CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 430	**Date: September 28, 2012**
	Change Request 7889

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

I. SUMMARY OF CHANGES: The purpose of this CR is to continue the process of updating chapter 15 of the PIM.

EFFECTIVE DATE: October 29, 2012
IMPLEMENTATION DATE: October 29,2012

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/15.4.1.4/Federally Qualified Health Centers (FQHCs)
R	15/15.4.2.7/Suppliers of Ambulance Services
R	15/15.5.18/Ambulance Attachment
R	15/15.9.2/Certified Providers and Certified Suppliers
R	15/15.11/Electronic Fund Transfers (EFT)
R	15/15.14.4/Non-Participating Emergency Hospitals, Veterans Administration (VA) Hospitals, and Department of Defense (DOD) Hospitals
R	15/15.16.2/Processing Initial Form CMS-855O Submissions
R	15/15.21/Special Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Instructions
R	15/15.21.1/DMEPOS Supplier Accreditation
R	15/15.21.2/Enrolling Indian Health Service (IHS) Facilities as DMEPOS Suppliers
R	15/15.21.3/Reserved for Future Use
R	15/15.21.4/Development and Use of Fraud Level Indicators
R	15/15.21.4.1/Fraud Prevention and Detection
R	15/15.21.5/Alert Codes
R	15/15.21.6/Reserved for Future Use
R	15/15.29/Provider and Supplier Revalidations and DMEPOS Re-enrollment

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; contractor's activities are to be carried out with their operating budgets.

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

IV. ATTACHMENTS:

Business Requirements

Manual Instructions
**Unless otherwise specified, the effective date is the date of service.*

Attachment – Business Requirements

Pub. 100-08	Transmittal: 430	Date: September 28, 2012	Change Request: 7889

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

Effective Date: **October 29, 2012**

Implementation Date: October 29, 2012

I. GENERAL INFORMATION

A. Background: This change request (CR) is the eighth in a series of transmittals designed to update chapter 15 of the PIM. The majority of revisions in this CR will either (1) be editorial in nature or (2) incorporate existing policies directly into chapter 15. Any new instructions are reflected in the CR's business requirements.

B. Policy: The purpose of this CR is to continue the process of updating chapter 15 of the PIM.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7889.1	For federally qualified health centers (FQHCs), the contractor shall ensure that the attestation statement (Exhibit 177) contains the same legal business name and address as that which the FQHC provided in section 2 and section 4, respectively, of the Form CMS-855A; if the attestation contains a different name, the contractor shall develop for the correct name.	X		X							
7889.2	When sending a recommendation for approval letter to the CMS regional office (RO) for an initial FQHC application, the contractor shall indicate in the letter the date on which the FQHC's application was complete.	X		X							
7889.3	The contractor shall inform an initial applicant (including a new owner that has rejected assignment of the provider or supplier agreement) that Medicare billing privileges will not begin before the date the survey and certification process has been completed and all Federal requirements have been met.	X		X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	None										

IV. SUPPORTING INFORMATION

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

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

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

V. CONTACTS

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

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

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

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

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

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

Medicare Program Integrity Manual
Chapter 15 - Medicare Enrollment

Table of Contents

(Rev.430,Issued: 09-28-12)

15.4.1.4 - Federally Qualified Health Centers (FQHCs)

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

*F*QHCs 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* 100-0*2, c*hapter 13, *for more information*). *Even though they complete the Form CMS-855A application, FQHCs* are considered Part B certified suppliers.

*F*QHCs 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 *to* 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 *health program or* facility operated by *a tribe or tribal organization under the Indian Self-Determination Act or by* an *Urban* Indian 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, c*hapter 2, sections 2825-2826D for more information.)

NOTE: *Additional information* 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.

- *F*QHCs can be based in a rural or urban area *that is designated as either a shortage area or an area that has a medically underserved population.*

- 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.*

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

- *The contractor shall ensure that the attestation statement (Exhibit 177) contains the same legal business name and address as that which the FQHC provided in section 2 and section 4, respectively, of the Form CMS-855A. If the attestation contains a different name, the contractor shall develop for the correct name.*

- *An* FQH*C* 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 as the date the application was complete.

