CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 561	**Date: December 12, 2014**
	Change Request 8901

SUBJECT: Incorporation of Certain Provider Enrollment Policies in CMS-4159-F into Pub. 100-08, Program Integrity Manual (PIM), Chapter 15

I. SUMMARY OF CHANGES: The purposes of this change request (CR) are to: (a) incorporate into chapter 15 of the PIM certain provider enrollment provisions contained in the final rule titled, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," and (b) revise various sections of chapter 15 to address policy issues that have arisen and to make certain technical edits.

EFFECTIVE DATE: March 18, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 18, 2015

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/Table of Contents
R	15/15/4.1.9/Indian Health Services (IHS) Facilities
R	15/15/4.1.14/Skilled Nursing Facilities (SNFs)
R	15/15/4.2.1/Ambulatory Surgical Centers (ASCs)
R	15/15/4.2.2/CLIA Labs
R	15/15/4.2.3/Mammography Screening Centers
R	15/15/4.2.4/Pharmacies
R	15/15/4.2.5/Portable X-Ray Suppliers (PXRSs)
R	15/15/4.2.6/Radiation Therapy Centers
R	15/15/4.2.7/Suppliers of Ambulance Services
R	15/15/4.2.8/Intensive Cardiac Rehabilitation (ICR)
R	15/15/4.6.1/Diabetes Self-Management Training (DSMT)
R	15/15/4.6.2/Mass Immunizers Who Roster Bill
R	15/15/5.20.1/Inter-Jurisdictional Reassignments
R	15/15/7.1.5/Receiving Missing/Clarifying Data/Documentation
R	15/15/7.3/Documentation
R	15/15/8.4/Denials
R	15/15/9.1/Non-Certified Suppliers and Individual Practitioners
R	15/15/9.2/Certified Providers and Certified Suppliers
R	15/15/17/Establishing an Effective Date of Medicare Billing Privileges
R	15/15/19.1/Application Fees
R	15/15/21.7.1/Claims against Surety Bonds
R	15/15/23.2/Release of Information
R	15/15/27.1.1/Deactivations
R	15/15/27.1.2/Reactivations
R	15/15/27.1.2.1/Reactivations - Deactivation for Reasons Other Than Non-Submission of a Claim
R	15/15/27.1.2.2/Reactivations - Deactivation for Non-Submission of a Claim
R	15/15/27.2/Revocations

III. FUNDING:

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 Instruction

Attachment - Business Requirements

Pub. 100-08	Transmittal: 561	Date: December 12, 2014	Change Request: 8901

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EFFECTIVE DATE: March 18, 2015
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I. GENERAL INFORMATION

A. Background: The purposes of this change request (CR) are to: (a) incorporate into chapter 15 of the PIM certain provider enrollment provisions contained in the final rule titled, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," and (b) revise various sections of chapter 15 to address policy issues that have arisen and to make certain technical edits.

B. Policy: This CR: (a) incorporates into chapter 15 of the PIM certain provider enrollment provisions contained in the final rule titled, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," and (b) revises various sections of chapter 15 to address policy issues that have arisen and to make certain technical edits.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8901.1	If the contractor believes that a Presidentially-declared disaster exception may apply in a particular case involving 42 CFR 424.521, it shall contact its CMS Provider Enrollment Business Function Lead for a determination on this issue.		X							
8901.2	Upon reactivating billing privileges for a Part B non-certified supplier, the contractor shall issue a new Provider Transaction Access Number (PTAN).		X							
8901.3	In the quarterly reports outlined in section 15.21.7.1, the contractor shall include data regarding sureties' non-payment of claims (as specified in that section).				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8901.4	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

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

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare Program Integrity Manual
Chapter 15 - Medicare Enrollment

Table of Contents
(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

15.4.2.8 - *I*ntensive Cardiac Rehabilitation (ICR)

15.4.1.9 - Indian Health Services (IHS) Facilities

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

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

IHS facilities and tribal providers may use Internet-based PECOS or the paper Form CMS-855 enrollment application for their enrollment transactions. The designated Medicare contractor for IHS facilities and tribal providers is Novitas Solutions (Novitas).

If the IHS facility or tribal provider mails its Form CMS-855 to a Medicare contractor other than Novitas, that contractor shall forward the application directly to Novitas at the following address:

Novitas Solutions, Inc.
P.O. Box *3115*
Mechanicsburg, PA 17055-1858

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 Novitas.

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 Pub. 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.

15.4.1.14 - Skilled Nursing Facilities (SNFs)

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. General Background Information

As stated in CMS Pub. 100-07, *State Operations Manual,* chapter 7, section 7004B, a SNF is *a facility* 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.

*T*he transfer agreement *mentioned above* 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. *SNFs cannot have multiple practice locations.*

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. *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.

- *"D*istinct part" designation is not equivalent to being "provider-based."

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.)

C. Additional Information

For more information on SNFs, refer to:

- Section 1819 of the Social Security Act

- *P*ub. 100-07, *State Operations Manual,* chapter 7

- Pub. 100-02, *Benefit Policy Manual,* chapter 8

15.4.2.1 - Ambulatory Surgical Centers (ASCs)

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. General Background Information

An ASC is defined in 42 CFR § 416.2 as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission; the entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in 42 CFR Part 416, subparts B and C. (The ASC supplier agreement (Form CMS-370) is similar to the provider agreement signed by Part A providers.)

As stated in § 416.26(a), CMS may deem an ASC to be in compliance with *any or all of* the ASC conditions of coverage *if:*

- *The ASC i*s accredited by a national accrediting body, or licensed by a *s*tate 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 *s*tate law requires licensure, the ASC complies with *s*tate licensure requirements; and

- *The ASC a*uthorizes the release to CM*S* of the findings of the accreditation survey.

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

ASCs can be fixed locations or mobile in nature.

B. ASCs and Hospitals

See the following instructions for guidance regarding hospital-operated/affiliated ASCs:

- *Pub. 100-04, Claims Processing Manual, chapter 14, section 10.1*

- *Pub. 100-02, Benefit Policy Manual, chapter 15, section 260.1*

C. Additional Information

For more information on ASCs, refer to:

- 42 CFR Part 416

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

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

- Pub. 100-04, *Claims Processing Manual,* chapter 14

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

15.4.2.2 - CLIA Labs

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. General Background Information

As explained in Pub. 100-07, State Operations Manual, chapter 6, sections 6000 and 6002, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) amended the Public Health Service Act (42 U.S.C. 263a) to extend jurisdiction of the Department of Health and Human Services (HHS) to regulate 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, human beings. CLIA mandates that virtually all laboratories, including physician office laboratories, meet applicable Federal requirements and have a CLIA certificate in order to operate.

Regulations implementing CLIA are codified under 42 CFR Part 493. These regulations require that all laboratories or entities that perform laboratory testing:

- *Pay user fees as assessed by CMS to finance the entire cost of administering the CLIA program;*
- *Submit specific information to HHS or its designee;*
- *Comply with specific administrative and program requirements;*
- *Submit to surveys to assess compliance with CLIA requirements;*
- *Be subject to specified enforcement actions; and*
- *Apply for CLIA certificates based on the complexity of testing performed in the laboratory or based on accreditation by a CMS-approved accreditation organization, or*
- *Be located in a State with a CMS approved State laboratory licensure program, be licensed or approved in accordance with state requirements.*

Section 6141 of the Omnibus Budget Reconciliation Act of 1989 requires that laboratories participating in the Medicare program comply with CLIA requirements. Therefore, all laboratories, with the exception of laboratories licensed by a state with a CMS-approved state laboratory licensure program (CLIA-exempt laboratories) must obtain a CLIA certificate to operate and to be eligible for payment under Medicare and Medicaid. Although CLIA-exempt laboratories do not need a CLIA certificate to operate, they are assigned a CLIA identification number for Medicare and Medicaid payment purposes.

Certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. These include:

- *Any facility or component of a facility that performs testing strictly for forensic purposes;*
- *Research laboratories that 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;*
- *Components or functions of laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA*

guidelines and regulations. (However, all other testing conducted by a SAMHSA certified laboratory is subject to this rule.);

- *Laboratories under the jurisdiction of the Department of Veterans Affairs;*

- *Department of Defense (DoD) laboratories are subject to requirements that CMS has determined to be comparable to those in CLIA. The DoD is responsible for assuring compliance with these requirements and for oversight of its laboratories under a Memorandum of Understanding (MOU) between the Secretary of HHS and the Secretary of DoD. (See §6022 for discussions on Federal laboratories.);*

- *Laboratory testing conducted in conjunction with the provision of home health or hospice care in an individual's home, where the home health agency or hospice employee merely **assists** the individual in performing a test, since tests performed by individuals in the home are not subject to CLIA;*

- *Laboratories licensed in a state whose laboratory licensure program is approved by CMS, (i.e., CLIA exempt as approved under 42 CFR part 493, Subpart E);*

- *Facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostic tests;*

- *Radiological facilities that perform only imaging procedures (e.g., x-rays, ultrasounds, Magnetic Resonance Imaging, Computerized Tomography);*

- *Facilities performing only physiological testing, e.g. spirometry, slit-lamp test for eyes, breath analysis, pulse oximetry; and*

- *Any facility or component of a facility that performs testing for drugs of abuse for employment purposes.*

B. *C*ertificates

See Pub. 100-07, State Operations Manual, chapter 6, sections 6006 through 6006.7 for information regarding the various types of CLIA certificates.

C. CLIA Enrollmen*t*

Unless stated otherwise in this chapter or in another CMS directive:

- 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, *State Operations Manual,* chapter 6, sections 6008, 6026*,* and 6034 *through* 6036.*3* for more information*, including guidance relating to home health agencies and hospices.)*

- The laboratory must submit to the contractor a separate certificate for each *s*tate 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 numbe*r.*

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, *State Operations Manual,* chapter 6 *(in full)*

- Publication 100-04, *Claims Processing* Manual, chapter 16

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

15.4.2.3 - Mammography Screening Centers

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

As *define*d in 42 CFR § 410.34(a)(2), a screening mammography is a radiologi*c p*rocedure "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." *Section 410.34(a)(4) defines a "supplier of screening mammography" as " a facility that is certified and responsible for ensuring that all screening mammography services furnished to Medicare beneficiaries meet the conditions and limitations for coverage of screening mammography services as specified in (§ 410.34)(c) and (d)."*

To enroll in Medicare, a mammography screening center must have a valid provisional certificate, or a valid certificate, that has been issued by the Food and Drug Administration (FDA) indicating that the supplier meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR Part 900, subpart B. (The FDA is responsible for collecting certificate fees and surveying mammography facilities (screening and diagnostic).*) Unless stated otherwise in this chapter or in another CMS directive, the supplier shall submit a copy of its FDA certificate with its application.*

It is important that the contractor review and adhere to the following regulations and instructions regarding the required qualifications of mammography screening centers:

- 42 CFR § 410.34 *(in full)*
- Pub. 100-04*, Claims Processing Manual,* chapter 18, sections 20 through 20.*1.2*
- Pub. 100-02, *Benefit Policy Manual,* chapter 15, section 280.3

15.4.2.4 - Pharmacies

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

Pharmacies typically enroll with the National Supplier Clearinghouse *via the Form CMS-855S*. 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.

For more information on the billing and coverage policies for Part B drugs, see:

- *P*ub. 100-04*, Claims Processing Manual,* chapter 17
- Pub. 100-02, *Benefit Policy Manual,* chapter 15, sections 50 through 50.*6*

15.4.2.5 - Portable X-Ray Suppliers (PXRSs)

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. General Background Information

To qualify as a portable x-ray supplier (PXRS), an entity must meet the conditions for coverage discussed in 42 CFR § 486.100-11*0.*

A PXRS can be simultaneously enrolled as a mobile IDTF, though they cannot bill for the same service*. A* PXR*S r*equires a State survey, while *a* mobile IDT*F does* not (although *an* IDT*F* require*s* a site visit).

A PXR*S does* 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*, unless stated otherwise in this chapter or in another CMS directive.*

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.

3. Reassignment

PXRSs may receive reassigned benefits. A PXRS need not separately enroll as a group practice in order to receive them.

C. Additional Information

For more information on PXRSs, refer to:

- 42 CFR §§ 486.100 – 486.110
- Pub. 100-07, *State Operations Manual, chapter 2*, sections 2420 – 2424*B*
- Pub. 100-02, *Benefit Policy Manual*, chapter 15, sections 80.4 – 80.4.*4*
- Pub. 100-04, *Claims Processing Manual*, chapter 13, sections 90 – 90.*5*

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.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

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.

Radiation therapy centers (RTCs) may receive reassigned benefits. An RTC need not separately enroll as a group practice in order to receive them.

For additional background on radiation therapy services, se*e:*

- *4*2 CFR § 410.35
- Pub. 100-04, *Claims Processing Manual,* chapter 13
- Pub. 100-*02*, *Benefit Policy Manual*, chapter 15, section 90

15.4.2.7 - Suppliers of Ambulance Services

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. Types of Ambulance Services

As stated in 42 CFR § 410.40, there are several types of ambulance services covered by Medicare. They are *generally* defined i*n §* 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 interventio*n.*

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 i*n §* 414.605.

3. **Air Ambulance** (Fixed-Wing and Rotary-Wing) *(See § 414.605 for specific definitions of fixed-wing and rotary-wing).*

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 § 414.605, EMT-Paramedic services furnished by an entity that does not furnish the ground transport, provided that the services meet the requirements in § 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. Under § 410.40(c), PI must meet the following requirements:

- Be furnished in an area that is designated as a rural area *(see § 410.40(c)(1) for more information on this requirement)*
- 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 § 410.41;
    - Furnish 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 § 410.41(b)(2); and
    - Bills all the *beneficiaries* who receive ALS intercept services from the entity, regardless of whether or not those *beneficiaries* 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

*Section 4*10.41(a) *states that* 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 *s*tate 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 *s*tate 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 *s*tate or local authority where the services are being furnished, to perform one or more ALS service*s.*

C. Completion of the *Form* 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 requirement*s if the statement itself meets the requirements of section 10.1.3. However, section 10.1.3* does not obviate 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-855B enrollment process.

It is important that the contractor review and adhere to the following regulations and instructions regarding the required qualifications of ambulance suppliers:

- *42 CFR §§ 410.40 and 410.41*
- Pub. 100-02, *Benefit Policy Manual,* chapter 10 *(in full)*
- Pub. 100-04, *Claims Processing Manual,* chapter 15

15.4.2.8 – *I*ntensive Cardiac Rehabilitation (ICR)

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. Background

*I*CR programs must be approved by CMS through the national coverage determination (NCD) process *and must meet certain criteria for approval.* Individual site*s s*eek*ing* 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 *verify* 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. *The contractor shall use one of these options to verify that the ICR program has met CMS approval.*

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.

It is important that the contractor review and adhere to the following regulations and instructions regarding the required qualifications of ICR suppliers:

- 42 CFR § 410.49
- Publication 100-04, *Medicare Claims Processing Manual,* chapter 32, sections 140.2.2 – 140.2.2.*6*
- Publication 100-02, *Medicare Benefit Policy Manual,* chapter 15, section 23*2*

15.4.6.1 - Diabetes Self-Management Training (DSMT)

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

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 appropriate accreditation* 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:

- 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.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

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.

- *The supplier, as well as* all personnel who administer the shots*,* must meet all applicable *s*tate 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.

In addition:

- 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, *Benefit Policy Manual,* chapter 15, section 50.4.4.*2*

- Publication 100-04, *Claims Processing Manual,* chapter 18, sections 10 through 10.3.2.*3*

15.5.20.1 – Inter-Jurisdictional Reassignments

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. General Policy

If a physician/NPP (reassignor) is reassigning his or her benefits to an entity (reassignee) located in another contractor jurisdiction – a practice that is permissible - the following principles apply:

1. The reassignor must be properly licensed or otherwise authorized to perform services in the state in which he or she has his or her practice location. The practice location can be an office or even the individual's home (for example, a physician interprets test results in his home for an independent diagnostic testing facility).

2. The reassignor need not – pursuant to the reassignment - enroll in the reassignee's contractor jurisdiction nor be licensed/authorized to practice in the reassignee's state. If the reassignor will be performing services within the reassignee's state, the reassignor must enroll with the Medicare contractor for – and be licensed/authorized to practice in – that state.

