.)

B. Ambulance Qualifications

1. Vehicle Design and Equipment

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

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

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

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

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

2. Vehicle Personnel

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

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

C. Ambulance Claims Jurisdiction

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

D. Completion of the CMS-855B

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

E. Miscellaneous Information

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

2. **Non-Emergency Transport** - As stated in 42CFR §410.40(d), non-emergency transportation by ambulance is appropriate if either: (1) the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or (2) if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required.

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

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

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

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

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

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

Per Pub. 100-02, chapter 10, section 10.3.8, ambulance service to a physician's office is

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

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

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

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

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

For additional information on ambulance services, refer to:

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

8. The contractor shall deny enrollment to an air ambulance supplier, using all of the enrollment instructions in this chapter, if the supplier does not maintain their FAA certification.

9. The contractor shall revoke enrollment to an air ambulance supplier, using all of the enrollment instructions in this chapter, if the supplier does not maintain their FAA certification.

10. The contractor shall access the following FAA website on a quarterly basis to validate all licenses/certifications of air ambulance operators: http://www.faa.gov/about/office_org/headquarters_offices/agc/operations/agc300/reports/

11. The air ambulance supplier shall maintain all applicable Federal and State licenses and certifications to include pilot certification, instrument and medical certifications and air worthiness certification.

15.4.2.8 – Intensive Cardiac Rehabilitation (ICR)

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

A. Background

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

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

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

B. ICR Enrollment

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

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

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

C. Additional Information

For more information on ICR suppliers, refer to:

- 42 CFR § 410.49
- Publication 100-04, chapter 32, sections 140.2.2 – 140.2.2.6 (Medicare Claims Processing Manual)
- Publication 100-02, chapter 15, section 232 (Medicare Benefit Policy Manual)

15.4.3 - Medicare Advantage and Other Managed Care Organizations
(Rev. 414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

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

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

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

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

- Is permitted by State law to administer anesthesia; and

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

For more information on anesthesiology assistants, refer to:

- Section 1861(bb)(2) of the Social Security Act

- 42 CFR §410.69(b)

- Pub. 100-04, chapter 12, sections 140 – 140.4.4 (Claims Processing Manual)

15.4.4.2 - Audiologists

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

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

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

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

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

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

OR

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

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

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

Thus, if the individual does not have a State license for either of the reasons stated in 42

CFR § 440.110(c)(3)(ii), the person must meet the certification requirement in 42 CFR § 440.110(c)(3)(ii)(A), OR all three of the criteria listed in 42 CFR § 440.110(c)(3)(ii)(B), in order to be eligible to enroll in Medicare.

For more information on audiologists, refer to:

- Section 1861(ll)(3)(B) of the Social Security Act
- Publication 100-02, chapter 15, sections 80.3 and 80.3.1 (Benefit Policy Manual)

15.4.4.3 - Certified Nurse-Midwives

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

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

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

(2) Meet one of the following requirements:

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

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

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

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

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

All certified nurse-midwives, therefore, must: (1) be State-licensed as a registered nurse in the State in which the person seeks to practice as a nurse-midwife, (2) be legally authorized by the State to practice as a nurse-midwife, and (3) have completed a State-specified program of study and clinical experience for nurse-midwives. If the State

does not specify such a program of study and clinical experience, the individual must meet one of the three criteria in 2(b) above.

For more information on certified nurse midwives, refer to:

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

15.4.4.4 - Certified Registered Nurse Anesthetists (CRNAs)
(Rev. 414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

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

(4) Meets the following criteria:

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

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

For more information on CRNAs, refer to:

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

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

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

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

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

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

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

- American Academy of Nurse Practitioners

- American Nurses Credentialing Center

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

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

- Oncology Nurses Certification Corporation

- AACN Certification Corporation

- National Board on Certification of Hospice and Palliative Nurse

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

For more information on clinical nurse specialists, refer to:

- 42 CFR § 410.76

- Publication 100-02, chapter 15, section 210 (Benefit Policy Manual)

- Publication 100-04, chapter 12, sections 120 and 120.1 (Claims Processing Manual)

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

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

- Hold a doctoral degree in psychology; and

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

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

For more information on clinical psychologists, refer to:

- Publication 100-04, chapter 12, sections 170 (Claims Processing Manual)

- Publication 100-02, chapter 15, section 160 (Benefit Policy Manual)

15.4.4.7 - Clinical Social Workers
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

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

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

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

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

    a. Is licensed or certified at the highest level of practice provided by the laws

of the State in which the services are performed; and

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

For more information on clinical social workers, refer to:

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

15.4.4.8 - Nurse Practitioners

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

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

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

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

(ii) Possesses 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 Publication 100-02, chapter 15, section 200, the following organizations are recognized national certifying bodies for nurse practitioners at the advanced practice level:

- American Academy of Nurse Practitioners
- American Nurses Credentialing Center

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

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

- Oncology Nurses Certification Corporation

- AACN Certification Corporation

- National Board on Certification of Hospice and Palliative Nurses

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

For more information on nurse practitioners, refer to:

- Pub. 100-02, chapter 15, section 200 (Benefit Policy Manual)

- Pub. 100-04, chapter 12, sections 120 and 120.1 (Claims Processing Manual)

- 42 CFR §410.150(b)(16)

15.4.4.9 - Occupational and Physical Therapists in Private Practice
(Rev. 414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. Occupational Therapists

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

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

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

- Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of

proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

B. Physical Therapists

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

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

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

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

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

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

C. Site Visits of Physical Therapists

Subject to subsection D below, site visits will be performed in accordance with the following:

- Initial application – If a physical therapist (PT) or PT group submits an initial application, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS). This is to ensure that the supplier is in compliance with CMS's enrollment requirements. The scope of the site visit will be

consistent with section 15.19.2.2(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.

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

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

D. Additional Site Visit Information

NOTE: The contractor shall also view the following:

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

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

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

- Unless CMS has directed otherwise, a site visit by the NSVC is required when a physical therapist submits an application for initial enrollment and reassignment of benefits (Form CMS-855I and Form CMS-855R). However, a site visit is not required for an enrolled physical therapist who is reassigning his or her benefits only (Form CMS-855R).

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

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

- 42 CFR § 410.59(c) (occupational therapists)

- 42 CFR § 410.60(c) (physical therapists)

- Pub. 100-02, chapter 15, sections 230.2 and 230.4 (Benefit Policy Manual) (occupational therapists)

- Pub. 100-02, chapter 15, sections 230.1 and 230.4 (Benefit Policy Manual) (physical therapists)

15.4.4.10 - Physicians

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

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

1. Doctors of:

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

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

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

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

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

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

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

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

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

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

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

For more information on PAs, refer to:

- 42 CFR § 410.74

- 42 CFR § 410.150(b)(15)

- Publication 100-04, chapter 12, sections 110 through 110.3 (Claims Processing Manual)

15.4.4.12 - Psychologists Practicing Independently

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

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

- He/she render services on his/her own responsibility, free of the administrative and professional control of an employer, such as a physician, institution or agency;

- The persons he/she treats are his/her own patients;

- He/she has the right to bill directly, collect and retain the fee for his/her services; and

- The psychologist is State-licensed or certified.

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

- The office is confined to a separately-identified part of the facility that is used solely as the psychologist's office and cannot be construed as extending throughout the entire institution; and

- The psychologist conducts a private practice (i.e., services are rendered to patients from outside the institution as well as to institutional patients).

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

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

15.4.4.13 - Registered Dietitians

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

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

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

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

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

There are two exceptions to these requirements:

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

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

For more information on registered dietitians, refer to:

- Sections 1861(vv) of the Social Security Act

- 42 CFR § 410.130 through § 410.134

15.4.4.14 – Speech Language Pathologists in Private Practice

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

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

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

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

(A) An unincorporated solo practice

(B) An unincorporated partnership or unincorporated group practice

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

(D) An employee of a physician group

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

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

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

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

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

15.4.6 - Other Part B Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.4.6.1 - Diabetes Self-Management Training (DSMT)

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

A. Background

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

All DSMT programs must be accredited as meeting quality standards by a CMS-approved national accreditation organization. Currently, CMS recognizes the American Diabetes Association (ADA) and the American Association of Diabetes Educators (AADE) as approved national accreditation organizations. A Medicare-enrolled provider or non-DMEPOS supplier that wishes to bill for DSMT may simply submit the ADA or AADE certificate to its contractor. No Form CMS-855 is required, unless the provider or supplier is not in the Provider Enrollment, Chain and Ownership System (PECOS), in which case a complete Form CMS-855 application must be submitted.

If the supplier is exclusively a DMEPOS supplier, it must complete and submit a Form CMS-855B application to its local Part A/B Medicare Administrative Contractor (A/B MAC). This is because A/B MACs, rather than Durable Medical Equipment Medicare Administrative Contractors, pay DSMT claims. Thus, the DMEPOS supplier must separately enroll with its A/B MAC, even if it has already completed a Form CMS-855S. If an A/B MAC receives an application from a DMEPOS supplier that would

like to bill for DMST, it shall verify with the National Supplier Clearinghouse that the applicant is currently enrolled and eligible to bill the Medicare program.

For more information on DSMT, refer to:

- Section 1861(qq) of the Social Security Act
- 42 CFR Part 410 (subpart H)
- Publication 100-02, Medicare Benefit Policy Manual, chapter 15, sections 300 – 300.5.1

15.4.6.2 - Mass Immunizers Who Roster Bill

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

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

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

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

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

- The effective date provision in 42 CFR § 424.520(d) does not apply to the enrollment of mass immunizers. This is because the individual/entity is not enrolling as a physician, non-physician practitioner, physician group or non-physician practitioner group.
- In section 4 of the Form CMS-855, the supplier need not list each off-site location (e.g., county fair, shopping mall) at which it furnishes services. It need only list its base of operations (e.g., county health department headquarters, drug store location).

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

- Publication 100-02, chapter 15, section 50.4.4.2 (Benefit Policy Manual)

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

NOTE: Section 10.3.1 outlines the requirements for submitting roster bills.

15.4.6.3 – Advanced Diagnostic Imaging
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1834(e) of the Social Security Act. It required the Secretary to designate organizations to accredit suppliers – including, but not limited to, physicians, non-physician practitioners and independent diagnostic testing facilities - that furnish the technical component (TC) of advanced diagnostic imaging services. MIPPA specifically defines advanced diagnostic imaging procedures as including diagnostic magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine imaging such as positron emission tomography (PET). The law also authorizes the Secretary to specify other diagnostic imaging services in consultation with physician specialty organizations and other stakeholders. In order to furnish the TC of advanced diagnostic imaging services for Medicare beneficiaries, suppliers must be accredited by January 1, 2012. The effective date of the previously named regulation is January 1, 2012.

CMS approved three national accreditation organizations (AOs) – the American College of Radiology, the Intersocietal Accreditation Commission, and the Joint Commission - to provide accreditation services for suppliers of the TC of advanced diagnostic imaging procedures. The accreditation will apply only to the suppliers of the images, not to the physician's interpretation of the image. Also, this accreditation only applies to those who are paid under the Physician Fee Schedule. All accreditation organizations have quality standards that address the safety of the equipment as well as the safety of the patients and staff. A provider submitting claims for the TC must be accredited by January 1, 2012 to be reimbursed for the claim if the service is performed on or after that date. Each of these designated AOs submits monthly reports to CMS that list the suppliers who have been or are accredited, as well as the beginning and end date of the accreditation and the respective modalities for which they receive accreditation.

Newly enrolling physicians and non-physician practitioners described above must complete the Internet-based PECOS or the appropriate CMS-855 and check the appropriate boxes for Advanced Diagnostic Imaging (ADI). Contractors shall accept applications from providers and suppliers who are accredited for the new ADI accreditation. The Medicare enrollment contractors shall verify the information sent on the application meets the current enrollment requirements. The Medicare enrollment contractors shall verify the ADI supplier is listed as one of the accredited individuals/organizations found at www.cms.hhs.gov/Medicareprovidersupenroll and

consistent with accreditation information found in section 2 of the CMS-855, and if the application is approved, will enter the information into the Provider Enrollment, Chain and Ownership System (PECOS).

15.4.7 - Medicaid State Agencies

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

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

15.4.8 - Suppliers Not Eligible to Participate

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

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

- Acupuncturist
- Assisted Living Facility
- Birthing Center
- Certified Alcohol and Drug Counselor
- Certified Social Worker
- Drug and Alcohol Rehabilitation Counselor
- Hearing Aid Center/Dealer
- Licensed Alcoholic and Drug Counselor
- Licensed Massage Therapist
- Licensed Practical Nurse
- Licensed Professional Counselor
- Marriage Family Therapist
- Master of Social Work
- Mental Health Counselor
- National Certified Counselor
- Occupational Therapist Assistant
- Physical Therapist Assistant
- Registered Nurse

- Speech and Hearing Center
- Substance Abuse Facility

15.5 – Sections of the Form CMS-855
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

Sections 15.5.1 through 15.5.16 below discuss the various provisions of the Form CMS-855A, Form CMS-855B, and Form CMS-855I. Not every data element on the forms is discussed here. Only those items that warrant additional instructions or policy clarifications are identified. However, contractors shall abide by all instructions in this chapter 15 in terms of the collection, processing, and verification of all data elements on the Form CMS-855 applications, regardless of whether the data element is discussed in sections 15.5.1 through 15.5.16.

For purposes of these sections, and unless otherwise indicated, the term "approval" includes recommendations for approval.

15.5.1 - Basic Information (Section 1 of the Form CMS-855)
(Rev. 414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

NOTE: That

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

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

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

15.5.2 – Identifying Information (Section 2 of the Form CMS-855)
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

Unless specifically indicated otherwise, the instructions in sections 15.5.1 through 15.5.2.3 below apply to the Form CMS-855A, the Form CMS-855B, and the Form CMS-855I.

The instructions in section 15.5.2.4 apply only to the Form CMS-855A; the instructions in section 15.5.2.5 apply only to the Form CMS-855B; and the instructions in section 15.5.2.6 only apply to the Form CMS-855I.

15.5.2.1 – Licenses and Certifications
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

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

A. CMS-855B and CMS-855I

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

- The State where the supplier is enrolling;

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

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

The contractor shall also adhere to the following:

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

The contractor need not verify licenses, certifications, and accreditations submitted by ASCs and portable x-ray suppliers. Instead, the contractor shall simply include such documents, if submitted, as part of the enrollment package that is forwarded to the State and/or RO.

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

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

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

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

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

See section 15.7.5.1, of this chapter for special instructions related to periodic license reviews and certain program integrity matters.

B. CMS-855A

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

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

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

15.5.2.2 – Correspondence Address

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

A. Background

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

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

B. Contact Person

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

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

circumstances dictate.

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

15.5.2.3 – Accreditation

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

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

15.5.2.4 – Section 2 of the Form CMS-855A

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

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

As explained in section 15.4.1.6, a branch is a location or site from which an HHA provides services within a portion of the total geographic area that the parent company serves. The branch is part of the HHA and is located sufficiently close to the parent agency such that it shares administration, supervision, and services with the parent. If an existing HHA wants to add a branch, it is considered a change of information on the Form CMS-855A. An HHA subunit, meanwhile, is a semi-autonomous organization under the same governing body as the parent HHA and serves patients in a geographic area different from that of the parent. Due to its distance from the subunit, the parent is incapable of sharing administration, supervision and services with the subunit on a daily basis. If the HHA wants to add an HHA subunit, it must complete an initial enrollment application for the subunit. (The subunit also signs a separate provider agreement.)

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

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

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

B. Critical Access Hospitals

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

C. Transplant Centers

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

15.5.2.5 – Section 2 of the Form CMS-855B

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

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

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

- If the group answers "yes" to question 2, 3, 4, or 5, the contractor shall request a copy of the lease agreement giving the group exclusive use of the facilities for PT/OT services only if it has reason to question the accuracy of the group's response. If the contractor makes this request and the provider cannot furnish a copy of the lease, the contractor shall deny the application.

15.5.2.6 – Section 2 of the Form CMS-855I

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. Specialties

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

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

B. Education for Non-Physician Practitioners

The contractor shall verify all required educational information for non-physician practitioners. While the non-physician practitioner must meet all Federal and State requirements, he/she need not provide documentation of courses or degrees taken to satisfy these requirements unless specifically requested to do so by the contractor. To the maximum extent possible, the contractor shall use means other than the practitioner's submission of documentation- such as a State or school Web site - to validate the person's educational qualifications.

A physician need not submit a copy of his/her degree unless specifically requested to do so by the contractor. To the maximum extent possible, the contractor shall use means other than the physician's submission of documentation- such as a State or school Web site - to validate the person's educational status.

C. Resident/Intern Status

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

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

D. Physician Assistants

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

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

Since PAs cannot reassign their benefits – even though they are reimbursed through

their employer – they should not complete a CMS-855R.

E. Psychologists Billing Independently

The contractor shall ensure that all persons who check "Psychologist Billing Independently" in section 2D2 of the CMS-855I answer all questions in section 2I. If the supplier answers "no" to question 1, 2, 3, 4a, or 4b, the contractor shall deny the application.

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

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

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

If the individual answers "yes" to question 2, 3, 4, or 5, the contractor shall request a copy of the lease agreement giving him/her exclusive use of the facilities for PT/OT services only if it has reason to question the accuracy of his/her response. If the contractor makes this request and the provider cannot furnish a copy of the lease, the contractor shall deny the application.

15.5.3 – *Final Adverse Actions*

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

Unless stated otherwise, the instructions in this section 15.5.3 apply to the following sections of the Form CMS-855:

- *Section 3*
- *Section 4A of the CMS-855I*
- *Section 5*
- *Section 6*

A. Disclosure of Final Adverse Action

If a final adverse action is disclosed on the Form CMS-855, the provider must furnish documentation concerning the type and date of the action, what court(s) and law enforcement authorities were involved, and how the adverse action was resolved. The documentation must be furnished regardless of whether the adverse action occurred in a State different from that in which the provider seeks enrollment or is enrolled.

Note further:

1. *Reinstatements - If the person or entity in question was excluded or debarred but has since been reinstated, the contractor shall confirm the reinstatement through the Office of Inspector General (OIG) or, in the case of debarment, through the federal agency that took the action. It shall also ensure that the provider submits written proof of the reinstatement (e.g., reinstatement letter).*

2. *Revocation Reversals – Medicare revocations that were reversed on appeal need not be reported on the Form CMS-855.*

3. *Scope of Disclosure – All final adverse actions that occurred under the legal business name (LBN) and tax identification number (TIN) of the disclosing entity (e.g., applicant; Section 5 owner) must be reported. This includes Medicare revocations that: (1) were initiated by a different Medicare contractor in another contractor jurisdiction, and (2) involve a different provider or supplier type. Consider the following examples:*

   Example (a) - Smith Pharmacy, Inc. had 22 separately enrolled locations in 2009. Each location was under Smith's LBN and TIN. In 2010, two locations were revoked, leaving 20 locations. Smith submits a Form CMS-855S application for a new location on Jones Street. The two revocations in 2010 must be reported on the Jones Street application. Suppose, however, that each of Smith's locations had its own LBN and TIN. The Jones Street application need not disclose the two revocations from 2010.

   Example (b) - A home health agency (HHA), hospice and hospital are enrolling under Corporation X's LBN and TIN. X is listed as the provider in section 2 of each applicant's Form CMS-855A. All three successfully enroll. Six months later, Company X's billing privileges for the HHA are revoked. Both the hospice and the hospital must report the revocation via a Form CMS-855A change request because the revocation occurred under the provider's LBN and TIN. Assume now that X seeks to enroll an ambulatory surgical center (ASC) under X's LBN and TIN. The HHA revocation would have to be reported in section 3 of the ASC's initial Form CMS-855B.

   Example (c) – Company Y is listed as the provider/supplier for two HHAs and 2 suppliers of durable medical equipment, prosthetics, orthotics and supplies

(DMEPOS). These 4 providers/suppliers are under Y's LBN and TIN. Each provider/supplier is located in a different State. All are enrolled. Y's billing privileges for one of the DMEPOS suppliers are revoked. Y now seeks to enroll an ASC in a fifth State. Y must disclose the DMEPOS revocation on the ASC's initial Form CMS-855, even though the revocation: (1) was done by a Medicare contractor other than that with which the ASC seeks enrollment, and (2) occurred in a State different from that in which the ASC is located.

Example (d) – Company Alpha is listed as an owner in section 5 of the Form CMS-855A. Alpha operates two health care providers – Y and Z - under its LBN and TIN. Y was subject to a General Services Administration debarment, which ended in 2009. The debarment would have to be reported in section 5, since it occurred under Z's LBN and TIN.

4. *Timeframe – With the exception of the felony convictions identified in #1 under "Convictions" in section 3 of the Form CMS-855, all final adverse actions must be reported regardless of when they occurred.*

5. *Corporate Integrity Agreements (CIAs) – CIAs need not be disclosed on the Form CMS-855.*

6. *Evidence to Indicate Adverse Action – There may be instances where the provider states in section 3, 4A of the CMS-855I, 5, and/or 6 that the person or entity has never had a final adverse action imposed against him/her/it, but the contractor finds evidence to indicate otherwise. In such cases, the contractor shall contact its Provider Enrollment Operations Group Business Function Lead (PEOG BFL) for guidance.*

B. Prior Approval

If a current exclusion or debarment is disclosed on the Form CMS-855, the contractor shall deny the application in accordance with the instructions in this chapter. Prior approval from PEOG is not necessary. If any other final adverse action is listed, the contractor shall refer the matter to its PEOG BFL for guidance.

C. Review of the Provider Enrollment, Chain and Ownership System (PECOS)

If the contractor denies an application or revokes a provider based on a final adverse action, the contactor shall search PECOS (or, if the provider is not in PECOS, the contractor's internal system) to determine:

- *Whether the person/entity with the adverse action has any other associations (e.g., is listed in PECOS as an owner of three Medicare-enrolled providers), or*

- *If the denial/revocation resulted from an adverse action imposed against an owner, managing employee, director, etc., of the provider, whether the person/entity in question has any other associations (e.g., a managing employee of the provider is identified as an owner of two other Medicare-enrolled HHAs).*

If such an association is found and, per 42 CFR §424.535, there are grounds for revoking the billing privileges of the other provider, the contractor shall initiate revocation proceedings with respect to the latter.

If the "other provider" is enrolled with a different contractor, the contractor shall notify the latter - via fax or e-mail – of the situation, at which time the latter shall take the revocation action. To illustrate, suppose John Smith attempted to enroll with Contractor X as a physician. Smith is currently listed as an owner of Jones Group Practice, which is enrolled with Contractor Y. Contractor X discovers that Smith was recently convicted of a felony. X therefore denies Smith's application. X must also notify Y of the felony conviction; Y shall then revoke Jones' billing privileges per 42 CFR § 424.535(a)(3).

D. Chain Home Offices, Billing Agencies, and HHA Nursing Registries

If the contractor discovers that an entity listed in sections 7, 8, or 12 of the Form CMS-855 has had a final adverse action imposed against it, the contractor shall contact its PEOG BFL for guidance.

15.5.4 – Practice Location Information

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

Unless specifically indicated otherwise, the instructions in this section 15.5.4 apply to the CMS-855A, the CMS-855B, and the CMS-855I.

The instructions in section 15.5.4.1 apply only to the CMS-855A; the instructions in section 15.5.4.2 apply only to the CMS-855B; and the instructions in section 15.5.4.3 only apply to the CMS-855I.

A. Practice Location Verification

The contractor shall verify that the practice locations listed on the application actually exist; note that the practice location name may be the "doing business as" name. If a particular location cannot at first be verified, the contractor shall request clarifying information. (For instance, the contractor can request that the applicant furnish letterhead showing the appropriate address.)

The contractor shall also verify that the reported telephone number is operational and connects to the practice location/business listed on the application. (The telephone number must be one where patients and/or customers can reach the applicant to ask questions or register complaints.) The contractor shall match the applicant's telephone

number with known, in-service telephone numbers - via, for instance, the Yellow Pages or the Internet - to correlate telephone numbers with addresses. If the applicant uses his/her/its cell phone for their business, the contractor shall verify that this is a telephone connected directly to the business. If the contractor cannot verify the telephone number, it shall request clarifying information from the applicant; the inability to confirm a telephone number may indicate that an onsite visit is necessary. In some instances, a 1-800 number or out-of-state number may be acceptable if the applicant's business location is in another State but his/her/its practice locations are within the contractor's jurisdiction.

In addition:

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

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

B. Do Not Forward (DNF)

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

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

C. Remittance Notices/Special Payments

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

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

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

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

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

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

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

- One of the provider's practice locations

- A P.O. Box

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

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

- Correspondence address

15.5.4.1 – Section 4 of the Form CMS-855A

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

A. General Information

A hospital or other provider must list all addresses where it - and not a separately enrolled provider or supplier it owns or operates, such as a nursing home - furnishes services. The provider's primary practice location should be the first location identified in section 4A and the contractor shall treat it as such – unless there is evidence indicating otherwise - for purposes of entry into the Provider Enrollment, Chain and Ownership System (PECOS).

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

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

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

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

B. Verification of HHA Sites

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

15.5.4.2 – Section 4 of the Form CMS-855B

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

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

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

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

B. Reassignment of Benefits

Per Pub. 100-04, chapter 1, section 30.2.7, a contractor may permit a reassignment of benefits to any eligible entity regardless of where the service was rendered or whether

the entity owned or leased that location. As such, the contractor need not verify the entity's ownership or leasing arrangement with respect to the reassignment.

C. Ambulance Companies

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

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

If the supplier will be furnishing services in more than one jurisdiction, it shall follow the applicable instructions in section 15.5.18 of this chapter.

15.5.4.3 – Section 4 of the Form CMS-855I

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. Solely-Owned Organizations

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

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

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

The contractor shall verify all data furnished in section 4A (e.g., legal business name,

TIN, adverse legal actions). If section 4A is left blank, the contractor may assume that it does not pertain to the applicant.

A solely-owned physician or practitioner organization that utilizes section 4A to enroll in Medicare can generally submit change of information requests to Medicare via the CMS-855I. However, if the change involves data not captured on the CMS-855I, the change must be made on the applicable CMS form (i.e., CMS-855B, CMS-855R).

B. Individual Affiliations

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

C. Practice Location Information

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

D. Sole Proprietor Use of EIN

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

E. NPI Information for Groups

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

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

15.5.5 – Owning and Managing Organizations

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

(This section only applies to section 5 of the *Form* CMS-855A and *Form* CMS-855B.

It does not apply to the *Form* CMS-855I.)

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

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

The following illustrates the difference between direct and indirect ownership:

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

See the instructions for section 5 of the Form CMS-855 for additional information on indirect ownership.

2. Mortgage or security interest

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

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

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

All entities with at least a 5 percent mortgage, deed of trust or other security interest in the provider must be reported in section 5. This frequently will include banks, other financial institutions, and investment firms,

3. Any general partnership interest in the provider, regardless of the percentage. This includes: (1) all interests in a non-limited partnership, and (2) all general partnership interests in a limited partnership.

4. For limited partnerships, any limited partnership interest that is 10 percent or greater.

5. Managing control of the provider or supplier

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

The organizations referred to above generally fall into one or more of the following categories:

- *Corporations*
- *Partnerships and limited partnerships*
- *Limited liability companies*
- *Charitable and religious organizations*
- *Governmental/tribal organizations*
- *Banks and financial institutions*
- *Investment firms*
- *Holding companies*
- *Trusts and trustees*
- *Medical providers/suppliers*
- *Consulting firms*
- *Management services companies*
- *Medical staffing companies*
- *Non-profit entities*

In section 5(A)(2) of the Form CMS-855, the provider must indicate the type(s) of organizational categories the reported entity falls into.

The contractor shall also note the following with respect to *section 5:*

a. <u>Diagrams</u> – In addition to completing section 5(A):

- *The provider must submit an organizational structure diagram/flowchart identifying all of the entities listed in section 5 and their relationships with the provider and each other. (This applies to the Form CMS-855A, CMS-855B and CMS-855S.)*

- *If the provider is a skilled nursing facility (SNF), it must submit a diagram/flowchart identifying the organizational structures of all of its owners, including those that were not required to be listed in section 5 or 6. This must be submitted in addition to the diagram/flowchart in the previous bullet.*

These diagrams/flowcharts must be submitted for initial enrollments, revalidations and reactivations, and upon any contractor requests.

b. <u>Percentage of Interest (section 5(B))</u> – The provider need not:

- *Disclose a percentage of managerial control*

- *Submit documentation verifying the percentage of ownership, partnership interest or security/mortgage interest, unless the contractor requests it.*

c. *Section 2* - Any entity listed as the *provider* in section 2 of the *Form* CMS-855 need not be reported in section 5A. The only *exception involves* governmental entities, which must be *identified* in section 5A even if they are already listed in section 2.

d. *Governmental Organization Letter* - *For* governmental organizations, the letter referred to in the *Form* CMS-855 instructions for section 5 must be signed by an appointed or elected official of the governmental entity who has the authority to legally and financially bind the government to the laws, regulations, and program instructions of Medicare. *This government official is not required to* be an authorized official, or vice versa.

e. *Non-Profit Organizations* - Many non-profit organizations are charitable or religious in nature, and are operated and/or managed by a Board of Trustees or other governing body. The actual name of the Board of Trustees or other governing body *must* be listed in section 5A of the *Form* CMS-855. The *provider must* submit a copy of its 501(c)(3) approval notification for non-profit status. If it does not possess such documentation but nevertheless claims it is a non-profit entity, the *provider* may submit any other documentation that supports its claim *(e.g., written documentation from the State).*

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

- *Documentation – Proof of ownership, managerial control, security interest, etc., need not be submitted unless the contractor requests it. This also means that articles of incorporation, partnership agreements, etc., need not be submitted absent a contractor's request.*

15.5.6 – Owning and Managing Individuals

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

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

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

2. A 5 percent or greater mortgage or security interest in the provider.

(See section 15.5.5 of this chapter for more information on direct and indirect ownership, and on mortgage and security interests.)

3. Any general partnership interest in the provider, regardless of the percentage. This includes: (1) all interests in a non-limited partnership, and (2) all general partnership interests in a limited partnership.

4. For limited partnerships, any limited partnership interest that is 10 percent or greater.

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

6. Officers and directors, if the applicant is a corporation. (For-profit and non-profit corporations must list all of their officers and directors. If a non-profit corporation has "trustees" instead of officers or directors, these trustees must be listed in section 6 of the Form CMS-855.) Note that only officers and directors of the provider must be reported. Board members of the provider's indirect owners need not be disclosed to the extent they are not otherwise required to be reported (e.g., as an owner or managing employee) in section 6.

The contractor shall note the following:

- *The provider need not disclose a percentage of: (1) control as an officer or director, (2) W-2 or contracted managerial control, or (3) operational control. Also, the provider need not submit documentation verifying the percentage of ownership, partnership interest or security/mortgage interest, unless the contractor requests it.*

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

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

- All managing employees at any of the practice locations listed in section 4C of the *Form* CMS-855I must be reported in section 6A. However, individuals who: (1) are

employed by hospitals, health care facilities, or other organizations shown in section 4C (e.g., the *chief executive officer* of a hospital listed in section 4C), or (2) are managing employees of any group/organization to which the practitioner will be reassigning his/her benefits, need not be reported.

- The contractor *need not* request a copy of the individual's W-2 to confirm that he/she *is a* W-2 employee (as opposed to a contracted employee), *although it reserves the right to do so.*

- *Proof of ownership, managerial control, security interests, etc., need not be submitted unless the contractor requests it.*

15.5.7 – Chain Organizations

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

All providers that are currently part of a chain organization *or are* joining a chain organization must complete *section 7* with information about the chain home office. *Under 42 CFR §421.404, a "home office" means the entity that provides centralized management and administrative services to the providers or suppliers under common ownership and common control, such as centralized accounting, purchasing, personnel services, management direction and control, and other similar services. Other definitions relevant to chain organizations (and which are in § 421.404) include:*

- *Chain provider - A group of two or more providers under common ownership or control.*

- *Common control - Exists when an individual, a group of individuals, or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of the group of suppliers or eligible providers.*

- *Common ownership – Exists when an individual, a group of individuals, or an organization possesses significant equity in the group of suppliers or eligible providers.*

The contractor shall not *delay its* processing of the provider's application while awaiting the issuance of a chain home office number (i.e., a determination as to whether a set of entities qualifies as a chain organization). Such an issuance/determination is *not required for a* recommendation for approval.

In addition, the contractor shall ensure that:

- The chain home office is identified in section 5A and that *final adverse action* data is furnished in section 5B. (For purposes of provider enrollment, a chain home

office automatically qualifies as an owning/managing organization.) Note that a *National Provider Identifier (NPI)* is typically not required for a chain home office.

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

For more information on chain organizations, refer to:

- Pub. 100-04, chapter 1, sections 20.3 through 20.3.*6*
- 42 CFR §421.404
- CMS change request 5720

15.5.8 – Billing Agencies

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

(Unless otherwise stated, this section applies to the Form CMS-855A, the Form CMS-855B, and the Form CMS-855I.)

A billing agency is an entity that furnishes billing and collection services on behalf of a provider or supplier. A billing agency is not enrolled in the Medicare program. A billing agency submits claims to Medicare in the name and billing number of the provider or supplier that furnished the service or services. In order to receive payment directly from Medicare on behalf of a provider or supplier, a billing agency must meet the conditions described in § 1842(b)(6)(D) of the Social Security Act.

The provider shall complete *section 8 of the Form CMS-855* with information about all billing agents *it utilizes.* As all Medicare payments must be made via electronic funds transfer, the contractor *need not* verify the provider's compliance with the "Payment to Agent" rules in CMS Publication 100-04, chapter 1, section 30.2. The only *exception is if* the contractor discovers that the "special payments" address in section 4 of the provider's Form CMS-855 application belongs to the billing agent or agency. In this situation, the contractor may obtain a copy of the billing agreement if it has reason to believe that the arrangement violates the "Payment to Agent" rules.

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

For further information on billing agencies, see CMS Publication 100-04, chapter 1, section 30.2.4.

15.5.9 – Reserved for Future Use

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.5.10 – Reserved for Future Use
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.5.11 – Reserved for Future Use
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.5.12 – Special Requirements for Home Health Agencies (HHAs)
(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

A. Capitalization

For initial applications, the contractor shall verify that the HHA meets all of the capitalization requirements addressed in 42 CFR §489.28. *(Note that capitalization need not be reviewed for revalidation or reactivation applications.)* The contractor may request from the provider any and all documentation deemed necessary to perform this task. Failure to meet the capitalization requirements shall result *in a denial or revocation, as appropriate.* For more information on HHA capitalization, *see §*489.28 and section 15.26.2 of this chapter.

B. Nursing Registries

If the HHA checks "yes" in section 12B, the contractor *shall ensure* that the information furnished *about* the HHA nursing registry *is accurate.* (A nursing registry is akin to a staffing agency, whereby a private company furnishes nursing personnel to hospitals, clinics, and other medical providers.)

15.5.13 – Contact Person
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

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

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

In short:

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

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

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

15.5.14 – Reserved for Future Use

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.5.15 – *Authorized Officials*

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

Unless indicated otherwise below or in another CMS directive, the instructions in sections 15.5.15.1 and 15.5.15.2 apply to: (1) signatures on the paper Form CMS-855, (2) signatures on the certification statement for Internet-based Provider Enrollment, Chain and Ownership System (PECOS) applications, and (3) electronic signatures.

15.5.15.1 – Form CMS-855I Signatories

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

15.5.15.2 – Form CMS-855A and Form CMS-855B Signatories

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

For CMS-855A and CMS-855B initial and revalidation applications, the certification

statement must be signed and dated by an authorized official of the provider. (See section 15.1.1 of this chapter for a definition of "authorized official.") The provider can have an unlimited number of authorized officials, so long as each meets the definition of an authorized official. Section 6 of the Form CMS-855 must be completed for each authorized official.

If an authorized official is listed as a "Contracted Managing Employee" in section 6 of the Form CMS-855 and does not qualify as an authorized official under some other category in section 6, he/she cannot be an authorized official. The contractor shall notify the provider accordingly. If the person is not listed as a "Contracted Managing Employee" in section 6 and the contractor has no reason to suspect that the person does not qualify as an authorized official, no further investigation is required. Should the contractor have doubts that the individual qualifies as an authorized official, it shall contact the 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 that the individual qualifies as an authorized official, it shall notify the provider that the person cannot be an authorized official. If that person is the only authorized official listed and the provider refuses to use a different authorized official, the contractor shall deny the application.

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 chief executive officer, chief financial officer, etc., of the provider's parent company, management company, or chain home office as a basis for his/her role as the provider's authorized official.

In addition:

1. Original Signatures - For non-electronic signatures, the signature of an authorized official must be original. Faxed, stamped, or photocopied signatures cannot be accepted.

2. Deletion of Authorized Official - If an authorized official is being deleted, the contractor need not obtain: (1) that official's signature, or (2) documentation verifying that the person is no longer an authorized official.

3. Change in Authorized Officials - A change in authorized officials does not impact the authority of existing delegated officials to report changes and/or updates to the provider's enrollment data.

4. Authorized Official Not on File - If the provider submits a change of information (e.g., change of address) 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 Form 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

encompassing two different actions) for purpose of enrollment processing and reporting.

5. Effective Date - The effective date in the Provider Enrollment, Chain and Ownership System for section 15 of the Form CMS-855 should be the date of signature.

6. Social Security Number - To be an authorized official, the person must have and must submit his/her social security number.

Identifying the Provider – As stated earlier, an authorized official must be an authorized official of the provider, not of an owning organization, parent company, chain home office, or management company. Identifying the provider is not - for purposes of determining an authorized official's qualifications - determined solely by the provider's tax identification number (TIN). Rather, the organizational structure is the central factor. For instance, suppose that a chain drug store, Company X, wants to enroll 100 of its pharmacies with the contractor. Each pharmacy has a separate TIN and must therefore enroll separately. Yet all of the pharmacies are part of a single corporate entity – Company 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.

15.5.16 – Delegated Officials

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

(*Unless indicated otherwise below or in another CMS directive, the instructions in this section apply to: (1) signatures on the paper Form CMS-855, (2) signatures on the certification statement for Internet-based Provider Enrollment, Chain and Ownership System (PECOS) applications, and (3) electronic signatures. Note also that t*his section only applies to the *Form* CMS-855A and the Form CMS-855B.)

A delegated official is an individual *to whom an authorized official listed in section 15 of the Form CMS-855 delegates 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 *§* 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

- *Someone with a partnership interest in the provider*, if the provider is a partnership

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/her role as the provider's delegated official.

The contractor shall note the following about delegated officials:

1. *Authority* - A delegated official has no authority to sign an *initial or revalidation application*. *However, the delegated official may sign off on changes/updates submitted in response to a contractor's request to clarify or submit information needed to continue processing the provider's initial or revalidation application.*

2. *Section 6* – Section 6 *of the Form CMS-855 must be completed for all delegated officials.*

3. *Managing Employees* - 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 *the provider hires Joe Smith as an independent contractor to* run its day-to-day-operations. Under the definition of "managing employee" *in* section 6 of the *Form* CMS-855, Smith would have to be listed *in that section*. *Yet* 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 *Form* CMS-855.

4. *W-2 Form – Unless the contractor requests it to do so, t*he provider is not required to submit a copy of the owning/managing individual's W-2 to verify an employment relationship.

5. *Number of Delegated Officials* - The provider can have as many delegated officials as it *chooses.* Conversely, the provider is not required to have any delegated official*s.* Should no delegated officials be listed, however, the authorized official(s) remains the only individual(s) who can *report* changes and/or updates to the provider's *enrollment data.*

6. *Effective Date* - The effective date in *PECOS* for section 16 of the *Form* CMS-855 should be the date of signature.

7. Social Security Number - *To* be a delegated official, the person must have and must submit his/her social security number.

8. Deletion - If a delegated official is being deleted, documentation verifying that the person no longer is or qualifies as a delegated official is not required. *Also,* the signature of the deleted official *is not* needed.

9. Further Delegation - 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 *data.*

10. Delegated Official Not on File - If the provider *submits* a change of information *(e.g., change* of address*)* 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 *Form* 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 encompass*ing* two different actions) for purpose of enrollment processing and reportin*g.*

11) Signature on Paper Application - If the provider submits a *paper Form* CMS-855 change *request*, the contractor may accept the signature of a delegated official in Section 15 or 16 of the *Form* CMS-855.

15.5.17 – Reserved for Future Use

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.5.18 – Ambulance Attachment

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. Geographic Area

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

B. Licensure Information

With respect to licensure:

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

- If the supplier performs services in multiples States within the same contractor jurisdiction, it must submit all necessary licenses and certificates for each State.

Separate full CMS-855Bs are not required for each State; however, the contractor shall create separate enrollment records in PECOS for each.

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

C. Paramedic Intercept Information

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

D. Vehicle Information

Air ambulance suppliers must submit the following:

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

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

E. Hospital-Based Ambulances

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

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

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

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

15.5.19 – IDTF Attachment
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

Sections 15.5.19 through 15.5.19.7 of this chapter contain provider enrollment instructions regarding entities that must enroll as and bill for the technical component of diagnostic tests as an independent diagnostic testing facility (IDTF).

15.5.19.1 – Independent Diagnostic Testing Facility (IDTF) Standards
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

A. IDTF Standards

Consistent with 42 CFR §410.33(g), each IDTF must certify on its Form 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 and to ensure that 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 final adverse actions must be reported to the contractor 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 Form CMS-855B whereby the supplier agrees to notify Medicare of any changes to its enrollment data within 90 days of the effective date of the change. By signing the certification statement, the IDTF agrees to abide by all Medicare rules for its supplier type, including the 30-day rule in 42 CFR §410.33(g)(2).