See CMS Publication 100-07, chapter 2, section 2826F for information regarding the effective date of an FQHC's agreement with CMS.

For additional general information on FQHCs, refer to:

- Section 1861(aa)(3-4) of the Social Security Ac*t*
- 42 CFR Part 49*1 and 42 CFR Part 405.2400*
- Pub. 100-07, chapter 2, sections 2825 – 2826*H*
- *Pub. 100-07, Exhibit 179*
- 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 2*0*
- Pub. 100-04, chapter 9, section 10.*3*
- CMS Change Request 620*7*

15.4.2.7 - Suppliers of Ambulance Services

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

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 42

CFR § 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 42 CFR § 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 42 CFR § 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 42 CFR § 414.605, EMT-Paramedic services furnished by an entity that does not furnish the ground transport, provided that the services meet the requirements in 42 CFR § 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 42 CFR § 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 42 CFR § 410.41*;*
    - Furnish*es* services only at the BLS level*; and*

- 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 42 CFR § 410.41(b)(2)*; and*
  - *Bills 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 42 CFR § 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 42 CFR § 410.41(b)(1)(i) *and* (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 42 CFR § 410.41(b)(*1*), 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.

NOTE: The contractor shall observe that this provision *does not* obviat*e* the need for the supplier to complete and submit to the contractor the *Form* CMS-855B *(including Attachment 1* and all supporting documents), and does not excuse the contractor from having to verify the data on the *Form* CMS-*855B in* accordance with *this chapter and all other applicable CMS instructions*. In other words, the "statement" referred to in section 10.1.3, does not supplant or replace the *Form* CMS-855*B e*nrollment process.

E. Miscellaneous Information

1. **Payment Amounts** - Per 42 CFR § 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 42 CFR § 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 42 CFR § 410.40(e), Medicare covers the following ambulance transportation:

- From any point of origin to the nearest hospital, *critical access hospital (*CAH*)*, or *skilled nursing facility (*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 *end-stage renal disease*, 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*; t*herefore, only mileage to the nearest appropriate facility equipped to treat the patient is covered.

6. **Part A** - For information on the Part A *contractor's* processing of claims for ambulance services furnished under arrangements by participating hospitals, SNFs, and *home health agencies*, 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.

*8. **Air Ambulance Certification Requirements** – For information on air ambulance certification requirements, see section 15.5.18 of this chapter.*

*9. **Effective Date of Billing –** The contractor shall not apply the effective date provisions of 42 CFR § 424.520(d) to ambulance suppliers. These provisions apply only to physicians, non-physician practitioners, and physician and non-physician practitioner groups.*

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

15.5.18 – Ambulance Attachment

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

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 *Form* CMS-855B to each contractor.

B. Licensure Information

With respect to licensure:

- The contractor shall ensure that the supplier *is appropriately licensed and/or certified, as applicable.*

- If the supplier performs services in multiples States within the same contractor jurisdiction, it must be *appropriately licensed and/or certified in each State in which services are performed, as applicable.* Separate, full *Form* CMS-855Bs are not required for each State; however, the contractor shall create separate enrollment records in *the Provider Enrollment, Chain and Ownership System (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. *Air Ambulances*

Air ambulance suppliers must submit the following:

(1) 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

(2) 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. *Any of the following constitutes acceptable proof:*

- *If the air ambulance supplier or provider owns the aircraft, the owner's name on the FAA Part 135 certificate must be the same as the supplier's or provider's name on the enrollment application.*

- *If the air ambulance supplier or provider owns the aircraft but contracts with an air services vendor to supply pilots, training and/or vehicle maintenance, the FAA Part 135 certificate must be issued in the name of the air services vendor. A certification from the supplier or provider must also attest that it has an agreement with the air services vendor and must list the date of that agreement. A copy of the FAA Part 135 Certificate must accompany the enrollment application.*

- *If the air ambulance supplier or provider 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 or provider's name on the enrollment application.*

The air ambulance supplier shall maintain all applicable Federal and State licenses and certifications, including pilot certifications, instrument and medical certifications and air worthiness certifications.