3. The reassignee must enroll in the contractor jurisdictions in which (1) it has its own practice location(s), and (2) the reassignor has his or her practice location(s). In Case (2), the reassignee:

- Shall identify the reassignor's practice location as its practice location on its Form CMS-855B

- In Section 4A of its Form CMS-855B shall select the practice location type as "Other health care facility" and specify "Telemedicine location."

- Need not be licensed/authorized to perform services in the reassignor's state.

To illustrate, suppose Dr. Smith is located in Contractor Jurisdiction X and is reassigning his benefits to Jones Medical Group in Contractor Jurisdiction Y. Jones must enroll with X and with Y. Jones need not be licensed/authorized to perform services in Dr. Smith's state. However, in Section 4 of the Form CMS- 855B it submits to X, Jones must list Dr. Smith's location as its practice location.

B. Applicability

The term "reassignee," as used in section 15.20.1(A), includes any provider or supplier that is permitted to bill and receive payment under a reassignment, in accordance with existing Medicare policy.

15.7.1.5 – Receiving Missing/Clarifying Data/Documentation

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

The procedures in this section 15.7.1.5 are subject to the processing alternatives identified in sections 15.7.1.3.1 through 15.7.1.3.4 of this chapter.

A. Requirement to Furnish All Missing/Clarifying Material

The provider must furnish all missing/clarifying data/documentation requested by the contractor within the 30-day timeframe. Whether the provider furnished all the information is a decision resting solely with the contractor. Should the provider furnish some (but not all) of the requested data/clarification within the specified time period, the contractor need not contact the provider again to request the remaining information. For instance, suppose the contractor requested missing data in sections 3, 4, and 5 of the Form CMS-855A. The provider only furnished the section 3 data. The contractor may reject the application without attempting another contact.

For Internet-based PECOS applications, the provider may mail its paper certification statement and its documentation separately. They need not be sent in the same package.

B. Format of Furnishing Missing Data

1. Paper Applications

Unless stated otherwise in this chapter or in another CMS directive, the provider shall: (1) provide the missing/clarification information (excluding documentation) on the applicable Form CMS-855 page(s) and (2) submit the missing material via mail, fax, or scanned e-mail. A newly signed and dated certification statement must accompany the Form CMS-855 page(s) containing the missing data – unless the only missing information is supporting documentation, in which case no new certification statement is needed.

2. Internet-Based PECOS Applications

Unless stated otherwise in this chapter or in another CMS directive, the provider may (1) submit the missing information by entering it into PECOS, (2) submit the missing documentation via fax, e-mail, mail, or the Digital Data Repository (DDR), and/or (3) submit the certification statement via paper or e-signature. (The provider *may* submit the missing data via the applicable paper Form CMS-855 pages if it submitted its application via Internet-based PECOS.)

C. Format of Clarifying Data

In cases where clarifying (as opposed to missing) information is requested, the contractor may accept the clarification by e-mail, fax, or letter. If the provider furnishes the clarification via telephone, the contractor

shall – unless another CMS directive states otherwise - request that the provider furnish said clarification in writing (preferably via e-mail).

If the provided clarification ultimately requires the provider to change or alter data that must be reported on the paper or Web Form CMS-855, the contractor shall instruct the provider via a follow-up e-mail or fax to submit the revised data on the applicable Form CMS-855 page or via Internet-based PECOS and to furnish a new certification statement. The provider must submit the revised data and new certification statement within 30 days of the original request for clarification (rather than 30 days from the date of the follow-up request to provide the data via the Form CMS-855).

Consider the following illustrations:

EXAMPLE 1: The contractor notifies the provider via an e-mailed letter on March 1 of a discrepancy regarding its ownership information on the Form CMS-855A. The provider e-mails the contractor on March 3 and explains the discrepancy. Based on this e-mail, the contractor determines that the provider must correct its ownership data in section 5 of its Form CMS-855A. The contractor sends a follow-up e-mail to the provider on March 7 instructing the provider to do so. The provider must submit the revised data on the Form CMS-855 (with a new certification statement) by March 31 (not April 6, or 30 days from the date of the follow-up e-mail).

EXAMPLE 2: The contractor notifies the provider via e-mailed letter on March 1 of a discrepancy regarding its ownership information on the Form CMS-855A. The provider telephones the contractor on March 6 and explains the discrepancy to the contractor's satisfaction. Although the discrepancy does not require the provider to make any revisions to its Form CMS-855A, the contractor shall request that the provider furnish its explanation in writing no later than 30 days from its March 1 e-mail (or March 31), not 30 days from the date of its March 6 request for the written explanation.

EXAMPLE 3: The contractor notifies the provider via e-mailed letter on March 1 of a discrepancy regarding its ownership information on its paper Form CMS-855A. Determining (based on the contractor's e-mail) that the ownership information it provided was incorrect, it submits a revised section 5 of its Form CMS-855A to the contractor with a new certification statement but without any accompanying explanation of the change (e.g., no accompanying letter or e-mail). The contractor receives the revised section 5 on March 12. If the contractor determines that the discrepancy has been resolved via the revised submission, it is not required to contact the provider for an accompanying written explanation. (This is because the clarification was furnished in writing via the CMS-855 itself.) If, however, the contractor would like a written explanation or otherwise needs clarification about the submission, it may request that a written explanation be submitted no later than March 31.

D. Maintenance of Received Material

The contractor shall maintain all missing/clarifying information or documentation received (including new certification statements) in the provider file. Storage can be electronic or via hard copy, but it must be in an otherwise easily accessible format.

15.7.3 - Documentation

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

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 *15.*7.3. CMS cannot stress enough how crucial it is for contractors to document their actions as carefully and thoroughly as possible.

The requirements in this section 15.7.3 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 *15.*7.3, "written correspondence" includes *mailed,* fax*ed*, and *e-mailed correspondence*.)

1. Written Correspondence

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 *correspondence to* providers. For instance, if the *contractor* 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 *ZPIC*, or the OIG

2. Telephonic or Face-to-Face Contact (hereafter referred to as "oral communication")

*The contractor shall d*ocument any and all actual or attempted *oral communication* with the provider, any representative thereof, or any other person *or entity* 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 *s*tate or another contractor concerning the applicant or enrollee

- Contacting the *ZPIC for an update concerning a particular case*

- Phone calls from the provider

- Conducting a meeting at the contractor's headquarters/offices with officials from a hospital concerning problems with its application

- *Telephoning* CO *(e.g., CO's provider enrollment unit)* or the *RO (e.g., the RO's survey and certification staff)* and receiving instructions *therefrom about* a problem the contractor is having with an applicant or an existing provider

- *Telephoning* 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 *the* 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 crafted and* stored electronicall*y if* the contractor can provide access within 24 hours upon request.

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 *15.*8.1 of *this chapter*, 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 the MED *and the System for Access Management (SAM).* 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 SAM*, 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.

15.8.4 – Denials

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. Denial Reasons

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. Except in the situations outlined in section 15.8.4(B) below, the contractor may issue a denial without prior approval from *CMS Central Office's p*rovider *e*nrollment *unit (COPEU).*

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)) – Not in Compliance with Medicare Requirements

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. (See section 15.4.8 of this chapter for examples of suppliers that are not eligible to participate.)

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: 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)) – Excluded/Debarred from Federal Program

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)) – Felony Conviction

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, *a re-enrollment bar will be established* 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 *COPEU via the ProviderEnrollmentRevocations@cms.hhs.gov mailbox for guidance.*

Denial Reason 4 (42 CFR §424.530(a)(4)) – False or Misleading Information on Application

The provider or supplier submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program.

Denial Reason 5 (42 CFR §424.530(a)(5)) – On-Site Review/Other Reliable Evidence that Requirements Not Met

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)) – Existing Overpayment at Time of Application

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)) – Medicare Payment Suspension

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)) – Home Health Agency (HHA) Capitalization

An 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)) – Hardship Exception Denial and Fee Not Paid

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)) – Temporary Moratorium

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.)

Denial Reason 11 (42 CFR § 424.530(a)(11)) – *DEA Certificate/State Prescribing Authority Suspension or Revocation*

(i) A physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked; or

(ii) The applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date the physician or eligible professional submits his or her enrollment application to the Medicare contractor.