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

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

    - The requirements in 42 CFR §410.33(g)(3) take precedence over the guidelines in sections 15.5.4 and 15.5.4.2 of this chapter 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 15.5.4 and 15.5.4.2 of this chapter regarding 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 non-relative-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; this 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: (a) is furnishing a consultation or treating a beneficiary for a specific medical problem, and (2) uses the results in the management of the beneficiary's specific medical problem. Non-physician practitioners may order tests as set forth in §410.32(a)(3).

   - By the signature of the authorized official in section 15 of the Form 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 purpose 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 Provider Enrollment Operations Group (PEOG) 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 an 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 Form 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 Form 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).)

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.

C. One Enrollment per Practice Location

An IDTF must separately enroll each of its practice locations (with the exception of locations that are used solely as warehouses or repair facilities). This means that an enrolling IDTF can only have one practice location on its Form CMS-855B enrollment application; thus, if an IDTF is adding a practice location to its existing enrollment, it must submit a new, complete Form 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.

Each separately enrolled practice location of the IDTF must meet all applicable IDTF requirements. The location’s failure to comply with any of these requirements will result in the revocation of its Medicare billing privileges.

D. Effective Date of Billing Privileges

The filing date of an IDTF Medicare enrollment application is the date that the contractor receives a signed 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 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: (1) diagnostic testing equipment; (2) non-physician personnel described in 42 CFR §410.33(c); or (3) 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.

15.5.19.2 – Multi-State Independent Diagnostic Testing Facilities (IDTFs)

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

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

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

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

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

15.5.19.3 – Interpreting Physicians
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

The applicant shall list all physicians for whose diagnostic test interpretations it will bill. This includes physicians who will provide interpretations subject to the anti-markup payment limitation as detailed in CMS Publication 100-04, chapter 1, §30.2.9 - whether the service is provided to the IDTF on a contract basis or is reassigned.

The contractor shall ensure and document that:

- All listed physicians are enrolled in Medicare

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

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

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

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

15.5.19.4 – Technicians
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

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

A. Licensure and Certification

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

B. Changes of Technicians

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

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

15.5.19.5 – Supervising Physicians

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

A. General Principles

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

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

Not every supervising physician has to be responsible for all of these functions. For instance, one supervising physician can be responsible for the operation and calibration of equipment, while another supervising physician can be responsible for test supervision and the qualifications of non-physician personnel. The basic requirement, however, is that all supervising physician functions must be properly met at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervising physicians at different locations. They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

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

B. Information about Supervising Physicians

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

In addition:

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

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

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

C. General, Direct, and Personal Supervision

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

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

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

D. Attestation Statement for Supervising Physicians

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

With respect to physician verification, the contractor shall:

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

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

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

15.5.19.6 – Desk and Site Reviews
(Rev. 414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

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

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

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

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

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

A. Mobile Units

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

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

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

- What their responsibilities are; and

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

B. Addition of Codes

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

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

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

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

15.5.19.7 – Special Procedures and Supplier Types

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

A. Diagnostic Mammography

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

B. CLIA Tests

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

15.5.20 – Processing Form CMS-855R Applications

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. General Information

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

If the individual who wants to reassign his or her benefits is not enrolled in Medicare, the person must complete a CMS-855I as well as the CMS-855R. (The CMS-855I and CMS-855R can be submitted concurrently.) Moreover, if the entity to which the person's benefits will be reassigned is not enrolled in Medicare, the organization must complete a CMS-855B. (See section 15.7.6 for additional instructions regarding the joint processing of CMS-855Rs, CMS-855Bs, and CMS-855Is.)

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

In addition:

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

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

- If the individual is initiating a reassignment, both he/she and the group's authorized or delegated official must sign section 4 of the CMS-855R. If either of the two signatures is missing, the contractor may return the application per section 15.8.1 of this chapter.

- If the person (or group) is terminating a reassignment, either party may sign section 4 of the CMS-855R; obtaining both signatures is not required. If no signatures are present, the contractor may return the application per section 15.8.1 of this chapter.

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

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

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

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

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

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

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

B. ASCs and Reassignment

Physicians and non-physician practitioners who meet the reassignment exceptions in 42 CFR §424.80, and Pub. 100-04, chapter 1, sections 30.2.6 and 30.2.7, may reassign their benefits to an ASC.

If a physician or non-physician practitioner wishes to reassign its benefits to an existing (that is, a currently-enrolled) ASC, both the individual and the entity must sign the CMS-855R. However, it is not necessary for the ASC to separately enroll as a group practice in order to receive benefits. It can accept reassignment as an ASC.

C. Reassignment and Revoked/Deceased Physicians and Non-Physician Practitioners

There are situations where a physician/non-physician practitioner (the "owning physician/practitioner") owns 100% of his/her own practice, employs another physician

(the "employed physician/practitioner") to work with him/her, and accepts reassigned benefits from the employed physician/practitioner. Should the sole proprietor or sole owner die or have his/her billing privileges revoked, the practice is automatically dissolved for purposes of Medicare enrollment and all reassignments to the practice are automatically terminated as well. Neither the owning physician/practitioner nor the practice is enrolled in Medicare any longer and the billing privileges for both shall be revoked in accordance with the revocation procedures outlined in this chapter. (It is immaterial whether the practice was established as a sole proprietorship, a PC, a PA, or a solely-owned LLC.) In addition, the contractor shall end-date the reassignment using, as applicable, the date of death or the effective date of the revocation.

Besides revoking the billing privileges of the owning physician/practitioner and the practice, the contractor shall notify the employed physician/practitioner that:

(1) The practice's billing privileges have been revoked;

(2) Any services furnished by him/her on behalf of the practice after the date of the owning physician/practitioner's death will not be paid; and

(3) If the employed physician/practitioner wishes to provide services at the former practice's location, he/she must submit via Internet-based PECOS (or a paper CMS-855 application) a CMS-855I change of information request to add the owning physician/practitioner's practice location as a new location of the employed physician/practitioner. For purposes of this section 15.5.20(C)(3) only, submission of a (1) complete CMS-855I application as an initial enrollment and (2) a terminating CMS-855R application are not required – even if the employed physician/non-physician practitioner had reassigned all of his/her benefits to the practice.

15.6 - Timeliness and Accuracy Standards

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

The processing of an application generally includes, but is not limited to, the following activities:

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

- Prescreening the *application.*

- Creating a *logging and tracking (L & T)* record and an enrollment record in *the Provider Enrollment, Chain and Ownership System (PECOS).*

- *Ensuring that the information on the application is verified.*

- Requesting and receiving clarifying information.

- Site visit (if necessary).

- Formal notification *to the SA and/or RO* of the contractor's *approval, denial or recommendation for approval of the application.*

15.6.1 – Standards for Initial Applications

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

1. *Form CMS-855 change of ownership*, acquisition/merger, and consolidation applications submitted by the new owner.

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

15.6.1.1 - Paper Applications - Timeliness

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

For purposes of sections 15.6.1.1.2 though 15.6.1.1.4 below, the term "development" means that the contractor needs to contact the supplier for additional information. (A prescreening letter to the provider is considered to be the first developmental request.)

15.6.1.1.1 – *Form* CMS-855A Applications

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

The contractor shall process 80 percent of *all Form* CMS-855A initial applications within 60 calendar days of receipt, process 90 percent of *all Form* CMS-855A initial applications within 120 calendar days of receipt, and process 99 percent of *all Form* CMS-855A initial applications within 180 calendar days of receipt.

15.6.1.1.2 – *Form* CMS-855I Applications

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

The contractor shall process 80 percent of all initial *Form* CMS-855I applications where no contractor development is needed within 60 calendar days of receipt, and

process 95 percent of *all* such applications within 90 calendar days of receipt.

The contractor shall process 80 percent of all initial *Form* CMS-855I applications where one developmental request is made by the contractor within 90 calendar days of receipt, *process* 90 percent of *all* such applications within 120 calendar days of receipt, and *process* 95 percent of *all* such applications within 180 calendar days of receipt.

The contractor shall process 70 percent of all initial *Form* CMS-855I applications where at least two developmental requests are made by the contractor within 90 calendar days of receipt, *process* 80 percent of *all* such applications within 120 calendar days of receipt, and *process* 90 percent of *all* such applications within 180 calendar days of receipt.

15.6.1.1.3 – *Form* CMS-855B Applications Submitted by Suppliers Other Than *Independent Diagnostic Testing Facilities (IDTFs)*

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

(This section *15.*6.1.1.3 applies only to initial *Form* CMS-855B applications submitted by suppliers other than IDTFs.)

The contractor shall process 80 percent of all initial *Form* CMS-855B applications where no contractor development is needed within 60 calendar days of receipt, and *process* 95 percent of *all* such applications within 90 calendar days of receipt.

The contractor shall process 80 percent of all initial *Form* CMS-855B applications where one developmental request is made by the contractor within 90 calendar days of receipt, *process* 90 percent of *all* such applications within 120 calendar days of receipt, and *process* 95 percent of *all* such applications within 180 calendar days of receipt.

The contractor shall process 70 percent of all initial *Form* CMS-855B applications where at least two developmental requests are made by the contractor within 90 calendar days of receipt, *process* 80 percent of *all* such applications within 120 calendar days of receipt, and *process* 90 percent of *all* such applications within 180 calendar days of receipt.

15.6.1.1.4 – *Form* CMS-855B Applications Submitted by *Independent Diagnostic Testing Facilities (IDTFs)*

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

The contractor shall process 70 percent of all initial IDTF *Form* CMS-855B applications where no contractor development is needed within 90 calendar days of receipt, *process* 80 percent of *all* such applications within 120 calendar days of receipt, and 95 percent of *all* such applications within 180 calendar days of receipt.

The contractor shall process 65 percent of all initial IDTF *Form* CMS-855B applications where one developmental request is made by the contractor within 90

calendar days of receipt, *process* 75 percent of *all* such applications within 120 calendar days of receipt, and *process* 90 percent of *all* such applications within 180 calendar days of receipt.

The contractor shall process 60 percent of all initial *Form* IDTF CMS-855B applications where two or more developmental requests are made by the contractor within 90 calendar days of receipt, *process* 70 percent of *all* such applications within 120 calendar days of receipt, and *process* 80 percent of *all* such applications within 180 calendar days of receipt.

15.6.1.2 - Paper Applications – Accuracy

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

The contractor shall process 98 percent of paper CMS-855 initial applications in full accordance with all of the instructions in this chapter (with the exception of the timeliness standards identified in sections 15.6.1.1.1 through 15.6.1.1.4 of this chapter) and all other applicable CMS directives.

15.6.1.3 - Web-Based Applications - Timeliness

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

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

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

- Verification of the application in accordance with existing instructions.

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

- Supplier site visit (if required).

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

15.6.1.4 - Web-Based Applications - Accuracy

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

The contractor shall process 98 percent of Form CMS-855 Web-based initial applications in full accordance with all of the instructions in this chapter (with the exception of the timeliness standards identified in section 15.6.1.3 above) and all other

applicable CMS directives.

15.6.2 – Standards for Changes of Information

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

1. *Form CMS-855 change of ownership*, acquisition/merger, and consolidation applications submitted by the old owner

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

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

4. *Form* CMS-855 voluntary terminations

15.6.2.1 - Paper Applications - Timeliness

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

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

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

- Prescreening the change request in accordance with existing instructions.

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

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

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

- Supplier site visit (if necessary).

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

15.6.2.2 - Paper Applications - Accuracy

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

The contractor shall process 98 percent of paper Form CMS-855 changes of information in full accordance with all of the instructions in this chapter (with the exception of the timeliness standards identified in section 15.6.2.1 above) and all other applicable CMS directives.

15.6.2.3 - Web-Based Applications - Timeliness

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

- Receipt of the provider's certification statement in the contractor's mailroom and forwarding it to the appropriate office for review. *(This obviously does not apply to applications submitted with an electronic signature.)*

- *Ensuring that the changed information has been verified*

- Requesting and receiving clarifying information

- Supplier site visit (if necessary)

- Formal notification to the *SA and/or RO* of the contractor's *approval, denial or recommendation for approval of the application*

15.6.2.4 - Web-Based Applications – Accuracy

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

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

15.6.3 - General Timeliness Principles

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

Unless stated otherwise in this chapter or in another CMS directive, the principles discussed below apply to all applications discussed in sections 15.6.1 through 15.6.2.4 of this chapter (e.g., change of ownership (CHOW) applications submitted by old and new owners, CMS-588 forms).

A. Clock Stoppages

The processing time clocks identified in sections 15.6.1 and 15.6.2.3 of this chapter cannot be stopped or suspended for any reason. This includes, but is not limited to, the following situations:

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

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

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

- Referring a provider to the Social Security Administration to resolve a discrepancy involving a social security number.

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

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

B. Calendar Days

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

C. Date-Stamping

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

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

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

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

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

For applications that do not require the submission of an fee, the timeliness clock begins on the date on which the application/envelope is date-stamped in the contractor's mailroom, not the date on which the application is date-stamped or received by the provider enrollment unit. As such, the date-stamping activities described in the above bullets must be performed in the contractor's mailroom. In cases where the mailroom staff fails to date-stamp a particular document, the provider enrollment unit may date-stamp the page in question. However, there shall not be long lapses between the time it was received in the mailroom and the time the provider enrollment unit date-stamped the pages.

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

D. When the Processing Cycle Ends

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

- Sends its recommendation of approval to the State agency

- Denies the application

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

For (1) Form CMS-855I applications, (2) Form CMS-855R applications, and (3) Form

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

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

E. PECOS

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

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

- For applications that require an application fee, no later than 20 calendar days after:

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

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

Moreover, the contractor must establish a complete enrollment record in PECOS – if applicable - prior to its approval, recommendation of approval, or denial of the provider's application. To the maximum extent possible, the contractor shall establish the enrollment record at one time, rather than on a piecemeal basis.

The L & T and enrollment record requirements in the previous paragraph apply to all applications identified in sections 15.6.1 through 15.6.2.4 of this chapter (e.g., reassignments, CHOW applications submitted by old and new owners).

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

15.7 – Application Review and Verification Activities

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

Unless stated otherwise in this *chapter,* the instructions in sections *15.*7 through *15.7.*3

apply to the *Form* CMS-855A, the *Form* CMS-855B and the *Form* CMS-855I. These instructions are in addition to, and not in lieu of, all other instructions in this *chapter.*

15.7.1 – General Verification Principles

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

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

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

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

- **Validation:** The contractor shall verify and validate all information furnished by the provider on the CMS-855. (See section 7.2 below for more information.)

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

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

15.7.1.1 – Pre-Screening Process

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. Paper Applications

Within 20 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 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 20-day period.)

- A list of all missing data or documentation;

- A request that the provider submit the data within 30 calendar days;

- 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. Also, and as a reminder, a prescreening letter is not required if the provider submitted a complete application and all applicable supporting 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 15.7.2.2 of this chapter for information on requesting additional (or "clarifying") information and how this is tied to the pre-screening process.

B. Internet-Based PECOS Applications

The prescreening process, as described in section 15.7.1.1, must be completed within 15 calendar days for Internet-based applications.

15.7.2 – Verification of Data

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

The general purpose of the verification process is to determine if any of the data furnished on the CMS-855 is incorrect. The contractor may begin the verification process at any time, including during the prescreening phase.

A. Concurrent Reviews

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

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

B. Mechanisms of Verification

Unless stated otherwise in this manual or in other CMS directives (e.g., JSMs), the contractor shall verify all data furnished on the CMS-855 via the most cost-effective method available. Such data includes, but is not limited to:

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

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

- Legal business names and employer identification numbers of all entities listed in sections 5, 7, 8, and 12 of the CMS-855.

Examples of verification techniques include:

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

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

- **Provider's "doing business as" name –** Searching State Web sites

If the discrepancy is found between the information of the application and the data found during the verification process, the contractor shall contact the provider for clarification.

In addition:

- There may be instances where CMS directs contractors to verify certain data via the Medicare Exclusion Database and/or the GSA Excluded Parties List System. If a potential hit is found on the GSA List and the contractor needs to make a positive identity, it shall contact the agency that took the action for further information; based on this data, the contractor shall determine whether it is the same person. If a positive match still cannot be made, the contractor may approve the application.

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

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

15.7.2.1 – Reserved for Future Use

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.7.2.2 – Requesting and Receiving Clarifying Information

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. Requesting Clarifying Data

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

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

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

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

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

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

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

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 15.7.2.2 apply to all CMS-855 applications identified in this chapter (e.g., changes of information, reassignments).

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

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

- **Rejections vs. Denials** – For providers and suppliers covered by section 15.8.4 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 15.8.4 of this chapter is implicated.

  If the contractor is faced with this situation, it is free to contact its Provider Enrollment Operations Group (PEOG) 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. 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-855A 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-855A 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 chapter, 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 contractor. On the 58th day – one day before the contractor planned to make its recommendation for approval – the provider on its own volition submitted updates to its section 6 data. The contractor 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.

15.7.3 - Documentation

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

To ensure that proper internal controls are maintained and that important information is recorded in case of potential litigation, the contractor shall maintain documentation as outlined in this section 7.3. CMS cannot stress enough how crucial it is for contractors to document their actions as carefully and thoroughly as possible.

Note that these requirements are in addition to, and not in lieu of, all other documentation or document maintenance requirements that CMS has mandated.

A. Written and Telephonic Communications

(For purposes of this section 7.3, "written correspondence" includes faxes and e-mails.)

The contractor shall:

- Retain copies of all written correspondence pertaining to the provider, regardless of whether the correspondence was initiated by the contractor, the provider, CMS, State officials, etc.

- Document when it sends written letters and faxes to providers. For instance, if the carrier crafts an approval letter to the supplier dated March 1 but sends it out on March 3, the contractor shall note this in the file.

- Document all referrals to CMS, the PSC, or the OIG.

- Document any and all actual or attempted telephonic or face-to-face contacts with the provider, any representative thereof, or any other person regarding a provider. This includes, but is not limited to, the following situations:

    - Telephoning a provider about its application. (Even if the provider official was unavailable and a voice mail message was left, this must be documented.)

    - Requesting information from the State or another contractor concerning the applicant or enrollee;

    - Contacting the PSC for an update concerning an application sent to them;

    - Phone calls from the provider;

    - Conducting a meeting at the contractor's headquarters/offices with officials from a hospital concerning problems with its application;

    - Contacting CO or the RO's survey and certification staff – and receiving instructions there from - about a problem the contractor is having with an applicant or an existing provider;

    - Contacting the provider's billing department with a question about the provider.

When documenting oral communications, the contractor shall indicate: (1) the time and date of the call or contact; (2) who initiated contact; (3) who was spoken with; and (4) what the conversation pertained to. Concerning the last requirement, the contractor need not write down every word that was said during the conversation. Rather, the documentation should merely be adequate to reflect the contents of the conversation. The documentation can be stored electronically, if the contractor can provide access within 24 hours upon request.

Note that the documentation requirements in this subsection (A) only apply to enrolled providers and to providers that have already submitted an enrollment application. In other words, these documentation requirements go into effect only after the provider submits an initial application. To illustrate, if a hospital contacts the contractor requesting information concerning how it should enroll in the Medicare program, this need not be documented because the hospital has not yet submitted an enrollment application.

If an application is returned per section 8.1 of this manual, the contractor shall document this. The manner of documentation lies within the contractor's discretion.

B. Verification of Data Elements

Once the contractor has completed its review of the CMS-855 (e.g., approved/denied application, approved change request), it shall provide a written statement asserting that it has: (1) verified all data elements on the application, and (2) reviewed all applicable names on the CMS-855 against Qualifier.net, the MED, and the GSA debarment list. The statement must be signed and dated. It can be drafted in any manner the contractor chooses so long as it certifies that the above-mentioned activities were completed. The record can be stored electronically.

For each person or entity that appeared on the MED or GSA lists, the contractor shall document the finding via a screen printout. In all other situations, the contractor is not encouraged to document their reviews via screen printouts. Simply using the verification statement described above is sufficient. Although the contractor has the discretion to use screen prints if it so chooses, the verification statement is still required.

15.7.4 - Tie-In Notices

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

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

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

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

In addition:

- **Approval Letters** – Depending on the RO, an approval letter may be issued in lieu of a tie-in notice.

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

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

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

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

15.7.5 – Special Program Integrity Procedures

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

This section contains additional verification procedures that the contractor shall utilize when processing the following transactions:

- Changes in the provider's practice location

- Changes in provider's correspondence or special payment address

- On the CMS-588, changes in the provider's bank name, depository routing transit number, or depository account number

- Reactivations

The purpose of these instructions is to ensure that the Medicare billing privileges of physicians, non-physician practitioners, and organizational providers/suppliers are

protected and that Medicare only pays qualified individuals and organizations. Note that the instructions in this section 15.7.5 are in addition to, and not in lieu of, all other verification instructions contained in this chapter. Also, unless otherwise stated, section 15.7.5 applies to the CMS-855A, the CMS-855B and the CMS-855I.

A. Change in Practice Location Address

In cases where a provider submits a CMS-855 request to change its practice location address, the contractor shall undertake the following activities:

1. Compare the signature thereon with the same person's signature on file to ensure that the signatures match. If they do not, the contractor shall request additional information from the signatory to confirm his or her identity. Proper identification includes a photocopy of a current passport or a photocopy of a driver's license. If the individual fails to submit this information or if the contractor determines that the supporting documentation does not verify the person's identity, the contractor shall deny the application.

For the CMS-855A and CMS-855B, 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.

2. Contact the location currently associated with the provider in PECOS or MCS to verify that the provider is no longer there and did in fact move.

3. Request that the provider fax to the contractor a copy of his/her driver's license or, if applicable, a copy of a phone bill/power bill containing the business's new LBN or DBA name and its new address.

B. Change in Correspondence or Special Payments Address

If the provider submits a change to its correspondence or special payments address, the contractor shall undertake the following activities:

1. Compare the signature thereon with the same person's signature on file to ensure that the signatures match. If they do not, the contractor shall request additional information from the signatory to confirm his or her identity. Proper identification includes a photocopy of a current passport or a photocopy of a driver's license. If the individual fails to submit this information or if the contractor determines that the supporting documentation does not verify the person's identity, the contractor shall deny the application.

For the CMS-855A and CMS-855B, 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.

2. Contact the provider (or, for a CMS-855A or CMS-855B application, an authorized or delegated official) to verify the change.

C. Change of EFT Information

If the provider submits a CMS-588 request to change the bank name, depository routing transit number, or depository account number, the contractor shall undertake the following activities:

1. Compare the signature thereon with the same person's signature on file to ensure that the signatures match. If they do not, the contractor shall request additional information from the signatory to confirm his or her identity. Proper identification includes a photocopy of a current passport or a photocopy of a driver's license. If the individual fails to submit this information or if the contractor determines that the supporting documentation does not verify the person's identity, the contractor shall deny the application.

For organizational providers, 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.

2. Contact the provider (or, for a CMS-855A or CMS-855B application, an authorized or delegated official thereof) to verify the change.

D. Reactivations and Revalidations

When processing a CMS-855 reactivation or revalidation application, the contractor shall undertake the following activities:

1. Compare the signature thereon with the same person's signature on file to ensure that the signatures match. If they do not, the contractor shall request additional information from the signatory to confirm his or her identity. Proper identification includes a photocopy of a current passport or a photocopy of a driver's license. If the individual fails to submit this information or if the contractor determines that the supporting documentation does not verify the person's identity, the contractor shall deny the application.

For the CMS-855A and CMS-855B, 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.

2. If the: (a) practice location address or (b) correspondence/special payment address on the application is different than that which is currently associated with the provider in PECOS or MCS, the contractor shall abide by the instructions in subsections A and B above, respectively.

3. (Reactivations only): Request that the provider furnish a copy of a claim that it plans to submit upon the reactivation of its billing privileges. Alternatively, the provider may submit on letterhead the following information regarding a beneficiary to whom the provider has furnished services and for whom it will submit a claim: (1) beneficiary name, (2) health insurance claim number (HICN), (3) date of service, and (4) phone number.

E. Reassignment of All Benefits

If a physician or non-physician practitioner who is currently reassigning all of his or her benefits attempts to enroll as a sole proprietorship or the sole owner of his or her professional corporation, association or LLC, the contractor shall:

1. Compare the signature thereon with the same person's signature on file to ensure that the signatures match. If they do not, the contractor shall request additional information from the signatory to confirm his or her identity. Proper identification includes a photocopy of a current passport or a photocopy of a driver's license. If the individual fails to submit this information or if the contractor determines that the supporting documentation does not verify the person's identity, the contractor shall deny the application.

2. Call the old practice location to determine if the physician or non-physician practitioner is still employed there; if he or she is not, contact the practitioner to verify that he or she is indeed attempting to enroll as a sole proprietorship or sole owner and request that he/she fax to the contractor a copy of his/her driver's license.

F. Referral to PSCs or ZPICs

In conducting the verification activities described in this section 16, if the contractor believes that a case of identify theft or other fraudulent activity likely exists (e.g., physician or practitioner indicates that he or she is not establishing a new practice location or changing his or her EFT information, and that the application submitted in his/her name is false), the contractor shall deny the application and refer the matter to the PSC or ZPIC.

15.7.5.1 – Special Procedures for Physicians and Non-Physician Practitioners

(Rev. 416, Issued: 04-13-12, Effective :02-27-12, Implementation: 02-27-12)

To help ensure that only qualified physicians and non-physician practitioners are enrolled in Medicare, the contractor shall undertake the activities described below.

For purposes of this section, the term "practitioner" includes both physicians and non-physician practitioners. In addition, the instructions in this section, apply only to these practitioners.

A. Monthly Reviews

No later than the 15th day of each month, the contractor shall review State licensing board information for each State within its jurisdiction to determine whether any of its currently enrolled practitioners have, within the previous 60 days:

1. Had their medical license revoked, suspended or inactivated (due to retirement, death, or voluntary surrender of license);

2. Otherwise lost their medical license or have had their licenses expire.

For those practitioners who no longer have a valid medical license, the contractor shall take the necessary steps to revoke the individual's billing privileges.

The mechanism by which the contractor shall perform these monthly licensure reviews lies within its discretion, though the most cost-effective method shall be used.

B. Relocation to a New State

1. Licensure Reviews

When a practitioner submits a CMS-855I application to either: (1) add a practice location in a new State, or (2) relocate to a new State entirely, the contractor that received the application shall review State licensing board information for the "prior" State to determine:

1. Whether the practitioner had his or her medical license revoked, suspended, or inactivated (due to retirement, death, or voluntary surrender of license), or otherwise lost his or her license, and

2. If the practitioner has indeed lost his or her medical license, whether he or she reported this information to Medicare via the CMS-855I within the timeframe specified in 42 CFR 424.520.

If the practitioner is currently enrolled and did not report the adverse action to Medicare in a timely manner, the contractor shall revoke the practitioner's Medicare billing privileges and establish a 1-year enrollment bar. If the practitioner is submitting an initial enrollment application (e.g., is moving to a new State and contractor jurisdiction) and did not report the adverse action in section 3 of the CMS-855I, the contractor shall deny the enrollment application and establish a 3-year enrollment bar.

2. Voluntary Withdrawal Reminder

When a practitioner submits a CMS-855I application to either: (1) add a practice location in a new State, or (2) relocate to a new State entirely, the contractor that received the application shall determine whether the practitioner still has an active

PECOS enrollment record in the "other" State(s). If PECOS indeed indicates that the individual has an active practice location in the other State(s), the contractor shall remind the practitioner that if he/she no longer intends to practice in that State, he/she must submit a CMS-855 voluntary termination application to the contractor for that jurisdiction. The reminder should be given in the approval letter that the receiving contractor sends to the practitioner or, if more appropriate, in an e-mail or other form of written correspondence.

C. Break in Medical Practice

If the contractor receives a CMS-855I from a practitioner who was once enrolled in Medicare but who has not been enrolled with any Medicare contractor for the previous 2 years, the contractor shall verify with the State where the practitioner last worked whether the practitioner was convicted of a felony or had his or her license suspended or revoked. If such an adverse action was imposed, the contractor shall take action in accordance with the instructions in this chapter.

D. Distant EFT Account

Whether as part of an initial enrollment or a change request, if the practitioner wants to establish an EFT account: (1) in a State other than where the practice location is listed, or (2) located at an institution that is more than 50 miles from any of the supplier's existing, in-State practice locations, the contractor shall contact the practitioner to verify that this is indeed his or her intention. If the practitioner indicates that he or she never submitted such a request, the contractor shall deny the enrollment/change application and refer the matter to the program safeguard contractor (PSC) or zone program integrity contractor (ZPIC).

E. State Relationships

To the maximum extent possible, and to help ensure that it becomes aware of recent felony convictions of practitioners and owners of health care organizations, the contractor shall establish relationships with appropriate State government entities – such as, but not limited to, Medicaid fraud units, State licensing boards, and criminal divisions – designed to facilitate the flow of felony information from the State to the contractor. For instance, the contractor can request that the State inform it of any new felony convictions of health care practitioners.

15.7.6 - Special *Processing Guidelines* for Form CMS-855B, Form CMS-855I and Form CMS-855R Applications

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

A. Reassignment Packages

In situations where an entity wants to simultaneously enroll a group practice, the individual practitioners therein, and to reassign benefits accordingly, the contractor

shall adhere to the instructions contained in the scenarios below. During the pre-screening process, the contractor shall examine the incoming forms to see if a reassignment may be involved.

- Only the *Form* CMS-855Rs are submitted - If a brand new group with new practitioners is attempting to enroll but submits only the *Form* CMS-855Rs for its group members (i.e., neither the initial *Form* CMS-855B nor the initial *Form* CMS-855Is were submitted), the contractor *shall develop for the other forms if they are not submitted* within 15 calendar days after receipt of the *Form* CMS-855Rs.

- Only the *Form* CMS-855B is submitted - If a brand new group wants to enroll but submits only the *Form* CMS-855B without *including* the *Form* CMS-855Is and *Form* CMS-855Rs for its group members (i.e., the *Form* CMS-855B arrives alone, without the other forms), the contractor *shall develop for the other forms if they are not submitted* within 15 calendar days after receipt of the *Form* CMS-855B.

- Only the *Form* CMS-855I is submitted – Suppose an individual: (1) submits only the *Form* CMS-855I without *including* the *Form* CMS-855B and *Form* CMS-855R*, and* (2) indicates on the *Form* CMS-855I that he/she will be reassigning all *or part* of his/her benefits to the group practice. *The contractor shall develop for the other forms if they are not submitted within 15 calendar days after receipt of the Form CMS-855B.*

B. Additional Instructions

The contractor shall note the following:

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

- If a supplier is changing its tax identification number *(TIN),* the transaction shall be treated as a brand new enrollment as opposed to a change of information. Consequently, the supplier must complete a full *Form* CMS-855 application and a new enrollment record must be created in *the Provider Enrollment, Chain and Ownership System (PECOS).* (This does not apply to ambulatory surgical centers and portable x-ray suppliers. These entities can submit a TIN change as a change of information unless a *change of ownership* is involved. If the latter is the case, the applicable instructions in sections 15.7.8.2.1 through 15.7.8.2.1.2 of this chapter should be followed.)

- If the supplier is adding or changing a practice location and the new location is in another State within the contractor's jurisdiction, the contractor shall ensure that *the supplier meets all the requirements necessary to practice in that State (e.g., licensure).* A complete *Form* CMS-*855 for* the new State is not required, though the contractor shall create a new enrollment record in PECOS for the new State.

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

15.7.7 – Special *Processing Guidelines* for Form CMS-855A Applications

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

Unless otherwise stated, all references to the "RO" in sections 15.7.7.1 through 15.7.7.7 of this chapter refer to the RO's survey & certification staff.

15.7.7.1 - Changes of Ownership (CHOWs)

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

Changes of ownership (CHOWs) are officially defined *in* and governed by 42 CFR §489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). The RO *– not the contractor –* make*s* the determination as to whether a CHOW has occurred (unless this function has been delegated).

Unless specified otherwise, the term "CHOW" - as used in sections 15.7.7.1 through 15.7.7.1.6 of this chapter - includes CHOWs, acquisitions/mergers and consolidations. *Though section 2 of the Form CMS-855A separates the applicable transactions into CHOWs, acquisition/mergers and consolidations for ease of disclosing and reporting, they fall with the general CHOW category under 42 CFR §489.18 (e.g., an acquisition/merger is a type of CHOW under §489.18).*

15.7.7.1.1 - Definitions

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

For purposes of provider enrollment <u>only</u>, there are three main categories of CHOWs captured on the *Form* CMS-855A application:

- **"Standard" CHOW** – This occurs when *a provider's CMS Certification Number (CCN)* and provider *agreement 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. *As explained in section 15.7.7.1*, *e*ven 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 – <u>on the *Form* CMS-855A</u>.

- **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. *E*ntity B's CCN number and provider agreement will be eliminated (leaving only Entity A's CCN number and provider agreement).

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 *Form* CMS-855A.

Unlike the new owner in a CHOW or consolidation, the new owner in an acquisition/merger need not complete the entire *Form* CMS-855A. This is because the new owner is already enrolled in Medicare. *A*s such, the provider being acquired *should be* reported as a practice location in section 4 of the new owner's *Form* 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, when* A and B combine there are no surviving entities. Rather, a new entity is created – Entity C.

*U*nder 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*lication* 100-07, chapter 3, section 3210.1D (4) for more information.)

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.

15.7.7.1.2 - *Exa*mining Whether a CHOW *May Have* Occurred

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

As stressed in section 15.7.7.1, the RO – not the contractor – determines whether a CHOW has occurred (unless this function has been delegated). However, in processing the application, the contractor shall perform all necessary background research regarding whether: (1) a CHOW *may have* occurred, and/or (2) the new owner *is* accepting assignment of the Medicare assets and liabilities of the old owner. *Such research may include* reviewing the sales agreement or lease agreement, contacting the

provider(s) to request clarification of the sales agreement, etc. *Note that an* RO CHOW determination is usually not required prior to the contractor making its recommendation.

While a CHOW is usually accompanied by *a tax identification number (TIN)* change, this is not always the case. There may be *isolated instances where* the TIN *remains* the same. Conversely, there may be 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 *may or may not have* occurred, it is not the most important factor; rather, the change in the provider's ownership arrangement is. Hence, the *contractor should* review the sales/lease agreement closely, as this will help indicate whether a CHOW *may or may not have* occurred.

Note further:

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

There may be instances where the contractor enters a particular transaction into the Provider Enrollment, Chain and Ownership System (PECOS) as a CHOW, but it turns out 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 contractor cannot change the transaction type in PECOS, it can leave the record in a CHOW status; *however, it* should note in the provider's file that the transaction was not a CHOW.

15.7.7.1.3 - Processing CHOW Applications

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

A. Old Owners

The old owner's *Form* CMS-855A CHOW application does not require a recommendation for *approval. Any* recommendations will be based *on* the CHOW application received from the new owner.

If the old owner's *Form* CMS-855A is available at the time of review, the contractor shall examine the information thereon against the new owner's *Form* CMS-855A to ensure consistency (e.g., same names). If the old owner's *Form* CMS-855A has not been received, the contractor shall contact the old owner and request it. However, the contractor 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 *Form* CMS-855A. The contractor, 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 the* terms of the sales agreement indicate as such.

If a certification statement is not on file for the old owner, the contractor shall request that section 6 be completed for the individual who is signing the certification *statement.*

Note that an old owner's *Form* CMS-855A CHOW application is essentially the equivalent of a *Form* 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 *Form* CMS-855 voluntary termination along with its *Form* CMS-855A CHOW application.

B. New Owners

If a *Form* CMS-855A is not received from the new owner within 14 calendar days of receipt of the old owner's *Form* CMS-855A, the contractor shall contact the new owner. If the new owner fails to: (1) submit a *Form* CMS-855A and (2) indicate that it accepts assignment of the provider agreement, within 30 calendar days after the contractor contacted it, the *contractor* 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 contractor ascertains that the provider accepts assignment.

C. Order of Processing

To the maximum extent practicable, *Form* CMS-855A applications from the old and new owners in a CHOW should be processed as they come in. The contractor 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 contractor 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 contractor 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 *is processed*. (For acquisition/mergers and consolidations, the contractor may send the applications *to the RO* separately, since one number is going away.)

D. Sales and Lease Agreements

The contractor shall abide by the following:

- **Verification of Terms** - The contractor shall determine *whether: (1) the* information contained in the sales/lease agreement is consistent with that reported on the new owner's *Form* CMS-855A (e.g., same names), and *(2) 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 "*Y*es" and the sales/lease agreement either confirms that the new owner will assume the agreement or is relatively silent on the matter, the contractor can proceed as normal. Conversely, if the agreement indicates that the assets and liabilities will not be accepted, the contractor should *deny the application*.

- **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 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 contractor 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 *Form* 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 contractor's receipt of the new owner's application, the contractor shall reject the application. Though the contractor must wait until the 90th day to reject the application, the contractor may do so regardless of how many times it contacted the new owner or what type*s* of responses (short of the actual receipt of the agreement) were obtained.

*Unless specified otherwise in this chapter, b*oth the old and new owners must submit separate *Form* 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., *home health agency (HHA)* subunits) must report its CHOW on a separate *Form* CMS-855A. *It* cannot report the CHOW via the main provider's *Form* CMS-855A. If the subunit has a separate *CMS Certification Number (CCN)* but not a separate provider agreement (e.g., hospital psychiatric unit, HHA branch), the CHOW can be disclosed on the main provider's *Form* 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 *in* the facility's provider subtype. *This 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

(COI), 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 *in* 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 *skilled nursing facility*) 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 *Form* CMS-855A as an initial enrollment, not as a CHOW.

F. Early Submission of CHOW Application

The contractor may accept Form CMS-855A CHOW applications *submitted up to 90 calendar days* prior to the anticipated date of *the ownership* change. Any application received more than 90 days *before* the projected sale date can be returned under section 15.8.1 of this chapter.

G. Unreported CHOW

If the contractor *learns via any means* that an enrolled provider has: (1) been purchased by another entity, or (2) purchased another Medicare enrolled provider, the contractor shall immediately request *Form* CMS-855A applications from both the old and new owners. If the new owner fails to submit *a Form* CMS-855A within the latter of: (1) the date of acquisition, or (2) *30* days after the request, the contractor shall stop payments to the provider. Payments may be resumed upon receipt of the completed *Form* 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 15.7.7.2 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 *CMS Publication* 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.

I. Transitioning to Provider-Based Status

Consistent with existing CMS policy, a provider undergoing a CHOW pursuant to

42 CFR §489.18 may be assigned to a new contractor jurisdiction only if the provider is transitioning from freestanding to provider-based status. In such cases, the contractor for the new jurisdiction (the "new contractor") shall process both the buyer's and seller's Form CMS-855A applications. Should the "old" (or current) contractor receive the buyer's or seller's Form CMS-855A application, it shall: (a) forward the application to the new contractor within 5 business days of receipt, and (b) notify the new contractor within that same timeframe that the application was sent.

15.7.7.1.4 - Intervening CHOWs

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

15.7.7.1.5 – *Electronic Funds Transfer (EFT)* Payments and CHOWs

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

In a CHOW, the contractor shall continue to pay the old owner until it receives the tie-in*/approval* notice from the RO. Hence, any application from the old or new owner to change the EFT account or special payment address to that of the new owner shall be *rejected.* It is ultimately the responsibility of the old and new owners to work out any payment arrangements between themselves while *the contractor and RO are processing the CHOW. It is advisable that the contractor notify the new owner of this while the application is being processed.*

15.7.7.1.6 – Pre-Approval *Changes of Information*

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

A. Seller

If – prior to the issuance of the tie-in notice – the contractor receives from the seller a *Form* CMS-855 request to change any of the provider's enrollment data, the contractor *shall reject the change request* if the information in question involves changing the provider's:

1. Electronic funds transfer or special payment address information to that of the buyer (as described in section 15.7.7.1.5 of this chapter*)*

2. Practice location or base of operations to that of the buyer

3. Ownership or managing control to that of the buyer

4. *Legal business name, tax identification number, or "doing business as"* name to that of the buyer.

All other *"pre-tie-in notice" Form* CMS-855 change requests *from the seller* can be processed normally.

B. Buyer

If – prior to the issuance of the tie-in notice – the contractor receives from the buyer a *Form* CMS-855 request to change any of the provider's existing enrollment information, the contractor shall *reject the change request.* Until the tie-in *notice* is issued, the seller remains the owner of record. *H*ence, the buyer has no standing to submit *Form* CMS-855 changes on behalf of the provider.

15.7.7.2 - Tie-In/Tie-Out Notices and *Referrals to the State/RO*

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

A. *Issuance of* Tie-In/Tie-*Out Notices*

A tie-in or tie-out notice (CMS-2007) *is* generally issued in the following circumstances:

1. Initial enrollments

2. CHOWs

3. Voluntary terminations

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

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

(Depending on the specific RO, certain changes of information may also result in the issuance of a CMS-2007.)

B. *Form* CMS-855 Changes of Information

1. **Referrals to State/RO**

The following is a list of *Form* CMS-855A changes of information that require a

recommendation and referral to the State/RO:

- Addition of *outpatient physician therapy/outpatient speech pathology* extension site
- Addition of hospice satellite
- Addition of *home health agency* branch
- Change in type of *Prospective Payment System (PPS)*-exempt unit
- Conversion of a hospital from one type to another (e.g., acute care to psychiatric)
- Change in practice location or subunit address in cases where a survey of the new site is required
- Stock transfer

In these situations, the *Provider Enrollment, Chain and Ownership System (PECOS)* record should not be switched to "approved" until the contractor receives notice from the RO that the latter *has authorized* the change/addition.