In addition:

- *The contractor shall access the following FAA Web site on a quarterly basis to validate all licenses/certifications of air ambulance operators that are enrolled with the contractor: http://www.faa.gov/about/office_org/headquarters_offices/agc/operations/agc300/reports*

- *The contractor shall deny or revoke the enrollment of an air ambulance supplier if the supplier does not maintain its FAA certification or any other applicable licenses.*

E. Hospital-Based Ambulances

An ambulance service that is owned and operated by a hospital need not complete a *Form* 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

Form CMS-855B if it wishes to bill Medicare.

15.9.2 - Certified Providers and Certified Suppliers

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

(This section only applies *to: (1)* initial Form CMS-855A applications or *change of ownership (CHOW)*, acquisition/merger, or consolidation applications submitted by the new owner; and (2) initial *ambulatory surgical center and portable x-ray supplier* applications.)

If the contractor decides to recommend approval of the provider or supplier's application, the contractor shall send *a recommendation letter* to the applicable State agency, with a *copy to the Regional Office's (RO)* survey and certification unit. (For those provider types that do not require a State survey, such as *federally qualified health centers*, the letter can be sent directly to the RO.) *The recommendation letter shall, at a minimum, contain the following information:*

- Supplier/Provider NPI Numbe*r*
- *CMS Certification* Number (if available*)*
- Type of enrollment transaction (CHOW, initial enrollment, branch addition, etc.*)*
- Contractor *n*umbe*r*
- Contractor *c*ontact *n*am*e*
- Contractor *c*ontact *p*hone *n*umbe*r*
- Date *a*pplication *r*ecommended for *a*pproval *(and, for FQHCs, the date that the package is complete)*
- An explanation of any special circumstances, findings, or other information that either the State or the RO should know about.
- *Any other information that, under this chapter 15, must be included in the recommendation letter.*

The contractor shall also:

- Send a photocopy (not the original) of the final completed *Form* CMS-855 to the State agency, along with all updated *Form* CMS-855 pages, explanatory data, documentation, correspondence, final sales agreements, etc. The photocopied *Form* CMS-855 should be sent in the same package as the recommendation letter.

The contractor shall not send a copy of the *Form* 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 *via e-mail, or via the letter identified in section 15.24.6 of this chapter,* and shall advise the applicant of the next steps in the enrollment process (e.g., site visit, survey). The contractor may, but is *not* 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.

- *Inform initial applicants (including new owners that have rejected assignment of the provider's or supplier's provider agreement) that Medicare billing privileges will not begin before the date the survey and certification process has been completed and all Federal requirements have been met.*

- *N*otify 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;* the applicant shall also be instructed that all questions related to this process shall be directed to the State agency and/or RO.

15.11 – Electronic Fund Transfers (EFT)

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

A. General Information

If a provider does not have an established enrollment record in *the Provider Enrollment, Chain and Ownership System (PECOS)* and wants to change any of its EFT information (e.g., bank routing number), it must submit a complete *Form* CMS-85*5* before the contractor can effectuate the change. *With the exception of the situation described in section (B) below*, it is immaterial whether the provider or the bank was responsible for triggering the changed data.

Under 42 CFR § 424.510(d)(2)(iv) and § 424.510(e):

- *A*ll providers (including Federal, State and local governments) *enrolling in Medicare* 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 *Form* CMS-*588 and* thereafter receive payments via EFT.

- *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*: (1)* continue to receive EFT payments *and (2)* submit a new *Form* CMS-588 for the new contractor.