B. Denial Letters

1. General

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. Absent a CMS instruction or directive to the contrary, the letter shall be sent to the provider or supplier:

- No later than 5 business days after the contractor concludes that the provider or supplier's

application should be denied, or

- If the denial requires prior *COPEU* authorization, no later than 5 business days after *COPEU* notifies the contractor of such authorization.

No reenrollment bar *is* established for denied applications. Reenrollment bars apply only to revocations.

2. Prior *COPEU* Approval

Prior to sending the denial letter, the contractor shall obtain approval of both the denial and the denial letter from its PEBFL if the denial involves any of the following situations:

- Situation (d), (e), (g) or (h) under Denial Reason 1 above.
- § 424.535(a)(2), (a)(3), (a)(4), *or (a)(11).*

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. Other Impacts of a Denial

1. Changes of Information and Changes of Ownership (CHOWs)

a. Expiration of Timeframe for Reporting Changes - If the contractor denies a change of information or CHOW submission per this section 15.8.4 and the applicable 90-day or 30-day period for reporting the change has expired, the contractor shall send an e-mail to its *(PEBFL)* notifying him or her of the denial. *COPEU* will determine whether the provider's Medicare billing privileges should be deactivated under 42 CFR §424.540(a)(2) or revoked under 42 CFR §424.535(a)(1) or (a)(9) and will notify the contractor of its decision.

b. Timeframe Not Yet Expired - If the contractor denies a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has not yet expired, the contractor shall send the e-mail referred to in (1)(a) above after the expiration of said time period unless the provider has resubmitted the change request/CHOW.

c. Second Denial, Return, or Denial – If, per (1)(b), the provider resubmits the change of information or CHOW application and the contractor either denies it again, returns it per section 15.8.1 of this chapter, or rejects it per section 15.8.2 of this chapter, the contractor shall send the e-mail referred to in (1)(a) above regardless of whether the applicable timeframe has expired. *COPEU* will determine whether the provider's Medicare billing privileges should be deactivated under 42 CFR §424.540(a)(2) or revoked under 42 CFR §424.535(a)(1) or (a)(9) and will notify the contractor of its decision.

2. Reactivations – If the contractor denies a reactivation application, the provider's Medicare billing privileges shall remain deactivated.

3. Revalidations – If the contractor denies a revalidation application per this section 15.8.*4*, the contractor shall – unless an existing CMS instruction or directive dictates otherwise - revoke the provider's Medicare billing privileges under 42 CFR §424.535(a)(1) if the applicable time period for submitting the revalidation application has expired. If it has not expired, the contractor shall revoke the provider's billing privileges after the applicable time period expires unless the provider has resubmitted the revalidation application. If the provider has resubmitted the application and the contractor (1) denies it again, (2) returns it per section 15.8.1 of this chapter, or (3) rejects it per section 15.8.2 of this chapter, the contractor shall - unless an existing CMS instruction or directive dictates otherwise – revoke the provider's billing privileges, assuming the applicable time period has expired.

F. Provider Enrollment Appeals Process

For more information regarding the provider enrollment appeals process, see section 15.25 of this chapter.

G. Final Adverse Actions

See section 15.5.3 of this chapter for information regarding the circumstances in which the contractor shall refer final adverse actions to *COPEU via the ProviderEnrollmentRevocations@cms.hhs.gov mailbox.*

15.9.1 - Non-Certified Suppliers and Individual Practitioners

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

(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 inquir*ies* 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.

Absent a CMS instruction or directive to the contrary, the letter shall be sent no later than 5 business days after the contractor concludes that the supplier meets all Medicare requirements and that his/her/its application can be approved. *The letter may be sent to the supplier's contact person.*

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.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

(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/supplier 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 Number
- CMS Certification 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 (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 letter can be sent to the State/RO via mail, fax, or e-mail.

The contractor shall also:

- Send either a photocopy (not the original), faxed version, or e-mail version of the final completed Form CMS-855 to the State agency or RO (as applicable), along with all updated Form CMS-855 pages, explanatory data, documentation, correspondence, final sales agreements, etc. (which can also be sent via mail, fax, or e-mail). If the CMS-855, associated documentation, and recommendation letter are mailed, they should be included in the same package.

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 *(which may be sent to the applicant's contact person)*, 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.

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

15.17 – Establishing an Effective Date of Medicare Billing Privileges

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

(This section only applies to the following individuals and organizations: physicians; physician assistants; nurse practitioners; clinical nurse specialists; certified registered nurse anesthetists; anesthesiology assistants; 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: 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.

If the contractor believes that the aforementioned Presidentially-declared disaster exception may apply in a particular case, it shall contact its CMS Provider Enrollment Business Function Lead for a determination on this issue.

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.

15.19.1 – Application Fees

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

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 (regardless of whether the revalidation application was requested by CMS or voluntarily submitted by the provider or supplier), 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. 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 (1) in which the application is submitted (for Internet-based PECOS applications) or (2) of the postmark date (for paper applications). The fee for March 25, 2011 through December 31, 2011 was $505.00. The fee for January 1, 2015 through December 31, 2015 is $553.00. 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 https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do, either via credit card, debit card, or check.

Also, 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 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 *CMS* Provider Enrollmen*t B*usiness Function Lead (*PEB*FL). *CMS* 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. *CMS* 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.

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 *PEB*FL. 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.

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 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).

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 *PEB*FL. If *CMS*:

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 determine whether 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 *PEB*FL. 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. Year-to-Year Transition

There may be isolated instances where, at the end of a calendar year, an institutional provider pays the fee amount for that year (Year 1), yet the submission date (for Internet-based PECOS applications) or the application postmark date (for paper applications) falls in the beginning of the following year (Year 2). Assuming that Year 2's fee is higher than Year 1's, the provider will be required to pay the Year 2 fee. The contractor shall not begin processing the application until the entire fee amount has been paid. Accordingly, the contractor shall (1) send an e-mail to its *PEB*FL requesting a full refund of the fee and including any pertinent documentation in support of the request, and (2) send a letter to the provider notifying it that it has 30 days from the date of the letter to pay the correct fee amount (i.e., the Year 2 amount) 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 determine whether the correct fee has been paid via Pay.gov. If it has been, the contractor may begin processing the application as normal. If it 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).

If, at any time during this 30-day period, the provider submits a Pay.gov receipt as proof that the correct fee amount (i.e., the Year 2 amount) has been paid, the contractor shall begin processing the application as normal.

F. Appeals of Hardship Determinations

A provider may appeal *CMS'* denial of its hardship exception request via the procedures outlined below:

1. If the provider is dissatisfied with *CMS'* decision to deny a hardship exception request, it may file a written reconsideration request with *CMS* within 60 calendar days from receipt of the notice of initial determination (e.g., *CMS*' 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.

CMS has 60 calendar days from the date of the reconsideration request to render a decision. The reconsideration shall be:

(a) Conducted by a *CMS* staff person who was independent from the initial decision to deny the hardship exception request.

(b) Based on *CMS'* review of the original letter and documentation submitted by the provider.

Upon receipt of the reconsideration, *CMS* will send a letter to the provider or supplier to acknowledge receipt of its request. In its acknowledgment letter, *CMS* 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 *CMS* denies the reconsideration, it will notify the provider of this via letter, with a copy to the contractor. If *CMS* 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.

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.

G. 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. (This includes the addition of a hospital unit – such as a psychiatric unit – in section 4 of the Form CMS-855A.) 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 unless the provider had been deactivated for failing to respond to a revalidation request, in which case the resubmitted application constitutes a revalidation (not a reactivation) application, hence requiring a fee.

    - Changing the physical location of an existing practice location (as opposed to reporting an additional/new practice location).

    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 15.19.1(D).

- Notify the applicant of the rejection or denial in accordance with section 15.19.1(D).

15.21.7.1 – Claims against Surety Bonds

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

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 services performed on or after March 3, 2009.

2. Collection

a. Delinquency Period

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 45 days have passed since the initial demand letter was sent to the DMEPOS supplier and full 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 have exceeded this 45-day period 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.

b. Request for Payment from Surety

If, however, the supplier has a surety bond (and subject to situations (1) through (5) below), the DME MAC shall send an "Intent to Refer" (ITR) letter to the supplier and a copy thereof to the supplier's surety. The letter and copy shall be sent (a) on the same date and (b) no earlier than the 45th day but no later than the 60th day after the initial demand letter was sent. (The copy to the surety can be sent via mail, e-mail, or fax.)