2. Post-Approval RO Contact Required

*Form CMS-855A c*hanges that do not mandate a recommendation to the State/RO but do require post-approval correspondence with the RO include:

- Deletions/voluntary terminations of practice locations or *hospital* subunits
- *Legal business name, tax identification number, or "doing business as name"* changes that do not involve a CHOW
- Address changes that do not require a survey of the new location
- Addition of hospital practice location

For these transactions, the contractor shall: *(1)* notify the provider via letter, *fax,* e-mail, or telephone that the change has been made, and *(2)* switch the PECOS record to "approved." The contractor shall also notify the State and RO of the changed information (via any mechanism it chooses, including copying the State/RO on the notification letter or e-mail) no later than 10 calendar days after it has completed processing the transaction. Such notice to the State/RO *shall* specify the type of information that is changing.

3. All Other Changes of Information

For all *Form* CMS-855A change requests not identified in (B)*(1)* or (B)*(2)* above, the contractor shall notify the provider via letter, *fax,* e-mail, or telephone that the change has been made and shall switch the PECOS record to "approved." The State and RO need not be notified of the change.

4. Revalidations, Reactivations and Complete *Form* CMS-855 Applications

In situations where the provider submits a: (1) *Form* CMS-855A reactivation, (2) *Form* CMS-855A revalidation, or (3) full *Form* CMS-855A as part of a change of information (i.e., the provider *has no* enrollment record in PECOS), the contractor shall make a recommendation to the State/RO and switch the PECOS record to "approval recommended" only if the application contains new/changed data falling *within one of the categories in* (B)(1) above. For instance, if a revalidation application reveals a new hospital psychiatric unit that *was never* reported to CMS via the *Form* CMS-855A, the contractor shall make a recommendation to the State/RO and await the RO's approval before switching the record to "approved." In this situation, the contractor should forward *the application* to the State with a note explaining that the only matter the State/RO needs to consider is the new hospital unit.

If the application contains new/changed data falling within *one of the categories in (B)(2) above*, the contractor can switch the PECOS record to "approved." It shall also notify the State and RO of the changed information (via any mechanism it chooses, including copying the State/RO on the notification letter or e-mail) no later than 10 calendar days after it has completed processing the transaction.

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

If the contractor receives a tie-in notice *or approval letter from the RO* for a transaction/change regarding information that is not collected on the *Form* CMS-855*A,* the *contractor need* not *ask* the provider to submit a *Form* CMS-855*A* change of information.

D. Involuntary Termination Prompted by State/RO

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

E. *Other Procedures Related to Tie-In Notices, Tie-Out Notices and Approval Letters*

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

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

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

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

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

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

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

15.7.7.2.1 – Processing Tie-In Notices

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

Within 21 calendar days after its receipt of the tie-in or approval notice, the contractor shall complete its processing of said notice. For purposes of this requirement, the term "processing" includes:

1. Entering all relevant data into PECOS;

2. Changing the provider's PECOS record to the appropriate status (e.g., "approved"); and

3. Notifying the provider (via any mechanism the contractor chooses) that it may begin billing.

15.7.7.3 - Out-of-State Practice Locations for Certified Providers

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

*T*he question of whether a *Form* CMS-855A *must* be completed for each State in which the provider performs services depends on three things: (1) State law, (2) the contractor jurisdictions involved, and (3) how the RO(s) wants to handle the *particular* situation. Consider the following scenarios:

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

1. Assume that X & Y are in the same contractor jurisdiction. If State Y requires an entity performing services in Y to be surveyed or the RO says that the provider must sign a separate provider agreement and obtain a separate *CMS Certification Number (CCN)* for its State Y services, the provider must submit an initial *Form* CMS-855A application for State Y in order to be a provider in that *S*tate. If a separate enrollment is not required, the provider would simply submit a *Form* CMS-855A *change request* that adds the out-of-state location.

2. Assume that X & Y are not in the same contractor jurisdiction. *T*he provider must submit an initial *Form* CMS-855A application to the State Y contractor - regardless of whether a separate survey, *provider* agreement, or *CCN is* needed.

In short, if a provider in one State wishes to perform services in another State and the latter State is serviced by a different contractor, a new enrollment is required with that contractor. If both States are in the same contractor jurisdiction, a *Form* CMS-855*A* initial application *or change request* is necessary; whether an initial application or a change request is required will depend on State law and what the RO says. In either case, the contractor must create *separate* enrollment record*s* in *the Provider Enrollment, Chain and Ownership System* for each Stat*e.*

15.7.7.4 - State Surveys and the Form CMS-855A

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

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

If these criteria are met, the contractor shall send a letter to the provider requesting an updated *Form* CMS-855A. The application must contain, at a minimum, any

information that is new or has changed since the recommendation for approval was made, as well as a newly-signed certification statement. If no information has changed, the provider may instead submit: (1) a letter on its business letterhead stating as such, and (2) a newly-signed *Form* CMS-855A certification statement.

NOTE: If the applicant is a *home health agency (HHA)*, it must resubmit capitalization data *per* section 12 of the *Form* CMS-855A *regardless* of whether any of the provider's other *Form* CMS-855A information has changed. To illustrate, if no *Form* CMS-855A data has changed, the HHA must submit the letter, capitalization data and the signed certification statement.

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

15.7.7.5 - Sole Proprietorships

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

- The *legal business name* in section 2B1 should list the person's (the sole proprietor's) legal name.

- The *tax identification number* in section 2B1 should list the person's *social security number*.

- Section 3 of the *Form* CMS-855A must be completed with information about the individual's *final adverse action* history.

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

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

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

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

15.7.7.6 - Additional Form CMS-855A Processing Instructions

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

A. Non-Enrollment Functions

In some instances, the contractor cannot forward an application to the State until it performs certain non-enrollment functions pertaining to th*e* application (e.g., the reimbursement unit needs to examine patient listing data). The contractor may flip the *provider's* status *in the Provider Enrollment, Chain and Ownership System (PECOS)* to "approval recommended" prior to the conclusion of *the* non-enrollment *activity if: (1) all required enrollment actions have been completed, and (2) the non-enrollment action is the only remaining activity to be performed.*

B. Multiple Providers under a Single Tax Identification Number (TIN)

Multiple providers may have the same TIN. However, each provider must submit a separate *Form* CMS-855A *application and* the contractor must create a separate enrollment record for each.

C. Future Effective Dates

If the contractor cannot enter *an* effective *date* into PECOS because the provider, practice location, etc., is not yet established, the contractor may use the authorized official's date of signature as the temporary effective date. Once the actual effective date is established (e.g., the tie-in notice is received), the contractor *shall change the effective date in PECOS.*

15.7.7.7 – *Contractor* Jurisdictional Issues

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

A. Audit and Claims *Contractors*

1. Background

For purposes of enrollment *via the Form CMS-855A*, there are generally two categories of *contractors*: audit *contractors* and claims *contractors*. The audit contractor enrolls the provider, conducts audits, etc. The claims contractor pays the provider's claims. In most cases, the provider's audit contractor and claims contractor will be the same. On occasion, *though*, they will *differ*; this *can happen, for instance,* with provider-based entities, whereby the provider's enrollment application will be processed by the parent provider's contractor (audit contractor) and its claims will be paid by a different contractor (claims contractor).

Should the audit and claims *contractors* differ, the audit contractor shall process all changes of information, including all *Form CMS-588* changes. The audit contractor shall notify the applicant during the initial enrollment process that all future changes of

information must be sent to the audit contractor, not the claims *contractor. If* the provider inadvertently sends *a change request to* the claims contractor, the latter shall return the application per section 15.8.1 of this chapter.

2. Process

Once the audit contractor finishes processing the *Form* CMS-855A initial enrollment application, *change request*, voluntary termination, *etc., it shall send an e-mail to the claims contractor identifying the specific Form CMS-855A transaction involved and confirming that the information has been updated in the Provider Enrollment, Chain and Ownership System (PECOS).* Pertinent identifying information, such as the *provider name, CMS Certification Number and National Provider Identifier,* should be included on the e-mail notification. Any supporting documentation that may contain *p*ersonal *h*ealth *i*nformation or *p*ersonally *i*dentifiable *i*nformation, such as *e*lectronic *f*unds *t*ransfer data, may still be faxed to the claims contractor.

Upon receipt of the e-mail notification, the claims contractor shall *access PECOS, review the enrollment record, and, as needed,* update its records accordingly.

The audit contractor *shall keep* the original copies *of the* Form CMS-855*A* paperwork and supporting documentation.

3. Tie-In/Tie-Out Notices and Approval Notices

If the provider's audit contractor and claims contractor are different, the audit contractor shall e-mail *or fax* a copy of all *tie-in/tie-out notices and approval letters* it receives to the claims *contractor. Thi*s is to ensure that the claims contractor is fully aware of the RO's action, as some ROs may only send copies of *tie-in/tie-out notices and approval letters* to the audit contractor. If the audit contractor chooses, it can simply contact the claims contractor by phone or e-mail and ask if the latter received the tie-in notice.

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

B. Provider Nomination

With respect *to provider* nomination and changes of *contractors*, the contractor shall *follow* the instructions in Pub. 100-04, chapter 1, sections 20 through 20.5.1.

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

15.7.8 – Special *Processing Guidelines for* Independent CLIA Labs, Ambulatory Surgical *Centers and* Portable X-ray Suppliers

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

Unless otherwise stated, all references to the "RO" in sections 15.7.8.2 through 15.7.8.5 of this chapter refer to the RO's survey & certification staff.

15.7.8.1 - CLIA Labs

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

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

If the lab is not "integrated," the lab must enroll as an independent CLIA lab via the *Form* CMS-855B application. The contractor shall advise the lab that it must contact the applicable CLIA office; the lab cannot be enrolled until it receives a CLIA number. The contractor shall also ensure that the lab *is CLIA-certified and, as applicable, State-licensed.*

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

For more information on the enrollment of CLIA labs, refer to section 15.4.2.2 of this chapter.

15.7.8.2 - *Ambulatory Surgical Centers (ASCs)* and Portable X-ray Suppliers (PXRS) - Initial Enrollment

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

Unlike other supplier types that enroll *via the Form CMS-855B*, ASCs and PXRSs must receive a State survey *and RO* approval before they *can enroll* in Medicare. *Accordingly,* once it finishes reviewing the supplier's application, the contractor *may* only make a recommendation for *approval to* the State. The contractor shall not enroll the *supplier until* it *receives a tie-in notice or approval letter from the RO and – in the case of PXRSs - a follow-up site visit is performed per section 15.4.2.5 of this chapter.*

When enrolling the ASC or PXRS, the contractor shall use the effective date that is indicated on the tie-in notice/approval letter. This is the date from which the supplier can bill for services.

15.7.8.2.1 - ASC/PXRS Changes of Ownership (CHOWs)

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

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

As discussed in more detail in sections 15.4.2.1 and 15.4.2.5 of this chapter, an ASC must sign a supplier agreement with Medicare prior to enrollment; PXRSs have no such requirement. The ROs may therefore handle CHOWs involving ASCs and PXRSs differently. To alleviate confusion and to ensure consistency, however, contractors will – unless stated otherwise – handle the CMS-855B processing of ASC CHOWs in the same manner as PXRS CHOWs.

15.7.8.2.1.1 - Determining Whether a CHOW Has Occurred
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. Review of Sales Agreement

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

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

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

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

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

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

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

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

- CMS-855B CHOW applications may be accepted by the contractor up to 90 calendar days prior to the anticipated date of the proposed ownership change. Any application received more than 3 months in advance of the projected sale date shall be returned under section 15.8.1 of this chapter.

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

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

B. Processing Steps

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

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

2. If the contractor believes that a CHOW has taken place and that the new owner is accepting the old owner's assets and liabilities, it shall process the application normally

and make a recommendation for approval/denial to the State (with a cc: to the RO). If the valid CHOW/acceptance of assignment was accompanied by a change in TIN, the transaction must be treated as a CHOW notwithstanding the general rule that a TIN change constitutes an initial enrollment. In other words, the reporting rules regarding CHOWs/assignments in this particular situation take precedence over the "change of TIN" principle.

3. If the contractor believes that a CHOW has not occurred and that the transaction merely represents an ownership change (e.g., minor stock transfer) that does not qualify as a 42 CFR §489.18-type CHOW, the transaction must be reported as a change of information. The only exception to this is if the change of information was accompanied by a change of TIN, in which case the supplier must enroll as a new entity.

Note that it is not uncommon for a supplier to undergo a financial or administrative change that it considers to be a CHOW but in actuality does not meet the regulatory definition identified in §489.18.

In scenario 2 above, the contractor shall not forward a copy of the CHOW application to the State agency until it has received and reviewed the final sales agreement. (In some cases, the supplier may submit an interim sales agreement with its application; this is acceptable, so long as it submits the final agreement in accordance with these instructions.) If the final sales agreement is not submitted within 90 days after the contractor's receipt of the new owner's application, the contractor shall reject the application. Though the contractor must wait until the 90th day to reject the application, the contractor may do so regardless of how many times it contacted the new owner or what type of responses (short of the actual receipt of the sales agreement) were obtained.

C. CHOWs and Address Changes

A new owner may propose to relocate the supplier concurrent with a CHOW. If the relocation is to a site in a different geographic area serving different clients than previously served and employing different personnel to serve those clients, the contractor shall notify the RO immediately. Unless the RO dictates otherwise, the supplier shall - per Pub. 100-7, chapter 3, section 3210.1(B)(5) - treat the transaction as an initial enrollment (and the supplier as a new applicant), rather than as an address change of the existing supplier.

15.7.8.2.1.2 - EFT Payments and CHOWs

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

In a CHOW, the contractor shall continue to pay the old owner until it receives the tie-in/approval notice from the RO. Hence, any application from the old or new owner to change the EFT account or special payment address to that of the new owner shall be returned in accordance with section 15.8.1 of this chapter. It is ultimately the

responsibility of the old and new owners to work out any payment arrangements between themselves while the CHOW is being processed by the contractor and the RO.

If – pursuant to the CHOW – the seller submits a CMS-855B voluntary termination, the contractor shall contact and explain to the seller that the ASC/PXRS will not receive any payments until the RO approves the CHOW. (This is because, as explained above, payments must be sent to the seller until the tie-in/approval letter is sent). If the seller insists that its application be processed, the contractor shall process said termination; however, it shall first notify the facility/new owner and explain that payments will cease once the seller's termination is effective. In fact, it is highly recommended that, upon receipt of a CMS-855B CHOW application, the contractor contact the supplier to notify it of the payment rule identified in the previous paragraph.

15.7.8.3 - *Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS)* Changes of Ownership (CHOWs)

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

Though ASCs and PXRSs are *not mentioned* in 42 CFR § 489.18, CMS generally applies the change of ownership (CHOW) provisions of § 489.18 to *them.* CHOWs involving ASCs and PXRSs are *thus* handled in accordance with the principles *in §*489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). Note that the *RO – not the contractor – determines whether a* CHOW has occurred (unless this function has been delegated).

As *discussed in* sections 15.4.2.1 and 15.4.2.5 of this chapter, an ASC must sign a supplier agreement with Medicare prior to *enrollment. PXRSs* have no such *requirement. However, the contractor shall* – unless *CMS instructs* otherwise – *process Form CMS-855B ASC CHOW applications* in the same manner as PXRS CHOW *applications.*

15.7.8.3.1 – *Exam*ining Whether a *Change of Ownership (CHOW) May Have* Occurred

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

A. Review of Sales Agreement

As stated in section 15.7.8.3, the RO – not the contractor – determines whether a CHOW has occurred.

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

1. The ownership change *may qualify* as a CHOW under the principles *of §489.18* and *Publication* 100-07, chapter 3, section 3210.1D.

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

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

If the sales agreement is unclear as to issues 1 and 2 above, the contractor shall request clarifying information from the supplier. (Note that some sales agreements may *not* specifically refer to Medicare supplier agreements, assets, and/or liabilities; *hence, the agreement should be examined* in its totality.) The information shall be in the form of additional legal documentation or a letter. If the *clarification requires* an update to the supplier's *Form* CMS-855B application, the contractor shall *request this update*. In addition, if the contractor discovers discrepancies between the data in the sales agreement and that on the *Form* CMS-855B (issue 3 above); the contractor shall *request* clarifying information and, if necessary, obtain an updated *Form* CMS-855B.

In reviewing the application and the sales agreement, the contractor shall *note* the following:

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

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

- *The contractor may accept Form* CMS-855B CHOW applications *submitted up to 90 calendar days* prior to the anticipated date of *the ownership* change. Any application received more than 3 months *before* the projected sale date shall be returned under section 15.8.1 of this chapter.

- *A*n ASC or PXRS may submit a *Form* CMS-855B *change request* to report a large-scale stock transfer or other significant ownership change that the supplier does not believe qualifies as a CHOW. If the contractor *suspects* that the *transaction may* indeed be a CHOW, it shall request clarifying information (e.g., copy of the stock transfer agreement).

- *An RO CHOW determination is usually not required prior to the contractor making its recommendation.*

B. *Disposition*

As already indicated, the contractor shall perform all necessary background research to determine whether: (1) a CHOW may have occurred, and (2) the new owner is accepting assignment of the Medicare assets and liabilities of the old owner. Once this is completed, the contractor shall abide by the following:

1. Scenario 1

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

2. Scenario 2

If the contractor believes that a CHOW has *likely occurred and the* new owner is accepting the old owner's assets and liabilities, it shall process the application normally and*, if warranted,* make a recommendation for *approval to* the State (with a cc: to the RO). If the *apparent CHOW was* accompanied by a change in TIN, the transaction must be treated as a CHOW notwithstanding the general rule *for Form CMS-855B submissions* that a TIN change constitutes an initial *enrollment.*

Under scenario 2, the contractor shall not forward a copy of the CHOW application to the State agency until it has received and reviewed the <u>final</u> sales agreement. (In some cases, the supplier may submit an interim sales agreement with its application. *Though this is acceptable, the supplier must still submit a final agreement.)* If the final sales agreement is not submitted within 90 days after the contractor's receipt of *the CHOW* application, the contractor shall reject the application. Though the contractor must wait until the 90th day to reject the application, the contractor may do so regardless of how many times it contacted the new owner or what type*s* of responses (short of the actual receipt of the sales agreement) were obtained.

3. Scenario 3

If the contractor believes that a CHOW has *likely* not occurred and that the transaction *is merely* an ownership change (e.g., minor stock transfer) that does not qualify as *a § 489.18*-type CHOW, the transaction must be reported as a change of information. The only *exception is if* the change of information was accompanied by a change of TIN, in which case the supplier must enroll as a new entity.

Note that it is not uncommon for a supplier to undergo a financial or administrative change that it considers to be a CHOW but does not *actually qualify as such.*

C. CHOWs and Address Changes

A new owner may propose to relocate the supplier concurrent with a CHOW. If the relocation is *to a* different geographic area serving different clients than previously served and employing different personnel to serve those clients, the contractor shall notify the RO immediately. Unless the RO dictates otherwise, the supplier shall - per Pub*lication* 100-7, chapter 3, section 3210.1(B)(5) - treat the transaction as an initial enrollment (and the supplier as a new applicant), rather than as an address change of the existing supplier.

15.7.8.3.2 – Electronic Funds Transfer (EFT) Payments and CHOWs

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

In a CHOW, the contractor shall continue to pay the old owner until it receives the tie-in/approval notice from the RO. Thus, any application from the old or new owner to change the EFT account or special payment address to that of the new owner shall be rejected. It is ultimately the responsibility of the old and new owners to work out any payment arrangements between themselves while the contractor and RO are processing the CHOW. It is advisable that the contractor notify the supplier of this while the application is being processed.

If – pursuant to the CHOW – the seller submits a Form CMS-855B voluntary termination application, the contractor shall contact and explain to the seller that the ambulatory surgical center/portable x-ray supplier will not receive any payments until the RO approves the CHOW. (This is because payments must be sent to the seller until the tie-in/approval letter is sent). If the seller insists that its application be processed, the contractor shall process it; however, it shall first notify the facility/new owner and explain that payments will cease once the seller's termination is effective.

15.7.8.4 - *Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO*

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

(For purposes of this section 15.7.8.*4*, the terms "tie-in notices" and approval letters will be collectively referred to as tie-in notices. "Tie-out notices" are notices from the RO to the contractor that, in effect, state that the *ASC's/PXRS's participation in Medicare* should be terminated.)

A. Issuance of Tie-*I*n/Tie-*O*ut *Notices*

A tie-in or tie-out notice is generally issued in the following circumstances:

1. Initial enrollment*s*
2. CHOW*s*

3. Voluntary terminations

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

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

(Depending on the specific RO, certain changes of information may also result in the issuance of a CMS-2007.)

B. *Form* CMS-855B Changes of Information

1. **Referrals to State/RO**

The following is a list of transactions that require a recommendation and referral to the State/RO:

- Addition of practice location
- Stock transfer
- Change in practice location *or address* in cases where a survey of the new site is required

In these situations, the *Provider Enrollment, Chain and Ownership System (PECOS)* record should not be switched to "approved" until the contractor receives notice from the RO that the latter *has authorized* the change/addition.

2. **Post-Approval RO Contact Required**

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

- Deletions/voluntary terminations of practice locations or subunits
- *Legal business name, tax identification number or "doing business as"* name changes that do not involve a CHOW
- Address changes that do not require a survey of the new location

For these transactions, the contractor shall: *(1)* notify the supplier via letter, *fax,* e-mail, or telephone that the change has been made, and *(2)* switch the PECOS record to "approved." The contractor shall also notify the State and RO of the changed information (via any mechanism it chooses, including copying the State/RO on the notification letter or e-mail) no later than 10 calendar days after it has completed

processing the transaction. *The* notice to the State/RO *shall* specify the type of information that is changing.

3. All Other Changes of Information

For all *Form* CMS-855B change requests not identified in *(B)*(1) or *(B)*(2) above, the contractor shall notify the supplier via letter, *fax,* e-mail, or telephone that the change has been made and shall switch the PECOS record to "approved." The State and RO need not be notified of the change.

4. Revalidations, Reactivations and Complete CMS-855 Applications

In situations where the provider submits a: (1) *Form* CMS-855B reactivation, (2) *Form* CMS-855B revalidation, or (3) full *Form* CMS-855B as part of a change of information (i.e., the supplier *has no* enrollment record in PECOS), the contractor shall make a recommendation to the State/RO and switch the record to "approval recommended" only if the application contains new/changed data falling *within one of the categories in (B)(1)* above. For instance, if a revalidation application reveals a new practice location that *was never reported* to CMS via the *Form* CMS-855B, the contractor shall make a recommendation to the State/RO and await the RO's approval before switching the record to "approved." In this situation, the contractor should forward *the application* to the State with a note explaining that the only matter the State/RO needs to consider is the new location.

If the application contains changed data falling *within one of the categories in (B)(2)* above, the contractor can switch the PECOS record to "approved." The contractor shall also notify the State and RO of the changed information (via any mechanism it chooses, including copying the State/RO on the notification letter or e-mail) no later than 10 days after it has completed processing the transaction.

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

If the contractor receives a tie-in notice *or approval letter* for a *transaction that concerns information not* collected on the *Form* CMS-855B application, *the contractor need not ask* the supplier to submit a *Form* CMS-855B change of information.

D. Involuntary Termination Prompted by State/RO

If the contractor receives a tie-out notice from the RO that involuntarily terminates the supplier's *Medicare* participation *because* the supplier no longer meets the conditions of coverage, the contractor need not send a letter to the supplier notifying *it* that *its Medicare participation/enrollment* has been terminated. The RO will issue such a letter and afford appeal rights.

E. *Other Procedures Related to Tie-In/Tie-Out Notices and Approval Letters*

1. Receipt of Tie-In When *Form* CMS-855B Not Completed

If the contractor receives a tie-in notice *or approval letter* from the RO but the supplier never completed the necessary *Form CMS-855B,* the contractor shall have the supplier complete and submit said *form.* This applies to initial applications, CHOWs, practice location additions, etc., but does not apply to the cases described in subsection C above.

2. Delegation to State Agency

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

3. Review for Consistency

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

4. Creation of New *Logging and Tracking (L & T)* Record Unnecessary

The contractor is not required to create a new L & T record in PECOS when the tie-in notice *or approval letter arrives*, as the existing record should not be in a final status and can therefore be modified. Simply changing the L & T status is sufficient.

5. *Supplier* Inquiries

Once the contractor *makes its* recommendation for approval to the State/RO, any inquiry the contractor receives from the *supplier* regarding the status of its request for Medicare participation shall be referred to the State or RO.

6. Timeframes

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

15.7.8.5 – *Out-of-State Practice Locations for Certified Suppliers*

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

The question of whether a *Form* CMS-855B *must* be completed for each State in which

the supplier performs services depends on three things: (1) State law, (2) the contractor jurisdictions involved, and (3) how the RO(s) wants to handle the *particular* situation. Consider the following scenario:

A supplier is enrolled in State X and now wants to perform services in State Y:

1. Assume that X & Y are in the same contractor jurisdiction. If State Y requires an entity performing services in Y to be surveyed or if the RO says that the supplier must sign a separate supplier agreement *and be separately certified*, the supplier must submit an initial *Form* CMS-855B application for State Y in order to be a *supplier* in that *S*tate. If a separate enrollment is not required, the supplier can simply submit a *Form* CMS-855B change *request that* adds the out-of-state location.

2. Assume that States X & Y are not in the same contractor jurisdiction. *T*he supplier must submit an initial *Form* CMS-855B application to the State Y contractor - irrespective of whether a separate survey*, agreement or certification* is needed.

In short, if *a supplier* wants to perform services in another State that is serviced by another contractor, a new enrollment with that contractor is required. If both States are in the same contractor jurisdiction, a *Form* CMS-855B initial application or a *Form* CMS-855B change *request is* necessary; whether an initial enrollment or a change request is required will depend on State law and what the RO says. In either case, the contractor must create *separate* enrollment record*s* in *the Provider Enrollment, Chain and Ownership System for each State.*

15.7.8.6 - State Surveys and the Form CMS-855B

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

A. Delay in State Survey

In general, information on the Form CMS-855B is still considered valid notwithstanding a delay in the State survey. However, the supplier must submit an updated Form CMS-855B application to the contractor if:

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

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

and (2) a newly-signed Form CMS-855B certification statement.

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

B. Future Effective Dates

If the contractor cannot enter an effective date into PECOS because the supplier, its practice location, etc., is not yet established, the contractor may use the authorized official's date of signature as the temporary effective date. Once the provider and the effective date is established (e.g., the tie-in notice is received), the contractor shall change the effective date in PECOS.

15.8 – Application Returns, Rejections and Denials

(Rev. 415, Issued: 04-13-12, Effective: 05-14-12, Implementation: 05-14-12)

15.8.1 – Returns

(Rev. 415, Issued: 04-13-12, Effective: 05-14-12, Implementation: 05-14-12)

A. Reasons for Return

Unless stated otherwise in this chapter or in another CMS directive, the contractor (including the National Supplier Clearinghouse) may immediately return the enrollment application to the provider or supplier only in the instances described below. This policy – again, unless stated otherwise in this chapter or in another CMS directive - applies to all applications identified in this chapter (e.g., initial applications, change requests, Form CMS-855O applications, Form CMS-588 submissions, change of ownership (CHOW) applications, revalidations, reactivations):

- The applicant sent its paper Form CMS-855 to the wrong contractor (e.g., the application was sent to Contractor X instead of Contractor Y).

- The contractor received the application more than 60 days prior to the effective date listed on the application. (This does not apply to: (1) providers and suppliers submitting a Form CMS-855A application, (2) ambulatory surgical centers (ASCs), or (3) portable x-ray suppliers (PXRSs).

- The contractor received an initial application from (1) a provider or supplier submitting a Form CMS-855A application, (2) an ASC, or (3) a PXRS, more than 180 days prior to the effective date listed on the application.

- An old owner or new owner in a CHOW submitted its application more than 90 days prior to the anticipated date of the sale. (This only applies to Form CMS-855A applications.)

- The contractor can confirm that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.

- The provider or supplier submitted an initial application prior to the expiration of a re-enrollment bar.

- The application is not needed for the transaction in question. Two common examples include:

    - An enrolled physician wants to change his/her reassignment of benefits from one group to another group and submits a Form CMS-855I and a Form CMS-855R. As only the Form CMS-855R is needed, the Form CMS-855I shall be returned.

    - A physician who is already enrolled in Medicare submits a Form CMS-855O application, thinking that he must do so in order to refer services for Medicare beneficiaries. The Form CMS-855O can be returned, as the physician is already enrolled via the Form CMS-855I.

The contractor need not request additional information in any of these scenarios. For instance, if the application is not necessary for the particular transaction, the contractor can return the application immediately. If an application fee has already been submitted, the contractor shall follow existing instructions regarding the return of the fee.

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

B. Procedures for Returning the Application

If the contractor returns the application:

- It shall notify the provider via letter (sent by mail 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 logging & tracking (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. (This does not apply to e-signature situations.)

It shall return all paper documents submitted with the paper or Internet-based PECOS

application (e.g., Form CMS-588, Form CMS-460). The contractor shall, however, make and keep a photocopy or scanned version of the paper application (if applicable) and any paper documents (regardless of whether the application was submitted via paper or electronically) prior to returning them.

15.8.2 –Rejections

(Rev. 415, Issued: 04-13-12, Effective: 05-14-12, Implementation: 05-14-12)

A. Background

In accordance with 42 CFR § 424.525(a)(1) and (2), the contractor (including the National Supplier Clearinghouse) may reject the provider's application if the provider fails to furnish complete information on the enrollment application - including all necessary documentation - within 30 calendar days from the date the contractor requested the missing information or documentation. For purposes of this policy, this includes situations in which the provider submitted an application that falls into one of the following categories and, upon the contractor's request to submit a new or corrected complete application, the provider failed to do so within 30 days of the request:

(1) The Form CMS-855 or Internet-based Provider Enrollment, Chain and Ownership System (PECOS) certification statement: (1) is unsigned; (2) is undated; (3) contains a copied or stamped signature; or (4) for paper Form CMS-855I and Form CMS-855O submissions, someone other than the physician or non-physician practitioner signed the form.

(2) The submitted paper application is an outdated version of the Form CMS-855.

(3) The applicant failed to submit all of the forms needed to process a reassignment package within 15 calendar days of receipt.

(4) The Form CMS-855 was completed in pencil.

(5) The wrong application was submitted (e.g., a Form CMS-855B was submitted for Part A enrollment).

(6) If a Web-generated application is submitted, it does not appear to have been downloaded from CMS' Web site.

(7) The provider sent in its application or Internet-based PECOS certification statement via fax or e-mail when it was not otherwise permitted to do so.

(8) The provider failed to submit an application fee (if applicable to the situation).

The applications described in (1) through (8) above shall be developed, rather than returned. For instance, if the provider submits an application completed in pencil, the

contractor shall request the provider to submit a new application, either in ink or via Internet-based PECOS.

B. Timeframe

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 or other request for information 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. However, 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.

C. 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, the contractor is not required to contact the provider again to request the remaining data. It can simply reject the application at the expiration of the aforementioned 30-day period. Consider the following examples:

- The provider submits a Form CMS-855A in which section 3 is blank. On March 1, the contractor requests that section 3 be fully completed. On March 14, the provider submits a completed section 3A. However, section 3B remains blank. The contractor need not make a second request for section 3B to be completed. It can reject the application on March 31, or 30 days after its initial request was made.

- The provider submits an outdated version of the Form CMS-855B. On July 1, the contractor requests that the provider resubmit its application using the current version of the Form CMS-855B. On July 15, the provider submits the correct version, but section 4B is blank. The contractor is not required to make a follow-up request regarding section 4B. It can reject the application on July 31.

D. Creation of Logging & Tracking (L & T) Record

If the contractor cannot create an L & T record in PECOS because of missing data and the application is subsequently rejected, the contractor shall document the provider file accordingly. If the contractor is able to create an L & T record for a rejected application, it shall flip the status to "rejected" in PECOS.

E. Additional Rejection Policies

1. **Resubmission after Rejection** – If the provider's application is rejected, the provider must complete and submit a new Form CMS-855 (either via paper or Internet-based PECOS) and all necessary documentation.

2. **Applicability –** Unless stated otherwise in this chapter or in another CMS directive, this section 15.8.2 applies to all applications identified in this chapter (e.g., initial applications, change requests, Form CMS-855O applications, Form CMS-588 submissions, change of ownership (CHOW) applications, revalidations, reactivations).

3. **Physicians and Non-Physician Practitioners** – Prior CMS guidance instructed contractors to deny, rather than reject, incomplete applications submitted by physicians and certain non-physician practitioners. This policy no longer applies. Such applications shall be rejected if the physician or practitioner fails to provide the requested information within the designated timeframe.

4. **Notice** – If the contractor rejects an application, it shall notify the provider via letter (sent via mail 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.

15.8.3 – Reserved for Future Use

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

15.8.4 – Denials

(Rev. 412, Issued: 03-30-12, Effective: 04- 30-12, Implementation: 04-30-12)

A. Denial Reasons

Per 42 CFR §424.530(a), the contractor 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 15 as the basis for denial.

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/Regional Office (RO). The contractor can simply: (1) deny the application, (2) close out the PECOS record, and (3) send a denial letter to the provider. 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. Such non-compliance includes, but is not limited to, the following situations:

a. The provider or supplier does not have a physical business address or mobile unit where services can be rendered.

b. The provider or supplier does not have a place where patient records are stored to determine the amounts due such provider or other person.

c. The provider or supplier is not appropriately licensed.

d. The provider or supplier is not authorized by the Federal/State/local government to perform the services that it intends to render.

e. The provider or supplier does not meet CMS regulatory requirements for the specialty that it seeks to enroll as.

f. The provider or supplier does not have a valid social security number (SSN) or employer identification number (EIN) for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or authorized or delegated official.

g. The applicant does not qualify as a provider of services or a supplier of medical and health services. (For instance, the applicant is not recognized by any Federal statute as a Medicare provider or supplier (e.g., marriage counselors.)) 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)).

h. The provider or supplier does not otherwise meet general enrollment requirements.

With respect to (e) above – and, as applicable, (c) and (d) - the contractor's denial letter shall cite the appropriate statutory and/or regulatory citation(s) containing the specific licensure/certification/authorization requirement(s) for that provider or supplier type. For a listing of some of these statutes and regulations, refer to section 15.4 et seq. of this chapter. Note that the contractor must identify in its denial letter the exact provision within said statute(s)/regulation(s) that the provider/supplier is not in compliance with.

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 non-procurement 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 15.27.2(D) of this chapter, the contractor shall establish an enrollment bar for providers and suppliers whose billing privileges are revoked, this does not preclude the contractor from denying re-enrollment to a provider or supplier that was convicted of a felony within the preceding 10-year period or that otherwise does not meet all of the criteria necessary to enroll in Medicare.

If the contractor is uncertain as to whether a particular felony falls within the purview of 42 CFR §424.530(a)(3), it should contact its Provider Enrollment Operations Group (PEOG) liaison for assistance.

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 PEOG liaison prior to denying an application on this ground.)

Denial Reason 5 (42 CFR §424.530(a)(5))

CMS or its contractor(s) determines, upon on-site review or other reliable evidence, that the provider or supplier is not operational or is not meeting Medicare enrollment requirements to furnish Medicare covered items or services. Upon on-site review, CMS

determines that—

(i) A Medicare Part A provider is not 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 not 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.

Denial Reason 6 (42 CFR §424.530(a)(6))

The current owner (as defined in §424.502), physician or non-physician practitioner has an existing overpayment at the time of filing an enrollment application.

Denial Reason 7 (42 CFR §424.530(a)(7))

The current owner (as defined in §424.502), physician or non-physician practitioner has been placed under a Medicare payment suspension as defined in §405.370 through §405.372.

Denial Reason 8 (42 CFR §424.530(a)(8))

A home health agency (HHA) submitting an initial application for enrollment:

- Cannot, within 30 days of a CMS or Medicare contractor request, furnish supporting documentation verifying that the HHA meets the initial reserve operating funds requirement in 42 CFR §489.28(a); or

- Fails to satisfy the initial reserve operating funds requirement in 42 CFR §489.28(a).

Denial Reason 9 (42 CFR §424.530(a)(9))

The institutional provider's (as that term is defined in 42 CFR §424.502) hardship exception request is not granted, and the institutional provider does not submit the required application fee within 30 days of notification that the hardship exception request was not approved.

(This denial reason should only be used when the institutional provider fails to submit the application fee after its hardship request was denied. The contractor shall use 42 CFR §424.530(a)(1) as a basis for denial when the institutional provider:

- Does not submit a hardship exception request and fails to submit the application fee within the prescribed timeframes, or

- Submits the fee, but it cannot be deposited into a government-owned account.)

Denial Reason 10 (42 CFR §424.530(a)(10))

The provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium. (This denial reason applies to initial enrollment applications and practice location additions.)

B. Denial Letters

When a decision to deny is made, the contractor shall send a letter to the provider identifying the reason(s) for denial and furnishing appeal rights. The letter shall follow the format of those shown in section 15.24 et seq. 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 may not submit a new enrollment application until either of the following has occurred:

- If the denial was not appealed, the provider or supplier's appeal rights have lapsed, or

- If the denial was appealed, the provider or supplier has 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 (e.g., exclusion, 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 15.25 of this chapter.

15.9 – Application Approvals
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.9.1 - Non-Certified Suppliers and Individual Practitioners
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

(This section does not apply to ambulatory surgical centers, portable x-ray suppliers, or providers and suppliers that complete the Form CMS-855A.)

If the contractor approves a supplier's enrollment, it shall notify the applicant via letter of the approval. The letter shall:

- Follow the content and format of the model letter in section 15.24.7 of this chapter;

- Include the National Provider Identifier (NPI) with which the supplier will bill Medicare and the Provider Transaction Access Number (PTAN) that has been assigned to the supplier as an identifier for inquiries.

- Provide instructions on how suppliers should use the assigned PTAN when they use the contractor interactive voice response (IVR) system for inquires concerning claims status, beneficiary eligibility, check status or other supplier-related IVR transactions.

- Include language reminding suppliers to update their NPPES record whenever their information changes.

For claims submitted by physicians and non-physicians prior to the date of enrollment, the contractor shall follow the instructions in Pub. 100-04, chapter 1, section 70, with respect to the claim filing limit. Payments cannot be made for services furnished prior to the date the applicant is appropriately licensed.

15.9.2 - Certified Providers and Certified Suppliers
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

(This section only applies to: (1) contractors when processing initial CMS-855A applications or CHOW, acquisition/merger, or consolidation applications submitted by the new owner; and (2) contractors when processing initial ASCs and PXRs applications.)

Once the contractor has completed its review of the provider or supplier's application and has decided to recommend approval, the contractor shall send a letter of recommendation for approval to the applicable State agency, with a copy going to the RO's survey and certification unit. (For those provider types that do not require a State survey, such as FQHCs, the letter can be sent directly to the RO.) The recommendation letter shall be written (not e-mailed) and, at a minimum, contain the following

information:

- Supplier/Provider NPI Number;
- CCN Number (if available);
- Type of enrollment transaction (CHOW, initial enrollment, branch addition, etc.);
- Contractor Number;
- Contractor Contact Name;
- Contractor Contact Phone Number;
- Date Application Recommended for Approval;
- An explanation of any special circumstances, findings, or other information that either the State or the RO should know about.

The contractor shall also:

- Send a photocopy (not the original) of the final completed CMS-855 to the State agency, along with all updated CMS-855 pages, explanatory data, documentation, correspondence, final sales agreements, etc. The photocopied CMS-855 should be sent in the same package as the recommendation letter.

The contractor shall not send a copy of the CMS-855 to the RO unless the latter specifically requests it or if the transaction in question is one for which State involvement is unnecessary.

- Notify the applicant that the contractor has completed its initial review of the application. The notification can be furnished orally or in writing, and shall advise the applicant of the next steps in the enrollment process (e.g., site visit, survey). The contractor may, but is by no means required to, send a copy of its recommendation letter to the provider as a means of satisfying this requirement. However, the contractor should not send a copy to the provider if the recommendation letter contains sensitive information. In addition, when notifying the provider that the review is finished, the contractor is under no obligation to inform the provider as to the contents of the recommendation (i.e., approval or denial).

- Inform the applicant that it could take 6 to 9 months (or longer) for the provider or supplier to obtain its billing number. (In the case of a CHOW, the contractor shall specify that CMS cannot send payments to the new owner until the tie-in notice is issued.) This can be done at any time prior to, or in conjunction with, the notification to the provider of the completion of its review of the application. The contractor may

notify the applicant of the phone numbers and e-mail addresses of the applicable State agency and RO that will be handling the survey and certification process from that point forward; the applicant shall also be instructed that all questions related to this process shall be directed to the State agency and/or RO.

15.9.3 - Approval of Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

As stated in 42 CFR §424.57(b), a DMEPOS supplier must, among other things, meet the following conditions to be eligible to receive payment for a Medicare-covered item:

- The supplier has submitted a complete Form CMS-855S, including all supporting documentation, to the National Supplier Clearinghouse (NSC); and

- The item was furnished on or after the date the NSC issued to the supplier a DMEPOS supplier number conveying Medicare billing privileges.

The date identified in the previous bullet represents the "date of approval."

15.10 – Changes of Information and Voluntary Terminations

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

Unless indicated otherwise, the instructions in sections 15.10.1 through 15.10.3 of this chapter apply to Part A and Part B enrollments.