B. Verification

Providers and suppliers may submit a Form CMS-588 via paper or through PECOS. In either case, the contractor shall ensure that:

- *The information submitted on the Form CMS-588 is complete and accurate.*

- *The provider/supplier submitted (1) a voided check or (2) a letter from the bank verifying the account information.*

- *The routing number and account number matches what was provided on the Form CMS-588.*

- *The signature is valid. (**Note:** For electronic Form CMS-588 submissions, the provider can either e-sign the form or submit a written signature via the paper Form CMS-588)*

Once the Form CMS-588 has been processed, the 588 form will be printed and delivered to the contractor's financial area along with the voided check and letter from the bank verifying account information, for proper processing of the EFT information. If this information cannot be verified and the provider fails to timely respond to a developmental request, the contractor shall reject the Form CMS-588 and, if applicable, the accompanying Form CMS-855.

C. Miscellaneous Policies

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 *arrangement*, the provider must select another financial institution.

2. Verification - The contractor shall *ensure* that all *EFT arrangements* comply with *CMS Publication* 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 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 *Form* CMS-855 in the *file.*

4. **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 the* same perso*n. I*f the person's signature is *not on* file, the contractor shall request that he/she complete section 6 of the *Form* CMS-855 and furnish his/her signature in section 15 or *16. (T*his shall be treated as part of the EFT change request for purposes of timeliness and reporting.)

5. **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 Counse*l.*

6. **Closure of Bank Account** – *If* a provider has closed its bank/EFT account but will remain enrolled in Medicare*, t*he contractor shall place the provider on payment withhold until an EFT agreement (and *Form* CMS-855, if applicable) is submitted and approved by the contractor. If

such an agreement is not submitted within 90 days after the contractor learned that the account was closed, the contractor shall commence revocation procedures in accordance with the instructions in this chapter.

7. **Reassignments** – If a physician or *non-physician* practitioner is reassigning all of his/her benefits to another supplier *and the latter is not currently on EFT*, neither the practitioner nor the *reassignee* needs to submit a *Form* CMS-588. 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. *If, however, the group later submits a* change of information request and is *not on* EFT, it must submit a *Form* CMS-588.

8. **Final Payments** – *If* a non-certified supplier (e.g., physician, ambulance company) voluntarily withdraws from Medicare and needs to obtain its final payments, the contractor shall send *such* 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 *aforementioned addresses* are *available*, the provider shall submit a *Form* CMS-855 or *Form* CMS-588 request identifying where it wants payments to be sent.

9. **Chain Organizations -** Per *CMS Publication* 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 *submitted and* 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 *Form* CMS-588s must be submitted. If any of the chain providers have never completed a *Form* CMS-855 before, they must do so at that time.

15.14.4 – Non-Participating Emergency Hospitals, Veterans Administration (VA) Hospitals, and Department of Defense (DOD) Hospitals

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

Non-participating emergency hospitals, VA hospitals and DOD hospitals no longer need to complete a Form CMS-855A enrollment application in order to bill Medicare.

15.16.2 – Processing Initial Form CMS-855O Submissions

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

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: 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: 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

NOTE: The contractor shall observe 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, the* IHS *or the Public Health Service (PHS),* 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, *DOD, IHS or PHS* 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.)

15.21 – Special Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Instructions

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

Sections 15.21.1 through 15.27.1 instruct the *National Supplier Clearinghouse* on the appropriate handling of certain situations involving DMEPOS suppliers.

15.21.1 – DMEPOS Supplier Accreditation

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

A. General Requirement

*D*MEPOS suppliers must be accredited prior to submitting an application to the *National Supplier Clearinghouse (NSC). T*he 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 that demonstrates that the supplier has an approved accreditation.