If the DME MAC does not receive full payment from the supplier within 30 days of sending the ITR letter (and subject to situations (1) through (5) below), the contractor 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 45 days from the date of the surety letter. (The DME MAC shall send a copy of the surety letter to the supplier on the same date.) The DME MAC shall send the surety letter no earlier than 30 days but no later than 75 days after sending the ITR letter, depending on the facts of the case. Consider the following situations:

(1) If a DMEPOS supplier has withdrawn from Medicare or has had its billing privileges deactivated or revoked, the contractor shall send the ITR and the surety letter on the earliest possible days.

(2) If the supplier has an extended repayment schedule (ERS) and is currently making payments, the DME MAC shall not send an ITR letter or a surety letter. If the DME MAC is currently reviewing an ERS application from the supplier, the contractor shall delay sending the ITR letter and the surety letter until after the ERS review is complete.

(3) If the aggregated principal balance of the debt is less than $25, the DME MAC shall not send an ITR letter or a surety letter. It shall instead follow the instructions in CMS Publication 100-06, chapter 4 regarding collection of the overpayment.

(4) If the DME MAC believes the debt will be collected through recoupment, it shall not send an ITR letter or a surety letter. It shall instead follow the instructions in Pub. 100-06, chapter 4 regarding collection of the overpayment.

(5) If the supplier has had a recent offset, the DME MAC may wait to see if future offsets will close the debt, without sending the surety a letter. If the debt is still not paid in full or an ERS has not been established, the DME MAC shall send the surety letter by day 121.

The DME MAC may choose to aggregate debts from the same supplier into one surety letter, provided they are at least 45 days delinquent. *Also, the DME MAC is not required to send a surety letter to the surety if the DME MAC is certain that the bond in question has been exhausted.*

The surety letter shall:

- Follow the format of the applicable model letter in section 15.21.7.1.1 of this chapter.

- 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." Although the contractor shall include the date the DMEPOS service was performed in the evidence it furnishes to the surety, it shall under no circumstances 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.

c. Follow-Up Contact

Between 8 and 12 calendar days after sending the surety letter, the DME MAC shall contact the surety by telephone or e-mail to determine whether the surety received the letter.

If the surety indicates that it did not receive the letter, the DME MAC shall immediately fax or e-mail a copy of the letter to the surety. The surety will have 45 days from the original date of the letter – not 45 days from the date the letter was resent to the surety – to submit payment. To illustrate, suppose the DME MAC on April 1 sends the surety letter, which is also dated April 1. It places the follow-up call to the surety on April 11. The surety states that it never received the letter, so the contractor e-mails a copy of it to the surety that same day. Payment must be received by May 16, or 45 days from the original date of the letter.

If the surety cannot be reached (including situations where a voicemail message must be left) or if the surety indicates that it did receive the letter, no further action by the contractor is required.

The contractor shall document any attempts to contact the surety by telephone and the content of any resultant conversations with the surety.

3. Verification of Payment

a. Full Payment Is Made

If full payment (including interest, as applicable) is made within the aforementioned 45-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.

b. Full Payment Is Not Made

If the surety fails to make full payment within the aforementioned 45-day timeframe, the DME MAC shall (1) continue collection efforts as outlined in Pub. 100-06, chapter 4, and (2) and (2) notify *CMS of the failure to make payment via the report outlined in section 15.21.7.1(C) below.*

c. Successful Appeal

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. Request for Payment from Surety

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 – regardless of the amount of the assessment or CMP - 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 45 calendar days from the date of the letter. The letter (on which the NSC and the supplier/debtor shall be copied) shall:

- Follow the format of the applicable model letter in section 15.21.7.1.1 of this chapter.
- Identify the specific amount to be paid and be accompanied by "sufficient evidence" (e.g., an OIG 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. Follow-Up Contact

Between 8 and 12 calendar days after sending the surety letter, the DME MAC shall contact the surety by telephone or e-mail to determine whether the surety received the letter.

If the surety indicates that it did not receive the letter, the DME MAC shall immediately fax or e-mail a copy of the letter to the surety. The surety will have 45 days from the original date of the letter – not 45 days from the date the letter was resent to the surety – to submit payment. To illustrate, suppose the DME MAC on April 1 sends the surety letter, which is also dated April 1. It places the follow-up call to the surety on April 11. The surety states that it never received the letter, so the contractor e-mails a copy of it to the surety that same day. Payment must be received by May 16, or 45 days from the original date of the letter.

If the surety cannot be reached (including situations where a voicemail message must be left) or if the surety indicates that it did receive the letter, no further action by the contractor is required.

The contractor shall document any attempts to contact the surety by telephone and the content of any resultant conversations with the surety.

3. Verification of Payment

a. Full Payment Is Made

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.

The DME MAC is not required to send a surety letter to the surety if the DME MAC is certain that the bond in question has been exhausted.

b. Full Payment Is Not Made

If the surety fails to make full payment within the aforementioned 45-day timeframe, the DME MAC shall (1) continue collection efforts as outlined in Pub. 100-06, chapter 4, and (2) notify *CMS of the failure to make payment via the report outlined in section 15.21.7.1(C) below.*

c. Successful Appeal

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.

C. Reporting Requirements

DME MACs shall compile a report on a quarterly basis in the format prescribed in existing CMS directives. The report will capture the following elements:

- Number of account receivables (debts) reviewed for possible surety bond letter development
- Number of debts sent to the surety for recovery
- Amount recovered via the surety collection process
- Amount paid by the supplier after the surety collection process was initiated
- Names of suppliers and NSC numbers for which letters were sent to the surety and/or surety bond recoveries were received
- *Names and addresses of sureties that have failed to make payment (as described in subsections (A)(3)(b) and (B)(3)(b) above); for each instance of non-payment, the report shall identify (a) the amount that was requested, (b) the amount that was paid (if any), (3) the name and TIN of the supplier in question, and (4) any information regarding the reason the surety did not pay (e.g., surety bond was exhausted).*

The quarterly reports shall encompass the following time periods: January through March, April through June, July through August, and September through December. Reports shall be submitted to the Provider Enrollment Operations Group through the MAC COR by the 10th day of the month following the end of the reporting quarter. Information on surety collections shall be reported once for each demand letter. That action shall be reported only when the collection process has been fully completed for that specific identified overpayment, which may be comprised of multiple claims. For example, suppose the surety was sent a letter in December but its payment was not received until January. That action would be documented in the report encompassing the months of January, February, and March.

15.23.2 – Release of Information

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

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(s) (section 15 of the CMS-855), delegated official(s), (section 16), contact persons (section 13), or authorized surrogate users. 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 letter can be mailed, faxed, or e-mailed to the contractor.*

- 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.

15.27.1.1 – Deactivations

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. Reasons

Unless indicated otherwise in this chapter or in another CMS instruction or directive, the contractor may - with prior approval from *its CMS Provider Enrollment B*usiness Function Lead (*PEB*FL) - deactivate a provider or supplier's Medicare billing privileges when:

- Per § 424.540(a)(1), 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;

- Per § 424.540(a)(2), 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

- Per § 424.540(a)(2), 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).

Should the contractor encounter one of the three deactivation situations described above, it shall contact its P*EB*FL (via any means) and request approval of the deactivation. *CMS' provider enrollment staff* will notify the contractor of its decision.

B. Effective Dates

The effective dates of a deactivation are as follows:

1. Non-Billing – The effective date is the date of the expiration of the applicable 12-month period.

2. Failure to Report Changed Information – The effective date is the date of the expiration of the application 30-day or 90-day reporting period. (See subsection A above.)

3. The "36-Month Rule" for HHAs – *CMS' provider enrollment staff* will determine the effective date during its review of the case.

C. Appeals Rights

The Medicare contractor shall not afford a provider or supplier appeal rights when a deactivation determination is made.

D. Miscellaneous Policies

1. In situations where a provider with multiple PTANs is to be deactivated for non-billing, the contractor shall only deactivate the non-billing PTAN(s). If a provider with multiple PTANs is to be deactivated for any reason other than (1) non-billing or (2) failing to respond to a revalidation request, the contractor shall contact its *PEB*FL for guidance as to the specific PTANs that should be deactivated.