15.10.1 – Changes of Information - General Procedures

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

Unless otherwise specified in this chapter or another CMS directive, if an enrolled provider is adding, deleting, or changing information under its existing tax identification number, it must report the change using the applicable Form CMS-855. Letterhead is not permitted.

The provider shall (1) furnish the changed data in the applicable section(s) of the form, and (2) sign and date the certification statement. In accordance with 42 CFR §424.516(d) and (e), the timeframes for providers to report changes to their Form CMS-855 information are as follows:

A. 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 15.10.1(A) must be reported within 90 days.

B. All providers and suppliers other than (1) those listed in section 15.10.1(A); (2) suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS); and (3) independent diagnostic testing facilities (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 15.10.1(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 15.5.19.1(A)(2) of this chapter. Reporting requirements for DMEPOS suppliers can be found in 42 CFR §424.57(c)(2)).

In addition:

- **Unsolicited Additional Information -** Any new or changed information that a provider submits 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 request. To illustrate, suppose a provider submits a Form CMS-855 change of information. On the 14th day, it submits additional information that it wants to change. Since the contractor has not finished processing the first change request, it should treat the data in the second change request as being part of the first one.

- **Unavoidable Phone Number or Address Changes** – Unless CMS specifies otherwise, any change in the provider's phone number or address that the provider did not cause (i.e., area code change, municipality renames the provider's street) must still be updated via the Form CMS-855.

- **Application Signatures -** If the signer has never been reported in section 6 of the Form CMS-855, section 6 must be completed in full with information about the individual. (This policy applies regardless of whether the provider already has a Form CMS-855 on file.) The contractor shall ensure that all validation required to be performed with respect to the individual is conducted.

- **Notifications** – For changes of information that do not require Regional Office approval (e.g., Form CMS-855I changes; Form CMS-855B changes not involving ambulatory surgical centers or portable x-ray suppliers; minor Form CMS-855A changes), the contractor shall (1) furnish written, e-mail, or telephonic confirmation to the provider that the change has been made, and (2) document (per section 15.7.3 of this chapter) 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.

15.10.1.1 – Changes of Information and Complete Form CMS-855 Applications

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

A provider must submit a complete Form CMS-855 application if it (1) submits any change request, and (2) does not have an established enrollment record in the Provider Enrollment, Chain and Ownership System (PECOS). (For purposes of this requirement, the term "change request" includes electronic funds transfer (EFT) changes.) It is immaterial (1) whether the provider or another party (e.g., local government changes street name) was responsible for triggering the changed data; or (2) the signer of the change request or EFT form already has a signature on file with the contractor.

If the contractor receives a change request from a provider that is not in PECOS, the contractor shall develop for the entire application in accordance with the procedures described in this chapter (i.e., the contractor shall treat the transaction as a request for additional information). Consistent with existing policies for requesting additional data, the provider has 30 calendar days from the date of the contractor's request to furnish a complete Form CMS-855. During this period, the contractor should "hold" (i.e., not process) the change request until the entire application arrives; no logging and tracking (L & T) record shall be created in PECOS at this point.

If the provider fails to submit a complete application within the aforementioned 30-day period, the contractor shall follow the instructions in section 15.10.1.2(B) of this chapter.

If the provider submits the application, the contractor shall process it in accordance with the instructions in this chapter and all other applicable CMS directives. This includes:

- Processing the complete application consistent with the timeframes for initial applications in section 15.6.1 of this chapter.

- Ensuring that all data elements on the Form CMS-855 have been validated, as it would with an initial enrollment application. The contractor shall not approve the change request until all data on the complete Form CMS-855 has been validated.

Creating an L & T record and enrollment record in PECOS prior to approving the change request. The transaction should be treated as an initial enrollment in PECOS; internally, the contractor shall treat it as a change of information. As the complete application will presumably incorporate the changed data reported on the original Form CMS-855 change request, the contractor shall not take two separate counts (one initial and one change request) for the transaction.

15.10.1.2 - Incomplete or Unverifiable Changes of Information
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

The contractor shall follow the instructions in this section 15.10.1.2 if a submitted change request cannot be processed to completion.

A. Provider Has an Established Enrollment Record in the Provider Enrollment, Chain and Ownership System (PECOS)

Assume that a provider with a PECOS enrollment record submits a Form CMS-855 change request and (1) fails to timely respond to the contractor's request for additional or clarifying information, or (2) the changed information cannot be validated. The contractor shall reject the change request in accordance with section 15.8.2 of this chapter. Moreover, if the changed information is of such materiality that the contractor cannot determine whether the provider still meets all enrollment requirements, the contractor shall refer the matter to its Provider Enrollment Integrity Group (PEOG) liaison for guidance. (For instance, if the data involves a change in the provider's lone practice location and the contractor cannot verify the validity of the new site, this clearly raises questions as to the provider's continued compliance with Medicare requirements.)

B. Provider is Not in PECOS

As stated in section 15.10.1.1 of this chapter, if a provider does not have an established enrollment record in PECOS and wants to change any of its existing enrollment or electronic funds transfer (EFT) information, it must submit a complete Form CMS-855 before the contractor can effectuate the change. If the provider fails to submit the completed form within the applicable 30-day period, the contractor shall request that the provider revalidate its Medicare enrollment information per 42 CFR §424.515.

15.10.2 - Special Instructions for Certified Providers, ASCs, and Portable X-ray Suppliers
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. Timeframe for RO Approval

In situations where RO approval of the change of information is required, it is strongly recommended that the contractor advise the provider that it may take 6 months (or longer) for the request to be approved. The manner and timing in which this information is relayed lies solely within the contractor's discretion.

B. Post-Recommendation Changes

If an applicant submits a change request after the contractor makes a recommendation on the provider's initial CMS-855 application but before the RO issues a tie-in/approval notice, the contractor shall process the newly-submitted data as a separate change of

information; it shall not take the changed information/corrected pages and, immediately upon receipt, send them directly to the State/RO to be incorporated into the existing application. The contractor, however, need not enter the change request into PECOS until the tie-in notice is issued.

In entering the change request into PECOS, the contractor shall use the date it received the change request in its mailroom as the actual receipt date in PECOS; the date the tie-in notice was issued shall not be used. The contractor shall explain the situation in the "Comments" section in PECOS and in the provider file.

C. Hospital Addition of Practice Location

- In situations where a hospital is adding a practice location, the contractor shall notify the provider in writing that its recommendation for approval does not constitute approval of the facility or group as provider-based under 42 CFR §413.65.

15.10.3 – Voluntary Terminations

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

Voluntary terminations shall be processed in accordance with the timeframes in section 15.6.2 et al. of this chapter.

If the termination involves a certified provider or certified supplier, the contractor may terminate the entity without making a recommendation to the State and Regional Office (RO). Within 3 business days after the contractor finishes processing the termination, however, it shall notify the State and RO of this via letter, e-mail, or fax.

Upon receipt of a voluntary termination, the contractor may ask the provider to complete the "Special Payments" portion of section 4 of the Form CMS-855 so that future payments can be sent thereto. If the provider has no special payments address already on file, the addition should be included in the same transaction as the termination (i.e., one transaction incorporating both items). If the provider wants to change its existing special payments address, the transaction should be treated as a separate change request (i.e., one termination and one change request). The provider is not required to submit a Form CMS-588 in conjunction with a termination.

15.11 – Electronic Fund Transfers (EFT)

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

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 section 15.10.1.1 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, 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 15.6.2 et al. 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 contractor – rather than the audit contractor – thereon.

15.12 – Reserved for Future Use

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.13 – Reserved for Future Use
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.14 – Special Processing Situations
(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

15.14.1 – Non-CMS-855 Enrollment Activities
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

There are situations where the contractor processes non-CMS-855 forms and other documentation relating to provider enrollment. Such activities include:

- EFT agreements (Form CMS-588) submitted alone
- "Do Not Forward" issues
- Par agreements (Form CMS-460)
- Returned remittance notices
- Informational letters received from other contractors
- Diabetes self-management notices
- Verification of new billing services
- Paramedic intercept contracts
- 1099 issues that need to be resolved

Unless specified otherwise in this chapter or another CMS directive, the contractor shall not create a logging and tracking record for any non-CMS-855 document or activity other than the processing of par agreements. The contractor should track and record all other activities internally.

15.14.2 – Contractor Communications
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

Medicare contractors create Associate and Enrollment Records in the Provider Enrollment, Chain and Ownership System (PECOS). Ownership of an Associate or Enrollment Record belongs to the contractor within whose jurisdiction the provider/supplier is located. PECOS only permits the contractor that created the Associate or Enrollment Record (the “owning contractor”) to make updates, changes, or corrections to those records. (That is, the owning contractor is the only contractor that can make changes to the associate record.)

Occasionally, updates, changes, or corrections do not come to the owning contractor's attention, but instead go to a different contractor. In those situations, the contractor that has been notified of the update/change/correction (the "requesting" contractor) must convey the changed information to the owning contractor so that the latter can update the record in PECOS.

The requesting contractor may notify the owning contractor via fax of the need to update/change/correct information in a provider's PECOS record. The notification must contain:

1. The provider's legal business name, Provider Transaction Access Number, and National Provider Identifier; and

2. The updated/changed/corrected data (by including a copy of the appropriate section of the Form CMS-855).

Within 7 calendar days of receiving the requesting contractor's request for a change to a PECOS record, the owning contractor shall make the change and notify the requesting contractor thereof via fax, e-mail, or telephone.

If the owning contractor is reluctant to make the change, it shall contact its Provider Enrollment Operations Group (PEOG) liaison for guidance. Note that the owning contractor may ask the requesting contractor for any additional information about the provider it deems necessary (e.g., IRS documentation, licenses).

The owning contractor need not ask the provider for a Form CMS-855 change of information in associate profile situations. It can simply use the Form CMS-855 copy that the requesting contractor sent/faxed to the owning contractor. For instance, suppose Provider X is enrolled in two different contractor jurisdictions – A and B. The provider enrolled with "A" first; its legal business name was listed as "John Brian Smith Hospital." It later enrolls with "B" as "John Bryan Smith Hospital." "B" has verified that "John Bryan Smith Hospital" is the correct name and sends a request to "A" to fix the name. "A" is not required to ask the provider to submit a Form CMS-855A change of information. It can use the CMS-855A copy that it received from "B."

15.14.3 – Provider-Based

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

The contractor shall adhere to the following regarding the enrollment of provider-based entities:

- **Certified Provider or Certified Supplier Initially Enrolling –** Suppose an HHA or other certified provider or certified supplier wishes to enroll and become provider-based to a hospital. The provider/supplier must enroll with the contractor as a

separate entity. It cannot be listed as a practice location on the hospital's Form CMS-855A.

- **Certified Provider or Certified Supplier Changing its Provider-Based Status –** If a certified provider or certified supplier is changing its status from provider-based to freestanding or vice versa, it need not submit any updates to its Form CMS-855 enrollment.

- **Group Practice Initially Enrolling –** If a group practice is enrolling in Medicare and will become provider-based to a hospital, the group generally must enroll via the Form CMS-855B if it wants to bill for practitioner services. The group would also need to be listed or added as a practice location on the hospital's Form CMS-855A.

- **Group Practice Changing from Provider-Based to Freestanding** – In this situation, the hospital should submit a Form CMS-855A change request that deletes the clinic as a practice location. The group may also need to change the type of clinic it is enrolled as; this may require a new Form CMS-855B.

- **Group Practice Changing from Freestanding to Provider-Based** – Here, the hospital must submit a Form CMS-855A change request adding the group as a practice location. The group may also need to change the type of clinic it is enrolled as; this may require a new Form CMS-855B.

Unless the CMS regional office (RO) dictates otherwise, the contractor shall not delay the processing of any practice location addition applications pending receipt of provider-based attestations or RO approval of provider-based status.

15.14.4 – Non-Participating Emergency Hospitals, Veterans Administration (VA) Hospitals, and Department of Defense (DOD) Hospitals

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A non-participating emergency hospital or DOD hospital must complete and submit a CMS-855A enrollment application and CMS-588 EFT form if it wishes to bill Medicare for any services performed.

A VA hospital must complete and submit a CMS-855A enrollment application and CMS-588 EFT form if it wishes to bill Medicare for any non-emergency services performed. Emergency VA services, however, do not require the completion of a CMS-855 or CMS-588 form.

When creating a PECOS enrollment record for one of these providers, the contractor shall select a Provider Type of "Other" and then enter the type of hospital in question.

15.14.5 – Form CMS-855B Applications Submitted by Hospitals

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

A. Group Practices

If an entity is enrolling via the Form CMS-855B as a hospital-owned clinic/physician practice, the contractor shall contact the applicant to determine whether the latter will be billing any of the listed locations as provider-based. If the applicant will not be billing as provider-based, the contractor shall process the application normally. If, however, the applicant will bill as provider-based, the contractor shall notify the applicant that the hospital must report any changed practice locations to its contractor via the Form CMS-855A.

If the supplier is enrolling as a hospital department (under the "Clinic/Group Practice" category on the Form CMS-855B) or an existing hospital department is undergoing a change of ownership (CHOW), the contractor shall only issue the necessary billing numbers upon notification that a provider agreement has been issued – or, in the case of a CHOW, the provider agreement has been transferred to the new owner. If, however, the supplier is enrolling as a group practice that is merely owned by a hospital (as opposed to being a hospital department), it is not necessary for the contractor to wait until the provider agreement is issued before conveying billing privileges to the group.

B. Individual Billings

Assume an individual physician works for a hospital and will be billing for services as an individual (i.e., not as part of the hospital service/payment). However, he/she wants to reassign these benefits to the hospital. The hospital will need to enroll with the contractor via the Form CMS-855B (e.g., as a hospital department, outpatient location).

15.14.6 – Participation (Par) Agreements and the Acceptance of Assignment

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

The contractor shall follow the instructions in CMS Publication 100-04, chapter 1, sections 30 through 30.3.12.3 when handling issues related to par agreements and assignment. Queries related to the interpretation of such instructions shall be referred to the responsible CMS component.

15.14.7 – Opt-Out

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

There are physicians and other individual practitioners who do not wish to enroll in the Medicare program. Physicians and practitioners (but not organizations) can "opt-out" of Medicare. This means that neither the physician nor the beneficiary submits the bill to Medicare for services performed. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. In fact, a private contract is signed between the physician and the beneficiary that states, in essence, that neither one can receive payment from Medicare for the services that were performed. (The contract, of

course, must be signed before the services are provided so the beneficiary is fully aware of the physician's opt-out status.) Moreover, the supplier must submit an affidavit to Medicare expressing his/her decision to opt-out of the program. The provider enrollment unit must process these affidavits.

The difference between opting-out and not accepting assignment is relatively straightforward. If the practitioner opts-out, neither he/she nor the beneficiary can bill Medicare. If the practitioner chooses not to accept assignment, he/she must still enroll in Medicare and must submit the bill to the contractor.

(For additional information on "opt-out," see Pub. 100-02, chapter 15, section 40.)

In an emergency care or urgent care situation, a physician or practitioner who opts out may treat a Medicare beneficiary with whom he or she does not have a private contract. In those circumstances, the physician or practitioner must complete a CMS-855 application after the emergency services were provided.

15.14.8 – Assignment of Part B Provider Transaction Access Numbers (PTANs)

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

The contractor shall only assign the minimum number of PTANs necessary to ensure that proper payments are made. The contractor shall not assign additional PTAN(s) to a supplier merely because the individual or entity requests one - the only exception being for hospitals that request separate billing numbers for their hospital departments in section 2C of the Form CMS-855B. However, a hospital requesting an additional PTAN must associate the new PTAN with a National Provider Identifier in section 4 of the Form CMS-855.

15.15 – Internet-based PECOS Applications

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

This section furnishes guidance to contractors on the proper handling and processing of CMS-855 applications submitted via the Internet (hereinafter referred to as "Internet-based PECOS" applications). Unless otherwise stated, the instructions in this section 15.15 apply only to Internet-based PECOS applications.

Contractors shall begin processing such applications as soon as the Internet-based capability is effective for their respective A/M MAC jurisdiction or State/processing area.

A. General Background Information

The principal logging and tracking (L & T) statuses for PECOS Internet applications that are not in a final status are:

- Received;
- In Review;
- Returned for Corrections;
- Corrections Received;
- Review Complete; and
- Application in Process.

The submission of a PECOS Internet application will immediately place the L & T record into a "Received" status.

B. Certification Statement

If the provider fails to submit a signed and dated certification statement to the contractor within 15 calendar days of the date on which it submitted its Internet-based PECOS application to the contractor, the contractor may – but is not required to - reject the application. (For purposes of this policy, the certification statement must be received by the contractor's provider enrollment unit by the 15th day.) The 15-day rule applies to all CMS-855 PECOS Internet applications, regardless of the transaction involved.

For initial PECOS Internet applications (as the term "initial" is defined in section 15.6.1 of this chapter), it is only necessary that the dated signature of at least one of the provider's authorized officials be on the certification statement that must be sent in by the 15th day; obtaining the signatures of the other authorized and delegated officials shall be done through the normal application development process. For PECOS Internet changes of information (as the term "changes of information" is defined in section 15.6.2 of this chapter), if the certification statement is signed by an individual who is not on file with the contractor as being an authorized or delegated official of the provider, the contractor may accept the certification statement but shall develop for information on the person in question in accordance with sections 15.5.15 and 15.5.16 of this chapter.

If the provider submits: (1) an undated certification statement, or (2) a certification statement on which the Web Tracking ID does not match that in PECOS, the contractor shall treat it as a non-submission; while it is recommended that the contractor contact the provider to request a signed/correct certification statement, it is not required. (This requirement applies to any CMS-855 transaction, including requests for additional/clarifying information.)

If the contractor elects to contact the provider to request a dated/valid certification statement, the contractor may give the provider an additional 15 days (or, for that matter, any additional time beyond the initial 15-day period) to submit the new certification statement. In determining whether to accept an untimely certification statement, the contractor shall take into account factors such as: (1) the degree of the provider's cooperation, (2) the time it took for the certification statement to be transferred from the contractor's main mailroom to the provider enrollment department,

and (3) the number of days by which the provider missed the 15-day deadline.

C. Pre-Screening

The contractor shall prescreen all PECOS Internet applications, as the term "prescreen" is defined in section 15.7.1.1 of this chapter.

If the contractor can determine (without actively processing the application) that an application can be returned under section 15.8.1 of this chapter (e.g., was submitted more than 30 days prior to the effective date), the contractor shall return the application without waiting for the arrival of the certification statement.

D. Switch to "In Review" Status

After – and only after - it receives and accepts the provider's certification statement, the contractor shall: (1) enter the date of signature into the "Certification Date" box in the L & T record, and (2) change the L & T status to "In Review." The contractor, in other words, shall not initiate any application verification activities prior to its receipt and acceptance of the certification statement and its completion of tasks (1) and (2) in the previous sentence.

After changing the L & T status to "In Review," the contractor shall review the Application Data Report (ADR), and shall commence all applicable validation activities identified in this chapter. Note that the ADR is only available for printing when the L & T record is in one of the following statuses: "In Review," "Returned for Corrections," or "Corrections Received."

E. Request for Additional/Clarifying Information

If, when performing verification activities, the contractor determines that additional or clarifying information is needed, the contractor shall – after switching the L & T status to "Returned for Corrections" - send an e-mail (via PECOS Internet) to the provider:

- Requesting said data along with, as necessary, a signed and dated certification statement; and

- Listing a date(s) by which the information and certification statement, respectively, must be submitted to the contractor. (The establishment of this submission due date shall be done in accordance with section 5.3(A)(2) of this chapter.)

(In accordance with sections 15.7.1 through 15.7.2.1 of chapter 15 – and to avoid multiple contacts with the provider - the contractor shall attempt to validate <u>all</u> of the data on the ADR prior to requesting additional/clarifying information from the provider.)

The contractor shall not attempt to contact the provider for additional/clarifying

information prior to sending the e-mail referenced above, though the contractor is free to make a follow-up contact with the provider after sending the e-mail. Note that this e-mail is the only contact that the contractor is required to make per section 5.3 of this chapter.

The provider must submit all applicable supporting documentation (e.g., licenses, CMS-588) with its PECOS Internet application. It is not necessary, however, for the provider to submit the supporting documentation: (1) in the same package as the certification statement, or (2) prior to its submission of the certification statement. Regardless, if the provider fails to submit all applicable supporting documentation, the contractor shall develop for it.

F. Submission of Additional/Clarifying Information

The contractor shall note that a provider may submit requested additional/clarifying data via PECOS Internet or any other mechanism permitted under chapter 15 (e.g., paper, fax).

If the provider fails to submit the requested additional/clarifying information and the accompanying certification statement within 30 calendar days from the date the contractor sent the e-mail referred to above, the contractor shall follow the procedures in sections 15.8.2 (or 15.8.4, as applicable) of this chapter. If, however, the contractor receives the additional/clarifying information from the provider, the contractor shall not recommence its processing of the application until the accompanying certification statement is received in the contractor's provider enrollment department. Once the contractor accepts the newly signed and dated certification statement, it shall enter the certification statement date into the L & T record.

If, after receiving the additional/clarifying information and certification statement from the provider, the contractor determines that further information is needed and elects to request this data from the provider (i.e., elects to waive the "one contact" threshold described in sections 15.7.1 through 15.7.2.1 of this chapter), the contractor shall do so in accordance with the instructions in this chapter.

G. Transferral of Data into PECOS

Once the contractor ties the L & T record to the enrollment record, the contractor shall begin the process of transferring the data into PECOS by accepting or rejecting the various data elements. The contractor shall note that: (1) it cannot undo any transfer of information into PECOS, and (2) once the L & T is tied to the enrollment record, the application cannot be returned to the provider for corrections.

H. Miscellaneous Instructions

The contractor shall note the following:

- **Deletion of Erroneous Record** - The contractor shall only delete an erroneously created L & T record by: (1) moving the L & T record to a status of "Rejected," and (2) using an L & T status reason of "Deleted."

- **Gatekeeper/Enrollment Screens** - The Gatekeeper and Enrollment screens are only used in the case of CMS-855 initial enrollment PECOS Internet submissions.

- **Post-Processing Recordkeeping** - After processing a particular PECOS Internet transaction, the contractor shall maintain in the provider's file: (1) a copy of the final version of the ADR, (2) all submitted certification statements and applicable supporting documents, and (3) documentation of all contacts with the provider (e.g., phone calls, e-mails) per section 15.7.3 of this chapter.

State Agencies - In situations described in this chapter in which the contractor is required to submit a copy of the provider's paper CMS-855 to the State agency, the contractor shall send a copy of the ADR in lieu of the CMS-855 if the provider sent in its application via the Internet.

15.16 – Ordering/Referring Suppliers Who Do Not Have Medicare Billing Privileges

(Rev. 410, Issued: 03-02-12, Effective: 06-04-12, Implementation: 06-04-12)

15.16.1 – Ordering/Referring Suppliers – Background

(Rev. 410, Issued: 03-02-12, Effective: 06-04-12, Implementation: 06-04-12)

Generally, depending upon State law, the following physicians and non-physician practitioners are permitted to order or refer items or services for Medicare beneficiaries:

- Doctors of medicine or osteopathy
- Doctors of dental surgery or dental medicine
- Doctors of podiatry
- Doctors of optometry
- Physician assistants
- Certified clinical nurse specialists
- Nurse practitioners
- Clinical psychologists
- Certified nurse midwives
- Clinical social workers

Most physicians and non-physician practitioners enroll in Medicare so they can receive reimbursement for covered services to Medicare beneficiaries. However, some physicians and non-physician practitioners who are not enrolled in Medicare via the Form CMS-855I may wish to order or refer items or services for Medicare beneficiaries. These individuals can become eligible to do so by completing the Form CMS-855O via paper or the Internet-based Provider Enrollment, Chain and Ownership

System (PECOS) process.

It is important to note that physicians and non-physician practitioners that complete the Form CMS-855O do not and will not send claims to a Medicare contractor for services they furnish. They are not afforded Medicare billing privileges for the purpose of submitting claims to Medicare directly for services that they furnish to beneficiaries. Such persons may be:

- Employed by the Department of Veterans Affairs (DVA)
- Employed by the Public Health Service (PHS)
- Employed by the Department of Defense (DOD) Tricare
- Employed by the Indian Health Service (IHS) or a tribal organization
- Employed by a federally qualified health center (FQHC), rural health clinic (RHC), or critical access hospital (CAH)
- Licensed residents and physicians in a fellowship
- Dentists, including oral surgeons
- Pediatricians

15.16.2 – Processing Initial Form CMS-855O Submissions

(Rev. 410, Issued: 03-02-12, Effective: 06-04-12, Implementation: 06-04-12)

A. Prescreening

Upon receipt of an initial Form CMS-855O (or - for Internet-based Provider Enrollment, Chain and Ownership System (PECOS) submissions - a certification statement), the contractor shall:

- Pre-screen the form in accordance with the same procedures that are required for pre-screening Form CMS-855I applications.

- Create a logging & tracking (L & T) record.

Note that the physician/non-physician practitioner need not submit a Form CMS-460, a Form CMS-588, or an application fee with its Form CMS-855O.

Section 15.8.1 of this chapter outlines the reasons for which the contractor may immediately return a Form CMS-855O. If the contractor determines that one or more of these reasons applies, it shall return the form in accordance with the instructions outlined in that section.

B. Verification

Unless stated otherwise in another CMS directive, the contractor shall verify all of the information on the Form CMS-855O. This includes, but is not limited to:

- Verification of the individual's name, date of birth, social security number, and

National Provider Identifier (NPI).

- Verification that the individual meets the requirements for his/her supplier type. (The contractor reserves the right to request that the individual submit documentation verifying his or her professional licensure, credentials, or education.)

- Verification that the individual is of a supplier type that can legally order or refer.

- Reviewing the Medicare Exclusion Database (MED) and General Services Administration (GSA) Excluded Parties List System to ensure that the individual is not excluded or debarred.

If, at any time during the pre-screening or verification process, the contractor needs additional or clarifying information from the physician/non-physician practitioner, it shall follow existing CMS instructions for obtaining said data (e.g., sending a developmental letter). The information must be furnished to the contractor within 30 calendar days of the contractor's request.

C. Timeliness

The contractor:

- Shall process 80 percent of all paper initial Form CMS-855O applications within 60 calendar days of receipt, and 95 percent of such applications within 90 calendar days of receipt.

- Shall process 90 percent of all Web-based initial Form CMS-855O applications within 45 calendar days of receipt, process 95 percent of such applications within 60 calendar days of receipt, and process 99 percent of such applications within 90 calendar days of receipt.

- Shall process 98 percent of all initial Form CMS-855O applications in full accordance with the instructions in this section 15.16.2 (with the exception of the timeliness standards mentioned above) and all other applicable CMS directives.

For purposes of these standards, the timeliness processing clock begins on the date that the paper application or Web-based certification statement was received in the contractor's mailroom.

D. Disposition

Upon completion of its review of the form, the contractor shall approve, deny, or reject it.

Grounds for denial are as follows:

- The supplier is not of a type that is eligible to use the Form CMS-855O.
- The supplier is not of a type that is eligible to order or refer items or services for Medicare beneficiaries.
- The supplier does not meet the licensure, certification or educational requirements for his or her supplier type.
- The supplier is excluded per the MED and/or debarred per the GSA Excluded Parties List System.

If the contractor believes that another ground for denial exists for a particular submission, it should contact its Provider Enrollment Operations Group liaison for guidance.

The Form CMS-855O shall be rejected if the supplier fails to furnish all required information on the form within 30 calendar days of the contractor's request to do so. (This includes situations in which information was submitted, but could not be verified.) The basis for rejection shall be 42 CFR § 424.525(a).

When denying or rejecting the Form CMS-855O submission, the contractor shall: (1) switch the PECOS record to a "denied" or "rejected" status (as applicable), and (2) send a letter to the supplier notifying him or her of the denial or rejection and the reason(s) for it. The letter shall follow the formats outlined in sections 15.24.22 (rejections) and 15.24.23 (denials) of this chapter. Denial letters shall be sent via certified mail. Rejection letters shall be sent by mail or e-mail. Note that a denial triggers appeal rights. A rejection does not.

If the Form CMS-855O is approved, the contractor shall: (1) switch the PECOS record to an "approved" status, and (2) send a letter (via mail or e-mail) to the supplier notifying him or her of the approval. The letter shall follow the format outlined in section 15.24.21 of this chapter.

E. Miscellaneous

The contractor shall note the following:

1. The supplier shall be treated as a non-participating supplier (or "non-par").

2. If the supplier is employed by the DVA, the DOD, or the IHS, he or she – for purposes of the Form CMS-855O - need only be licensed or certified in one State. Said State need not be the one in which the DVA or DOD office is located.

3. Nothing in sections 15.16.2 through 15.16.4 affects any existing CMS instructions

regarding the processing of opt-out affidavits.

4. Suppliers cannot submit an abbreviated version of the Form CMS-855I in lieu of the Form CMS-855O.

5. The effective date of enrollment shall be the date on which the contractor received the paper form or Web-based certification statement in its mailroom.

6. If the supplier's Form CMS-855O has been approved and he or she later wants to obtain Medicare billing privileges, he or she must voluntarily withdraw his or her Form CMS-855O enrollment prior to receiving Medicare billing privileges. (The supplier, of course, must complete the Form CMS-855I in order to receive Medicare billing privileges.)

15.16.3 – Processing Form CMS-855O Change of Information Requests

(Rev. 410, Issued: 03-02-12, Effective: 06-04-12, Implementation: 06-04-12)

A. Prescreening

Upon receipt of a Form CMS-855O change of information request (or - for Internet-based Provider Enrollment, Chain and Ownership System (PECOS) change requests - a certification statement), the contractor shall:

- Pre-screen the Form CMS-855O in accordance with the same procedures that are required for pre-screening Form CMS-855I change requests.

- Create a logging and tracking (L & T) record.

Section 15.8.1 of this chapter outlines the reasons for which the contractor may immediately return a Form CMS-855O. If the contractor determines that one or more of these reasons applies, it shall return the change request via the instructions outlined in that section.

Note that suppliers who are enrolled in Medicare via the Form CMS-855I may not report changes to their enrollment information via the Form CMS-855O. They must use the Form CMS-855I. Similarly, suppliers whose Form CMS-855O submissions have been approved must use the Form CMS-855O to report information changes; they cannot use the Form CMS-855I for this purpose.

B. Verification

Unless stated otherwise in another CMS directive, the contractor shall verify the new information that the supplier furnished on the Form CMS-855O. (This includes checking the supplier against the Medicare Exclusion Database and the General Services Administration Excluded Parties List System.) If, at any time during the pre-

screening or verification process, the contractor needs additional or clarifying information, it shall follow existing CMS instructions for obtaining said data (e.g., sending a developmental letter). The information must be furnished to the contractor within 30 calendar days of the contractor's request.

C. Timeliness

The contractor:

- Shall process 80 percent of paper Form CMS-855O changes of information within 60 calendar days of receipt, process 90 percent of such applications within 90 calendar days of receipt, and process 95 percent of such applications within 120 calendar days of receipt.

- Shall process 90 percent of Web-based Form CMS-855O changes of information within 45 calendar days of receipt, process 95 percent of such applications within 60 calendar days of receipt, and process 99 percent of such applications within 90 calendar days of receipt.

- Shall process 98 percent of all Form CMS-855O changes of information in full accordance with the instructions in this section 15.16.3 (with the exception of the timeliness standards mentioned above) and all other applicable CMS directives. For purposes of these standards, the timeliness processing clock begins on the date that the paper application or Web-based certification statement was received in the contractor's mailroom.

D. Disposition

Upon completion of its review of the change request, the contractor shall approve, deny, or reject the submission. The principal ground for denial will be that the new information was furnished, but could not be verified. If the contractor believes that another ground for denial exists with respect to a particular submission, it should contact its Provider Enrollment Operations Group liaison for guidance.

The change request shall be rejected if the supplier failed to furnish all required information on the form within 30 calendar days of the contractor's request to do so. The basis for rejection shall be 42 CFR § 424.525(a).

When denying or rejecting the change request, the contractor shall: (1) switch the PECOS record to a "denied" or "rejected" status (as applicable), and (2) send a letter (via mail or e-mail) to the supplier notifying him or her of the denial or rejection and the reason(s) for it.

If the change request is approved, the contractor shall (1) switch the PECOS record to an "approved" status, and (2) send a letter (via mail or e-mail) to the supplier notifying him or her of the approval.

15.16.4 – Form CMS-855O Revocations
(Rev. 410, Issued: 03-02-12, Effective: 06-04-12, Implementation: 06-04-12)

If the contractor determines that grounds exist for revoking the supplier's Form CMS-855O enrollment, it shall:

- Switch the supplier's Provider Enrollment, Chain and Ownership System (PECOS) record to a " revoked" status,
- End-date the PECOS record, and
- Send a letter via certified mail to the supplier stating that his or her Form CMS-855O enrollment has been revoked. The letter shall follow the format outlined in section 15.24.24 of this chapter.

Grounds for revoking the supplier's Form CMS-855O enrollment are as follows:

- The supplier is no longer of a type that is eligible to order or refer.
- The supplier no longer meets the licensure, certification or educational requirements for his or her supplier type.
- The supplier is excluded per the Medicare Exclusion Database (MED) and/or debarred per the General Services Administration (GSA) Excluded Parties List System.

For purposes of the Form CMS-855O only, the term "revocation" effectively means that:

- The supplier may no longer order or refer Medicare services based on his or her having completed the Form CMS-855O process.
- If the supplier wishes to submit another Form CMS-855O, he or she must do so as an initial applicant.

There are appeal rights associated with the revocation of a supplier's Form CMS-855O enrollment.

15.17 – Establishing an Effective Date of Medicare Billing Privileges
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

(This section 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.)

A. Background

In accordance with 42 CFR §424.520(d), the effective date for the individuals and organizations identified above is the later of:

- The date the physician filed an enrollment application that was subsequently approved, or

- The date the physician first began furnishing services at a new practice location.

Note that the date of filing for Internet-based Provider Enrollment, Chain and Ownership System (PECOS) applications is the date that the contractor received an electronic version of the enrollment application and a signed certification statement submitted via paper or electronically.

B. Retrospective Billing

Consistent with 42 CFR §424.521(a), the individuals and organizations identified above 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 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 contractor shall interpret the phase "circumstances precluded enrollment" to mean that the physician, non-physician practitioner, or physician or non-physician practitioner organization meets all program requirements (including State licensure) during the 30-day period before an application was submitted and no final adverse action, as identified in 42 CFR §424.502, precluded enrollment. If a final adverse action precluded enrollment during this 30-day period, the contractor shall only establish an effective billing date the day after the date that the final adverse action was resolved, as long as it is not more than 30 days prior to the date on which the application was submitted.

C. Legal Distinction between Effective Date of Enrollment and retrospective Billing Date

The effective date of enrollment is "the later of the date of filing or the date (the supplier) first began furnishing services at a new practice location." The retrospective billing date, however, is "up to…30 days prior to (the supplier's) effective date (of enrollment)." To illustrate, suppose that a non-Medicare enrolled physician begins furnishing services at an office on March 1. She submits a Form CMS-855I initial enrollment application on May 1. The application is approved on June 1. The physician's effective date of enrollment is May 1, which is the later of: (1) the date of filing, and (2) the date she began furnishing services. The retrospective billing date is April 1 (or 30 days prior to the effective date of enrollment), assuming that the requirements of 42 CFR §424.521(a) are met.

Note, however, that the effective date entered into the Provider Enrollment, Chain and Ownership System (PECOS) and the Multi-Carrier System will be April 1 and that claims submitted for services provided before April 1 will not be paid.

15.17.1 - Effective Date for Certified Providers and Certified Suppliers

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

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

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

These clarifications were necessary because of a September 28, 2009 decision of the Appellate Division of the Department Appeals Board (DAB). The DAB's interpretation of §489.13 was that it did not include enrollment application processing as among the Federal requirements that must be met. In that case, a State Agency (SA) had conducted a survey of an applicant on July 6, 2007, prior to receiving the November 21, 2007 notice from the Medicare contractor that was recommending approval of the applicant's enrollment application. The CMS Regional Office (RO) issued a provider approval effective November 21, 2007, consistent with our traditional interpretation of §489.13. The DAB, however, ruled that the effective date must be July 6, 2007. The DAB agreed with the applicant that the requirement for the Medicare contractor to verify and determine whether an application should be approved is not a requirement for the provider to meet [under §489.13], but rather a requirement for

Medicare contractor action (DAB Decision No. 2271, page 5).

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

Accordingly, §489.13(b) now states that:

"Federal requirements include, but are not limited to –

(1) Enrollment requirements established in part 424, Subpart P, of this chapter. CMS determines, based upon its review and verification of the prospective provider's or supplier's enrollment application, the date on which enrollment requirements have been met;

(2) The requirements identified in §§489.10 and 489.12; and

(3) The applicable Medicare health and safety standards, such as the applicable conditions of participation, the requirements for participation, the conditions for coverage, or the conditions for certification."

15.18 – Reserved for Future Use

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

15.19 – Application Fees and Additional Screening Requirements

(Rev 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

15.19.1 – Application Fees

(Rev. 412, Issued: 03-30-12, Effective: 04- 30-12, Implementation: 04-30-12)

A. Background

Pursuant to 42 CFR §424.514 - and with the exception of physicians, non-physician practitioners, physician group practices and non-physician group practices – institutional providers that are (1) initially enrolling in Medicare, (2) adding a practice location, or (3) revalidating their enrollment information per 42 CFR §424.515, must submit with their application:

- An application fee in an amount prescribed by CMS, and/or

- A request for a hardship exception to the application fee.

This requirement applies to applications that the contractor receives on or after March 25, 2011.

For purposes of this requirement, the term "institutional provider," as defined in 42 CFR §424.502, means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS- 855B (not including physician and non-physician practitioner organizations), Form CMS-855S or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application. Note that a physician, non-physician practitioner, physician group, or non-physician practitioner group that is enrolling as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) via the Form CMS-855S application must submit the required application fee with its Form CMS-855S form.

B. Fee

1. Amount

The application fee must be in the amount prescribed by CMS for the calendar year in which the application is submitted. The fee for March 25, 2011 through December 31, 2011 is $505.00. The fee for January 1, 2012 through December 31, 2012 is $523.00. Fee amounts for future years will be adjusted by the percentage change in the consumer price index (for all urban consumers) for the 12-month period ending on June 30 of the prior year. CMS will give the contractor and the public advance notice of any change in the fee amount for the coming calendar year.

2. Non-Refundable

Per 42 CFR §424.514(d)(2)(v), the application fee is non-refundable, except if it was submitted with one of the following:

a. A hardship exception request that is subsequently approved;

b. An application that was rejected prior to the contractor's initiation of the screening process, or

c. An application that is subsequently denied as a result of the imposition of a temporary moratorium under 42 CFR §424.570.

(For purposes of (B)(2)(b) above, the term "rejected" includes applications that are returned pursuant to section 15.8.1 of this Chapter.)

In addition, the fee should be refunded if:

- It was not required for the transaction in question (e.g., the provider submitted a fee with its application to report a change in phone number).

- It was not part of an application submission.

3. Format

The provider or supplier must submit the application fee electronically through Pay.gov, either via credit card, debit card, or check. Note that CMS will send to the contractor on a regular basis a listing of providers and suppliers (the "Fee Submitter List") that have paid an application fee via Pay.gov.

The contractor shall also note with respect to the application fee requirement:

- The fee is based on the Form CMS-855 application submission, not on how enrollment records are created in PECOS. For instance, suppose a hospital submits an initial Form CMS-855A. In section 2A2 of the application, the hospital indicates that it has a psychiatric unit and a rehabilitation unit. Separate PECOS enrollment records must be created for each unit. However, only one application fee is required because only one Form CMS-855A application was submitted.

- A physician/non-physician practitioner clinic or group practice enrolling via the Form CMS-855B is exempt from the fee even if it is: (1) Tribally-owned/operated, or (2) hospital-owned. However, if a hospital is adding a physician/non-physician practitioner clinic or group practice to its Form CMS-855A enrollment, a fee is required because the hospital is adding a practice location.

C. Hardship Exception

1. Background

A provider or supplier requesting a hardship exception from the application fee must include with its enrollment application a letter (and any supporting documentation) that describes the hardship and why the hardship justifies an exception. If a paper Form CMS-855 application is submitted, the hardship exception letter must accompany the application; if the application is submitted via Internet-based PECOS, the hardship exception letter must accompany the certification statement. Hardship exception letters shall not be considered if they were submitted separately from the application or certification statement, as applicable. If the contractor receives a hardship exception request separately from the application or certification statement, it shall: (1) return it to the provider, and (2) notify the provider via letter, e-mail or telephone that it will not be considered.

2. Criteria for Determination

The application fee for Calendar Year 2012 is $523 and generally should not represent a

significant burden for an adequately capitalized provider or supplier. Hardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship. The provider must instead make a strong argument to support its request, including providing comprehensive documentation (which may include, without limitation, historical cost reports, recent financial reports such as balance sheets and income statements, cash flow statements, tax returns, etc.).

Other factors that may suggest that a hardship exception is appropriate include the following:

(a) Considerable bad debt expenses,

(b) Significant amount of charity care/financial assistance furnished to patients,

(c) Presence of substantive partnerships (whereby clinical, financial integration are present) with those who furnish medical care to a disproportionately low-income population;

(d) Whether an institutional provider receives considerable amounts of funding through disproportionate share hospital payments, or

(e) Whether the provider is enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act).