The NSC shall revoke *an enrolled* DMEPOS supplier's billing privileges if the DMEPOS supplier fails to*: (1)* obtain and submit supporting documentation that the DMEPOS supplier has been accredited, *or (2) maintain its required accreditation.*

B. Exemptions

Individual medical practitioners, inclusive of group practices of same, *do not require*

accreditation as a condition of enrollment. The practitioner types are those specifically stated in Sections 1848(K)(3)(B) and 1842(b)(18)(C) of the Social Security *Act.* In addition, the practitioner categories of physicians, orthotists, prosthetists, optometrists, opticians, audiologists, occupational therapists, physical therapists and suppliers who provide drugs and pharmaceuticals (only) do not require accreditation as a condition of *enrollment.*

*Although s*uppliers that provide only drugs and pharmaceuticals are exempt from the accreditation requirement, *suppliers that* provide equipment to administer drugs or pharmaceuticals must be accredited.

C. Special Situations

1. Changes of Ownership

a. 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 42 CFR § 424.525) if the new owner does not have an accreditation that covers all of its locations. If the old owner *has* such an accreditation, the new owner *can* 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 42 CFR §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.

b. 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.

c. A *non-exempt* DMEPOS supplier requesting reactivation after a deactivation (regardless of the deactivation reason) is required to be accredited.

d. 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.

15.21.2 – Enrolling Indian Health Service (IHS) Facilities as DMEPOS Suppliers

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

A. Background

The *National Supplier Clearinghouse (NSC)* shall enroll IHS facilities as DMEPOS suppliers in accordance with *(a)* the general enrollment procedures cited in chapter 15, *(b)* the statement of work contained in the NSC contract with Medicare, and *(c) the* special *procedures cited* in this section.

For enrollment purposes, Medicare recognizes two types of IHS facilities*: (1)* facilities wholly owned and operated by the IHS, and *(2) facilities owned* by the IHS but tribally operated or totally owned and operated by a tribe. CMS *will* provide the NSC with a list of IHS facilities *that* distinguish*es* between these two types.

On the list, the NSC shall use the column entitled, "FAC OPERATED BY", for this purpose.

B. Enrollment

The provider/supplier shall complete the Form CMS-855S shall be completed in accordance with the instructions shown therein.

NOTE: *Facilities that are:*

- *To*tally owned and operated by the IHS are considere*d g*overnmental organization*s*. An Area Director of the IHS must sign *section 15 of the Form* CMS–855S, be listed in section 6 of the form, and sign the letter required *under* section 5 of the form *that* attests that the IHS will be legally and financially responsible in the even*t t*here is any outstanding debt owed to CMS.

- *T*ribally operated are considered tribal organizations. *S*ection 15 of the *Form* CMS–855S must be signed by a tribal official who meets the definition of an *"*authorized official*" under 42 CFR § 424.502*. *The individual must also* be listed in section 6 of the *form,* and must sign the letter required *under* section 5 of the form *that* attests that the tribe will be legally and financially responsible in the even*t t*here is any outstanding debt owed to CMS.

C. Supplier Standards, Exceptions and Site Visits

All IHS facilities, whether operated by the IHS or a tribe:

- *S*hall meet all required standards, *with the exception of:*

- *T*he comprehensive liability insurance requirements under 42 CFR 424.57(c)(10).

- *T*he requirement to provide State *l*icenses 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 *it* provide*s* a DMEPOS item that requires a licensed professional in order to properly provide the item, *it* shall provide a copy of the professional license. The licensed professional can be licensed in any State or have a Federal license *(e.g.,* a pharmacy does not need a pharmacy license, but shall have a licensed pharmacist*)*.

- *Shall, like all other DMEPOS suppliers, undergo site visits in accordance with section 15.19.2.1 through 15.19.2.4 of this chapter. (T*his includes all hospitals and pharmacies enrolling as DMEPOS suppliers*.)*

D. Provider Education for IHS Facilities

The NSC shall *ensure that* its Web site *includes* the information contained in *this section 15.21.2 that* is specific to enrollment of IHS facilities (whether operated by the IHS or a tribe).

E. Specialty Codes

The NSC shall apply the specialty code A9 (IHS) *to* all IHS enrollments (whether operated by the IHS or a tribe). However, the specialty code A9/A0 shall be applied *to* facilities that are IHS/tribal hospitals.