2. A "no payment" bill with a condition code 21 (billing for denial notice) is considered a Medicare claim for purposes of 42 CFR § 424.540. A "demand bill" (as described in Pub. 100-08, *Program Integrity Manual,* chapter 3, section 5.4 (Exhibit 1)) is considered a Medicare claim for purposes of 42 CFR § 424.540. Thus, for instance, if the provider only submitted "no payment" or "demand" bills over a 12-month period and furnished no claims for payment, the provider still submitted Medicare claims under § 424.540. Deactivation for non-billing would therefore be inappropriate.

3. Consistent with prior CMS direction, Medicare claims administration contractors and the EDCs shall not run the following deactivation jobs:

- Multi-Carrier System - Job names MV50, MV51, MV52 and MV53
- Fiscal Intermediary Shared System – Job name FSSJ9220

CMS, of course, retains the discretion to deactivate a provider or supplier's Medicare billing privileges if any of the situations described in 42 CFR § 424.540(a) are implicated.

4. Prior to deactivating an HHA's billing privileges for any reason (including under the "36-month rule"), the contractor shall refer the matter to its *PEBFL* for review and approval.

15.27.1.2 – Reactivations

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

Sections 15.27.1.2.1 through 15.27.2.2 below discuss the requirements for reactivating a provider or supplier's billing privileges.

If the contractor approves a provider or supplier's reactivation application or reactivation certification package (RCP) *for a Part B non-certified supplier*, the reactivation effective date *shall be the date the contractor received the application or RCP that was processed to completion. Also, upon reactivating billing privileges for a Part B non-certified supplier, the contractor shall issue a new Provider Transaction Access Number (PTAN).*

*W*ith the exception of HHAs, reactivation of Medicare billing privileges does not require a new State survey or the establishment of a new provider agreement or participation agreement. Per 42 CFR § 424.540(b)(3)(i), an HHA must undergo a new State survey or obtain accreditation by an approved accreditation organization before its billing privileges can be reactivated. (See section 15.26.3 of this chapter for more information.)

15.27.1.2.1 – Reactivations - Deactivation for Reasons Other Than Non-Submission of a Claim

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. Background

To reactivate its billing privileges, a provider or supplier deactivated for failing to timely notify the contractor of a change of information (see section 15.27.1.1(A) above) must either:

1. Submit a complete Medicare enrollment application, or

2. Recertify that its enrollment information currently on file with Medicare is correct.

B. Certification Option

1. General Requirements

To utilize option (A)(2) above, the provider or supplier must submit to the contractor (a) a hard copy print-out of its PECOS Web enrollment data, (b) a hard copy Form CMS-855 certification statement signed and dated by the enrolled individual practitioner or, as applicable, the provider or supplier's authorized or delegated official, and (c) a letter certifying as to the data's accuracy. The letter must:

(i) Be on the provider or supplier's letterhead.

(ii) List the provider or supplier's birth name or legal business name, doing business as name (if applicable), National Provider Identifier, and the Provider Transaction Access Number(s) (PTAN) in the provider or supplier's enrollment record to be reactivated.

(iii) Must state that the provider is seeking to reactivate his/her/its billing privileges.

(iv) Be signed and dated by the enrolled individual practitioner or, as applicable, the provider or supplier's authorized or delegated official (who must be the same person who signed the Form CMS-855 certification statement).

(v) Contain the following language:

For Individual Practitioners

> "I, _____, certify that all of the information contained in Medicare enrollment record (the record's PAC ID number) is truthful and accurate. I understand that by this statement and by my signature below, I am bound by all of the terms and conditions of the attached, signed Form CMS-855 certification statement and agree to abide by them."

For Authorized/Delegated Officials

> "I, _____, in my capacity as an authorized or delegated official of (provider/supplier), certify on behalf of (provider/supplier) that all of the information contained in (provider/supplier's) Medicare enrollment record (the record's PAC ID number) is truthful and accurate. I understand that by this statement and by my signature below, (provider/supplier) is bound by all of the terms and conditions of the attached, signed Form CMS-855 certification statement and agrees to abide by them."

A separate Form CMS-855 certification statement and letter must be submitted with each PECOS enrollment record (and the PTANs in that record) the provider or supplier seeks to have reactivated. To illustrate, suppose a supplier has three separate enrollments it wants to reactivate. Each enrollment has its own PECOS enrollment record. Two of the records have one PTAN; the third record contains two PTANs.

The supplier must submit three separate PECOS Web printouts, three separate certification statements, and three separate letters. (The letter pertaining to the third enrollment record must list both PTANs.) The certification statement and letter should be attached to the PECOS Web printout to which it pertains – meaning, per our example, that there would be three separate "reactivation certification packages" (RCPs). All RCPs must be submitted via mail. They cannot be faxed or e-mailed.

The provider or supplier cannot utilize the certification option and must submit a complete Form CMS-855 application if:

- There is any information in the provider or supplier's PECOS Web enrollment record that is not correct.

- The provider or supplier cannot produce a printout of the applicable PECOS Web enrollment record (e.g., provider has no enrollment record in PECOS).

- The provider or supplier cannot otherwise produce a valid RCP.

2. Contractor Processing

Upon receipt of an RCP, the contractor:

- Shall ensure that it is complete and contains all of the elements identified in (B)(1) above. If the RCP is in any way deficient or incomplete, the contractor shall develop for the missing/incomplete information or documentation consistent with existing procedures (e.g., requesting the submission of a revised letter). Examples of a deficient RCP include, but are not limited to, the following: (1) the package is missing the printout, certification statement, or letter; (2) the letter does not contain the required language or contains verbiage that offsets the required language; (3) the certification statement or letter is signed by an individual who is not on record as an authorized or delegated official; (4) the certification statement or letter is undated; (5) the letter refers to the incorrect PAC ID number. The contractor may reject the RCP if the provider fails to furnish the requested material within 30 days of the request.

- Shall review all names listed in the provider's enrollment record against the Medicare Exclusion Database (MED) *and the System for Award Management (SAM).*

- Shall ensure that the provider is still appropriately licensed and/or certified (e.g., the contractor can check State Web sites).

- Consistent with section 15.19.2.4 of this chapter, shall perform a site visit if the provider is in the moderate or high screening category.

- Reserves the right to request a full Form CMS-855 application if the contractor has reason to believe that any data in the provider's enrollment record is inaccurate or outdated. However, it shall obtain the approval of its *CMS* Provider Enrollmen*t B*usiness Function Lead (P*EB*FL) before making this request.

The contractor need not prescreen the RCP.

If the contractor determines that (1) the RCP complies with the requirements of this section 15.27.1.2.1(B), (2) remains appropriately licensed and/or certified, (3) none of the names in the provider or supplier's enrollment record are excluded or debarred, (4) the provider is operational per the site visit, and (5) for HHAs, has undergone a new State survey or accreditation, the contractor may reactivate the provider's Medicare billing privileges in accordance with existing procedures. If the contractor determines that any of these criteria are not met, it shall deny the reactivation application in accordance with existing procedures. (As stated earlier, though, rejection is appropriate if the provider does not adequately respond to the provider's developmental request.) If the contractor believes that a denial ground other than the

aforementioned exists, it shall contact its *CMS* Provider Enrollment *B*usiness Function Lead (*PEB*FL) for guidance.

15.27.1.2.2 – Reactivations - Deactivation for Non-Submission of a Claim

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

To reactivate its billing privileges, a provider or supplier deactivated for non-billing must recertify that its enrollment information currently on file with Medicare is correct. This section 15.27.1.2.2 discusses this requirement.

A. All of Provider's Data in Enrollment Record Is Correct

1. General Requirements

If all of the data in the provider or supplier's enrollment record is correct, the provider must submit to the contractor: (a) a hard copy print-out of its PECOS Web enrollment data, (b) a hard copy Form CMS-855 certification statement signed and dated by the enrolled individual practitioner or, as applicable, the provider or supplier's authorized or delegated official, (c) the claim data described in section 15.27.1.2.3(B) of this chapter, and (d) a letter certifying as to the data's accuracy. The letter must:

(i) Be on the provider or supplier's letterhead.