Upon receipt of a hardship exception request with the application or certification statement, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its Provider Enrollment Operations Group (PEOG) liaison. PEOG has 60 calendar days from the date of the contractor's receipt of the hardship exception request to determine whether it should be approved; during this period, the contractor shall not commence processing the provider's application. PEOG will communicate its decision to the provider and the contractor via letter, after which the contractor shall carry out the applicable instructions in section 19.1(D) below.

Note that if the provider fails to submit appropriate documentation to support its request, the contractor is not required to contact the provider to request it. The contractor can simply forward the request "as is" to its PEOG liaison. Ultimately, it is the provider's responsibility to furnish the necessary supporting evidence at the time it submits its hardship exception request.

D. Receipt

Upon receipt of a paper application (or, if the application is submitted via Internet-based PECOS, upon receipt of a certification statement) from a provider or supplier that

is otherwise required to submit an application fee, the contractor shall first determine whether the application is an initial enrollment, a revalidation, or involves the addition of a practice location. If the application does not fall within any of these categories, the contractor shall process the application as normal. If it does fall within one of these categories, the contractor shall undertake the following:

a. Determine whether the provider has: (1) paid the application fee via Pay.gov, and/or (2) included a hardship exception request with the application or certification statement. The contractor can verify payment of the application fee by checking:

- Whether the provider has included with its application or certification statement a Pay.gov receipt as proof of payment, and/or

- The Fee Submitter List

b. If the provider:

i. Has neither paid the fee nor submitted the hardship exception request, the contractor shall send a letter to the provider notifying it that it has 30 days from the date of the letter to pay the application fee via Pay.gov, and that failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations). The letter shall also state that because a hardship exception request was not submitted with the original application, CMS will not consider granting a hardship exception in lieu of the fee.

   During this 30-day period, the contractor shall review each updated Fee Submitter List to determine whether the fee has been paid via Pay.gov. If the fee is paid within the 30-day period, the contractor may begin processing the application as normal. If the fee is not paid within the 30-day period, the contractor shall reject the application (initial enrollments and new locations) under 42 CFR §424.525(a)(3) or revoke the provider's Medicare billing privileges under 42 CFR §424.535(a)(6) (revalidations).

   Note that if, at any time during this 30-day period, the provider submits a Pay.gov receipt as proof of payment, the contractor shall begin processing the application as normal.

ii. Has paid the fee but has not submitted a hardship exception request, the contractor shall begin processing the application as normal.

iii. Has submitted a hardship exception request but has not paid a fee, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG liaison. If PEOG:

a. Denies the hardship exception request, it will notify the provider in the decision letter (on which the contractor will be copied) that the application fee must be paid within 30 calendar days from the date of the letter. During this 30-day period, the contractor shall review each updated Fee Submitter List to determine if the fee has been submitted via Pay.gov. If the fee is not paid within 30 calendar days, the contractor shall deny the application (initial enrollments and new locations) pursuant to 42 CFR §424.530(a)(9) or revoke the provider's Medicare billing privileges under 42 CFR §424.535(a)(6) (revalidations).

   If, at any time during this 30-day period, the provider submits a Pay.gov receipt as proof of payment, the contractor shall begin processing the application as normal.

b. Approves the hardship exception request, it will notify the provider of such in the decision letter (on which the contractor will be copied). The contractor shall begin processing the application as normal.

iv. Has submitted a hardship exception request and has paid a fee, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG liaison. As the fee has been paid, the contractor shall begin processing the application as normal.

In all cases, the contractor shall not begin processing the provider's application until: (1) the fee has been paid, or (2) the hardship exception request has been approved.

E. Appeals of Hardship Determinations

A provider may appeal PEOG's denial of its hardship exception request via the procedures outlined below:

1. If the provider is dissatisfied with PEOG's decision to deny a hardship exception request, it may file a written reconsideration request with PEOG within 60 calendar days from receipt of the notice of initial determination (e.g., PEOG's denial letter). The request must be signed by the individual provider or supplier, a legal representative, or any authorized official within the entity. Failure to file a reconsideration request within this timeframe is deemed a waiver of all rights to further administrative review.

The reconsideration request should be mailed to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment Operations Group
7500 Security Boulevard
Mailstop: AR 18-50
Baltimore, MD 21244-1850

Notwithstanding the filing of a reconsideration request, the contractor shall still carry out the post-hardship exception request instructions in subsections (D)(b)(iii)(a) and (iv) above, as applicable. A reconsideration request, in other words, does not stay the execution of the instructions in section 19.1(D) above.

PEOG has 60 calendar days from the date of the reconsideration request to render a decision. The reconsideration shall be:

(a) Conducted by a PEOG staff person who was independent from the initial decision to deny the hardship exception request.

(b) Based on PEOG's review of the original letter and documentation submitted by the provider.

Upon receipt of the reconsideration, PEOG will send a letter to the provider or supplier to acknowledge receipt of its request. In its acknowledgment letter, PEOG will advise the requesting party that the reconsideration will be conducted and a determination issued within 60 days from the date of the request.

If PEOG denies the reconsideration, it will notify the provider of this via letter, with a copy to the contractor. If PEOG approves the reconsideration request, it will notify the provider of this via letter, with a copy to the contractor, after which the contractor shall process the application as normal, or, to the extent applicable:

i. If the application has already been rejected, request that the provider resubmit the application without the fee, or

ii. If Medicare billing privileges have already been revoked, reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

Note that Corrective Action Plans (CAPs) may not be submitted in lieu of or in addition to a request for reconsideration of a hardship exception request denial.

2. If the provider is dissatisfied with the reconsideration determination regarding the application fee, it may request a hearing before an Administrative Law Judge (ALJ). Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201

ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

If the ALJ reverses PEOG's reconsideration decision and approves the hardship exception request, and the application has already been rejected, the contractor – once PEOG informs it of the ALJ's decision - shall notify the provider via letter, e-mail or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

3. If the provider is dissatisfied with the ALJ's decision, it may request Board review by the Departmental Appeals Board (DAB). Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

If the DAB reverses the ALJ's decision and approves the hardship exception request, and the application has already been rejected, the contractor - once PEOG informs it of the DAB's decision - shall notify the provider via letter, e-mail or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

To the extent permitted by law, a provider or supplier dissatisfied with a DAB decision may seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.

F. Miscellaneous

The contractor shall abide by the following:

1. Paper Checks Submitted Outside of Pay.gov – As stated earlier, all payments must be made via Pay.gov. Should the provider submit an application with a paper check or any other hard copy form of payment (e.g., money order), the contractor shall not deposit the instrument. It shall instead treat the situation as a non-submission of the fee and follow the instructions in (D)(b)(i) or (iii) above (depending on whether a hardship exception request was submitted). When sending the applicable letter requesting payment within 30 days, the contractor shall explain that all payments must be made via.Pay.gov, stamp the submitted paper check "VOID," and include the voided paper check with the letter.

2. Practice Locations – DMEPOS suppliers, federally qualified health centers

(FQHCs), and independent diagnostic testing facilities (IDTFs) must individually enroll each site. Consequently, the enrollment of each site requires a separate fee. For **all other providers and suppliers** (except physicians, non-physician practitioners, and physician and non-physician practitioner groups, none of which are required to submit the fee), a fee must accompany any application that adds a practice location. If multiple locations are being added on a single application, however, only one fee is required. The fee for providers and suppliers other than DMEPOS suppliers, FQHCs, and IDTFs is based on the application submission, not the number of locations being added on a single application.

3. Other Application Submissions – A provider or supplier need not pay an application fee if the application is:

   - Reporting a change of ownership via the Form CMS-855B or Form CMS-855S. (For providers and suppliers reporting a change of ownership via the Form CMS-855A, the ownership change does not necessitate an application fee if the change does not require the provider or supplier to enroll as a new provider or supplier.)

   - Reporting a change in tax identification number (whether Part A, Part B, or DMEPOS)

   - Requesting a reactivation of the provider's Medicare billing privileges

   - Changing the physical location of an existing practice location (as opposed to reporting an additional/new practice location).

   Note that the application fee requirement is separate and distinct from the site visit requirement and risk categories discussed below. Physicians, non-physician practitioners, physician groups and non-physician practitioner groups are exempt from the application fee even if they fall within the "high" level of categorical screening per section 15.19.2.5 of this chapter. Similarly, physical therapists enrolling as individuals or group practices need not pay an application fee even though they fall within the "moderate" level of categorical screening and are subject to a site visit.

4. Non-Payment of the Fee - If the application is rejected or denied due to non-payment of the fee, the contractor shall:

   - Enter the application into PECOS, with the receipt date being the date on which the contractor received the application in its mailroom.

   - Indicate in PECOS that a developmental request was made.

   - Switch the enrollment record to a "denied" or "rejected" status, as applicable per section 19.1(D).

- Notify the applicant of the rejection or denial in accordance with section 19.1(D).

15.19.2 – Screening Categories
(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

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

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

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

A. Limited

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

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

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

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

B. Moderate

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

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

For providers and suppliers in the "moderate" level of categorical screening, the contractor shall (unless section 15.19.2.2 of this chapter or another CMS directive applies):

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

2. Except for revalidating DMEPOS suppliers, order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) in accordance with sections 2(a) through (e) below. The site visit, which the National Site Visit Contractor (NVSC) will perform, is to ensure that the supplier is in compliance with CMS's

enrollment requirements. Unless stated otherwise in this chapter, the scope of the site visit will be consistent with section 15.19.2.2.

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

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

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

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

b. CMHCs

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

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

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

c. CORFs, hospices and PXRSs

- Initial application – If the provider/supplier submits an initial application, the contractor shall order a site visit after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the provider/supplier. The contractor shall not convey Medicare billing privileges to the provider/supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.

- Revalidation – If the provider/supplier submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

- New location - The contractor shall order a site visit of the location after the contractor receives notice of approval from the RO but before the contractor switches the provider/supplier's enrollment record to "Approved." The contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

d. IDTFs

   - Initial applications – The NSVC will conduct site visits of initially enrolling IDTFs consistent with section 15.4.19.6 of this chapter.

   - Revalidations - The NVSC will conduct site visits of revalidating IDTFs (prior to the contractor's final decision regarding the revalidation application) consistent with section 15.4.19.6 of this chapter.

   - Code Changes – The NSVC will conduct site visits for IDTF code changes as specified in section 15.4.19.6(B) of this chapter.

e. Revalidating HHAs – If an HHA submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

f. Revalidating DMEPOS suppliers – The National Supplier Clearinghouse (NSC) shall conduct a site visit of the DMEPOS supplier prior to making a final decision regarding the revalidation application.

C. High

The "high" level of categorical screening consists of the following provider and supplier types:

- Newly enrolling DMEPOS suppliers
- Newly enrolling HHAs

For providers and suppliers in the "high" level of categorical screening:

1. The contractor shall process the application in accordance with existing instructions; and

2. The NSVC will perform a site visit for newly enrolling HHAs. (The NSC will perform a site visit for newly enrolling DMEPOS suppliers.) For initially enrolling HHAs, the contractor shall order a site visit via PECOS after the contractor receives the tie-in notice or approval letter from the RO but before the contractor switches the provider's enrollment record to "Approved." The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

Note: Also, the following:

- Enrolled DMEPOS suppliers that are adding another location will be classified as "high" for screening purposes. (See section 19.2.3 below for information regarding DMEPOS changes of ownership and tax identification number (TIN) changes.)

- Newly-enrolling HHA sub-units fall within the "high" level of categorical screening.

- The addition of a new HHA branch falls within the "moderate" level of categorical screening. The contractor shall order a site visit of the location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." This is to ensure that the provider is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

This is the only site visit of the new HHA branch that must be performed prior to the record being switched to "Approved."

15.19.2.2 - Scope of Site Visit

(Rev. 414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. DMEPOS Suppliers and IDTFs

The scope of site visits of DMEPOS suppliers and IDTFs shall continue to be conducted in accordance with existing CMS instructions and guidance.

B. Other Provider and Supplier Types

For all provider and supplier types – other than DMEPOS suppliers and IDTFs – that are subject to a site visit in accordance with this section, the SVC will perform such visits consistent with the procedures outlined in sections 20 and 20.1 of this chapter. This includes the following:

- Documenting the date and time of the visit, and including the name of the individual attempting the visit;

- Photographing the provider or supplier's business for inclusion in the provider/supplier's file. All photographs will be date/time stamped;

- Fully documenting observations made at the facility, which could include facts such as: (a) the facility was vacant and free of all furniture; (b) a notice of eviction or similar documentation is posted at the facility, and (c) the space is now occupied by another company;

- Writing a report of the findings regarding each site verification; and

- Including a signed declaration stating the facts and verifying the completion of the site verification. (The sample declaration identified in section 20.1 of this chapter is recommended.)

In terms of the extent of the visit, the SVC will determine whether the following criteria are met:

- The facility is open

- Personnel are at the facility

- Customers are at the facility (if applicable to that provider or supplier type)

- The facility appears to be operational

This will require the site visitor(s) to enter the provider or supplier's practice location/site, rather than simply conducting an external review.

If any of the 4 elements listed above are not met, the enrollment contractor will, as applicable - and using the procedures outlined in this chapter and in existing CMS instructions - deny the provider's enrollment application pursuant to §424.530(a)(5)(i) or (ii), or revoke the provider's Medicare billing privileges under §424.535(a)(5)(i) or (ii).

15.19.2.3 – Changes of Information and Ownership
(Rev. 414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. Limited

Changes of information (including additions of practice locations) submitted by providers and suppliers in the "limited" level of categorical screening shall be processed in accordance with existing instructions.

B. Moderate and High

Unless otherwise specified in this chapter or in another CMS directive, this section 15.19.2.3(B) applies to providers and suppliers in the "moderate" or "high" level of categorical screening.

1. Addition of Practice Location

With the exception of suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), if a provider or supplier submits a Form CMS-855 request to add a practice location (including a home health agency (HHA) branch):

- The contractor shall process the application in accordance with existing instructions, and

- A site visit shall be performed consistent with section 15.19.2.1 above.

(As explained earlier, a DMEPOS supplier that is adding a new practice location falls within the "high" screening category.)

2. Change of Location

a. DMEPOS Suppliers

If a DMEPOS supplier reports a change in the physical location of an existing practice location, the National Supplier Clearinghouse shall perform a site visit in accordance with existing instructions.

b. Non-DMEPOS Suppliers

If a provider or non-DMEPOS supplier reports a change in the physical location of an existing practice location, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) in accordance with the following:

i. Ambulance service suppliers, independent clinical laboratories, independent diagnostic testing facilities, physical therapists enrolling as individuals or group

practices – The contractor shall order a site visit of the changed location prior to the contractor's final decision regarding the application. This is to ensure that the location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2 of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not make its final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

ii. Community mental health centers, comprehensive outpatient rehabilitation facilities, hospices, portable x-ray suppliers, HHAs - The contractor shall order a site visit of the changed location after the contractor receives notice of approval from the RO but before the contractor switches the provider/supplier's enrollment record to "Approved." This is to ensure that the location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2 of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

For purposes of this requirement:

- A change of location includes situations in which the provider/supplier is switching suite numbers or floors within a building. A site visit is required.

- If the provider/supplier's physical location is not changing (e.g., the provider's street name is changing but its actual office space is not), no site visit is required.

3. Change of Ownership

With the exception of DMEPOS suppliers and HHAs, if a provider or supplier undergoes a change of ownership resulting in a new tax identification number (TIN), the contractor shall:

(1) Process the application in accordance with existing instructions, and

(2) Order a site visit through PECOS in accordance with the following:

- For ownership changes that must be approved by the RO under current CMS instructions, the site visit shall be ordered and performed after the contractor receives notice of approval from the RO but before the contractor switches the provider/supplier's enrollment record to an "Approved" status. The contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

- For ownership changes that do not require RO approval under current CMS instructions, the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.

A DMEPOS supplier that is:

- Undergoing a change of ownership with a change in TIN falls within the "high" screening category.

- Undergoing a change of ownership with no change in TIN falls within the "moderate" screening category.

- Undergoing a change in TIN with no change in ownership falls within the "moderate screening category.

With respect to HHAs:

- For HHAs undergoing a change in majority ownership, the contractor shall – consistent with section 15.26.1 of this chapter – determine whether the provisions of 42 CFR §424.550(b)(1) and (2) apply. If the contractor determines that a change in majority ownership has occurred and that none of the exceptions in §424.550(b)(2) apply, the HHA must enroll as a new entity, in which case the newly-enrolling HHA will be placed into the "high" level of categorical screening. If the contractor determines that an exception does apply, the transaction will be subject to the "moderate" level of categorical screening; a site visit will be necessary.

  In addition, if: (1) the contractor determines that one of the exceptions to the 36-month rule applies, and (2) the ownership change is one that requires a recommendation for approval to the RO, the contractor shall ensure that its recommendation letter specifies:

  - That the transaction qualifies as a change in majority ownership

  - The particular exception that applies.

- For HHAs reporting an ownership change that is not a change in majority ownership as that term is defined in §424.502, the contractor shall process the change in accordance with existing instructions. A site visit is not necessary.

- For HHAs seeking to reactivate their Medicare billing privileges, the transaction shall be processed under the "moderate" level of categorical screening. A site visit will be necessary prior to the reactivation of the provider's billing privileges.

4. All Other Changes of Information

All other changes of information for providers and suppliers in the moderate or high level of categorical screening shall be processed in accordance with existing instructions.

15.19.2.4 – Reactivations
(Rev. 414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

A. Limited

Reactivation applications submitted by providers and suppliers in the "limited" level of categorical screening shall be processed in accordance with existing instructions.

B. Moderate

Reactivation applications submitted by providers and suppliers in the "moderate" level of categorical screening – including existing home health agencies and suppliers of durable medical equipment, prosthetics, orthotics and suppliers (DMEPOS) – shall be processed in accordance with the screening procedures for this category. A site visit will therefore be necessary prior to the contractor's final decision regarding the application.

C. High

Reactivation applications submitted by providers and suppliers in the "high" level of categorical screening shall be processed in accordance with the screening procedures for this category. A site visit will therefore be necessary prior to the contractor's final decision regarding the application.

15.19.2.5 – Movement of Providers and Suppliers into the High Level
(Rev. 414, Issued: 04-06-12, Effective: 05-07-12, Implementation: 05-07-12)

Under §424.518(c)(3), CMS may adjust a particular provider or supplier's screening level from "limited" or "moderate" to "high" if any of the following occur:

1. CMS imposes a payment suspension on a provider or supplier at any time within the last 10 years;

2. The provider or supplier:

    a. Has been excluded from Medicare by the Office of Inspector General; or

    b. Had its billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by:

i. Enrolling as a new provider or supplier; or
ii. Obtaining billing privileges for a new practice location

c. Has been terminated or is otherwise precluded from billing Medicaid

d. Has been excluded from any Federal health care program

e. Has been subject to any final adverse action (as defined in §424.502) within the previous 10 years.

2. CMS lifts a temporary moratorium for a particular provider or supplier type, and a provider or supplier that was prevented from enrolling based on the moratorium applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

CMS sends to the contractor on a bi-monthly basis a list of current and former Medicare providers and suppliers within the contractor's jurisdiction that meet any of the criteria in subsection (1) or (2) above. Upon receipt of an initial or revalidation application from a provider or supplier that otherwise falls within the limited or moderate screening category (and after the appropriate fee has been paid, etc.), the contractor shall determine whether the provider or supplier is on the bi-monthly "high" screening list. If the provider or supplier is, the contractor shall process the application using the procedures in the "high" screening category. If the provider or supplier is not on said list, the contractor shall process the application in accordance with existing instructions.

With respect to subsection (3) above, if the contractor receives an initial or new location application from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the procedures in the "high" screening category.

15.19.3 – Temporary Moratoria

(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

Under §424.570(a), CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. In general, a moratorium will not apply to:

- Reactivations
- Revalidations
- A change in practice location
- A change of ownership (with the exception of situations in which an HHA must enroll as a new HHA in accordance with 42 CFR §424.550(b), in which case the

new application is treated as an initial enrollment and is therefore subject to the moratorium)

- Any other change in the provider or supplier's enrollment information

The announcement of a moratorium will be made via the Federal Register, though the contractor will also be separately notified of the moratorium. For initial and new location applications involving the affected provider and supplier type, the moratorium:

- Will not apply to applications for which an approval or a recommendation for approval has been made as of the effective date of the moratorium, even if the contractor has not yet formally granted Medicare billing privileges. Such applications can continue to be processed to completion.

- Will apply to applications that are pending as of the effective date of the moratorium and for which the contractor has not yet made a final approval/denial decision or recommendation for approval. The contractor shall deny such applications, using §424.535(a)(10) as the basis.

- Will apply to applications that the contractor receives on or after the effective date of the moratorium, and for as long as the moratorium is in effect. The contractor shall deny such applications, using §424.535(a)(10) as the basis.

If a particular moratorium is lifted, all applications pending with the contractor as of the effective date of the moratorium's cessation are no longer subject to the moratorium and may be processed. However, consistent with §424.518(a)(3), such applications shall be processed in accordance with the "high" level of categorical screening. In addition, any initial application received from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the "high" level of categorical screening.

15.19.4 – Tracking

(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

In April 2011, PEOG will send to each contractor an Excel spreadsheet that the contractor shall complete and submit to its PEOG liaison via e-mail no later than the 15th day of each month. The first report will be due on May 15, 2011. The spreadsheet will contain data elements such as, but not limited to:

- Number of enrolled providers and suppliers in each risk category, broken down by provider/supplier sub-type (e.g., hospital, HHA)

- Amount of fees collected (i.e., fees that were cleared), broken down by provider and supplier type

15.20 – On-site Inspections and Site Verifications
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

The contractor shall not conduct site verifications to determine if a provider or supplier (including physicians and non-physician practitioners) is operational unless CMS: (1) has already issued formal guidance to do so, or (2) issues instructions directing the contractor to conduct a pre-enrollment or post-enrollment site verification.

15.20.1 - Site Verifications
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

(Unless otherwise stated in this chapter or in another CMS directive, this section 15.20.1 only applies to site visits/verifications that are not performed pursuant to sections 15.19.2.1 through 15.19.2.4 of this chapter.)

A. Background

1. Operational Status

When conducting a site verification to determine whether a practice location is operational, the contractor shall make every effort to limit its site verification to an external review of the practice location. If the contractor cannot determine whether the practice location is operational based on an external review of the location, the contractor shall conduct an unobtrusive site verification by limiting its encounter with provider or supplier personnel or medical patients.

2. Determining Whether the Provider or Supplier Meets Regulatory Requirements for Its Provider or Supplier Type

When conducting a site verification to determine whether a provider or supplier continues to meet the regulatory provisions for its provider or supplier type, the contractor shall conduct its site verification in a manner which limits the disruption for the provider or supplier.

B. Timing

Site verifications should be done Monday through Friday (excluding holidays) during their posted business hours. If there are no hours posted, the site verification should occur between 9 a.m. and 5 p.m. If, during the first attempt, there are obvious signs that facility is no longer operational no second attempt is required. If, on the first attempt the facility is closed but there are no obvious indications the facility is non-operational, a second attempt on a different day during posted hours of operation should be made.

C. Documentation

When conducting site verifications to determine whether a practice location is operational, the contractor shall:

- Document the date and time of the attempted visit and include the name of the individual attempting the visit;

- As appropriate, photograph the provider or supplier's business for inclusion in the provider or supplier's file on an as needed basis. All photographs should be date/time stamped;

- Fully document all observations made at the facility (e.g., the facility was vacant and free of all furniture, a notice of eviction or similar documentation was posted at the facility, the space is now occupied by another company); and

- Write a report of its findings regarding each site verification.

D. Signed Declaration

The contractor shall also include a signed declaration stating the facts and verifying the completion of the site verification. (A sample declaration is below and may be revised as necessary)

Declaration of <u>(Name of Inspector/Investigator)</u>
In the Case of _____
Provider/Supplier No._____

I, **<u>(Name of Inspector/Investigator)</u>**, declare as follows:

1. I have personal knowledge of each of the following matters in this Declaration except to those facts alleged on information and belief, and as to those matters, I believe them to be true. I am competent to testify to the following:

2. I am an Investigator for [Insert Contractor Name]. [Insert Contractor Name] is a CMS-contracted [Intermediary/Carrier/A/B Medicare Administrative Contractor (MAC)].

3. I have been trained as an Investigator and Site Inspector by [Insert Contractor Name], and I am knowledgeable of Medicare's compliance statutes, regulations and standards for suppliers enrolled in the Medicare program. I have worked in this capacity for [Insert years] years. During this period, I have conducted over [Insert Number] site inspections of the offices and facilities of providers/suppliers; and since January [Year in which case occurs], I have conducted over [Insert Number] site inspections related to the compliance of suppliers with Medicare's requirements.

4. I prepared the attached document entitled "[Title of Document]," which is the report of my attempts to inspect Petitioner's facility. This report is a true and accurate account of the events that occurred and transpired on the dates described therein. I am

capable and willing to testify as a witness at a hearing about the content of this report.

5. The foregoing information is based on my personal knowledge or is information provided to me in my official capacity. I declare under penalty of perjury that this information is true and correct to the best of my knowledge and belief.

Executed this _**(Date)**__ day of _**(Month) (Year)**_ in _**(City)**_, _**(State)**_.

_____
SIGNATURE OF DECLARANT

E. Determination

If a provider or supplier is determined not to be operational or not to be in compliance with the regulatory requirements for its provider/supplier type, the contractor shall revoke the Medicare billing privileges of the provider or supplier - unless the provider or supplier has submitted a change that notified the contractor of a change in practice location. Within 7 calendar days of CMS or the Medicare contractor determining that the provider or supplier is not operational, the Medicare contractor shall update PECOS or the applicable claims processing system (if the provider does not have an enrollment record in PECOS) to revoke billing Medicare billing privileges and issue a revocation notice to the provider or supplier. The Medicare contractor shall afford the provider or supplier applicable appeal rights in the revocation notification letter.

For non-operational status revocations, the contractor shall use either 42 CFR §424.535(a)(5)(i) or 42 CFR §424.535(a)(5)(ii) as the legal basis for revocation.

Consistent with 42 CFR §424.535(g), the date of revocation is the date on which CMS or the contractor determines that the provider or supplier is no longer operational. The Medicare contractor shall establish a 2-year enrollment bar for suppliers that are not operational.

For regulatory non-compliance revocations, the contractor shall use 42 CFR §424.535(a)(1) as the legal basis for revocation. Consistent with 42 CFR §424.535(g), the date of revocation is the date on which CMS or the contractor determines that the provider or supplier is no longer in compliance with regulatory provisions for their provider or supplier type. The Medicare contractor shall establish a 2-year enrollment bar for the providers and suppliers that are not in compliance with provisions for their enrolled provider or supplier type.

15.20.2 - Reserved for Future Use

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

15.20.3 - National Supplier Clearinghouse (NSC)

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

The (NSC) shall continue to conduct onsite inspections consistent with its Statement of Work and any instructions issued by the NSC project officer.

15.21 – Special Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Instructions

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

This section instructs the NSC on the appropriate handling of certain situations involving DMEPOS suppliers.

15.21.1 – DMEPOS Supplier Accreditation

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

The DMEPOS suppliers must be accredited prior to submitting an application to NSC on or after March 1, 2008. The NSC shall not approve any DMEPOS supplier's enrollment application if the enrollment package does not contain an approved accreditation upon receipt or in response to a developmental request. The NSC may reject an enrollment application if the DMEPOS supplier fails to provide supporting documentation which demonstrates that the supplier has an approved accreditation. Moreover, for any application that is pending (i.e., not processed to completion) as of March 1, 2008, the contractor shall develop for accreditation.

The DMEPOS suppliers that are enrolled for the first time with the NSC between January 1, 2008, and February 28, 2008, must obtain and submit an approved accreditation to the NSC by January 1, 2009. The NSC shall revoke a DMEPOS supplier's billing privileges if the DMEPOS supplier fails to obtain and submit supporting documentation that the DMEPOS supplier has been accredited.

The DMEPOS suppliers enrolled in the Medicare program prior to January 1, 2008, are required to obtain and submit an approved accreditation to the NSC by September 30, 2009. The NSC shall revoke a DMEPOS supplier's billing privileges if the DMEPOS supplier fails to obtain and submit supporting documentation that the DMEPOS supplier has been accredited.

15.21.1.1 – Compliance Standards for Pharmacy Accreditation

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

The National Supplier Clearinghouse (NSC) shall not require that a pharmacy be accredited as a condition of enrollment before January 1, 2011.

The NSC-Medicare Administrative Contractor (MAC) shall determine which enrolled suppliers are pharmacies that are not accredited and who will be enrolled for 5 calendar years prior to January 1 of the next calendar year. The NSC-MAC shall then send a notice of revocation by January 10, 2011, to all enrolled pharmacies that are not accredited and who will not be enrolled for 5 calendar years as of January 1, 2011.

The NSC-MAC shall prepare a letter which enables all individually enrolled practice locations of pharmacies who have been enrolled for 5 calendar years prior to January 1, 2011, to attest that they are exempt from the requirement to be accredited because their total durable medical equipment, prosthetics orthotics and supplies (DMEPOS) billings subject to accreditation are less than 5 percent of their total pharmacy sales, as determined based upon the total pharmacy sales of the pharmacy for the previous 3 calendar or fiscal years. The letter shall cite that the attestation requires the signature of the authorized or delegated official of the entity. The authorized and delegated officials are defined in Section 15, of the Medicare Enrollment Application (CMS-855S), and as described in the internet enrollment application version of the Provider Enrollment, Chain and Ownership System (PECOS). Before mailing the letters, the NSC-MAC shall obtain NSC project officer approval of the letter. The mailing shall be in the form of an endorsement letter with an enclosed stamped self addressed envelope. The mailing should be performed between October 1, 2010 and October 31, 2010. For pharmacies with more than one practice location, the letters shall cite the need for each individually enrolled practice location to attest that they are exempt from the accreditation requirements. New locations of enrolled chain pharmacies shall not be considered to have been enrolled for 5 calendar years. Pharmacies that have had a change of ownership in the prior 5 years which resulted in a change in their legal business entity, including a change in their tax identification number (TIN), shall not qualify for an attestation accreditation exemption and therefore shall not be sent the attestation letter.

The NSC-MAC shall review the attestations received from pharmacies. Pharmacies that properly signed the attestation letter shall be given an accreditation status of exempt. The NSC shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their attestations. The NSC-MAC shall send a notice of revocation by January 10, 2011, to all enrolled pharmacies who were sent an attestation letter and have not properly completed it as of the date of the notice of revocation. The notice of revocation shall cite that the revocation is for a lack of required accreditation.

Between April 1, 2011 and April 30, 2011, the NSC-MAC shall compile a sample listing of at least 10 percent of the pharmacies that have submitted an NSC accepted attestation exempting them from accreditation. The NSC-MAC shall develop a letter to be sent to pharmacies that will be audited to determine if their accreditation exemption attestations are correct. The letter shall request submission of evidence substantiating that the validity of the pharmacy supplier's attestation. At a minimum, requested materials for this evidence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods. The NSC-MAC shall obtain NSC project officer approval of the letter. Within 45 days after project officer approval of the letter the NSC-MAC shall mail a copy of the letter to the random sample of pharmacies which claimed exemption through an attestation. The NSC-MAC shall determine the acceptability of the replies received in response to the audit verification random sample mailing. The NSC shall use

DMEPOS billing data for only products and services requiring accreditation to assist in the determination. The NSC shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their audit verifications. The NSC-MAC shall consult with the NSC project officer in cases where they are uncertain as to the acceptability of the supplier's response to the audit request. By June 30, 2011, the NSC-MAC shall send a notice of revocation to all enrolled pharmacies that were sent an audit verification letter who did not submit satisfactory evidence that they were in compliance with the requirements to obtain an accreditation exemption. The notice of revocation shall cite that the revocation is for a lack of required accreditation.

The NSC-MAC shall follow the procedures shown above concerning issuance of attestation letters and audit survey letters for all succeeding years after they have been performed for the first time.

15.21.2 – Enrolling Indian Health Service (IHS) Facilities as DMEPOS Suppliers

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

The NSC shall enroll IHS facilities as DMEPOS suppliers in accordance with the general enrollment procedures cited in chapter 15 and the statement of work contained in the NSC contract with Medicare, with the addition of the special procedures and clarifications cited in this section.

For enrollment purposes Medicare recognizes two types of IHS facilities. They are: a) those facilities wholly owned and operated by the IHS and b) facilities which are owned by the IHS but tribally operated or totally owned and operated by a tribe. CMS shall provide the NSC with a list of IHS facilities which distinguish between these two types.

On the list the NSC shall use the column entitled, "FAC OPERATED BY", for this purpose.

1. Completion of the Medicare Supplier Enrollment Application: CMS-855S Application for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers. The CMS-855S shall be completed in accordance with the instructions shown therein except as follows:

a. Facilities that are totally owned and operated by the IHS are considered a governmental organization. An Area Director of the IHS must sign the section 15 Certification Statement of the CMS–855S, be listed in section 6 of the form and sign the letter required by section 5 of the form which attests that the IHS will be legally and financially responsible in the event that there is any outstanding debt owed to CMS.

b. Facilities that are tribally operated are considered tribal organizations. The section 15 Certification Statement of the CMS–855S must be signed by a tribal official who meets the definition of an authorized official in accordance with the page 2

definitions shown on the CMS– 855S. The same authorized official must be listed in section 6 of the CMS–855S and must sign the letter required by section 5 of the form which attests that the tribe will be legally and financially responsible in the event that there is any outstanding debt owed to CMS.

2. The DMEPOS Supplier Standards, Exceptions for Liability Insurance and State Licensure, and Site Visits

All IHS facilities, whether operated by the IHS or a tribe, enrolled by the NSC, shall meet all required standards as verified by the review procedures for all other DMEPOS suppliers except as discussed herein.

All IHS facilities, whether operated by the IHS or a tribe, shall be exempt from the comprehensive liability insurance requirements under 42 CFR 424.57(c)(10).

All IHS facilities, whether operated by the IHS or a tribe, shall be exempt from the requirement to provide any State Licenses for their facility/business. For example, if the DMEPOS supplier indicates on its application that it will be providing hospital beds and is located in a State that requires a bedding license, such licensure is not required. However, if they provide a DMEPOS item that requires a licensed professional in order to properly provide the item, they shall provide a copy of the professional license. The licensed professional can be licensed in any State or have a Federal license. For example, a pharmacy does not need a pharmacy license, but shall have a licensed pharmacist.

Site visits shall be required for all IHS facilities (whether operated by the IHS or a tribe) enrolling for DMEPOS. This includes all hospitals and pharmacies.

3. Provider Education for IHS Facilities

The NSC shall modify its Web site to include the information contained in this section which is specific to enrollment of IHS facilities (whether operated by the IHS or a tribe).

4. Specialty Codes

The NSC shall apply the specialty code A9 (IHS) for all IHS enrollments (whether operated by the IHS or a tribe). However, the specialty code A9/A0 shall be applied for facilities that are IHS/tribal hospitals. Additionally other specialty codes should be applied as applicable (e.g., pharmacy).

15.21.3 - Special Situations Concerning Accreditation and Enrollment

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

1. A change of ownership application for an existing supplier location submitted by a new owner company with a new tax identification number (TIN) shall be rejected

(consistent with 42CFR §424.525) if the new owner does not have an accreditation that covers all of its locations. If the old owner does have such an accreditation, the new owner could be enrolled as of the date of sale if the accreditor determines that the accreditation should remain in effect as of the date of sale. (This, however, is only applicable when the new owner also meets all other enrollment criteria found at 42CFR §424.57). If the new owner submits an application without evidence that the accreditation is still in effect for the new owner, the application should be rejected.

2. Some ownership changes do not result in a complete change of ownership, since the business entity remains the same with no change in TIN. However, in cases where more than 5 percent of the ownership has changed, the following principles apply:

- If the change in ownership has not been reported to the NSC within the required 30-day period, the NSC shall proceed with revocation action.

- If the change has been received within the required 30-day period and the supplier has been accredited, the NSC shall immediately notify the accreditor of the ownership change and request that the latter advise the NSC if the accreditation should still remain in effect.

3. A DMEPOS supplier requesting reactivation after a deactivation for non-billing shall be required to be accredited on or after March 1, 2008.

4. A revoked DMEPOS supplier that has submitted an acceptable corrective action plan can be reinstated without accreditation unless the accreditation was already required prior to revocation.

5. A DMEPOS supplier that has been deactivated for failing to respond to a reenrollment request shall obtain accreditation if the reenrollment occurs after February 29, 2008.

6. DMEPOS suppliers with 25 or more enrolled locations prior to March 1, 2008, may enroll additional locations without accreditation until September 30, 2009.

15.21.4 - Development and Use of Fraud Level Indicators

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

The NSC-MAC shall perform a fraud potential analysis of all DMEPOS applicants and current DMEPOS suppliers. The fraud level indicator shall represent the potential for fraud and/or abuse. The NSC-MAC shall use four fraud level indicator codes as follows:

1. Low Risk (e.g., national drug store chains),

2. Limited Risk (e.g., prosthetist in a low fraud area),

3. Medium Risk (e.g., midsize general medical supplier in a high fraud area), and

4. High Risk (e.g., very small space diabetic supplier with low inventory in a high fraud area whose owner has previously had a chapter 7 bankruptcy). High fraud areas shall be determined by contractor analysis with concurrence of the NSC-MAC's project officer.

In assessing a fraud level indicator, the NSC-MAC shall consider such factors as:

1. Experience as a DMEPOS supplier with other payers,
2. Prior Medicare experience,
3. The geographic area,
4. Fraud potential of products and services listed,
5. Site visit results,
6. Inventory observed and contracted, and
7. Accreditation of the supplier.

After a fraud level indicator is assigned and the DMEPOS supplier is enrolled, the NSC-MAC shall establish a DMEPOS Review Plan based on the fraud level assessment. The DMEPOS Review Plan would contain information regarding:

1. Frequency of unscheduled site visits,
2. Maximum billing amounts before recommendation for prepay medical review,
3. Maximum billing spike amounts before recommendation for payment suspensions/prepay medical review, etc.

The fraud level indicator shall be updated based upon information obtained through the Medicare enrollment process, such as reported changes of information.

Information obtained by the Office of Inspector General (OIG), CMS (including CMS satellite office) and/or a PSC shall be reported to the NSC-MAC project officer or its designee. The NSC-MAC shall update the fraud level indicator based on information obtained by the OIG, CMS (including CMS satellite office) and/or a PSC only after the review and concurrence of the NSC-MAC project officer or its designee.

In addition, the NSC-MAC should monitor and assess geographic trends which indicate or demonstrate that one geographic area has a higher potential for having fraudulent suppliers.

15.21.4.1 - Fraud Prevention and Detection

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

The NSC-MAC shall have documented evidence that they have, as a minimum, met the requirements shown below:

- Assign an appropriate fraud level indicator for at least 95 percent of all DMEPOS suppliers, upon initial or reenrollment. The fraud level indicator shall accurately reflect the risk the supplier poses to the Medicare program based on pre-defined criteria above.

- Update the DMEPOS fraud level indicator for each enrolled DMEPOS supplier on an annual basis.

15.21.5 - Alert Codes

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

The NSC-MAC shall receive and maintain the following "alert indicators" from the DME-MACs and payment safeguard contractors (PSCs)/zone program integrity contractors (ZPICs):

Alert Code	Definition
A	possible fraudulent or abusive claims identified;
B	overpayments;
D	violations of disclosure of ownership requirements;
E	violations of participation agreements;
L	suspended by Contractor outside alert code process; and
M	supplier is going through claims appeal process.

The NSC-MAC shall append the supplier file and transfer to the DME-MACs and PSCs/ZPICs the following alert codes in the following circumstances:

Alert Code	Definition
C	Violations of supplier standards;
F	Sanctioned by the Office of Inspector General or excluded by the GSA;
H	Meets supplier standards; however, the NSC-MAC recommends increased scrutiny by the contractor (initiated by NSC-MAC only);
N	Supplier being investigated under the "Do Not Forward" initiative (initiated by NSC-MAC only);
Q	Low Risk Fraud Level Indicator;

R Limited Risk Fraud Level Indicator;

S Medium Risk Fraud Level Indicator; and

T High Risk Fraud Level Indicator.

The NSC-MAC shall append an Alert Code "H" for any supplier that meets present supplier standards but appears suspect in one of the areas that are verified by the NSC-MAC. This alert code notifies the contractors that a supplier may be inclined to submit a high percentage of questionable claims.

The NSC-MAC shall share the above information with the DME-MACs and PSCs/ZPICs by sending alerts within 7 calendar days after identification of a supplier having common ownership or business ties with a sanctioned or suspect supplier for their research and/or action. The NSC-MAC also shall forward alert codes submitted by the contractors with the other contractors within 7 calendar days after receipt.

15.21.6 - Accreditation

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

The NSC-MAC shall follow the accreditation requirements in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

Individual medical practitioners, inclusive of group practices of same, shall not currently require accreditation for enrollment. The practitioner types are those specifically stated in Sections 1848(K)(3)(B) and 1842(b)(18)(C) of the Social Security Act as Amended. In addition, the practitioner categories of physicians, orthotists, prosthetists, optometrists, opticians, audiologists, occupational therapists, physical therapists and suppliers who provide drugs and pharmaceuticals (only) shall not currently require accreditation for enrollment.

Suppliers that provide only drugs and pharmaceuticals are exempt from the accreditation requirement; however, if the supplier provides equipment to administer drugs or pharmaceuticals, the supplier must be accredited.