*O*ther specialty codes should be applied as applicable (e.g., pharmac*ies*).

15.21.3 – *Reserved for Future Use*

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

15.21.4 - Development and Use of Fraud Level Indicators

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

The *National Supplier Clearinghouse (NSC)* 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 NS*C* 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*)*

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* project officer.

*(**NOTE:** These risk categories are in addition to, and not in lieu of, those specified in section 15.19.2 of this chapter.)*

In assessing a fraud level indicator, the *NSC* shall consider such factors as:

1. Experience as a DMEPOS supplier with other payer*s*
2. Prior Medicare experienc*e*
3. The geographic are*a*
4. Fraud potential of products and services liste*d*
5. Site visit result*s*
6. Inventory observed and contracte*d*
7. Accreditation of the supplie*r*

After a fraud level indicator is assigned and the DMEPOS supplier is enrolled, the NS*C* shall establish a DMEPOS Review Plan based on the fraud level assessment. The DMEPOS Review Plan *shall* contain information regarding:

1. Frequency of unscheduled site visit*s*
2. Maximum billing amounts before recommendation for prepay medical revie*w*
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 *Zone Program Integrity Contractor (ZPIC)* shall be reported to the *NSC* project office*r*. The NS*C s*hall update the fraud level indicator based on information obtained by the OIG, CMS (including CMS satellite office) and/or a *ZPIC* only after the review and concurrence of the NS*C* project office*r*.

In addition, the NS*C shall* 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.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

The NS*C* shall have documented evidence that *it* ha*s*, as a minimum, met *the following* requirement*s:*

- Assign an appropriate fraud level indicator for at least 95 percent of all DMEPOS suppliers, upon initial *enrollment or revalidation*. 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.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

The *NSC* shall receive and maintain the following "alert indicators" from the DME MACs AND *Z*one *P*rogram *I*ntegrity *C*ontractors (ZPICs):

Alert Code	Definition
A	*P*ossible fraudulent or abusive claims identifie*d*
B	*O*verpayment*s*
D	*V*iolations of disclosure of ownership requirement*s*
E	*V*iolations of participation agreement*s*
L	*S*uspended by *c*ontractor outside alert code proces*s*
M	*S*upplier is going through claims appeal proces*s*

The NS*C* shall append the supplier file and transfer to the DME-MACs *and Z*PICs the following alert codes in the following circumstances:

Alert Code	Definition
C	Violations of supplier standard*s*
F	*Excluded* by the Office of Inspector General or debarred *per the* GSA *debarment list*
H	Meets supplier standards; however, the NS*C* recommends increased scrutiny by the contractor (initiated by NSC-MAC only*)*
N	Supplier being investigated under the "Do Not Forward" initiative (initiated by NS*C* only*)*
Q	Low Risk Fraud Level Indicato*r*
R	Limited Risk Fraud Level Indicato*r*

S Medium Risk Fraud Level Indicator

T High Risk Fraud Level Indicator

The NSC 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. This alert code notifies the contractors that a supplier may be inclined to submit a high percentage of questionable claims.

The NSC shall share the above information with the DME MACs and 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 also shall forward alert codes submitted by the contractors with the other contractors within 7 calendar days after receipt.

15.21.6 – *Reserved for Future Use*

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

15.29 - Provider and Supplier Revalidations and DMEPOS Re-enrollment

(Rev.430, 09-28-12, Effective: 10-29-12, Implementation: 10-29-12)

(Any CMS instructions regarding special revalidation projects shall take precedence over any contrary guidance in this section 15.29.)

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. *The* contractor 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 *15.6.1* of this *chapter* – apply to revalidation applications.

- Per 42 CFR § 424.515, *the* provider *must* furnish all requested information (as part of the revalidation*) w*ithin 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.

*As with initial enrollments, t*he contractor shall ensure *that all data* furnished on the *revalidation* application *is verified.*