(ii) List the provider or supplier's birth name or legal business name, doing business as name (if applicable), National Provider Identifier, and the Provider Transaction Access Number(s) (PTAN) in the provider or supplier's enrollment record to be reactivated.

(iii) Must state that the provider is seeking to reactivate his/her/its billing privileges.

(iv) Be signed and dated by the enrolled individual practitioner or, as applicable, the provider or supplier's authorized or delegated official (who must be the same person who signed the Form CMS-855 certification statement).

(v) Contain the following language:

For Individual Practitioners

> "I, _____, certify that all of the information contained in Medicare enrollment record (the record's PAC ID number) is truthful and accurate. I understand that by this statement and by my signature below, I am bound by all of the terms and conditions of the attached, signed Form CMS-855 certification statement and agree to abide by them."

For Authorized/Delegated Officials

> "I, _____, in my capacity as an authorized or delegated official of (Provider/Supplier), certify on behalf of (Provider/Supplier) that all of the information contained in (Provider/Supplier's) Medicare enrollment record (the record's PAC ID number) is truthful and accurate. I understand that by this statement and by my signature below, (Provider/Supplier) is bound by all of the terms and conditions of the attached, signed Form CMS-855 certification statement and agrees to abide by them."

As explained in section 15.27.1.2.2(A), a separate Form CMS-855 certification statement and letter must be submitted with each PECOS enrollment record the provider or supplier seeks to have reactivated. The certification statement and letter should be attached to the PECOS Web printout to which it applies. All

such “reactivation certification packages” (RCPs) must be submitted via mail. They cannot be faxed or e-mailed.

2. Contractor Processing

Upon receipt of an RCP, the contractor:

- Shall ensure that it is complete and contains all of the elements identified in (A)(1) above.

If the RCP is in any way deficient or incomplete, the contractor shall develop for the missing/incomplete information or documentation consistent with existing procedures (e.g., requesting the submission of a revised letter). Examples of a deficient RCP include, but are not limited to, the following: (1) the package is missing the printout, certification statement, or letter; (2) the letter does not contain the required language or contains verbiage that offsets the required language; (3) the certification statement or letter is signed by an individual who is not on record as an authorized or delegated official; (4) the certification statement or letter is undated; (5) the letter refers to the incorrect PAC ID number. The contractor may reject the RCP if the provider fails to furnish the requested material within 30 days of the request.

- Shall review all names listed in the provider’s enrollment *record* against the Medicare Exclusion Database (MED) and *the System for Award Management (SAM).*

- Shall ensure that the provider is still appropriately licensed and/or certified (e.g., the contractor can check State Web sites).

- Consistent with section 15.19.2.4 of this chapter, shall perform a site visit if the provider is in the moderate or high screening category.

The contractor need not prescreen the RCP.

If the contractor determines that (1) the RCP complies with the requirements of this section 15.27.1.2.2(A), (2) remains appropriately licensed and/or certified, (3) none of the names in the provider or supplier’s enrollment record are excluded or debarred, (4) the provider (if in the moderate or high screening category) is operational per the site visit, and (5) for HHAs, the provider has undergone a new State survey or accreditation, the contractor may reactivate the provider’s Medicare billing privileges in accordance with existing procedures. If the contractor determines that any of these criteria are not met, it shall deny the reactivation application in accordance with existing procedures. (Rejection is appropriate, however, if the provider does not adequately respond to the contractor’s developmental request.) If the contractor believes that a denial ground other than the aforementioned exists, it shall contact its *CMS* Provider Enrollment *B*usiness Function Lead (P*EB*FL) for guidance.

B. Some of Provider’s Data in Enrollment Record Is Incorrect

1. General Requirements

If any data in the provider or supplier’s enrollment record is incorrect, the provider must submit to the contractor: (a) a hard copy print-out of its PECOS Web enrollment data, (b) applicable hard-copy page(s) of the Form CMS-855 containing the corrected information (e.g., new section 8 reporting a change to the billing company address), (c) a certification statement signed and dated by the enrolled individual practitioner or, as applicable, the provider or supplier’s authorized or delegated official, (d) the claim data described in section 15.27.1.2.3(B) of this chapter, and (e) a letter certifying as to the rest of the enrollment data’s accuracy. The letter must:

(i) Be on the provider or supplier’s letterhead.

(ii) List the provider or supplier's birth name or legal business name, doing business as name (if applicable), NPI, and PTAN(s).

(iii) Must state that the provider is seeking to reactivate his/her/its billing privileges.

(iv) Be signed and dated by the enrolled individual practitioner or, as applicable, the provider or supplier's authorized or delegated official (who must be the same person who signed the Form CMS-855 certification statement).

(v) Contain the following language:

For Individual Practitioners

"I, _____, certify that - with the exception of (list the data elements that are currently incorrect and are being updated via the submitted Form CMS-855 pages) - all of the information currently contained in Medicare enrollment record (the record's PAC ID number) is truthful and accurate. I understand that by this statement and by my signature below, I am bound by all of the terms and conditions of the attached, signed Form CMS-855 certification statement and agree to abide by them."

For Authorized/Delegated Officials

"I, _____, in my capacity as an authorized or delegated official of (provider/supplier), certify on behalf of (provider/supplier) that - with the exception of (list the data elements that are currently incorrect and are being updated via the submitted Form CMS-855 pages) - all of the information contained in (provider/supplier's) Medicare enrollment record (the record's PAC ID number) is truthful and accurate. I understand that by this statement and by my signature below, (provider/supplier) is bound by all of the terms and conditions of the attached, signed Form CMS-855 certification statement and agrees to abide by them."

As explained in section 15.27.1.2.2(B), a separate Form CMS-855 certification statement and letter must be submitted with each PECOS enrollment record the provider or supplier seeks to have reactivated. The certification statement and letter should be attached to the PECOS Web printout to which it applies. All RCPs must be submitted via mail. They cannot be faxed or e-mailed.

2. Contractor Processing

Upon receipt of an RCP, the contractor:

- Shall ensure that it is complete and contains all of the elements identified in (B)(1) above.

If the RCP is in any way deficient or incomplete, the contractor shall develop for the missing/incomplete information or documentation consistent with existing procedures (e.g., requesting the submission of a revised letter). Examples of a deficient RCP include, but are not limited to, the following: (1) the package is missing the printout, certification statement, or letter; (2) the letter does not contain the required language or contains verbiage that offsets the required language; (3) the letter does not identify the information in the enrollment record that is incorrect; (4) the certification statement or letter is signed by an individual who is not on record as an authorized or delegated official; (5) the certification statement or letter is undated; (6) the letter refers to the incorrect PAC ID number. The contractor may reject the RCP if the provider fails to furnish the requested material within 30 days of the request.

- Shall review all names listed in the provider's enrollment *record* against the MED and *the SAM.*

- Shall ensure that the provider is still appropriately licensed and/or certified (e.g., the contractor can check State Web sites).

- Consistent with section 15.19.2.4 of this chapter, shall perform a site visit if the provider is in the moderate or high screening category.

- Process the changed information in accordance with the instructions in this chapter. The entire RCP transaction (including the changed data) shall, however, be processed as a revalidation.

The contractor need not prescreen the RCP.

If the contractor determines that (1) the RCP complies with the requirements of this section 15.27.1.2.2(B), (2) remains appropriately licensed and/or certified, (3) none of the names in the provider or supplier's enrollment record are excluded or debarred, (4) the provider (if in the moderate or high screening category) is operational per the site visit, (5) all of the changed information can be processed to approval, and (6) for HHAs, the provider has undergone a new State survey or accreditation, the contractor may reactivate the provider's Medicare billing privileges in accordance with existing procedures. If the contractor determines that any of these criteria are not met, it shall deny the reactivation application in accordance with existing procedures. (Rejection is appropriate, however, if the provider does not adequately respond to the contractor's developmental request.) If the contractor believes that a denial ground other than the aforementioned exists, it shall contact its (P*EB*FL) for guidance.

C. PECOS Web Printout

If the provider or supplier cannot produce a printout of the applicable PECOS Web enrollment record (e.g., provider has no enrollment record in PECOS) or cannot otherwise submit a valid RCP, it must submit a complete Form CMS-855 application in order to reactivate its Medicare billing privileges.