If a previously exempted supplier enrollment application was returned for non-accreditation, the supplier must resubmit its CMS-855S Medicare enrollment application to the NSC to obtain/maintain Medicare billing privileges.

15.21.7 – Surety Bonds

(Rev. 416, Issued: 04-13-12, Effective: 02-27-12, Implementation: 02-27-12)

A. Background

1. Surety Bond Exemptions

All DMEPOS suppliers are subject to the surety bond requirement, except:

- Government-operated DMEPOS suppliers are exempted if the supplier has provided CMS with a comparable surety bond under State law.

- State-licensed orthotic and prosthetic personnel (which, for purposes of the surety bond requirement, does not include pedorthists) in private practice making custom-made orthotics and prosthetics are exempted if—

    - The business is solely-owned and operated by the orthotic and prosthetic personnel, and

    - The business is only billing for orthotic, prosthetics, and supplies.

- Physicians and non-physician practitioners, as defined in section 1842(b)(18) of the Social Security Act, are exempted if the items are furnished only to the physician or non-physician practitioner's own patients as part of his or her physician service. The non-physicians covered under this exception are: 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.

- Physical and occupational therapists in private practice are exempted if—

    - The business is solely-owned and operated by the physical or occupational therapist;

    - The items are furnished only to the physical or occupational therapist's own patients as part of his or her professional service; and

    - The business is only billing for orthotics, prosthetics, and supplies.

If a previously-exempted DMEPOS supplier no longer qualifies for an exception, it must submit a surety bond to the NSC - in accordance with the requirements in 42 CFR §424.57 - within 60 days after it knows or has reason to know that it no longer meets the criteria for an exception.

2. Bond Submission

Effective May 4, 2009, DMEPOS suppliers submitting: (1) an initial enrollment application to enroll in the Medicare program for the first time, (2) an initial application to establish a new practice location, or (3) an enrollment application to change the ownership of an existing supplier, are required to obtain and submit a copy of its required surety bond to the NSC with their CMS-855S enrollment application. (**NOTE:** Ownership changes that do not involve a change in the status of the legal entity as evidenced by no change in the tax identification number, or changes that result in the

same ownership at the level of individuals (corporate reorganizations and individuals incorporating) are not considered to be "changes of ownership" for purposes of the May 4, 2009, effective date – meaning that such suppliers are considered "existing" suppliers).

For any CMS-855S application submitted on or after May 4, 2009, by a supplier described in this section (2), the NSC shall reject the application if the supplier does not furnish a valid surety bond at the time it submits its application. The rejection shall be done in accordance with existing procedures (e.g., reject application after 30 days).

3. Amount and Basis

The surety bond must be in an amount of not less than $50,000 and is predicated on the NPI, not the tax identification number. Thus, if a supplier has two separately-enrolled DMEPOS locations, each with its own NPI, a $50,000 bond must be obtained for each site.

A supplier may obtain a single bond that encompasses multiple NPIs/locations. For instance, if a supplier has 10 separately-enrolled DMEPOS locations, it may obtain a $500,000 bond that covers all 10 locations.

As stated in 42 CFR §424.57(d)(3), a supplier will be required to maintain an elevated surety bond amount of $50,000 for each final adverse action imposed against it within the 10 years preceding enrollment or reenrollment. This amount is in addition to, and not in lieu of, the base $50,000 amount that must be maintained. Thus, if a supplier has had two adverse actions imposed against it, the bond amount will be $150,000.

A final adverse action is one of the following:

- A Medicare-imposed revocation of Medicare billing privileges;
- Suspension or revocation of a license to provide health care by any State licensing authority;
- Revocation or suspension by an accreditation organization;
- A conviction of a Federal or State felony offense (as defined in §424.535(a)(3)(i)) within the last 10 years preceding enrollment or re-enrollment; or
- An exclusion or debarment from participation in a Federal or State health care program.

4. Bond Terms

The supplier is required to submit a copy of the bond that - on its face - reflects the requirements of 42 CFR §424.57(d). Specific terms that the bond must contain include:

- A guarantee that the surety will - within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond of unpaid claims, civil monetary penalties (CMPs), or assessments - pay CMS a total of up to the full penal amount of the bond in the following amounts:

- The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible, and

- The amount of any unpaid claims, CMPs, or assessments imposed by CMS or the OIG on the DMEPOS supplier, plus accrued interest.

- A statement that the surety is liable for unpaid claims, CMPs, or assessments that occur during the term of the bond.

- A statement that actions under the bond may be brought by CMS or by CMS contractors.

- The surety's name, street address or post office box number, city, State, and zip code.

- Identification of the DMEPOS supplier as the Principal, CMS as the Obligee, and the surety (and its heirs, executors, administrators, successors and assignees, jointly and severally) as the surety.

The term of the initial surety bond must be effective on the date that the application is submitted to the NSC. Moreover, the bond must be continuous.

5. Sureties

The list of sureties from which a bond can be secured is found at Department of the Treasury's "Listing of Certified (Surety Bond) Companies;" the Web site is **www.fms.treas.gov/c570/c570_a-z.html**. For purposes of the surety bond requirement, these sureties are considered "authorized" sureties, and are therefore the only sureties from which the supplier may obtain a bond.

6. Bond Cancellations and Gaps in Coverage

A DMEPOS supplier may cancel its surety bond, but must provide written notice of such to the NSC and the surety at least 30 days before the effective date of the cancellation. Cancellation of a surety bond is grounds for revocation of the supplier's Medicare billing privileges unless the supplier provides a new bond before the effective date of the cancellation. The liability of the surety continues through the termination effective date.

If a gap in coverage exists, the NSC shall revoke the supplier's billing privileges. If a

supplier changes its surety during the term of the bond, the new surety is responsible for any overpayments, CMPs, or assessments incurred by the DMEPOS supplier beginning with the effective date of the new surety bond; the previous surety is responsible for any overpayments, CMPs, or assessments that occurred up to the date of the change of surety.

Pursuant to 42 CFR 424.57(d)(6)(iv), the surety must notify the NSC if there is a lapse in the surety's coverage of the DMEPOS supplier. This can be done via letter, fax, or e-mail to the NSC; the appropriate addresses can be found on the NSC's Web site at www.palmettogba.com/nsc.

7. Reenrollment and Reactivation

The supplier must furnish the paperwork described in subsection (A)(4) above with any CMS-855S reenrollment or reactivation application it submits to the NSC unless it already has the information on file with the NSC. For example, if a supplier has submitted a continuous surety bond to the NSC prior to submission of its reenrollment application, a new copy of surety bond is not be required unless the NSC specifically requests it.

B. Bond Changes

A DMEPOS supplier must submit an addendum to the existing bond (or, if the supplier prefers, a new bond) to the NSC in the following instances: (1) change in bond terms, (2) change in bond amount, or (3) a location on a bond covering multiple non-chain locations is being added or deleted.

15.21.7.1 – Claims Against Surety Bonds

(Rev. 403, Issued: 01-20-12, Effective: 02-21-12, Implementation: 02-21-12)

Pursuant to 42 CFR § 424.57(d)(5)(i), the surety must pay CMS - within 30 days of receiving written notice to do so - the following amounts up to the full penal sum of the bond:

(1) The amount of any unpaid claim, plus accrued interest, for which the supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) is responsible.

(2) The amount of any unpaid claim, civil monetary penalty (CMP) or assessment imposed by CMS or the Office of Inspector General (OIG) on the DMEPOS supplier, plus accrued interest.

This section 15.21.7.1 describes the procedures involved in making a claim against a surety bond.

A. Unpaid Claims

1. Background

For purposes of the surety bond requirement, 42 CFR § 424.57(a) defines an "unpaid claim" as an overpayment (including accrued interest, as applicable) made by the Medicare program to the DMEPOS supplier for which the supplier is responsible.

A surety is liable for any overpayments incurred during the term of the surety bond. This includes overpayment determinations made on or after the surety bond effective date. These overpayment determinations can relate to payments made on or after March 3, 2009. Thus, the policies in this section 15.21.7.1(A) only apply to overpayment determinations that relate to payments made on or after March 3, 2009.

2. Collection

If the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) determines – in accordance with CMS's existing procedures for making overpayment determinations - that (1) the DMEPOS supplier has an unpaid claim for which it is liable, and (2) no waiver of recovery under the provisions of Section 1870 of the Social Security Act is warranted, the DME MAC shall attempt to recover the overpayment in accordance with the instructions in CMS Pub. 100-06, chapter 4.

If 101 days have passed since the initial demand letter was sent to the DMEPOS supplier and full or partial payment has not been received, the DME MAC shall attempt to recover the overpayment via the surety bond collection process. The DME MAC shall review the "List of Bonded Suppliers" the last week of each month to determine which suppliers that are at least 101 days delinquent have a surety bond. Said List:

- Will be electronically sent to the DME MACs by the Provider Enrollment Operations Group on a monthly basis.

- Will be in the form of an Excel spreadsheet.

- Will contain the supplier's legal business name, tax identification number, National Provider Identifier, surety bond amount and other pertinent information.

If the supplier does not have a surety bond (i.e., is exempt from the surety bond requirement), the DME MAC shall continue to follow the instructions in Pub. 100-06, chapter 4, regarding collection of the overpayment.

If, however, the supplier has a surety bond, the DME MAC shall notify the surety via letter that in accordance with 42 CFR §424.57(d)(5)(i)(A), payment of the claim must be made to CMS within 30 calendar days from the date of the letter. The letter (on which the National Supplier Clearinghouse (NSC) and the supplier/debtor shall be copied) shall:

- Identify the specific amount to be paid and be accompanied by "sufficient evidence" of the unpaid claim. "Sufficient evidence" is defined in 42 CFR §424.57(a) as documents that CMS may supply to the DMEPOS supplier's surety to establish that the supplier had received Medicare funds in excess of the amount due and payable under the statute and regulations. The specific types of documents to be supplied can include Medicare overpayment determination letters and may vary according to the supplier's particular circumstances; the DME MAC therefore has significant discretion in determining what constitutes "sufficient evidence." Under no circumstances, however, shall said evidence include any personally identifiable information that is protected under the Privacy Act.

- State that payment shall be made via check or money order and that the Payee shall be the DME MAC.

- Identify the address to which payment shall be sent.

The DME MAC shall only seek repayment up to the full penal sum amount of the surety bond. Thus, if the supplier has a $60,000 unpaid claim and the amount of the supplier's bond coverage is $50,000, the DME MAC shall only seek the $50,000 amount. The remaining $10,000 will have to be obtained from the supplier via the existing overpayment collection process.

3. Verification of Payment

If full payment (including interest, as applicable) is made within the aforementioned 30-day period, the DME MAC shall, no later than 15 calendar days after payment was made:

- Update all applicable records to reflect that payment was made. (Payment from the surety shall be treated as payment from the supplier for purposes of said record updates.)

- Notify the supplier via letter (on which the NSC shall be copied) that payment has been made and that the supplier must, within 30 calendar days of the date of the letter, obtain and submit to the NSC additional bond coverage so as to ensure that the amount equals or exceeds $50,000 (or higher if an elevated bond amount is involved due to a final adverse action). Thus, if the surety made payment on a $10,000 claim, the supplier must obtain $10,000 worth of additional surety bond coverage by either: (1) adding to the amount of the existing surety bond, or (2) cancelling its current surety bond and securing a new $50,000 surety bond. (Obtaining a separate $10,000 surety bond is impermissible.)

  If the NSC does not receive the additional bond coverage within this 30-day

period, it shall revoke the supplier's Medicare billing privileges in accordance with existing procedures.

If full payment is not made within the aforementioned 30-day timeframe, the DME MAC shall refer the debt to the Department of Treasury.

If the supplier successfully appeals the overpayment and the surety has already made payment to the DME MAC on the overpayment, the DME MAC shall – within 30 calendar days of receiving notice of the successful appeal - notify the surety via letter of the successful appeal and repay the surety via check or money order.

B. Assessments and CMPs

1. Background

Per 42 CFR §424.57(a), an assessment is defined as a "sum certain that CMS or the OIG may assess against a DMEPOS supplier under Titles XI, XVIII, or XXI of the Social Security Act." Under 42 CFR §424.57(a), a CMP is defined as a sum that CMS has the authority, as implemented by 42 CFR 402.1(c) (or the OIG has the authority, under section 1128A of the Act or 42 CFR Part 1003) to impose on a supplier as a penalty.

CMS will notify the DME MAC of the need for the latter to collect payment from the surety on an assessment or CMP imposed against a particular bonded DMEPOS supplier. Upon receipt of this notification, the DME MAC shall notify the surety via letter that, in accordance with 42 CFR § 424.57(d)(5)(i)(B), payment of the assessment or CMP must be made within 30 calendar days from the date of the letter. The letter (on which the NSC and the supplier/debtor shall be copied) shall:

- Identify the specific amount to be paid and be accompanied by "sufficient evidence" (e.g., an OIG or CMS demand letter).
- State that payment shall be made via check or money order and that the Payee shall be CMS.
- Identify the address to which payment shall be sent.

2. Verification of Payment

If full payment (including interest, as applicable) is made within the aforementioned 30-day period, the DME MAC shall, no later than 15 calendar days after payment was made:

- Update all applicable records to reflect that payment was made. (Payment from the surety shall be treated as payment from the supplier for purposes of said record updates.)

- Notify the applicable CMS Regional Office (RO) via letter or e-mail that payment was made.

- If the OIG imposed the CMP or assessment, notify the OIG via letter that payment was made.

- Notify the supplier via letter (on which the NSC shall be copied) that payment has been made and that the supplier must, within 30 calendar days of the date of the letter, obtain and submit to the NSC additional bond coverage so as to ensure that the amount equals or exceeds $50,000 (or higher if an elevated bond amount is involved due to a final adverse action). Thus, if the surety made payment on a $10,000 CMP, the supplier must obtain $10,000 worth of additional surety bond coverage by either: (1) adding to the amount of the existing surety bond, or (2) cancelling its current surety bond and securing a new $50,000 surety bond. (Obtaining a separate $10,000 surety bond is impermissible.)

  If the NSC does not receive the additional bond coverage within this 30-day period, it shall revoke the DMEPOS supplier's Medicare billing privileges in accordance with existing procedures.

If full payment is not made within the aforementioned 30-day timeframe, the DME MAC shall notify the applicable RO via letter or e-mail and await further direction.

If the DMEPOS supplier successfully appeals the CMP or assessment and the surety has already made payment, CMS will – within 30 days of receiving notice of the successful appeal - notify the surety via letter of the successful appeal and repay the surety.

15.21.7.1.1 – Model Letters for Claims against Surety Bonds
(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

When making a claim against a surety bond n accordance with section 15.21.7.1 of this chapter, the contractor shall use the applicable model letter below:

A. Letter for Overpayments – Supplier is Still Enrolled in Medicare

Date

Surety Name
Surety Address

RE: Supplier Legal Business Name
Supplier DBA Name (if any)
Supplier Address

Dear Surety:

(Supplier legal business name) is currently enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). As a condition of its Medicare enrollment, (Supplier) is required – under Federal regulations at 42 C.F.R. §424.57(d) - to maintain a surety bond in an amount of no less than $50,000. In accordance with this provision, (Supplier) has a $_____ surety bond with your company.

Pursuant to 42 C.F.R. §424.57(d)(5)(i)(A), the surety must pay CMS – within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond – the amount of any unpaid claim for which the DMEPOS supplier is responsible, up to the full penal amount of the bond. An "unpaid claim" is defined in 42 C.F.R. §424.57(a) as an overpayment made by the Medicare program to the DMEPOS supplier for which the DMEPOS supplier is responsible.

CMS has determined that (Supplier) has incurred an overpayment in the amount of (insert dollar amount). This determination was made based on the following:

The DME MAC should outline the facts behind the determination, including:
(1) why the original payment was not correct,
(2) how the overpayment was calculated, and
(3) when the overpayment occurred.

Relevant documentation supporting our determination is attached to this letter.

CMS has been unable to recover the full overpayment from (Supplier) using its existing recoupment procedures. (Supplier) has repaid (insert "none" or "only $_____) of the overpayment amount. Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), therefore, CMS requests that (Surety) make payment to CMS in the amount of (insert applicable amount) no later than 30 days from the date of this letter. Payment shall be made via check or money order and sent to the following address:

Contractor Name
Address
City, State and Postal ZIP Code

The payee shall be (insert DME MAC), which is CMS's Durable Medical Equipment Medicare Administrative Contractor for (Supplier)'s location.

Should you have any questions about this letter, please do not hesitate to contact _____ at _____.

Sincerely,
(Name and title)

cc: National Supplier Clearinghouse
Supplier Name

B. Letter for Overpayments – Supplier is No Longer Enrolled in Medicare

Date

Surety Name
Surety Address

RE: Former Supplier Legal Business Name
Former Supplier DBA Name (if any)
Former Supplier Address

Dear Surety:

(Former Supplier legal business name) was enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) until (insert effective date of termination/revocation). As a condition of its Medicare enrollment, (Former Supplier) was required – under Federal regulations at 42 C.F.R. §424.57(d) - to maintain a surety bond in an amount of no less than $50,000. In accordance with this provision, (Former Supplier) obtained a $_____ surety bond with your company.

Pursuant to 42 C.F.R. §424.57(d)(5)(i)(A), the surety must pay CMS – within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond – the amount of any unpaid claim for which the DMEPOS supplier is responsible, up to the full penal amount of the bond. An "unpaid claim" is defined in 42 C.F.R. §424.57(a) as an overpayment made by the Medicare program to the DMEPOS supplier for which the DMEPOS supplier is responsible.

CMS has determined that (Supplier) incurred an overpayment in the amount of (insert dollar amount). This determination was made based on the following:

The DME MAC should outline the facts behind the determination, including:
(1) why the original payment was not correct,
(2) how the overpayment was calculated, and
(3) when the overpayment occurred.

Relevant documentation supporting our determination is attached to this letter.

CMS has been unable to recover the full overpayment from (Former Supplier) using its existing recoupment procedures. (Former Supplier) has repaid (insert "none" or "only $_____) of the overpayment amount.

(Former Supplier's) surety bond coverage with your company ended on (insert date). However, consistent with 42 C.F.R. § 424.57(d)(5)(iii), the surety is liable for unpaid claims that:

(1) CMS assessed against the supplier based on overpayments that took place during the term of the bond or rider, and

(2) Were assessed by CMS during the 2 years following the date that the supplier failed to submit a bond or required rider or the date that the supplier's Medicare enrollment was terminated, whichever is later.

The overpayment occurred on (insert date), which was within the period of (Former Supplier)'s surety bond coverage with your company. Moreover, CMS has made its overpayment determination within the 2-year period following the date of the termination of (Former Supplier)'s Medicare enrollment. Consistent with 42 C.F.R. § 424.57(d)(5)(i)(A), therefore, CMS requests that (Surety) make payment to CMS in the amount of (insert applicable amount) no later than 30 days from the date of this letter. Payment shall be made via check or money order and sent to the following address:

Contractor Name
Address
City, State and Postal ZIP Code

The payee shall be (insert DME MAC), which is CMS's Durable Medical Equipment Medicare Administrative Contractor for (Supplier)'s location.

Should you have any questions about this letter, please do not hesitate to contact _____ at _____.

Sincerely,
(Name and title)

cc: National Supplier Clearinghouse
Supplier Name

C. Letter for Civil Monetary Penalties and Assessments – Supplier is Still Enrolled in Medicare

Date

Surety Name
Surety Address

RE: Supplier Legal Business Name
Supplier DBA Name (if any)
Supplier Address

Dear Surety:

(Supplier legal business name) is currently enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). As a condition of its Medicare enrollment, (Supplier) is required – under Federal regulations at 42 C.F.R. §424.57(d) - to maintain a surety bond in an amount of no less than $50,000. In accordance with this provision, (Supplier) has a $_____ surety bond with your company.

Pursuant to 42 C.F.R. §424.57(d)(5)(i)(A), the surety must pay CMS – within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond – the amount of any civil monetary penalty (CMP) and/or assessment for which the DMEPOS supplier is responsible, up to the full penal amount of the bond. (Insert applicable language……..

> A CMP is defined in § 424.57(a) as a sum that CMS has the authority, as implemented by 42 C.F.R. §402.1(c) (or the Department of Health and Human Services Office of Inspector General (OIG)) has the authority, under section 1128A of the Act or 42 C.F.R. Part 1003) to impose on a supplier as a penalty.
>
> OR
>
> An assessment is defined as a sum certain that CMS or the Department of Health and Human Services Office of Inspector General (OIG) may assess against a DMEPOS supplier under Titles XI, XVIII or XXI of the Social Security Act.)

(CMS or OIG, as applicable) imposed a (CMP and/or assessment, as applicable) on (Supplier) on (date) in the amount of ($ _____). The (CMP and/or assessment) was imposed because (insert explanation, using information furnished by CMS or OIG).

Relevant documentation supporting our determination is attached to this letter. (Attach

copy of notice of CMP/assessment that was sent to supplier.)

(CMS or OIG, as applicable) has attempted to recover the amount of the (CMP or assessment) from (Supplier) using its existing collection procedures. (Supplier), however, has repaid (insert "none" or "only $_____) of this amount. Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), therefore, CMS requests that (Surety) make payment to CMS in the amount of (insert applicable amount) no later than 30 days from the date of this letter. Payment shall be made via check or money order and sent to the following address:

Contractor Name
Address
City, State and Postal ZIP Code

The payee shall be the Centers for Medicare and Medicaid Services.

Should you have any questions about this letter, please do not hesitate to contact _____ at _____.

Sincerely,
(Name and title)

cc: National Supplier Clearinghouse
Supplier Name

D. Letter for Civil Monetary Penalties and Assessments – Supplier is No Longer Enrolled in Medicare

Date

Surety Name
Surety Address

RE: Former Supplier Legal Business Name
Former Supplier DBA Name (if any)
Former Supplier Address

Dear Surety:

(Former Supplier legal business name) was enrolled in Medicare as a supplier of

durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) until (insert effective date of termination/revocation). As a condition of its Medicare enrollment, (Former Supplier) was required – under Federal regulations at 42 C.F.R. §424.57(d) - to maintain a surety bond in an amount of no less than $50,000. In accordance with this provision, (Former Supplier) obtained a $_____ surety bond with your company.

Pursuant to 42 C.F.R. §424.57(d)(5)(i)(A), the surety must pay CMS – within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond – the amount of any civil monetary penalty (CMP) and/or assessment for which the DMEPOS supplier is responsible, up to the full penal amount of the bond. (Insert applicable language……..

> A CMP is defined in §424.57(a) as a sum that CMS has the authority, as implemented by 42 C.F.R. §402.1(c) (or the Department of Health and Human Services Office of Inspector General (OIG) has the authority, under section 1128A of the Act or 42 C.F.R. Part 1003)) to impose on a supplier as a penalty.
>
> OR
>
> An assessment is defined as a sum certain that CMS or the Department of Health and Human Services Office of Inspector General (OIG) may assess against a DMEPOS supplier under Titles XI, XVIII or XXI of the Social Security Act.)

(CMS or OIG, as applicable) imposed a (CMP and/or assessment, as applicable) on (Former Supplier) on (date) in the amount of ($ _____). The (CMP and/or assessment) was imposed because (insert explanation, using information furnished by CMS or OIG).

Relevant documentation supporting our determination is attached to this letter. (Attach copy of notice of CMP/assessment that was sent to former supplier.)

(CMS or OIG, as applicable) has attempted to recover the amount of the (CMP or assessment) from (Former Supplier) using its existing collection procedures. (Former Supplier), however, has repaid (insert "none" or "only $_____) of this amount.

(Former Supplier)'s surety bond coverage with your company ended on (insert date). However, consistent with 42 C.F.R. §424.57(d)(5)(iii), the surety is liable for CMPs and/or assessments that:

(1) CMS or OIG imposed or asserted against the supplier during the term of the bond or rider, and

(2) Were imposed or assessed by CMS during the 2 years following the date that the supplier failed to submit a bond or required rider or the date that the supplier's Medicare enrollment was terminated, whichever is later.

The (CMP and/or assessment) was based on events that occurred (insert relevant date(s)), which was within the period of (Former Supplier's) surety bond coverage with your company. Moreover, CMS imposed the (CMP and/or assessment) within the 2-year period following the date of the termination of (Former Supplier)'s Medicare enrollment. Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), therefore, CMS requests that (Surety) make payment to CMS in the amount of (insert applicable amount) no later than 30 days from the date of this letter. Payment shall be made via check or money order and sent to the following address:

Contractor Name
Address
City, State and Postal ZIP Code

The payee shall be the Centers for Medicare & Medicaid Services.

Should you have any questions about this letter, please do not hesitate to contact _____ at _____.

Sincerely,
(Name and title)

cc: National Supplier Clearinghouse
Supplier Name

15.22 – Customer Service/Outreach

(Rev.423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

15.22.1 – Web Sites

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

The contractor must provide a link to CMS' provider/supplier enrollment Web site located at http://www.cms.hhs.gov/MedicareProviderSupEnroll . The link shall: (1) be available on the contractor's existing provider outreach Web site (which should be an established sub-domain of the contractor's current commercial Web site), and (2) comply with the guidelines stated in the Provider/Supplier Information and Education Web site section (Activity Code 14101) under the Provider Communications (PCOM) Budget and Performance Requirements (BPRs). Bulletins, newsletters, seminars/workshops and other information concerning provider enrollment issues shall also be made available on the existing provider outreach Web site. All contractor Web sites must comply with section 508 of the Rehabilitation Act of 1973 in accordance with, 36 CFR §1194, and must comply with CMS' Contractor Web site Standards and

Guidelines posted on CMS's Web site.

The CMS Provider/Supplier Enrollment Web site, http://www.cms.hhs.gov/MedicareProviderSupEnroll, furnishes the user with access to provider/supplier enrollment forms, specific requirements for provider/supplier types, manual instructions, frequently asked questions (FAQs), contact information, hot topics, and other pertinent provider/supplier information. The contractor shall not duplicate content already provided at the CMS provider/supplier enrollment Web site, and shall not reproduce the forms or establish the contractor's own links to forms. It shall, however, have a link on its Web site that goes directly to the forms section of the CMS provider/supplier enrollment site.

On a quarterly basis, each contractor shall review and provide updates regarding its contact information shown at URL:

http://www.cms.hhs.gov/MedicareProviderSupEnroll/downloads/contact_list.pdf

If the contractor services several States with a universal address and telephone number, the contractor shall report that information. In situations where no actions are required, a response from the contractor is still required (i.e., the contact information is accurate). In addition, only such information that pertains to provider enrollment activity for the contractor's jurisdiction is to be reported. All updates shall be sent directly via e-mail to the contractor's Provider Enrollment Operations Group Business Function Lead.

15.22.2 – Provider Enrollment Inquiries

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

The contractor's customer service unit may handle provider enrollment inquiries that do not involve complex enrollment issues. Examples of inquiries that can be processed by customer service units include:

- *Application status checks (e.g., "Has the contractor finished processing my application?") (The contractor may wish to establish electronic mechanisms by which providers can obtain updates on the status of their enrollment applications via the contractor's Web site or automated voice response (AVR).*

- *Furnishing information on where to access the Form CMS-855 applications (and other general enrollment information) on-line*

- *Explaining to providers/suppliers which Form CMS-855 applications should be completed.*

The contractor is strongly encouraged to establish e-mail "list serves" with the provider community to disseminate important information thereto, such as contractor address changes, new CMS enrollment policies or internal contractor procedures,

reminders about existing policies, etc. By being proactive in distributing information to its providers and suppliers on a regular basis (e.g., weekly, bi-weekly), the contractor can reduce the number of policy inquiries it receives and help facilitate the submission of complete and accurate Form CMS-855 applications.

15.23 – Document Retention

(Rev.423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

15.23.1 - Security

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

The contractor shall ensure that the highest level of security is maintained for all systems and its physical and operational processes, in accordance with the CMS/Business Partners Systems Security Manual (BPSSM) and the Program Integrity Manual.

Applications shall never be removed from the controlled area to be worked on at home or in a non-secure location. Additionally, provider enrollment staff must control and monitor all applications accessed by other contractor personnel.

All contractor staff shall be trained on security procedures as well as relevant aspects of the Privacy Act and the Freedom of Information Act. This applies to all management, users, system owners/managers, system maintainers, system developers, operators and administrators - including contractors and third parties - of CMS information systems, facilities, communication networks and information.

Note that these instructions are in addition to, and not in lieu of, all other instructions issued by CMS regarding security.

15.23.2 – Release of Information

(Rev.423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

On October 13, 2006, CMS published System of Records Notice for the Provider Enrollment, Chain and Ownership System (PECOS) in the Federal Register. Consistent with this notice, once the provider has submitted an enrollment application (as well as after it has been enrolled), the contractor shall not release – either orally or in writing - provider-specific data to any other person or entity. This includes, but is not limited to, national or State medical associations or societies, clearinghouses, billing agents, provider associations, or any person within the provider's organization other than the provider's authorized official (section 15 of the CMS-855), delegated official (section 16) or contact person (section 13). The only exceptions to this policy are:

- *A routine use found in the aforementioned System of Records applies.*

- *The provider (or, in the case of an organizational provider, an authorized or delegated official): (1) furnishes a signed written letter on the provider's letterhead stating that the release of the provider data is authorized, and (2) the contractor has no reason to question the authenticity of the person's signature.*

- *The release of the data is specifically authorized in some other CMS instruction or directive.*

(These provisions also apply in cases where the provider requests a copy of any Form CMS-855 paperwork the contractor has on file.)

It is recommended that the contractor notify the provider of the broad parameters of the aforementioned policy as early in the enrollment process as possible.

In addition:

- *When sending e-mails, the contractor shall not transmit sensitive data, such as social security numbers or employer identification numbers.*

- *The contractor may not send PECOS screen printouts to the provider.*

- *The contractor shall not send an individual's provider transaction access numbers (PTAN) to a group or organization (including the group's authorized or delegated official). If a group/organization needs to know an individual provider's PTAN, it must contact the provider directly for this information or have the individual provider request this information in writing from the contractor. If the individual provider requests his/her PTAN number, the contractor can mail it to the provider's practice location. The contractor should never give this information over the phone.*

15.23.3 – File Maintenance

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

The contractor 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.*

The contractor 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.

15.24 – Model Correspondence Letters

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor shall use the following model provider enrollment letter format or some similar variation and standard language paragraphs.

NOTE: These are model letters and should be adjusted on a case by case basis, if needed. The fill-in-the-blank information (specific to each contractor determination) is in brackets. The contractor must ensure that the information identified in each section of the model letters below are included and addressed, as needed.

15.24.1 – Model Acknowledgement Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Supplier name]:

Your Medicare enrollment application [insert application type] was received on [date] and is/are currently being reviewed. You will receive a letter within 30 calendar days if we need any additional information.
[Insert this language if a reference number is provided: Your application reference number is: (insert reference number)]

Please retain this letter [insert this language if a reference number is provided: (insert reference number)] in the event that you must submit additional information in support of your application. If you have any questions, please contact our office at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.2 – Model Development Letter
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

[Insert application reference number]

Dear [Insert Provider/Suppler name]:

We have received your Medicare enrollment application(s). In order to complete processing your application(s), we request the following revisions and/or supporting documentation. Consistent with regulations found at 42 CFR 424.525, we may reject your application(s) if you do not furnish complete information within 30 calendar days of the postmark date of this letter.

Requested Revisions:

(The following are examples)

- [Insert section number and subsection letter (if applicable)]

    - [Insert a brief description of the revision(s) needed. Try to limit the description(s) to two sentences or less. (See examples below.)]

- Section 1A
    - National Provider Identifier

- Section 6 and 16
    - Complete these sections for each Delegated Official

- Section 15
    - Print, sign and date this section to approve the changes requested

- Section 17
    - Completed Form CMS-460, Medicare Participating Physician or Supplier Agreement

- If a Change of Ownership (CHOW), provide your Medicare Year-End Cost Report date (Month & Day)

To facilitate the processing of your application(s), you should submit the requested revisions and/or supporting documentation within 30 days to the address listed below:

[Insert contact address]

Finally, please attach a copy of this letter with your revised application(s). If you have any questions, please contact our office at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]
[Enclosure]

15.24.3 – Model Rejection Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

Dear [Insert Provider/Suppler name]:

We received your Medicare enrollment application(s) on [insert date]. We are rejecting your Medicare enrollment application(s) and returning your application(s) for the following reason(s):

FACTS: [Insert ALL rejection reason(s) and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

In compliance with Federal regulations found at 42 CFR 424.525, providers and suppliers are required to submit complete application(s) and all supporting documentation within 30 calendar days from the postmark date of the contractor request for missing/incomplete information. If you would like to resubmit an application, you must complete a new Medicare enrollment application(s). Please make sure to address

the issues stated above as well as sign and date the new certification statement page on your resubmitted application(s).

Providers and suppliers (except DMEPOS suppliers) can enroll in the Medicare program using either the:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper application process. To apply by paper, download and complete the Medicare enrollment application(s) from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll. DMEPOS suppliers that would like to apply should download and complete the paper application(s) and sent to the National Supplier Clearinghouse (NSC).

You should return the complete application(s) to the address listed below:

[Insert contact address]

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.4 – Model Returned Application Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

[Insert application reference number]

Dear [Insert Provider/Suppler name]:

We received your Medicare enrollment application(s) on [insert date]. We are closing

this request and returning your application(s) for the following reason(s):

FACTS: [Insert ALL return reason(s) and cite the applicable regulatory authority, if applicable]

In order to resubmit your application(s) you must complete the [insert application type] application(s) with an original signature and date before we can begin processing your application(s). Please make sure to address the issues stated above on your resubmitted application(s).

Providers and suppliers (except DMEPOS suppliers) can enroll in the Medicare program using either the:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper application process. To apply by paper, download and complete the Medicare enrollment application(s) from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll. DMEPOS suppliers that would like to apply should download and complete the paper application(s) and sent to the National Supplier Clearinghouse (NSC).

You should return the complete application(s) to the address listed below:

[Insert contact address]

If you have any questions regarding this letter, please call [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.5 – Model Revalidation Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]

[City, State & ZIP Code]

Dear [Insert Provider/Suppler name]:

Consistent with Medicare regulations found at 42 CFR 424.515, [insert contractor name], a Medicare contractor, requires that you complete and submit a Medicare enrollment application(s) and submit all applicable supporting documentation within 60 calendar days of the postmark date of this letter.

Providers and suppliers (except DMEPOS suppliers) can enroll in the Medicare program using either the:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper application process. To apply by paper, download and complete the Medicare enrollment application(s) from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll. DMEPOS suppliers that would like to apply should download and complete the paper application(s) and sent to the National Supplier Clearinghouse (NSC).

While the submission of your Medicare enrollment application(s) will start your 5-year revalidation cycle, you are required by regulations found at 42 CFR 424.516 to submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Failure to submit complete enrollment application(s) and all supporting documentation within 60 calendar days of the postmark date of this letter may result in your Medicare billing privileges being revoked.
Please return the completed application(s) to:

[Insert application return address]

If you have any questions regarding this letter, please call [insert phone number] between the hours of [insert office hours] or visit our Web site at [insert Web site] for additional information regarding the enrollment process or the [insert application type].

Sincerely,

[Your Name]
[Title]
[Enclosure]

15.24.6 – Model Approval Recommended Letter for Part A Providers & Certified Suppliers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

[Name of contractor] has processed your Medicare enrollment application [insert application type] to enroll in the Medicare Program and have made our preliminary assessment and forwarded it to the Centers for Medicare & Medicaid Services (CMS) regional office for review. The next step of the enrollment process involves a site visit or survey conducted by a State Survey Agency or a CMS approved deemed accrediting organization to ensure compliance with the Conditions of Participation for your provider or supplier type. Once the regional office confirms that your organization meets the Conditions of Participation for your provider or supplier type, we will finalize our review of your enrollment application.

If you have any questions concerning this letter, please contact the State or CMS regional office at [insert phone number(s)].

Sincerely,

[Your Name]
[Title]
Enclosure
cc:

15.24.7 – Model Approval Letter for Initial Enrollment

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

NOTE: Per regulations 42 CFR 405.874, a provider or supplier may only appeal a

denial or revocation decision. Accordingly, a physician, non-physician practitioner and a physician or non-physician practitioner group may not formally appeal the established effective date of billing. Of course, if a physician or non-physician practitioner and a physician or non-physician practitioner group notify a Medicare contractor that an error may have occurred, the contractor should review this matter.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

We are pleased to inform you that your Medicare enrollment application is approved. Listed below is the information reflected in your Medicare enrollment record, including your National Provider Identifier (NPI) and Provider Transaction Access Number (PTAN).

If you are an existing Medicare provider and currently do not submit claims electronically, or are new to the Medicare program and plan on filing claims electronically, please contact our EDI department at [insert phone number]. To start billing the Medicare program, you must use your NPI on all Medicare claim submissions. Your PTAN is also activated for use and will be the required authentication element for all inquiries to customer service representatives (CSRs), written inquiry units and the interactive voice response (IVR) system for inquiries concerning claims status, beneficiary eligibility and to check status or other supplier related transactions, therefore keep your PTAN secure. Because the PTAN is not considered a Medicare legacy identifier, do <u>not</u> report this identifier to the National Plan and Provider Enumeration System (NPPES) as an "other" provider identification number.

<u>Medicare Enrollment Information</u>

Provider \ Supplier name:	[Insert name]
Practice location:	[Insert address]
National Provider Identifier (NPI):	[Insert NPI]
Provider Transaction Access Number (PTAN):	[Insert PTAN]
Specialty:	[Insert provider/supplier specialty]
You are a:	[Insert participating or non-participating]
Effective date [Insert "of termination" if the applicant is voluntarily terminating	[Insert effective date or effective date of termination]

Medicare participation]

(Repeat for multiple, if necessary, for each additional location and NPI/PTAN combination)

Please verify the accuracy of your enrollment information. If you disagree with this initial determination or have any questions regarding the information above, call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation]. Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision.

You are required by regulations found at 42 CFR 424.516 to submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Providers and suppliers may enroll or make changes to their existing enrollment in the Medicare program using the Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS or to download the CMS-855 enrollment applications, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

Additional information about the Medicare program, including billing, fee schedules, and Medicare polices and regulations can be found at our Web site at [insert Web site address] or the Centers for Medicare & Medicaid Services' (CMS) Web site at http://www.cms.hhs.gov/home/medicare.asp.

Sincerely,

[Your Name]
[Title]

15.24.8 – Model Approval Letter for Change of Information
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

NOTE: Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision. Accordingly, a physician, non-physician practitioner and a physician or non-physician practitioner group may not formally appeal the established effective date of billing. Of course, if a physician or non-physician practitioner and a physician or non-physician practitioner group notify a Medicare contractor that an error

may have occurred, the contractor should review this matter.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

We have approved your information change request. Listed below is the [insert "new" or "updated"] information reflected in your Medicare enrollment record.

Medicare Enrollment Information

Provider \ Supplier name:	[Insert name]
[Insert revised item on the application]:	[Insert updated or changed item on the application]
National Provider Identifier (NPI):	[Insert NPI]
Provider Transaction Access Number (PTAN):	[Insert active or inactive PTAN]
Specialty:	[Insert provider/supplier specialty]
You are a:	[Insert participating or non-participating]
Effective date [Insert "of termination" if the applicant is voluntarily terminating Medicare participation]	[Insert effective date or effective date of termination]
If a Change of Ownership (CHOW, insert Medicare Year-End Cost Report date:	[Insert Month and Day]

(Repeat for multiple, if necessary, for each additional location and NPI/PTAN combination)

Please verify the accuracy of your enrollment information. If you disagree with the information above, call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation]. Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision.

ADDITIONAL INFORMATION

If you are an existing Medicare provider and currently do not submit claims electronically, or are new to the Medicare program and plan on filing claims

electronically, contact our EDI department at [insert phone number]. To start billing the Medicare program, you must use your NPI on all Medicare claims submissions. Your PTAN will be the required authentication element for all inquiries to customer service representatives (CSRs), written inquiry units and the Interactive Voice Response (IVR) system for inquiries concerning claims status, beneficiary eligibility and to check status or other supplier related transactions, therefore keep your PTAN secure.

To maintain an active enrollment status in the Medicare program, regulations found at 42 CFR 424.516 require that you submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Providers and suppliers may enroll or make changes to their existing enrollment in the Medicare program using the Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS or to download the CMS-855 enrollment applications, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

Sincerely,

[Your Name]
[Title]

15.24.9 – Model Revalidation Approval Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

NOTE: Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision. Accordingly, a physician, non-physician practitioner and a physician or non-physician practitioner group may not formally appeal the established effective date of billing. Of course, if a physician or non-physician practitioner and a physician or non-physician practitioner group notify a Medicare contractor that an error may have occurred, the contractor should review this matter.
CMS alpha representation
Contractor

[Month Day & Year]
[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

We have processed your Medicare enrollment application(s) to revalidate your Medicare enrollment information.

Listed below is the information reflected in your Medicare enrollment record.

Medicare Enrollment Information:

Provider Name:	[Insert name]
Practice Location:	[Insert address]
National Provider Identifier (NPI):	[Insert NPI]
Provider Transaction Access Number (PTAN):	[Insert PTAN]
You are a:	[Insert participating or non-participating]
Effective Date:	[Insert month day, year]

(Repeat for multiple, if necessary, for each additional location and NPI/PTAN combination)

Please verify the accuracy of your enrollment information. If you disagree with the information above, call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation]. Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision.