15.27.2 – Revocations

(Rev.561, Issued: 12-12-14, Effective: 03-18-15, Implementation: 03-18-15)

A. Revocation Reasons

(The contractor *shall not* issue a*ny* revocation *or revocation letter* without prior approval from *CMS Central Office's p*rovider *e*nrollment *unit (COPEU*).)

When *drafting* a revocation *letter (which, in all cases, must be sent to COPEU via the ProviderEnrollmentRevocations@cms.hhs.gov for approval)*, the contractor shall insert the appropriate regulatory basis (e.g., 42 CFR §424.535(a)(1)) into *the* letter. The contractor shall not use provisions from this chapter as the basis for revocation.

1. Revocation Reason 1 (42 CFR §424.535(a)(1)) – Not in Compliance with Medicare Requirements

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 § 424.535(a)(1) *may be used* 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. (This revocation reason *will* not be used in these cases if CMS has explicitly instructed the contractor to use deactivation reason §424.540(a)(3) in lieu thereof.)

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: 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.

2. Revocation Reason 2 (42 CFR §424.535(a)(2)) – Excluded/Debarred from Federal Program

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 *PEBFL* immediately. *COPEU* will notify the Contracting Officer's Representative (COR) for the appropriate Zone Program Integrity Contractor. The COR will, in turn, contact the Office of Inspector General's office with the findings for further investigation.

3. Revocation Reason 3 (42 CFR §424.535(a)(3)) – Felony Conviction

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.

4. Revocation Reason 4 (42 CFR §424.535(a)(4)) – False or Misleading Information on Application

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.)

5. Revocation Reason 5 (42 CFR §424.535(a)(5)) - On-Site Review/Other Reliable Evidence that Requirements Not Met

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.

6. Revocation Reason 6 (§424.535(a)(6)) - Hardship Exception Denial and Fee Not Paid

(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.

7. Revocation Reason 7 (42 CFR §424.535(a)(7)) – Misuse of Billing Number

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.

8. Revocation Reason 8 (42 CFR §424.535(a)(8)) – Abuse of Billing Privileges

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.

9. Revocation Reason 9 (42 CFR §424.535(a)(9)) – Failure to Report Changes

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.

With respect to Revocation Reason 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 *pursue a revocation* 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 *pursue a revocation (e.g., seeking COPEU's approval to revoke).*

10. Revocation Reason 10 (42 CFR §424.535(a)(10)) – Non-Compliance with Documentation Requirements

The provider or supplier did not comply with the documentation requirements specified in 42 CFR §424.516(f).

11. Revocation Reason 11 (42 CFR §424.535(a)(11)) - Home Health Agency (HHA) Capitalization

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).

12. Revocation Reason 12 (42 CFR §424.535(a)(12)) – Medicaid Billing Privileges Revoked

The provider or supplier's Medicaid billing privileges are terminated or revoked by a State Medicaid Agency.

(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).

13. Revocation Reason 13 (42 CFR § 424.535(a)(13)) - DEA Certificate/State Prescribing Authority Suspension or Revocation

(i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs.

14. Revocation Reason 14 (42 CFR § 424.535(a)(14)) - CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements.

B. Prior *COPEU* Approval

Prior to sending a*ny* revocation letter *(regardless of the basis for the revocation)*, the contractor shall obtain approval of both the revocation and the revocation letter from *COPEU via the ProviderEnrollmentRevocations@cms.hhs.gov mailbox.*

During this review, CMS will also determine (1) the extent to which the revoked provider or supplier's other locations are affected by the revocation, (2) the geographic application of the reenrollment bar, *and (3) the effective date of the revocation. CMS will notify the contractor of its determinations and instruct the contractor as to how to proceed.*

C. Effective Date of Revocations

Per 42 CFR *§ 424.535(g), a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier. However, 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:** 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 *PEB*FL 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 *(with prior COPEU approval)* 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 th*e d*iscretion to determine whether sufficient "proof" exists.

D. Re-enrollment Bar

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. Per §424.535(c), however, the reenrollment bar does not apply if the revocation (1) is based on §424.535(a)(1), and (2) stems from a provider or supplier's failure to respond timely to a revalidation request or other request for information. If both of these conditions are met, no reenrollment bar *will* be applied.

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 revocatio*n*.

*T*he 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:** Reenrollment bars apply only to revocations*, not to denials.* The contractor shall not impose a reenrollment bar following a denial of an application.*)*

In general, and unless stated otherwise above, any re-enrollment bar at a minimum applies to (1) all practice locations under the provider's PECOS or legacy enrollment record, (2) any effort to re-establish any of these locations (i) at a different address, and/or (ii) under a different business or legal identity, structure, or TIN. If the contractor receives an application and is unsure as to whether a revoked provider is attempting to re-establish a revoked location, it shall contact its P*EB*FL for guidance. Instances where the provider might be attempting to do so include - but are *not* limited to – the following:

- John Smith was the sole owner of Group Practice X, a sole proprietorship. Six months after X was revoked under § 424.535(a)(9), the contractor receives an initial application from Group Practice Medicine, LLC, of which John Smith is the sole owner/member.

- Jack Jones and Stan Smith were 50 percent owners of World Home Health Agency, a partnership. One year after World Home Health was revoked under § 424.535(a)(7), the contractor receives an initial application from XYZ Home Health, a corporation owned by Jack Jones and his wife, Jane Jones.

- John Smith was the sole owner of XYZ Medical Supplies, Inc. XYZ's lone location was at 1 Jones Street. XYZ's billing privileges were revoked after it was determined that the site was non-operational. Nine months later, the contractor receives an initial application from Johnson Supplies, LLC. The entity has two locations in the same city in which 1 Jones Street is located, and John Smith is listed as a 75 percent owner.

E. Submission of Claims for Services Furnished Before Revocation

Per 42 CFR § 424.535(*h*), 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. Timeframe for Processing of Revocation Actions

If the contractor receives approval from *CO*PE*U* (or receives an unrelated request from *CO*PE*U*) to revoke a provider or supplier's billing privileges, the contractor shall complete all steps associated with the revocation no later than 5 business days from the date it received *CO*PE*U*'s approval/request. The contractor shall notify *CO*PE*U* that it has completed all of the revocation steps no later than 3 business days after these steps have been completed.

G. Provider Enrollment Appeals Process

For more information regarding the provider enrollment appeals process, see section 15.25 of this chapter.

H. 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:

- *Preparing a draft revocation letter;*

- *E-mailing the letter to COPEU via the ProviderEnrollmentRevocations@cms.hhs.gov mailbox with additional pertinent information regarding the basis for revocation;*

- *Receiving COPEU's determinations and abiding by COPEU's instructions regarding the case;*

- *If COPEU authorizes the revocation:*

  - Revoking the provider's billing privileges back to the appropriate date;

  - Establish*ing* the applicable reenrollment bar;

  - Updating PECOS to show the length of the reenrollment bar;

- Assess*ing* an overpayment, as applicable;

- Providing *the contractor's BFL* with the amount of the assessed overpayment within 10 days of the overpayment assessment; and

- Affording appeal rights.

I. 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 or denied.

To accomplish this task, *C*MS will provide a monthly revoked and denied provider list to all contractors via the Share Point Ensemble site. *The c*ontracto*r* shall access this list on the 5th day of each month through the Share Point Ensemble site. *The c*ontracto*r* shall review the monthly revoked and denied provider list for the names of Medicare providers revoked and denied in PECOS. *The c*ontracto*r* shall document any appeals actions a provider/supplier may have submitted subsequent to the provider or supplier's revocation or denial.

The contracto*r* shall update the last three columns on the tab named "Filtered Revocations" of the spreadsheet for every provider/supplier revocation or denial action taken. *The c*ontracto*r* 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
Denial Upheld
Denial 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 *COPEU* 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 P*EB*FL.

J. Special Instructions Regarding Revocations of Certified Providers and Certified Suppliers

The contractor need not obtain prior approval from the *s*tate/RO prior to revoking a certified provider or certified supplier's billing privileges. When revoking the provider/supplier, however, the contractor shall:

- E-mail a copy of the revocation letter to the applicable RO's Division of Survey & Certification corporate mailbox. (The RO will notify the *s*tate 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 25 of this chapter.