To maintain an active enrollment status in the Medicare program, regulations found at 42 CFR 424.516 require that you submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Providers and suppliers may enroll or make changes to their existing enrollment in the Medicare program using the Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS or to download the CMS-855 enrollment applications, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

Sincerely,

[Your Name]
[Title]

15.24.10 – Model Denial Letter for Certified Providers & Suppliers: Denial Based on a Condition of Participation

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.530 to view circumstances that warrant a fee-for-service contractor to deny a provider or supplier's enrollment in the Medicare program. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is denied based on a condition of participation, then the applicant or enrolled entity must submit a reconsideration or a corrective action plan with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Denial

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., hospital, skilled nursing facility, hospice]

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed by the authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.11 – Model Denial Letter for Certified Providers & Suppliers: Denial Based on an Enrollment Reason(s)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.530 to view circumstances that warrant a fee-for-service contractor to deny a provider or supplier's enrollment in the Medicare program. If the certified provider or certified supplier is denied (i.e., ambulatory surgery center (ASC) and portable x-ray) based on an enrollment reason(s), then the applicant or enrolled entity must file a reconsideration with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Denial

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., hospital, skilled nursing facility, hospice].

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed and dated by the individual provider or the authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated

by the individual provider or authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.12 – Model Denial Letter for Suppliers, Non-IDTF, Furnishing Part B Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.530 to view circumstances that warrant a fee-for-service contractor to deny a provider or supplier's enrollment in the Medicare program.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

RE: [insert decision]

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet

the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., doctor of medicine, physicians assistant, nurse practitioner].

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Insert contact address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

[Insert contact address]

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.13 – Model Denial Letter for IDTFs

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 410.33 for the IDTF performance standards and requirements.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Re: [Subject]

Dear [Insert Provider/Suppler Name]:

We have received your request to enroll in the Medicare program. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirements to qualify as an Independent Diagnostic Testing Facility (IDTF). Accordingly, your application(s) to enroll in the Medicare program is denied.

In order to obtain Medicare billing privileges, an IDTF must meet all of the performance standards found at 42 CFR 410.33. [Insert Provider Name] failed to meet the following standards:

STANDARDS: [Insert ALL performance standards not met].

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority that corresponds to the performance standards not met e.g., 42 CFR 410.33(c), 42 CFR 410.33(g)(4)(i) and 42 CFR 410.33(g)(5)(ii)].

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Contractor Address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a

waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

[Contractor Address]

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.14 – Model Revocation Letter for Certified Providers & Suppliers: Revocation Based on a Condition of Participation

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is revoked based on a condition of participation, then the applicant or enrolled entity must submit a reconsideration or corrective action plan with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare privileges are being revoked effective [insert effective date of revocation]. Pursuant to 42 CFR 424.545(a), this action will also terminate your corresponding provider agreement.
FACTS: [Insert ALL reason(s) for revocation and cite the applicable regulatory authority]

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed and dated by the authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

Pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

If you have any questions regarding this determination, please contact [insert contact name] at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

Enclosure [Attach a copy of the development letter if applicable]

15.24.15 – Model Revocation Letter for Certified Providers & Suppliers: Revocation Based on an Enrollment Reason(s)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is revoked based on an enrollment reason(s), then the applicant or enrolled entity must file a reconsideration with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare billing privileges are being revoked effective [insert effective date of revocation]. Pursuant to 42 CFR 424.545(a), this action will also terminate your corresponding provider agreement.

FACTS: [Insert ALL the reason(s) for revocation and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment

7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

Pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.16 – Model Revocation Letter for Suppliers Furnishing Part B Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare billing privileges are being revoked effective [insert effective date of revocation]. Note: The revocation date in this letter must comport to the provisions found in 42 CFR 424.535(g).

FACTS: [Insert ALL reason(s) for revocation and cite the applicable regulatory authority]

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Insert contract address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

[Insert contact address]

Pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

[The following statement should only be used if a contractor determines that a Final Adverse Action occurred: Finally, in accordance with 42 CFR 424.565, [insert name of contractor] is assessing an overpayment in the amount of [insert dollar amount] because the physician or non-physician practitioner continued to furnish services to Medicare beneficiaries after a final adverse action precluded enrollment in the Medicare program.] [Note: As stated in 42 CFR 424.565, Medicare contractors should assess an overpayment back to January 1, 2009, not the date of the final adverse action if the adverse action occurred prior to January 1, 2009.]

If you have any questions regarding this determination, please contact [insert contact name] at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.17 – Model Revocation Letter for OIG Sanctioned Providers/Suppliers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Supplier name]:

This letter is to inform you that your Medicare Provider Transaction Access Number (PTAN) [insert PTAN number] that is associated to the National Provider Identifier (NPI) [insert NPI number] has been revoked effective [insert date of OIG debarment or exclusion].

According to federal regulations 42 CFR 424.535(a)(2), the provider or any owner, managing employee, authorized or delegated official, medical director, supervising physician or other health care personnel of the provider or supplier who has been debarred, suspended or excluded from the Medicare, Medicaid or any other Federal

health care or other government program, cannot maintain enrollment in the Medicare program. According to information obtained from the U.S. Department of Health & Human Services (Office of Inspector General), [insert provider/supplier name] has been excluded from participating in the Medicare program.

FACTS: The Department of Health and Human Services, Office of Inspector General notified us that you are excluded from the 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. You are excluded as of [insert effective date of exclusion] for [Cite the regulatory basis for exclusion. For example: 1128(b)(14)-Default on health education loan and scholarship obligations].

You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action. However, if you believe that this revocation is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

[For Part B Supplier, insert contractor address]
[For Certified Providers/Suppliers, insert CMS address]

Finally, in accordance with 42 CFR 424.565, [insert name of contractor] is assessing an overpayment in the amount of [insert dollar amount] because the physician or non-physician practitioner continued to furnish services to Medicare beneficiaries after a final adverse action precluded enrollment in the Medicare program.] [Note: As stated in 42 CFR 424.565, Medicare contractors should assess an overpayment back to January 1, 2009, not the date of the final adverse action if the adverse action occurred prior to January 1, 2009.]

If you have any questions regarding this letter, please call [insert phone number] between the hours of [insert office hours]

Sincerely,

[Your name]
[Title]

15.24.18 – Model Revocation Letter for National Supplier Clearinghouse (NSC)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Supplier Name]
[Address]
[City, State & Zip Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Supplier Name]:

This is to inform you that your Medicare billing privileges are being revoked effective [insert date 30 days from the date of the letter], 30 days from the postmark date of this letter.

The durable medical equipment Medicare administrative contractors (DME MACs) use these numbers to identify suppliers. This revocation has the concurrence of the Centers for Medicare & Medicaid Services (CMS). In addition, pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time] year(s) from the effective date of the revocation. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your supplier type.

[This next paragraph will be included if a response to the development request was received in the field below, remember the date needs to be written out.]

The Supplier Audit and Compliance Unit (SACU) reviewed and evaluated the documents you submitted in response to the developmental letter dated [insert date]. This developmental letter afforded you the opportunity to demonstrate your full compliance with the durable medical equipment, prosthetics & orthotics standards (DMEPOS) supplier standards and/or to correct the deficient compliance requirement(s). However, after review of the information, it has been determined that you have not demonstrated compliance with the supplier standards noted below:

STANDARDS: [Insert ALL performance standard(s) not met and cite the applicable

regulatory authority that corresponds to the performance standard(s) not met e.g., 42 CFR 410.33(c), 42 CFR 410.33(g)(4)(i) and 42 CFR 410.33(g)(5)(ii)].

[The next paragraph will be included if a response to the development request was not received.]

The Supplier Audit and Compliance Unit (SACU) has not received a response to the developmental letter sent to you on [insert date]. This request afforded you the opportunity to demonstrate your full compliance with the durable medical equipment, prosthetics & orthotics standards (DMEPOS) supplier standards and/or to correct the deficient compliance requirement(s). Therefore, we have determined that you are not in compliance with the supplier standards noted below:

STANDARDS: [Insert ALL performance standard(s) not met and cite the applicable regulatory authority that corresponds to the performance standard(s) not met e.g., 42 CFR 410.33(c), 42 CFR 410.33(g)(4)(i) and 42 CFR 410.33(g)(5)(ii)].

For Example: Supplier standard number one states that a supplier "Operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements." Explanation of specific deficiency goes here [regulatory cite to applicable standard(s) for revocation]

Section 1834 (j) of the Social Security Act states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items furnished by a supplier unless the supplier has a valid Medicare billing number. Therefore, any expenses for items you supply to a Medicare beneficiary on or after the effective date of the revocation of your billing numbers are your responsibility and not the beneficiary's, unless you have proof that you have notified the beneficiary in accordance with section 1834 (a) (18) (ii) of the Social Security Act, and the beneficiary has agreed to take financial responsibility if the items you supply are not covered by Medicare. You will be required to refund on a timely basis to the beneficiary (and will be liable to the beneficiary for) any amounts collected from the beneficiary for such items. If you fail to refund the beneficiary as required under 1834 (j) (4) and 1879 (h) of the Social Security Act, you may be liable for Civil Monetary penalties.

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The National Supplier Clearinghouse (NSC), with Centers for Medicare & Medicaid Services (CMS) approval, may reinstate your supplier number after it reviews your CAP and any additional evidence you submit and determines you are now in compliance with all supplier standards [see 42 C.F.R. 424.57(c)]. CAP requests should be sent to:

[Insert contract address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. The request must be made in writing and signed by an authorized official, owner or partner of the business. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

[Insert contact address]

If you choose not to request a reconsideration of this decision, or you do not receive a favorable decision through the administrative review process, you must wait [insert number of year(s)] before resubmitting your CMS-855S application, per the re-enrollment bar cited above. Applications received in the NSC prior to this timeframe will be returned.

If you have any questions regarding this determination, please contact [insert contact name] at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.19 – Model Reconsideration Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

[Reference number]

Dear [Insert Provider/Suppler name]:

This decision letter is in response to your reconsideration request received by [insert contractor name]. The reconsideration request is based on the above referenced provider or suppliers [revocation or denial]. The initial determination letter was dated [insert date of initial determination letter] and thus, this appeal is timely submitted. This letter contains the decision.

The decision is based on Social Security Act, Medicare regulations and/or CMS manual instructions. This decision is based on the evidence in the file, and any information that you may have sent with or since the time of your hearing request.

FACTS: [Insert Regulation]

RATIONALE: [Insert denial/revocation rationale based on the regulation]

(Repeat for multiple, if necessary)

SUMMARY OF SUBMITTED DOCUMENTATION: [Insert all documentation/supporting information submitted]

EVALUATION OF SUBMITTED DOCUMENTATION: [Insert evaluation of documentation/supporting information submitted]

DECISION: All of the documentation in the file for this case has been reviewed and the decision has been made in accordance with Medicare guidelines as outlined in [insert regulation]. Specifically, [name of provider/supplier] [has or has not] provided evidence to show you have fully complied with the standards for which you were [revoked or denied]. Therefore, we [grant or cannot grant] you access to the Medicare Trust Fund (by way or issuance) of a Medicare number.

This decision is [a FAVORABLE DECISION (or) an UNFAVORABLE DECISION]. Please see below for additional appeal rights.

FURTHER APPEAL RIGHTS: ADMINISTRATIVE LAW JUDGE (ALJ)

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request a final ALJ review, you must act quickly and you must meet the requirements for requesting a final ALJ review. You must file your appeal within 60 calendar days after the date of receipt of this decision by writing to the following address:

Department of Health and Human Services
Departmental Appeals Board

Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Building, Room G-644
Washington, D.C. 20201
Attn: CMS Enrollment Appeal

Appeal rights can be found at 42 CFR 498. The regulation explains the appeal rights following the determination by the Centers for Medicare & Medicaid Services as to whether such entities [meet and/or continue to meet] the requirements for enrollment in the Medicare program.

If you have any questions regarding this decision, please call [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.20 – Model Identity Theft Prevention Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor shall use the following model letter for changes of information and reassignment enrollment applications received, paper and web-submitted, where suspicious provider/supplier enrollment activity may be suspected, except in circumstances where the application can be returned based on the manual instructions. This model letter shall be sent to the address previously established and on file.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier]
[Address]
[City, State & ZIP Code]

Dear [Insert Provider/Suppler]:

As a security precaution, we are writing to confirm that you submitted a Medicare enrollment application(s) to enroll or change an existing enrollment at the following address:

[Insert Provider/Supplier Address]

If this application was submitted without your authorization, please call the Medicare contractor that processes your claims. The Medicare Fee-For-Service contact information can be found at www.cms.hhs.gov/MedicareProviderSupEnroll.

We will process your application(s) according to The Centers for Medicare & Medicaid (CMS) timeliness standards and will contact you if there is a need for additional information. We will notify you once processing is complete.

Please contact our office with any questions at [insert phone number] between the hours of [insert office hours] and refer to your application(s) reference number [insert reference number].

Sincerely,

[Your Name]
[Title]

15.24.21 – Model Approval Letter – Initial Form CMS-855O Submissions

(Rev. 410, Issued: 03-02-12, Effective: 06-04-12, Implementation: 06-04-12)

CMS alpha representation
Contractor

[Month Day & Year]

[Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Supplier name]:

We are pleased to inform you that your Form CMS-855O enrollment is approved. Listed below is the information reflected in your Medicare Form CMS-855O record:

Medicare Enrollment Information

Provider\Supplier name:	[Insert name]
Practice location:	[Insert address]
National Provider Identifier (NPI):	[Insert NPI]
Specialty:	[Insert provider/supplier specialty]
Effective date	[Insert date that paper submission or Web-based certification statement was received in contractor's mailroom.]

Please verify the accuracy of your information. If you have any questions regarding this letter, please call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation].

As stated in the Form CMS-855O certification statement that you signed, you are required to notify the Medicare contractor of:

- Any change to the information you reported in Section 2 or Section 3 of the Form CMS-855O within 30 days of the reportable event, and

- Any other change to your Form CMS-855O information within 90 days of the effective date of the change.

Such changes to your information can be reported to CMS via the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) or the paper version of the Form CMS-855O. For information on accessing Internet-based PECOS or to download the Form CMS-855O, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

If you wish to enroll in Medicare to obtain Medicare billing privileges, you must: (1) complete and submit a Form CMS-855I application, and (2) withdraw your Form CMS-855O status.

Additional information about the Medicare program can be found at our Web site at [insert Web site address] or the Centers for Medicare & Medicaid Services' (CMS) Web site at http://www.cms.hhs.gov/home/medicare.asp.

Sincerely,

[Your Name]
[Title]

15.24.22 – Model Rejection Letter – Form CMS-855O Submissions

(Rev. 410, Issued: 03-02-12, Effective: 06-04-12, Implementation: 06-04-12)

CMS alpha representation
Contractor

[Month Day & Year]

[Supplier Name]
[Address]
[City, State & ZIP Code]

Dear [Insert Supplier name]:

We received your Form CMS-855O submission on [insert date]. We are rejecting your submission and returning it to you for the following reason(s):

FACTS: [Insert ALL rejection reason(s)]

If you would like to submit a new Form CMS-855O, please make sure to address the issues stated above, as well as sign and date a new certification statement page on your resubmitted form.

You may complete a Form CMS-855O using either the:

1. Internet-based Provider Enrollment, Chain and Ownership System (PECOS). To use Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper process. You may download and complete the Form CMS-855O from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll.

You should return the completed form to the address listed below:

[Insert contact address]

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.23 – Model Denial Letter – Form CMS-855O Submissions

(Rev. 410, Issued: 03-02-12, Effective: 06-04-12, Implementation: 06-04-12)

CMS alpha representation
Contractor

[Month Day & Year]

[Supplier Name]
[Address]
[City, State & Zip Code]

RE: Notice of Denial of Form CMS-855O Enrollment Application

Dear [Insert Supplier name]:

This is to inform you that your Form CMS-855O enrollment application has been denied.

FACTS: [Insert ALL reason(s) for denial]

If you believe that you are able to correct the deficiencies and establish your eligibility to enroll via the Form CMS-855O, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with the requirements for enrolling via the Form CMS-855O. You must sign and date the CAP. The CAP must be sent to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment Operations Group
7500 Security Boulevard
Mailstop: AR 18-50
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. You must sign and date the reconsideration request. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. The request for reconsideration must be sent to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment Operations Group
7500 Security Boulevard
Mailstop: AR 18-50
Baltimore, MD 21244-1850

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.24 – Model Revocation Letter - Form CMS-855O

(Rev. 410, Issued: 03-02-12, Effective: 06-04-12, Implementation: 06-04-12)

CMS alpha representation
Contractor

[Month Day & Year]

[Supplier Name]
[Address]
[City, State & Zip Code]

RE: Notice of Revocation of Form CMS-855O Enrollment

Dear [Insert Supplier name]:

This is to inform you that your Form CMS-855O enrollment has been revoked.

FACTS: [Insert ALL reason(s) for revocation]

If you believe that you are able to correct the deficiencies and establish your eligibility to enroll via the Form CMS-855O, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with the requirements for enrolling via the Form CMS-855O. You must sign and date the CAP. The CAP must be sent to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment Operations Group
7500 Security Boulevard
Mailstop: AR 18-50
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. You must sign and date the reconsideration request. Failure to

timely request a reconsideration is deemed a waiver of all rights to further administrative review. The request for reconsideration must be sent to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment Operations Group
7500 Security Boulevard
Mailstop: AR 18-50
Baltimore, MD 21244-1850

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.25 – Appeals Process

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A provider or supplier whose Medicare enrollment is denied or whose Medicare billing privilege is revoked can request an appeal of that determination. In addition, some providers and suppliers may submit an appeal for any type of application submitted (i.e., initial application, change request or reassignment) that resulted in a denial.

This appeal process applies to all providers and suppliers, not just those defined in 42 CFR §498, and ensures that all applicants receive a fair and full opportunity to be heard. With the implementation of the appeals provision of Section 936 of the Medicare Prescription Drug Modernization and Improvement Act (MMA), all providers and suppliers that wish to appeal will be given the opportunity to request an appeal of a reconsideration decision to an administrative law judge (ALJ) of the Department of Health and Human Services (DHHS). Providers and suppliers then can seek review by the Departmental Appeals Board (DAB) and then may request judicial review.

Denial/Revocation of Medicare Billing Privileges

A. Carriers (including NSC and A/B MACs)

If a Medicare contractor reviews an initial enrollment application for a provider or supplier and finds a basis for denying the application pursuant to 42 CFR §424.530, such as; the provider or supplier does not meet one or more of the Federal or State requirements, the Medicare contractor shall deny the application and notify the provider or supplier by letter. The denial letter shall contain:

- A legal (i.e., regulatory) basis for each reason for the denial;

- A clear explanation of why the application is being denied, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to enroll in the Medicare program;

- Procedures for submitting a corrective action plan (CAP); and

- Complete and accurate information about the provider or supplier's further appeal rights.

Similarly, when a Medicare contractor discovers that there is a basis for revoking a provider or supplier's billing privileges, such as; the provider or supplier no longer meets one of the requirements for billing privileges, the contractor shall revoke billing privileges and notify the provider or supplier by letter. The revocation letter shall contain:

- A legal (i.e., regulatory) basis for each reason for revocation;

- A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to maintain enrollment in the Medicare program;

- The effective date of the revocation (30 days from the date the notice is mailed for providers or suppliers, or 15 days from the date the notice is mailed for DMEPOS suppliers. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment. The effective date of a license suspension/revocation is effective with the date of the suspension/revocation;

- Procedures for submitting a CAP; and

- Complete and accurate information about the provider or supplier's further appeal rights.

Corrective Actions Plan (CAP)

A CAP is the process that gives the provider or supplier an opportunity to correct the

deficiencies (if possible) that resulted in the denial or revocation of billing privileges. The CAP should provide evidence that the provider or supplier is in compliance with Medicare requirements.

The Medicare contractors shall emphasize to the providers and suppliers, through denial/revocation letters, that the submission of a CAP addressing the issues that resulted in the denial or revocation of billing privileges will expedite the enrollment process and issue a faster determination.

The Medicare contractor, including the NSC, shall accept, for review, the submission of a CAP for denied or revoked billing privileges if the CAP is submitted within 30 days from the date of the notice. All part B certified supplier CAP requests should be forwarded to CMS for processing at:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

The CAPs shall be submitted in the form of a letter and shall contain, at a minimum, verifiable evidence of provider or supplier compliance with enrollment requirements. The letter shall be signed and dated by the individual provider, the authorized or delegated official or a legal representative. Contractors may also create a standard CAP form to be sent out with their denial letters to easily identify it as a CAP when it is returned.

Contractors may accept a CAP by fax. If all the missing information originally requested is not received contractors should make one contact to the provider or supplier, preferably via e-mail or fax, to obtain the additional information before making a final determination. Contractor may use the model development letter, found in section 14 of this chapter, to request the information.

If a CAP for a denied application or revoked billing privileges is approved by a Medicare contractor, billing privileges can be issued. Contractors shall notify the applicant via letter that the enrollment has been approved. The effective date of Medicare billing privileges is based on the date the provider or supplier came into compliance with all Medicare requirements or the receipt date of the application. For an approved CAP, contractors shall use the receipt date of the CAP request as the receipt date they enter in PECOS.

For DMEPOS suppliers the effective date is the date it is awarded by the NSC. CMS' approval is required prior to restoring billing privileges.

The Medicare contractor shall process a CAP within 60 days. During this process, the contractor shall not toll the filing requirements associated with an appeal. However, the

contractor can make a good cause determination in order to accept any appeal that has been submitted beyond the timely filing period.

NOTE: If a CAP and a reconsideration request (i.e., appeal request) are submitted concurrently, the Medicare contractor shall first process and make a determination on the CAP. The reconsideration request should then be processed by a Hearing Officer (HO) unrelated to the initial determination or CAP to ensure the applicant receives an independent review of their reconsideration. The Medicare contractor and the HO shall coordinate prior to acting on a CAP or reconsideration request to determine if the other party has received a request. If the CAP is accepted, the standard approval letter shall be sent to the provider or supplier acknowledging enrollment into Medicare and that their reconsideration request should be withdrawn. If the CAP is denied, the provider or supplier shall be notified by letter and may continue with the appeals process if it has filed a request for reconsideration or is preparing to submit such a request and has not exceeded the timeframe to do so. Providers and suppliers may not appeal a corrective action plan decision.

Reconsideration (formerly Contractor Hearing)

A provider, supplier or DMEPOS supplier that wishes to request a reconsideration must file its request, in writing, with the Medicare contractor within 60 days after the postmark of the notice to be considered timely filed. Medicare contractors shall extend the filing period an additional 5 days to allow for mail time. Reconsideration requests submitted on the 65th day of which falls on a weekend or holiday should still be considered timely filed and not rejected. The date the request is received by the Medicare contractor is treated as the date of filing. The request must be signed by the physician, non-physician practitioner, a legal representative, or any responsible authorized official within the entity. For DMEPOS suppliers, the request must be signed by the authorized representative, delegated official, owner or partner. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

Medicare contractor reconsiderations shall be conducted by a HO or senior staff having expertise in provider enrollment and who was independent from the initial decision to deny or revoke enrollment.

The NSC reconsiderations shall be conducted by a HO. All part B certified supplier reconsiderations will be conducted by CMS and shall be forwarded to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

Upon receipt of the reconsideration, the HO shall send a letter to the provider or

supplier to acknowledge receipt of their request. In its acknowledgment letter, the HO shall advise the requesting party that the reconsideration will be conducted and a determination issued within 90 days from the date of the request. The HO shall include a copy of its acknowledgment letter in the reconsideration file.

If a timely request for a reconsideration is made, the HO, not involved in the original adverse determination, must hold an on-the-record reconsideration and issue a determination within 90 days from the date of the appeal request. The provider, supplier or the Medicare contractor may offer new evidence. It is the responsibility of the provider or supplier to show that its enrollment application was incorrectly denied or that its billing privileges were revoked erroneously.

In reviewing an initial enrollment decision or a revocation, the HO should limit the scope of its review to the Medicare contractor's reason for imposing a denial or revocation at the time it issued the action and whether the Medicare contractor made the correct decision (i.e., denial/revocation). Medicare contractors cannot introduce new denial or revocation reasons or change a denial or revocation reason listed in the initial determination during the reconsideration process. If a provider or supplier provides evidence that demonstrates or proves that they met or maintained compliance after the date of denial or revocation, the HO shall exclude this information from the scope of its review.

If a request for reconsideration is filed late, the HO shall make a finding of good cause before taking any other action on the appeal. The time limits may be extended if good cause for late filing is shown. Good cause may be found when the record clearly shows, or the party alleges and the record does not negate that the delay in filing was due to one of the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

The HO shall issue a written decision within 90 days from the date of the request and forward the decision to the Medicare contractor and by mail to the provider, supplier or the authorized representative. The reconsideration letter shall include:

- The re-stated facts and findings, including the regulatory basis for the action as determined by the contractor in their initial determination;

- A summary of the documentation submitted by the prospective provider/supplier or the enrolled provider/supplier;

- A clear explanation of why the HO is upholding or overturning the denial or revocation action in sufficient detail for the provider or supplier to understand the nature of its deficiencies;

- If applicable, the regulatory basis to support each reason or reasons for the denial or revocation;

- An explanation of how the provider or supplier does not meet the enrollment criteria or requirements to enroll;

- Further appeal rights, procedures for requesting an administrative law judge (ALJ) hearing, and the address to which the written appeal must be mailed; and

- Information the appellant must include with their appeal (name/legal business name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision).

If an appeal for a denied application or revoked billing privileges is approved by a Medicare contractor, billing privileges can be issued. The effective date of Medicare billing privileges is based on the date the provider or supplier came into compliance with all Medicare requirements or the receipt date of the application being appealed. Contractors shall use the receipt date of the appeal as the receipt date they enter in PECOS.

A request for reconsideration may be withdrawn at any time prior to the mailing of the reconsideration decision either by the party that filed the appeal request or their authorized representative. The request for withdrawal must be in writing, signed, and filed with the Medicare contractor.

When the Medicare contractor receives a withdrawal request, it sends a letter to the provider or supplier acknowledging its receipt and advising that the reconsideration action will be terminated.

Medicare contractors shall maintain a report detailing the number of reconsideration requests they receive and their outcome (e.g., decision withheld, reversed, or further appeal requested or requests withdrawn). Medicare contractors are not required to submit this information to CMS but it must be provided upon request.

Administrative Law Judge (ALJ) Hearing

The CMS, a Medicare contractor, or a provider or supplier dissatisfied with a reconsidered determination is entitled to a hearing before an ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

Upon receipt of the request to file an ALJ hearing, an ALJ at the DAB will issue a letter by certified mail to the provider or supplier, CMS and the regional office of General Counsel (OGC) acknowledging receipt of an appeals request and detailing a scheduled pre-hearing conference. The OGC will assign an attorney that will represent CMS during the appeals process and who will also serve as the DAB point of contact. Neither CMS nor the Medicare contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the pre-hearing to discuss any issues. The Medicare contractors shall work with and provide the OGC attorney with all necessary documentation. Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS.

Departmental Appeals Board (DAB) Hearing

The CMS, a Medicare contractor, or a provider or supplier dissatisfied with the ALJ hearing decision may request Board review by the DAB. Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented orally to the DAB, then a transcript will be prepared and made available to any party upon request.

Judicial Review

A provider or supplier dissatisfied with a DAB decision has a right to seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.

B. Fiscal Intermediary

If a Medicare contractor reviews an initial enrollment application for a provider or certified supplier and finds that the application should be denied pursuant to 42 CFR §424.530, such as a facility's failure to meet one or more of the Federal or State requirements, the Medicare contractor shall deny/recommend denial to the regional office (RO) and notify the provider or certified supplier by letter (see section 14 of this chapter). The denial letter shall contain:

- A legal (i.e., regulatory) basis for each reason for the denial;

- A clear explanation of why the application is being denied, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to enroll in the Medicare program;

- Procedures for submitting a corrective action plan (CAP); and

- Complete and accurate information about the provider or supplier's further appeal rights.

Similarly, when a Medicare contractor discovers that there is a basis for revoking a provider or certified supplier's billing privileges, such as the provider or certified supplier no longer meets one of the requirements for billing privileges, the Medicare contractor shall revoke billing privileges and notify the provider or certified supplier by letter with a copy to the State and the RO. The revocation letter must contain:

- A legal (i.e., regulatory) basis for <u>each</u> reason for revocation;

- A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to maintain enrollment in the Medicare program;

- The effective date of the revocation (30 days from the date the notice is mailed. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment. The effective date of a license suspension/revocation is effective with the date of the suspension/revocation);

- Procedures for submitting a CAP; and

- Complete and accurate information about the provider or supplier's further appeal rights.

Corrective Action Plan (CAP)

A CAP is the process that gives the provider or certified supplier an opportunity to correct the deficiencies (if possible) that resulted in the denial or revocation of billing privileges. The CAP should provide evidence that the provider or certified supplier is in compliance with Medicare requirements.

The Medicare contractors shall emphasize to the providers and suppliers, through denial/revocation letters, that the submission of a CAP addressing the issues that resulted in the denial or revocation of billing privileges will expedite the enrollment process and issue a faster determination.

The submission of a CAP for denied or revoked billing privileges must be submitted within 30 days from the date of the notice. The CAP shall contain, at a minimum, verifiable evidence of the provider or certified supplier's compliance with enrollment requirements. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

If a CAP for a denied application or revoked billing privileges is approved by the CMS, billing privileges can be issued. The effective date is based on the date the provider or certified supplier came into compliance with all Medicare requirements. That is, once the provider or certified supplier has passed the state survey and been issued a certification date.

CAP requests will be processed within 60 days. During this process, the CMS will not toll the filing requirements associated with an appeal. However, the CMS can make a good cause determination in order to accept any appeal that has been submitted beyond the timely filing period.

Reconsideration

A provider or certified supplier that wishes to request a reconsideration must file its request, in writing, with the CMS within 60 days after the postmark of the notice to be considered timely filed. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

The date the request is received by the CMS is treated as the date of filing. The request may be signed by the authorized official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

If a timely request for a reconsideration is made, the CMS will hold an on-the-record reconsideration and issue a determination within 90 days from the date of the appeal request. The provider, certified supplier or the Medicare contractor may offer new evidence. It is the responsibility of the provider or certified supplier to show that its enrollment application was incorrectly denied or that its billing privileges were revoked erroneously.

In reviewing an initial enrollment decision or a revocation, the CMS will limit the scope of its review to the Medicare contractor/RO's initial reason for imposing a denial or revocation at the time that it issued the action and whether the Medicare contractor/ RO made the correct decision (i.e., denial/revocation). The Medicare contractor/ RO cannot introduce new denial or revocation reasons or change a denial or revocation reason listed in the initial determination during the reconsideration process. If a provider or certified supplier provides evidence that demonstrates or proves that they met or maintained compliance, after the date of denial or revocation, the CMS will exclude this information from the scope of its review.

If a reconsideration request is filed late, the CMS will make a finding of good cause before taking any other action on the appeal. These time limits may be extended if good cause for late filing is shown. Good cause may be found when the record clearly shows, or the party alleges and the record does not negate that the delay in filing was due to one of the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

The CMS will issue a written decision within 90 days from the date of the request and forwards the decision by certified mail to the Medicare contractor, the provider, certified supplier or the authorized representative. The reconsideration letter shall include:

- The re-stated facts and findings, including regulatory basis for the action as, determined by the Medicare contractor/ RO in their initial determination;

- A summary of the documentation submitted by the prospective provider/supplier or the enrolled provider/supplier;

- A clear explanation of why the CMS is upholding or overturning the denial or revocation action in sufficient detail for the provider or certified supplier to understand the nature of its deficiencies;

- If applicable, the regulatory basis to support each reason or reasons for the denial or revocation;

- An explanation of how the provider or certified supplier does not meet the enrollment criteria or requirements to enroll;

- Further appeal rights, procedures for requesting an ALJ hearing, and the address to which the written appeal must be mailed; and

- Information the appellant must include with their appeal (name/legal business name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision).

A request for reconsideration may be withdrawn at any time prior to the mailing of the reconsideration decision either by the party that filed the appeal request or their authorized representative. The request for withdrawal must be in writing, signed, and filed with the CMS.

When the CMS receives a withdrawal request, it sends a letter to the provider or certified supplier acknowledging its receipt and advising that the reconsideration action will be terminated.

ALJ Hearing

The CMS, a Medicare contractor, or a provider or certified supplier dissatisfied with a reconsidered determination is entitled to a hearing before the ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from the receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request the ALJ hearing is deemed a waiver of all rights to further administrative review.

Upon receipt of the request to file an ALJ hearing, an ALJ at the Departmental Appeals Board (DAB) will issue a letter by certified mail to the provider or certified supplier, CMS, the RO and the RO of General Counsel (OGC) acknowledging receipt of an appeals request and detailing a scheduled prehearing conference. The OGC will assign an attorney that will represent CMS during the appeal's process and who will also serve as the DAB point of contact. Neither CMS, the RO, nor the Medicare contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the pre-hearing to discuss any issues. The Medicare contractor shall work with and provide the OGC attorney with all necessary documentation. Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS.

DAB Hearing

The CMS, a Medicare contractor, or a provider or certified supplier dissatisfied with the ALJ hearing decision may request Board review by the DAB. Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented orally to the DAB then a transcript will be prepared and made available to any party upon request.

Judicial Review

A provider or certified supplier dissatisfied with DAB review has a right to seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.

15.26 – Special Provisions for HHAs

(Rev. 362, Issued: 12-17-10, Effective: 01-01-11, Implementation: 01-01-11)

15.26.1 – HHA Ownership Changes

(Rev. 362, Issued: 12-17-10, Effective: 01-01-11, Implementation: 01-01-11)

A. Background

Effective January 1, 2011, and in accordance with 42 CFR §424.550(b)(1) - if there is a change in majority ownership of an HHA by sale (including asset sales, stock transfers,

mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead:

- Enroll in the Medicare program as a new (initial) HHA under the provisions of §424.510, and

- Obtain a State survey or an accreditation from an approved accreditation organization.

For purposes of §424.550(b)(1), a "change in majority ownership" (as defined in 42 CFR §424.502) occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sales, stock transfers, mergers, or consolidations). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.

B. Exceptions

There are several exceptions to §424.550(b)(1). Specifically, the requirements of §424.550(b)(1) do not apply if:

- The HHA has submitted 2 consecutive years of full cost reports. (For purposes of this exception, low utilization or no utilization cost reports do not quality as full cost reports.)

- The HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

- The HHA is changing its existing business structure – such as from a corporation, a partnership (general or limited), or an LLC to a corporation, a partnership (general or limited) or an LLC - and the owners remain the same.

- An individual owner of the HHA dies.

In addition, §424.550(b)(1) does not apply to "indirect" ownership changes.

C. Effective Date

As indicated earlier, the provisions of 42 CFR §424.550(b)(1) and (2) as enacted in "CMS-6010-F, Medicare Program; Home Health Prospective Payment System Rate

Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices; Final Rule" – are effective January 1, 2011. This means that these provisions impact only those HHA ownership transactions whose effective date is on or after January 1, 2011. However, the provisions can apply irrespective of when the HHA first enrolled in Medicare. Consider the following illustrations:

- Example 1 – Smith HHA initially enrolls in Medicare effective July 1, 2009. Smith undergoes a change in majority ownership effective September 1, 2011. The provisions of §424.550(b)(1) apply to Smith because it underwent a change in majority ownership within 36 months of its initial enrollment.

- Example 2 – Jones HHA initially enrolls in Medicare effective July 1, 2007. Jones undergoes a change in majority ownership effective February 1, 2011. Section 424.550(b)(1) does not apply to this transaction because it occurred more than 36 months after Jones's initial enrollment. Suppose, however, than Jones undergoes another change in majority ownership effective February 1, 2012. Section 424.550(b)(1) would apply to this transaction because it took place within 36 months after Jones's most recent change in majority ownership (i.e., on February 1, 2011).

- Example 3- Johnson HHA initially enrolls in Medicare effective July 1, 2006. It undergoes a change in majority ownership effective October 1, 2010. This transaction is not affected by §424.550(b)(1) – as enacted in CMS-6010-F – because: (1) its effective date was prior to January 1, 2011, and (2) it occurred more than 36 months after the effective date of Johnson's initial enrollment. Johnson undergoes another change in majority ownership effective October 1, 2012. This change would be affected by §424.550(b)(1) because it occurred within 36 months of the HHA's most recent change in majority ownership (i.e., on October 1, 2010).

- Example 4 – Davis HHA initially enrolls in Medicare effective July 1, 1999. It undergoes its first change in majority ownership effective February 1, 2011. This change is not affected by §424.550(b)(1) because it occurred more than 36 months after Davis's initial enrollment. Davis undergoes another change in majority ownership effective July 1, 2014. This change, too, would be unaffected by §424.550(b)(1), as it occurred more than 36 months after the HHA's most recent change in majority ownership (i.e., on February 1, 2011). Davis undergoes another majority ownership change on July 1, 2016. This change would be impacted by §424.550(b)(1), since it occurred within 36 months of the HHA's most recent change in majority ownership (i.e., on July 1, 2014).

D. Section 424.550(b)(1)'s Applicability

If the contractor receives a CMS-855A application reporting an HHA ownership change, it shall undertake the following steps:

1. Step 1 – Change in Majority Ownership

The contractor shall determine whether a change in direct majority ownership has occurred. Through its review of the transfer agreement, sales agreement, bill of sale, etc., the contractor shall verify whether:

- The ownership change was a direct ownership change and not a mere indirect ownership change, and

- The change involves a party assuming a greater than 50 percent ownership interest in the HHA.

Assumption of a greater than 50 percent direct ownership interest can generally occur in one of two ways. First, an outside party that is currently not an owner can purchase more than 50 percent of the business in a single transaction. Second, an existing owner can purchase an additional interest that brings its total ownership stake in the business to greater than 50 percent. For instance, if a 40 percent owner purchased an additional 15 percent share of the HHA, this would constitute a change in majority ownership. This is consistent with the verbiage in the aforementioned definition of "change in majority ownership" regarding the "cumulative effect" of asset sales, transfers, etc.

If the transfer does not qualify as a change in majority ownership, the contractor can process the application normally. If it does qualify, the contractor shall proceed to Step 2:

2. Step 2 – 36-Month Period

The contractor shall determine whether the effective date of the transfer is within 36 months after the effective date of the HHA's: (1) initial enrollment in Medicare, or (2) most recent change in majority ownership. The contractor shall verify the effective date of the reported transfer by reviewing a copy of the transfer agreement, sales agreement, bill of sale, etc., rather than relying upon the date of the sale as listed on the application. It shall also review its records – and, if necessary, request additional information from the HHA – regarding the effective date of the HHA's most recent change in majority ownership, if applicable.

If the effective date of the transfer does not fall within either of the aforementioned 36-month periods, the contractor may process the application normally. If the transfer's effective date falls within one of these timeframes, the contractor shall proceed to Step 3.

3. Step 3 – Applicability of Exceptions

If the contractor determines that a change in majority ownership has occurred within either of the above-mentioned 36-month periods, the contractor shall also determine

whether any of the exceptions in §424.550(b)(2) apply. As alluded to earlier, the exceptions are as follows:

a. The HHA has submitted 2 consecutive years of full cost reports.

- For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports. As stated in Pub. 15-2 (Provider Reimbursement Manual, Part 2), section 3204, refer to 42 CFR §413.24(h) for a definition of low Medicare utilization.

- The cost reports must have been: (1) consecutive, meaning that they were submitted in each of the 2 years preceding the effective date of the transfer, and (2) accepted by the contractor.

b. The HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

c. The HHA is changing its existing business structure – such as from a corporation, a partnership (general or limited), or an LLC to a corporation, a partnership (general or limited) or an LLC - and the owners remain the same.

- If the HHA is undergoing a change in business structure other than those which are specifically mentioned in this exemption (e.g., corporation to an LLC), the contractor shall contact its DPSE liaison for guidance.

- For the exemption to apply, the owners must remain the same.

d. An individual owner of the HHA dies – regardless of the percentage of ownership the person had in the HHA.

E. Determination

If the contractor concludes that one of the aforementioned exceptions applies, it may process the application normally. If no exception applies, the contractor shall after first obtaining approval from CMS liaison to do so - send a letter to the HHA notifying it that, as a result of §424.550(b)(1), the HHA must:

- Enroll as an initial applicant; and

- Obtain a new State survey or accreditation after it has submitted its initial enrollment application and the contractor has made a recommendation for approval to the State/RO;

As the new owner must enroll as a new provider, the contractor shall also deactivate the HHA's billing privileges if the sale has already occurred. If the sale has not occurred, the contractor shall alert the HHA that it must submit a CMS-855A voluntary

termination application.

F. Additional Notes

The contractor is advised of the following:

1. If the contractor learns of an HHA ownership change by means other than the submission of a CMS-855A application, it shall notify its DPSE liaison immediately.

2. If the contractor determines, under Step 3 above, that one of the §424.550(b)(2) exceptions applies, the ownership transfer still qualifies as a change in majority ownership for purposes of the 36-month clock. To illustrate, assume that an HHA initially enrolled in Medicare effective July 1, 2010. It undergoes a change in majority ownership effective February 1, 2012. The contractor determined that the transaction was exempt from §424.550(b)(1) because the HHA submitted full cost reports in the previous 2 years. On February 1, 2014, the HHA undergoes another change in majority ownership that did not qualify for an exception. The HHA must enroll as a new HHA under §424.550(b)(1) because the transaction occurred within 36 months of the HHA's most recent change in majority ownership - even though the February 2012 change was exempt from §424.550(b)(1).

15.26.2 – Capitalization

(Rev. 362, Issued: 12-17-10, Effective: 01-01-11, Implementation: 01-01-11)

A. Background

Effective January 1, 2011, and pursuant to 42 CFR §489.28(a) and §424.510(d)(9), an HHA entering the Medicare program - including a new HHA as a result of a change of ownership if the change of ownership results in a new provider number being issued - must have available sufficient funds, which we term initial reserve operating funds, at (1) the time of application submission, and (2) all times during the enrollment process, to operate the HHA for the three-month period after Medicare billing privileges are conveyed by the Medicare contractor (exclusive of actual or projected accounts receivable from Medicare). This means that the HHA must also have available sufficient initial reserve operating funds during the 3-month period following the conveyance of Medicare billing privileges.

B. Points of Review

At a minimum, the contractor shall verify that the HHA meets the required amount of capitalization:

1. Prior to making its recommendation for approval;

2. After a recommendation for approval is made but before the RO review process is completed;

3. After the RO review process is completed but before the contractor conveys Medicare billing privileges to the HHA; and

4. During the 3-month period after the contractor conveys Medicare billing privileges to the HHA.

The HHA must submit proof of capitalization within 30 calendar days of being requested to do so by the contractor. Should the HHA fail to furnish said proof and billing privileges have not yet been conveyed, the contractor shall deny the HHA's application pursuant to §424.530(a)(8)(i) or (ii), as applicable. If billing privileges have been conveyed, the contractor shall revoke the HHA's billing privileges per §424.535(a)(11).

Should the contractor believe it is necessary to verify the HHA's level of capitalization more than once within a given period, e.g., more than once between the time a recommendation is made and the completion of the RO review process – the contractor shall seek approval from its DPSE liaison.

C. Determining Initial Reserve Operating Funds

Initial reserve operating funds are sufficient to meet the requirement of 42 CFR §489.28(a) if the total amount of such funds is equal to or greater than the product of the actual average cost per visit of 3 or more similarly situated HHAs in their first year of operation (selected by CMS for comparative purposes) multiplied by the number of visits projected by the HHA for its first 3 months of operation--or 22.5 percent (one fourth of 90 percent) of the average number of visits reported by the comparison HHAs--whichever is greater.

The contractor shall determine the amount of the initial reserve operating funds using reported cost and visit data from submitted cost reports for the first full year of operation from at least 3 HHAs that the contractor serves that are comparable to the HHA that is seeking to enter the Medicare program. Factors to be used in making this determination shall include:

- Geographic location and urban/rural status;
- Number of visits;
- Provider-based versus free-standing status; and
- Proprietary versus non-proprietary status.

The determination of the adequacy of the required initial reserve operating funds is based on the average cost per visit of the comparable HHAs, by dividing the sum of total reported costs of the HHAs in their first year of operation by the sum of the HHAs' total reported visits. The resulting average cost per visit is then multiplied by the projected visits for the first 3 months of operation of the HHA seeking to enter the program, but not less than 90 percent of average visits for a 3-month period for the

HHAs used in determining the average cost per visit.

D. Proof of Operating Funds

The HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. Such proof, at a minimum, must include a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA.

In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For the purpose of this section, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial 3-month period for which the initial reserve operating funds are required does not qualify in meeting the initial reserve operating funds requirement. Examples of cash equivalents for the purpose of this section are Treasury bills, commercial paper, and money market funds.

As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS may later require the HHA to furnish another attestation from the financial institution that the funds remain available, or, if applicable, documentation from the HHA that any cash equivalents remain available, until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds constitutes non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

E. Borrowed Funds

If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds, including furnishing an attestation from a financial institution or other source, as may be appropriate, and to establish that such funds will remain available until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization.

F. Line of Credit

If the HHA chooses to support the availability of a portion of the initial reserve operating funds with a line of credit, it must provide CMS with a letter of credit from the lender. CMS later may require the HHA to furnish an attestation from the lender that the HHA, upon its certification into the Medicare program, continues to be approved to borrow the amount specified in the letter of credit.

G. Documents

As part of ensuring the prospective HHA's compliance with the capitalization requirements, the contractor shall obtain the following from the provider:

- A document outlining the provider's projected budget – preferably, a full year's budget broken out by month
- A document outlining the number of anticipated visits - preferably a full year broken out by month
- An attestation statement from an officer of the HHA defining the source of funds
- Copies of bank statements, certificates of deposits, etc., supporting that cash is available (must be current)
- Letter from officer of the bank attesting that funds are available
- If available, audited financial statements

The contractor shall also ensure that the capitalization information in section 12, of the CMS-855A is provided.

15.26.3 – Additional *Home Health Agency (HHA)* Review Activities

(Rev. 423, Issued: 06-01-12, Effective: 07-02-12, Implementation: 07-02-12)

As stated in section 15.26.2(B)(3) of this chapter, the contractor must verify that a newly *enrolling HHA* has the required amount of capitalization after the regional office (RO) review process is completed but before the contractor conveys Medicare billing privileges to the HHA. Accordingly, the HHA must submit proof of capitalization during this "post-RO review" period.

To confirm that the HHA is still in compliance with Medicare enrollment requirements prior to the issuance of a provider agreement, the contractor shall *also* – during the post-RO review period *ensure that* each entity and individual listed in sections 2, 5 and 6 of the HHA's *Form* CMS-855A application *is again reviewed* against the Medicare Exclusion Database (MED) (or the Office of Inspector General's (OIG) List of Excluded Individuals and Entities) and the General Services Administration Excluded

Parties List System (GSA List). This activity applies: *(1)* regardless of whether the HHA is provider-based or freestanding, and *(2) o*nly to initial enrollments.

The capitalization *and* MED/GSA *re-reviews* described above shall be performed once the RO notifies the contractor *via e-mail* that the RO's review is complete. *(Per sections 15.4.1.6 and 15.19.2.2 of this chapter, a site visit will be performed after the contractor receives the tie-in/approval notice from the RO but before the contractor conveys Medicare billing privileges to the HHA.) If:*

a. ***The HHA is still in compliance*** *(e.g., no owners or managing employees are excluded, capitalization is met):*

1. *The contractor shall notify the RO of this via e-mail. The notice shall specify the date on which the contractor completed the aforementioned reviews.*

2. *The RO will: (1) issue a CMS Certification Number (CCN), (2) sign a provider agreement, and (3) send a tie-in notice or approval letter to the contractor. Per CMS Publication 100-08, chapter 10, section 5.5.3.1, the contractor shall complete its processing of the tie-in notice/approval letter within 45 calendar days of receipt (during which time a site visit will be performed).*

b. ***The HHA is not in compliance*** *(e.g., capitalization is not met):*

1. *The contractor shall notify the HHA of this via letter. This letter is not a formal denial, but merely alerts the HHA that (a) it has not met the capitalization or MED/GSA list requirements (as applicable) and (b) the matter is being referred to the RO.*

2. *T*he RO will: (1) notify the HHA and the contractor via letter of the denial of certification, and (2) afford appeal rights to the HHA. Upon receipt of this notice from the RO, the contractor shall switch the HHA's Provider Enrollment, Chain and Ownership System (PECOS) record to a "denied" status. (The denial date shall be the date on which the contractor *completed its capitalization and MED/GSA reviews.)* The contractor, however, need not send a denial letter to the HHA or afford appeal rights; the RO performs these activities.

While, therefore, the process of enrolling certified suppliers and certified providers other than HHAs will remain the same (i.e., recommendation is made to State/RO, after which the RO sends tie-in notice to contractor, etc.), the HHA process will now contain additional steps – specifically, Steps 4 and 5, as outlined below:

1. Contractor processes incoming HHA application and either (1) denies application, or (2) recommends approval to State/RO.

2. State performs survey (if applicable) and makes recommendation to RO.

3. If State recommends approval and RO concurs, RO will – instead of issuing CCN, signing provider agreement and sending tie-in notice/approval letter to contractor at this point, as is done with other certified provider and certified supplier applications – notify contractor that its review is complete.

4. Upon receipt of RO's notification, contractor will perform capitalization and MED/GSA reviews discussed in sections 15.26.2 and 15.26.3 of this chapter.

5. Once contractor completes its review, it will notify RO as to whether HHA is still in compliance with enrollment requirements.

If *the* provider *is* not in compliance, *the* RO will deny certification and issue appeal rights, while *the* contractor will switch *the* PECOS record to "denied" once it receives notice of denial from RO. If *the* provider is in compliance, *the* RO will: (1) issue *a* CCN, (2) sign *a* provider agreement, and (3) send *a* tie-in notice/approval letter to contractor.

15.27 – Deactivations and Revocations

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

If circumstances warrant, a fee-for-service contractor shall deactivate or revoke a provider or supplier's Medicare billing privileges under certain circumstances. Deactivation or revocation of Medicare billing privileges will not impact a provider or supplier's ability to submit claims to non-Medicare payers using their National Provider Identifier.

15.27.1 – CMS or Contractor Issued Deactivations

(Rev. 412, Issued: 03-30-12, Effective: 04- 30-12, Implementation: 04-30-12)

A. General Instructions

Unless indicated otherwise in this chapter or in another CMS instruction or directive, the contractor may deactivate a provider or supplier's Medicare billing privileges when:

- A provider or supplier does not submit any Medicare claims for 12 consecutive calendar months. The 12 month period begins on the 1st day of the 1st month without a claims submission through the last day of the 12th month without a submitted claim;

- A provider or supplier fails to report a change to the information supplied on the enrollment application within 90 calendar days of when the change occurred. Changes that must be reported include, but are not limited to, a change in practice location, a change of any managing employee, and a change in billing services; or

- A provider or supplier fails to report a change in ownership or control within 30 calendar days.

The deactivation of Medicare billing privileges does not affect a supplier's participation agreement (CMS-460).

Providers and suppliers deactivated for non-submission of a claim are required to complete and submit a Medicare enrollment application to recertify that the enrollment information currently on file with Medicare is correct and must furnish any missing information as appropriate. The provider or supplier must meet all current Medicare requirements in place at the time of reactivation.

Providers and suppliers that fail to promptly notify the contractor of a change (as described above) must submit a complete Medicare enrollment application to reactivate their Medicare billing privileges or, when deemed appropriate, recertify that the enrollment information currently on file with Medicare is correct. Reactivation of Medicare billing privileges does not require a new State survey or the establishment of a new provider agreement or participation agreement. However, per 42 CFR §424.540(b)(3)(i), and as described in subsection E below, an HHA whose billing privileges are deactivated must undergo a State survey or obtain accreditation prior to having its billing privileges reactivated.

Each contractor shall forward a copy of the Deactivation Summary Report provided by the Multi-Carrier System (MCS) to its designated DPSE contractor liaison no later than the last calendar day of each month.

B. Special Reactivation Instructions for Part B Suppliers

(This section 27.1(B) does not apply to: (1) providers and suppliers that complete the CMS-855A application, and (2) suppliers of durable medical equipment, prosthetics, orthotics and suppliers (DMEPOS)).

To ensure that a supplier that has reactivated its Medicare billing privileges does not become subject to a second deactivation for non-billing within 30 days of the reactivation, the contractor shall:

1. End-date the existing Provider Transaction Access Number (PTAN)-National Provider Identifier (NPI) combination in sections 1 and 4 of the Provider Enrollment, Chain and Ownership System (PECOS) with the non-billing end-date in MCS, and

2. Issue a new Provider Transaction Access Number (PTAN) to the provider or supplier, and associate the new PTAN with the NPI in sections 1 and 4 of PECOS.

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, or organizations (e.g., group practices) consisting of any of the aforementioned categories of individuals, the contractor shall establish the reactivation effective date as the later of: (a) the filing of a Medicare enrollment application that was subsequently approved by a Medicare

contractor, or (b) the date the supplier first started furnishing services at a new practice location.

The exception to this is if the supplier has at least one other enrolled practice location (under the same TIN) for which it is actively billing Medicare; here, the contractor shall establish and enter the effective date as either: (a) the date the supplier first saw a Medicare patient at the location indicated on the CMS-855, or (b) the same date as the non-billing end-date in MCS, whichever is later. To illustrate, if the supplier has only one enrolled practice location and that site is deactivated for non-billing, the effective date is the later of: (a) the filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor, or (b) the date the supplier first started furnishing services at a new practice location. On the other hand, suppose the supplier has two enrolled locations – X and Y - under its TIN. Location X is actively billing Medicare, but Y is deactivated for non-billing. The reactivation effective date for Y would be the later of: (a) the date the supplier first saw a Medicare patient at the location indicated on the CMS-855, or (b) the same date as the non-billing end-date in MCS. This is because the supplier has at least one other location – Location X – that is actively billing Medicare.

For individual and organizational suppliers other than those identified in the beginning of the previous paragraph, the contractor shall enter the effective date as either: (a) the date the supplier first saw a Medicare patient at the location indicated on the CMS-855, or (b) the same date as the non-billing end-date in MCS, whichever is later.

If the supplier's PTAN is only established in MCS, no action is required if the end-dated non-billing number is not in PECOS.

C. DMEPOS Deactivation

The National Supplier Clearinghouse (NSC) shall require a DMEPOS supplier whose billing privileges are deactivated for non-submission of claims (see CFR 42 CFR §424.540) to submit a new Medicare enrollment application and meet all applicable enrollment criteria, including a site visit, and accreditation when applicable, before an applicant can be approved. The NSC may not establish a retrospective billing date for a DMEPOS supplier whose billing privileges were deactivated due to claims inactivity.

D. Deactivation and Appeals Rights

The Medicare contractor shall not afford a provider or supplier appeal rights when a deactivation determination is made.

15.27.2 – Revocations

(Rev. 412, Issued: 03-30-12, Effective: 04- 30-12, Implementation: 04-30-12)

A. Revocation Reasons

The contractor may issue a revocation using revocation reasons 1-7 and 9-13 below without prior approval from CMS. Sections 15.27.3 through 15.27.3.2 below address revocation reason 8 (42 CFR §424.535(a)(8)), which requires review and approval by the Provider Enrollment Operations Group (PEOG).

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.

Revocation Reason 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.

Other situations in which the contractor shall use §424.535(a)(1) as a revocation reason include, but are not limited to, the following:

a. The provider or supplier does not have a physical business address or mobile unit where services can be rendered.

b. The provider or supplier does not have a place where patient records are stored to determine the amounts due such provider or other person.

c. The provider or supplier is not appropriately licensed.

d. The provider or supplier is not authorized by the Federal/State/local government to perform the services that it intends to render.

e. The provider or supplier does not meet CMS regulatory requirements for the specialty that it is enrolled as.

f. The provider or supplier does not have a valid social security number (SSN) or employer identification number (EIN) for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or authorized or delegated official.

g. The provider or supplier fails to furnish complete and accurate information and all

supporting documentation within 60 calendar days of the provider or supplier's notification from CMS or its contractor to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

h. The provider or supplier does not otherwise meet general enrollment requirements.

With respect to (e) above – and, as applicable, (c) and (d) - the contractor's revocation letter shall cite the appropriate statutory and/or regulatory citation(s) containing the specific licensure/certification/authorization requirement(s) for that provider or supplier type. For a listing of some of these statutes and regulations, refer to section 15.4 et seq. of this chapter. Note that the contractor must identify in its revocation letter the exact provision within said statute(s)/regulation(s) that the provider/supplier is not in compliance with.

Revocation Reason 2 (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 CFR part 76.

If an excluded party is found, the contractor shall notify its Provider Enrollment Operations Group (PEOG) liaison immediately. PEOG will notify the Government Task Leader (GTL) for the appropriate Zone Program Integrity Contractor. The GTL will, in turn, contact the Office of Inspector General's office with the findings for further investigation.

Revocation Reason 3 (42 CFR §424.535(a)(3))

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.

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 that was convicted of a felony within the preceding 10-year period or that otherwise does not meet all criteria necessary to enroll in Medicare.

If the contractor is uncertain as to whether a particular felony falls within the purview of 42 CFR §424.530(a)(3), it should contact its Provider Enrollment Operations Group (PEOG) liaison for assistance.

Revocation Reason 4 (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 laws and regulations.)

Prior to revoking a provider or supplier’s Medicare billing privileges pursuant to §424.535(a)(4), the contractor shall contact its PEOG liaison for guidance.

Revocation Reason 5 (42 CFR §424.535(a)(5))

The 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 Reason 6 (§424.535(a)(6))

(i) (A) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in §424.514 with the Medicare revalidation application; or

(B) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(ii) (A) Either of the following occurs:

(1) CMS is not able to deposit the full application amount into a government-owned account; or

(2) The funds are not able to be credited to the United States Treasury;

(B) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(C) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

Revocation Reason 7 (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 that 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.

Revocation Reason 8 (42 CFR §424.535(a)(8))

The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service.

Please see sections 15.27.3 through 15.27.3.2 of this chapter for instructions regarding the use of this revocation reason.

Revocation Reason 9 (42 CFR §424.535(a)(9))

The physician, non-physician practitioner, physician organization or non-physician organization failed to comply with the reporting requirements specified in 42 CFR §424.516(d)(1)(ii) or (iii), which pertain to the reporting of changes in adverse actions and practice locations, respectively, within 30 days of the reportable event.

Note the following with respect to Revocation 9:

- 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.

- If the individual or organization reports a change in practice location more than 30 days after the effective date of the change, the contractor shall not revoke the supplier's billing privileges on this basis. However, if the contractor independently determines – through an on-site inspection under 42 CFR §424.535(a)(5)(ii) or via another verification process - that the individual's or organization's address has changed and the supplier has not notified the contractor of this within the aforementioned 30-day timeframe, the contractor may revoke the supplier's billing privileges.

Revocation Reason 10 (42 CFR §424.535(a)(10))

The provider or supplier did not comply with the documentation requirements specified in 42 § 424.516(f).

Revocation Reason 11 (42 CFR §424.535(a)(11))

A home health agency (HHA) fails to furnish - within 30 days of a CMS or Medicare contractor request - supporting documentation verifying that the HHA meets the initial reserve operating funds requirement found in 42 CFR § 489.28(a).

Revocation Reason 12 (42 CFR §424.535(a)(12))

The provider or supplier's Medicaid billing privileges are terminated or revoked by a State Medicaid Agency.

(Note that Medicare may not terminate a provider or supplier's Medicare billing privileges unless and until the provider or supplier has exhausted all applicable Medicaid appeal rights).

B. Effective Date of Revocations

Per 42 CFR §405.874(b)(2), a revocation is effective 30 days after CMS or its contractor (including the National Supplier Clearinghouse (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 42 CFR §424.565, if a physician, non-physician practitioner, physician organization or non-physician practitioner organization fails to comply with the reporting requirements specified in 42 CFR §424.516(d)(1)(ii), the contractor may assess 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 PEOG 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 revocation 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 authorized official 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, 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 (AR 73) – 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 (AR 74) – The provider is no longer operational.

3 years (AR 81) – 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 PEOG liaison. PEOG will establish the appropriate enrollment bar for that particular case.

The contractor shall update the Provider Enrollment, Chain and Ownership System (PECOS) to reflect that the individual is prohibited from participating in Medicare for the applicable 1, 2, or 3-year period.

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. Reporting of Final Adverse Action - Compliance

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; and

- Establish an overpayment back to the date of the reportable event if the practitioner furnished services after 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, 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. Notification to Other Contractors

If the contractor revokes a provider or supplier's Medicare billing privileges, the contractor shall determine, via a search of PECOS, whether the provider/supplier is enrolled with any other Medicare contractors. If the contractor determines that the revoked provider/supplier is indeed enrolled with another contractor(s), the revoking contractor shall notify these other contractors of the revocation. The notification shall be done via e-mail and shall contain a short description of the reason for the revocation.

Upon receipt of this notification from the revoking contractor, the receiving contractor shall determine whether the provider or supplier's billing privileges should be revoked in its jurisdiction as well. Should the contractor need assistance in making this determination, it may contact its PEOG liaison.

H. Provider Enrollment Appeals Process

For more information regarding the provider enrollment appeals process, see section 19 of this chapter.

I. Summary

If the contractor determines that a provider's billing privileges should be revoked, it shall undertake the activities described in this section, 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 PEOG with the amount of the assessed overpayment within 10 days of the overpayment assessment; and
- Affording appeal rights.

J. Reporting Revocations/Terminations to the State Medicaid Agencies and Children's Health Program (CHIP)

Section 6401(b)(2) of the Patient Protection and Affordable Health Care Act (i.e., the Affordable Care Act), enacted on March 23, 2010, requires that the Administrator of CMS establish a process for making available to each State Medicaid Plan or Child Health Plan the name, National Provider Identifier, and other identifying information for any provider of medical or other items or services or supplier who have their Medicare billing privileges revoked.

To accomplish this task, the CMS will provide a monthly revoked provider list to all contractors via the Share Point Ensemble site. Contractors shall access this list on the 5th day of each month through the Share Point Ensemble site. Contractors shall review the monthly revoked provider list for the names of Medicare providers revoked in PECOS. Contractors shall document any appeals actions a provider/supplier may have submitted subsequent to the provider or supplier's revocation.

Contractors shall be required to update the last three columns on the tab named "Filtered Revocations" of the spreadsheet for every provider/supplier revocation action taken. Contractors shall not make any other modifications to the format of this form or its contents. The following terms are the only authorized entries to be made on the report:

Appeal Submitted:
Yes - (definition: an appeal has been received. This includes either a CAP or Reconsideration request or notification of an ALJ or DAB action.)
No - (definition: no appeal of any type has been submitted)

Appeal Type:
CAP
Reconsideration
ALJ
DAB

Appeal Status:
Under Review
Revocation Upheld
Revocation Overturned
CAP accepted
CAP denied
Reconsideration Accepted
Reconsideration Denied

If a contractor is reporting that no appeal has been submitted, the appeal type and status columns will be noted as N/A.

If an appeal action has been submitted to Provider Enrollment Operations Group (PEOG) for certified providers or suppliers, contractors shall access the PEOG appeal's log via the Share Point Ensemble site to determine the appeal status to include on the spreadsheet.

Contractors shall submit their completed reports by the 20th of each month to its designated BFL or Liaison within the PEOG.

15.27.2.1 - Special Instructions Regarding Revocations of Certified Providers and Certified Suppliers

(Rev. 412, Issued: 03-30-12, Effective: 04- 30-12, Implementation: 04-30-12)

If the contractor determines that one or more of the revocation reasons identified in section 15.27.2 of this chapter are applicable, the contractor may revoke the billing privileges of a certified provider or certified supplier without making a recommendation for revocation to the State and CMS regional office (RO). It can, in other words, revoke billing privileges at the contractor level.

In revoking the provider or supplier, the contractor shall:

- Issue the revocation letter to the provider in accordance with section 15.27.2 of this chapter.

- E-mail a copy of the revocation letter to the applicable RO's Division of Survey & Certification corporate mailbox. (The RO will notify the State of the revocation.)

- After determining the effective date of the revocation, end-date the entity's enrollment record in the Provider Enrollment, Chain and Ownership System (PECOS) in the same manner as it would upon receipt of a tie-out notice from the RO.

- Afford the appropriate appeal rights per section 19 of this chapter.

15.27.3 - DPSE Issued Revocations

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

Based on information from a Program Safeguard Contractor (PSC), CMS satellite office, or other CMS component, including a regional office, DPSE may request that fee-for-service contractors revoke a provider or supplier's Medicare billing privileges using revocation 12. Fee-for-service contractors shall only issue a revocation using Revocation 12 when they receive a properly executed Joint Signature Memorandum from CMS.

15.27.3.1 - Zone Program Integrity Contractor (ZPIC) Identified Revocations

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

Revocation Reason 8 (cited in 42 CFR §424.535(a)(8)) states as follows:

The provider, supplier or DMEPOS supplier submits a claim or claims for services or supplies that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

If a ZPIC believes that the use of Revocation Reason 8 is appropriate, the ZPIC will develop a case file - including the reason(s) for revocation - and submit the file and all supporting documentation to its respective government task leader (GTL). The ZPIC will provide the GTL with the name, all known identification numbers - including the National Provider Identifier and associated Provider Transaction Access Numbers - and locations of the provider or supplier, as well as detailed information to substantiate the revocation action.

The GTL will review the ZPIC case file and:

- Return the case file to ZPIC for additional development, or
- Recommend that the Provider Enrollment Operations Group (PEOG) consider approval the ZPIC recommendation for revocation.

If PEOG concurs with the GTL's revocation recommendation, PEOG will: (1) ensure that the applicable fee-for-service contractor is instructed to revoke the provider/supplier's Medicare billing privileges, and (2) notify the Division of Medicare Integrity Contractor Operations of the action taken.

15.27.3.2 - CMS Satellite Office or Regional Office Identified Revocations

(Rev. 424, Issued: 06-13-12, Effective: 06-19-12, Implementation: 06-19-12)

If a CMS satellite office (SO) or regional office (RO) believes that the use of Revocation Reason 8 (see section 15.27.3.1 above) is appropriate, the SO/RO will develop a case file - including the reason(s) for revocation - and submit the file and all supporting documentation to the Provider Enrollment Operations Group (PEOG). The case file must include the name, all known identification numbers - including the National Provider Identifier and associated Provider Transaction Access Numbers - and locations of the provider or supplier, as well as detailed information to substantiate the revocation action.

If PEOG concurs with the SO/RO's revocation recommendation, PEOG will: (1) ensure that the applicable fee-for-service contractor is instructed to revoke the provider/supplier's Medicare billing privileges, and (2) notify the SO/RO of the action taken.

15.27.4 - External Reporting Requirements

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

No later than the last day of January, April, July and October of each year, the contractor shall furnish to its DPSE liaison via e-mail the following information for the previous quarter:

A. Fiscal Intermediaries (includes A/B MACs)

- Number of recommendations for denial of initial CMS-855A applications (including new owner CHOWs) and the three most frequent reasons for said recommendations;

- Number of revocations (or recommendations for revocations) and the three most frequent reasons for said actions.

B. Carriers (includes A/B MACs)

- Number of denials of initial CMS-855 applications (this includes denial recommendations for ASCs and PXRS) and the three most frequent reasons for said denials. (CMS-855B and CMS-855I denials shall be listed separately.)

- Number of revocations and the three most frequent reasons therefore. (CMS-855B and CMS-855I revocations shall be listed separately.)

The contractor need not submit this data to CMS via any sort of spreadsheet. A simple e-mail is sufficient. The first report is due by January 31, 2008, and shall cover actions taken in October, November and December of 2007.

15.28 – Deceased Practitioners

(Rev. 357, Issued: 10-01-10, Effective: 10-01-10, Implementation: 10-04-10)

A. Reports of Death from the Social Security Administration (SSA)

Contractors, including DME MACs and the NSC MAC, will receive from CMS a monthly file that lists individuals who have been reported as deceased to the SSA. To help ensure that Medicare maintains current enrollment and payment information and to prevent others from utilizing the enrollment data of deceased individuals, the contractor shall undertake the activities described below.

B. Verification Activities

1. Individuals Other than Physicians, Non-Physician Practitioners and/or Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

If the person is an owner, managing employee, director, officer, authorized official, etc., the contractor shall verify and document that the person is deceased using the

verification process described in 16(B) above.

Once the contractor verifies the report of death, it shall notify the provider or supplier organization with whom the individual is associated that it needs to submit a CMS-855 change request that deletes the individual from the provider or supplier's enrollment record. If a provider fails to submit this information within 90 calendar days of the contractor's request, the contractor shall deactivate the provider's Medicare billing privileges in accordance with 42 CFR §424.540(a)(2). DMEPOS Suppliers Only - If a DMEPOS supplier fails to submit this information within 30 calendar days of the contractor's request, the contractor shall deactivate the supplier's billing privileges in accordance with 42 CFR § 424.57(c)(2).

The contractor need not, however, solicit a CMS-855 change request if:

- The associate was the sole owner of his or her professional corporation or professional association. The contractor can simply terminate that organization's enrollment in Medicare and then undertake all actions normally associated with a termination of a supplier's billing privileges, including sending a termination letter to the supplier; or

- The organization is enrolled with another contractor. Here, the contractor shall notify (via fax or e-mail) the contractor with which the organization is enrolled of the situation, at which time the latter contractor shall take actions consistent with this section 16.

C. Reports of Death from Third-Parties

If a contractor, including DME MACs or the NSC MAC, receives a report of death from a third-party (State provider association, State medical society, academic medical institution, etc.), the contractor shall verify that the individual practitioner, non-physician practitioner or DMEPOS supplier is deceased by:

- Obtaining oral or written confirmation of the death from an authorized or delegated official of the group practice to which the individual practitioner, non-physician practitioner or DMEPOS supplier had reassigned his or her benefits; or

- Obtaining an obituary notice from the newspaper; or

- Obtaining oral or written confirmation from the State licensing board (e.g., telephone, e-mail, computer screen printout); or

- Obtaining oral or written confirmation from the State Bureau of Vital Statistics; or

- Obtaining a death certificate, Form SSA-704, or Form SSA-721 (Statement of Funeral Director).

Once the contractor verifies the death, it shall:

1. Undertake all actions normally associated with the termination of a supplier's billing privileges, with the exception of sending a termination letter to the practitioner, non-physician practitioner or DMEPOS supplier.

2. Search PECOS to determine whether the individual is listed therein as an owner, managing employee, director, officer, partner, authorized official, or delegated official.

3. If the person is not in PECOS, no further action with respect to that individual is needed.

4. If the supplier is indeed identified in PECOS as an owner, officer, etc., the contractor shall notify the organization with whom the person is associated that it needs to submit a CMS-855 change request that deletes the individual from the entity's enrollment record. If a provider fails to submit this information within 90 calendar days of the contractor's request, the contractor shall deactivate the provider's billing privileges in accordance with 42 CFR §424.540(a)(2). DMEPOS Suppliers Only - If a DMEPOS supplier fails to submit this information within 30 calendar days of the contractor's request, the contractor shall deactivate the supplier's billing privileges in accordance with 42 CFR § 424.57(c)(2).

The contractor need not, however, ask for a CMS-855 change request if:

a. The practitioner, non-physician practitioner or DMEPOS supplier was the sole owner of his/hers professional corporation or professional association. The contractor can simply terminate the organization's enrollment in Medicare. It shall then undertake all termination actions normally associated with the termination of a supplier's billing privileges, including sending a termination letter to the supplier; or

b. The organization is enrolled with another contractor. In this situation, the contractor shall notify (via fax or e-mail) the contractor with which the organization is enrolled of the situation, at which time the latter contractor shall take actions consistent with this section 16.

The contractor shall place verification documentation in the provider or supplier file in accordance with section 10 of this chapter.

D. Education & Outreach

Contractors, including DME MACs and the NSC MAC, shall conduct outreach to State provider associations, State medical societies, academic medical institution, and group practices, etc., regarding the need to promptly inform contractors of the death physicians, non-physician practitioners participating in the Medicare program.

E. Trustees/Legal Representatives

1. NPI - The trustee/legal representative of a deceased provider, non-physician practitioner or DMEPOS supplier's estate may deactivate the NPI of the deceased provider by providing written documentation to the NPI enumerator.

2. Special Payment Address - In situations where an individual practitioner, non-physician practitioner or DMEPOS supplier has died, the contractor can make payments to the individual's estate per the instructions in Pub. 100-04, chapter 1. When the contractor receives a request from the trustee or other legally-recognized representative of the provider, non-physician practitioner or DMEPOS supplier's estate to change the provider, non-physician practitioner or DMEPOS supplier's special payment address, the contractor shall, at a minimum, ensure that the following information is furnished:

- CMS-855 change of information request that updates the "Special Payment" address in the application. The CMS-855 can be signed by the trustee/legal representative.

- Any evidence – within reason - verifying that the practitioner, non-physician practitioner or DMEPOS supplier is in fact deceased.

- Legal documentation verifying that the trustee/legal representative has the legal authority to act on behalf of the provider, non-physician practitioner or DMEPOS supplier's estate.

The policies in this section 16(E)(1) and (2) apply only to individual practitioners, non-physician practitioners and DMEPOS suppliers who operated their business as sole proprietors. It does not apply to solely-owned corporations, limited liability companies, etc., nor does it apply to situations in which the practitioner, non-physician practitioner or DMEPOS supplier reassigned his or her benefits to another entity.

15.29 - Provider and Supplier Revalidations and DMEPOS Re-enrollment

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

Per 42 CFR § 424.515, Medicare providers and suppliers (other than DMEPOS suppliers) must resubmit and recertify the accuracy of their enrollment information every five years in order to maintain Medicare billing privileges. Contractors may initiate revalidation activities at any time during the fiscal year.

The following principles apply to revalidation:

- The processing times for "initial" applications – outlined in section **6**.1 of this manual – apply to revalidation applications.

- Per 42 CFR § 424.515, a provider whom the contractor requested to furnish all requested information (as part of the revalidation) must do so within 60 calendar days after the date the contractor notified the provider of the need to revalidate. If the provider fails to do so, the contractor shall revoke the provider's billing privileges using existing revocation procedures.

- The provider must submit all required documentation with its application, even if such documentation is already on file with the contractor.

The contractor shall verify all data furnished on the application – just as it would with an initial enrollment – using the procedures identified in this manual (e.g., section 8.2)

15.29.1 - Supplementary Revalidation Activities

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

If, as of the last day of the eighth month of the fiscal year for legacy contractors (May 31) or the current contract year for A/B MAC contractors, the contractor's provider enrollment workload and costs are both less than what was projected to CMS at the beginning of the fiscal/contract year, the contractor shall undertake revalidation efforts commensurate with the amount of surplus funding. In doing so, the contractor shall first revalidate those providers that do not have an established enrollment record in PECOS.

Revalidation of the remaining providers shall be conducted in roughly the following order:

1. Providers that have not updated their enrollment information within the previous 5 years (i.e., have not submitted a CMS-855 change of information within that time span).

2. High-risk providers (e.g., provider is located in a historically high-risk metropolitan area or is of a high-risk provider/supplier type).

3. Providers that are not receiving payments via EFT.

4. High-reimbursement providers.

15.31 - Provider Enrollment Fraud Detection Program for High Risk Areas

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

The PSCs shall identify an area as a potential high risk for provider/supplier enrollment and shall notify the A/B MACs and ACs, excluding the NSC, through the JOA process. High risk areas may be identified by emerging or widespread anomalies that may lead to potential fraud and abuse in, for example, claim type, provider type and geographic area. (See PIM, chapter 4, §§4.32 and 4.32.1 for additional information concerning the responsibilities of the PSC.)

After receiving and reviewing the information on the potential high risk areas the AC or the A/B MAC shall determine if the information is a high risk for provider/ supplier enrollment and, if so, provide a written request to the Director of the Division of Provider and Supplier Enrollment (DPSE), requesting approval that the area be designated as high risk. The request should include the name of the AC or the A/B MAC, a contact name, phone number and a justification for designating an area as high risk for fraud and abuse.

The A/B MAC shall notify its project officer of the request for designation as a high risk fraud and abuse area concurrent with the A/B MAC's request for approval to the Director of DPSE.

15.31.1 – Submission of Proposed Implementation Plan for High Risk Areas

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

Upon obtaining approval from the Director of the DPSE within the Program Integrity Group regarding the designation of a high risk area, the A/B MAC or AC shall submit, for approval, an implementation plan that addresses the problems identified in the high risk areas. The request shall include the name of the A/B MAC or AC, a contact name, phone number, and a description of the proposed action plan.

The A/B MAC or AC shall propose an implementation plan that includes, but is not limited to the following actions to remediate the identified problems in the high areas:

- Conduct revalidation activities;
- Conduct unannounced site visits;
- Expand verification and validation activities to include felony searches for individuals, owners, managing officials, and delegated officials;
- Establish a risk assessment for newly enrolled providers/suppliers.

The A/B shall work with its project officer in coordination with DPSE to determine the specific support functions needed for ongoing and proposed project activities.

If the A/B MAC or AC determines that a provider or supplier no longer meets Medicare enrollment standards, the MAC or AC shall follow the procedures set forth in section 13 of this chapter.

15.17 – Establishing an Effective Date of Medicare Billing Privileges

(Rev.)

15.17.4 – Certified Provider or Supplier Agreement or Approval

(Rev.)

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R424PI	06/13/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM)-Part VI	06/19/2012	7827
R423PI	06/01/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM)-Part VII	07/02/2012	7839
R421PI	05/18/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM)-Part VI	06/19/2012	7827
R416PI	04/13/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM)-Part III	02/27/2012	7698
R415PI	04/13/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM)-Part V	05/14/2012	7797
R414PI	04/06/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM)-Part IV	05/07/2012	7763
R412PI	03/30/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM)-Part II	04/30/2012	7646
R410PI	03/02/2012	Instructions for Processing Form CMS-855O Submissions	06/04/2012	7723
R408PI	02/22/2012	Additional Provider and Supplier Enrollment Requirements for Fixed Wing and Helicopter Air Ambulance Operators	02/03/2012	7363
R407PI	02/09/2012	Advanced Diagnostic Imaging (ADI) Accreditation Enrollment Procedures(This CR Fully Rescinds and Replaces CR 7177)	01/27/2012	7681
R405PI	01/26/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM) –Part III – Rescinded and replaced by Transmittal 416	02/27/2012	7698
R404PI	01/20/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM)-Part I	04/22/2012	7579
R403PI	01/20/2012	Claims Against Surety Bonds for Suppliers of Durable Medicare Equipment, Prosthetics. Orthotics and Supplies (DMEPOS)	02/21/2012	7167
R402PI	01/13/2012	Advanced Diagnostic Imaging (ADI) Accreditation Enrollment Procedures(This CR Fully Rescinds and Replaces CR 7177) – Rescinded and replaced by Transmittal 407	01/27/2012	7681
R400PI	11/21/2011	Additional Provider and Supplier Enrollment Requirements for Fixed Wing and Helicopter Air Ambulance Operators – Rescinded and replaced by Transmittal 408	02/03/2012	7363

Rev #	Issue Date	Subject	Impl Date	CR#
R394PI	10/27/2011	Additional Provider and Supplier Enrollment Requirements for Fixed Wing and Helicopter Air Ambulance Operators – Rescinded and replaced by Transmittal 400	02/03/2012	7363
R392PI	10/14/2011	Update to Notifications Sent to State Medicaid Agencies and Child Health Plans of Medicare Terminations for Certified Providers and Suppliers and Medicare Revocations for Providers and Suppliers. This CR rescinds and fully replaces CR 7017, 7074 and 7334	11/15/2011	7532
R388PI	09/16/2011	Additional Review Activities for Home Health Agencies (HHAs)	12/17/2011	7525
R387PI	09/01/2011	Eligible Physicians and Practitioners Who Need to Enroll in the Medicare Program for the Sole Purpose of Ordering and Referring Services for Medicare Beneficiaries	10/18/2010	7097
R380PI	08/03/2011	Advanced Diagnostic Imaging Accreditation Enrollment Procedures	07/05/2011	7177
R374PI	05/06/2011	Update to Notifications Sent to State Medicaid Agencies and Child Health Plans of Medicare Terminations for Certified Providers and Suppliers and Medicare Revocations for Providers and Suppliers	06/06/2011	7334
R373PI	04/07/2011	Advanced Diagnostic Imaging Accreditation Enrollment Procedures – Rescinded and replaced by Transmittal 380	07/05/2011	7177
R372PI	03/25/2011	Effective Date of Certified Provider or Supplier Agreement or Approval	04/25/2011	7232
R371PI	03/23/2011	Implementation of Provider Enrollment Provisions in CMS-6028-FC	03/25/2011	7350
R369PI	03/11/2011	Advanced Diagnostic Imaging Accreditation Enrollment Procedures – Rescinded and replaced by Transmittal 373	06/12/2011	7177
R365PI	01/28/2011	Diabetes Self-Management Training (DSMT)	04/29/2011	7236
R363PI	01/14/2011	Clarification for Part A Contractors Including Audit and Claims Intermediaries Notifying Each Other via E-mail Upon Processing of the Initial Enrollment Application, Change of Information,	02/15/2011	7221

Rev #	Issue Date	Subject	Impl Date	CR#
		Voluntary Termination, or Any Other CMS-855 Transaction		
R358PI	10/29/2010	Indian Health Service (IHS) Facilities and Tribal Provider's Use of Internet-based Provider Enrollment, Chain and Ownership System (PECOS)	11/29/2010	7174
R357PI	10/01/2010	Durable Medical Equipment (DME MAC) and the National Supplier Clearinghouse (NSC MAC) Procedures for Third Party Notification of Deceased Durable Medical Equipment, Prosthetic, Orthotic and Supplies (DMEPOS) Supplier Associates	10/04/2010	6714
R356PI	09/24/2010	Manual Redesign	10/26/2010	7083
R355PI	09/17/2010	Eligible Physicians and Practitioners Who Need to Enroll in the Medicare Program for the Sole Purpose of Ordering and Referring Services for Medicare Beneficiaries	10/18/2010	7097
R354PI	08/27/2010	Manual Redesign	09/28/2010	7016
R353PI	08/27/2010	Notification to State Medicaid Agencies and Child Health Plans of Medicare Terminations for Certified Providers and Suppliers	09/28/2010	7074
R350PI	08/20/2010	Notification to State Medicaid Agencies and Child Health plans of Medicare Revocation	09/21/2010	7017
R347PI	07/15/2010	Chapter 10 Manual Redesign - Initial release of Chapter 15	07/30/2010	6938
R346PI	06/25/2010	Guidance on Implementing Section 3109 of the Patient Protection and Affordable Care Act (PPACA)	01/03/2011	7021
R344PI	06/18/2010	Chapter 10 Manual Redesign - Initial release of Chapter 15 - Rescinded and replaced by Transmittal 347	07/05/2011	6938

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