

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10467	Date: November 13, 2020
	Change Request 11954

Transmittal 10434, dated October 30, 2020, is being rescinded and replaced by Transmittal 10467, dated November 13, 2020, to revise business requirement 11954.5.3 and to add additional updates to the manual. All other information remains the same.

SUBJECT: Update to Chapter 10 of Publication (Pub.) 100-08 - Enrollment Policies for Home Infusion Therapy (HIT) Suppliers

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make the Medicare Administrative Contractors (MACs) aware of the policies and procedures for enrolling HIT suppliers in Medicare. Enrollment will begin on or after November 1, 2020. Payments will begin on or after January 1, 2021.

EFFECTIVE DATE: January 1, 2021

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

IMPLEMENTATION DATE: November 1, 2020

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	10/10.2/10.2.2/Suppliers that enroll via the form CMS-855B
R	10/10.6/10.6.15/Risk-based screening

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 obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

Pub. 100-08	Transmittal: 10467	Date: November 13, 2020	Change Request: 11954
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SUBJECT: Update to Chapter 10 of Publication (Pub.) 100-08 - Enrollment Policies for Home Infusion Therapy (HIT) Suppliers

EFFECTIVE DATE: January 1, 2021

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

IMPLEMENTATION DATE: November 1, 2020

I. GENERAL INFORMATION

A. Background: Section 5012 of the 21st Century Cures Act (“the Cures Act”) (Pub. L. 114-255), which amended sections 1861(s)(2) and 1861(iii) of the Social Security Act (the Act), established a new Medicare HIT services benefit. The Medicare HIT services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of HIT and home infusion drugs furnished by a qualified HIT supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries.

Section 50401 of the BBA of 2018 amended section 1834(u) of the Act by adding a new paragraph (7) that established a HIT services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of the same items and services, as defined in section 1861(iii)(2)(A) and (B) of the Act, related to the administration of home infusion drugs. The temporary transitional payment began on January 1, 2019 and will end the day before the full implementation of the HIT services benefit on January 1, 2021, as required by section 5012 of the 21st Century Cures Act.

B. Policy: Section 1861(s)(2)(HH)(jjj) of the Act and Section 5012 of the Cures Act

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MA C	Shared-System Maintainers				Othe r
		A	B	HH H		FIS S	MC S	VM S	CW F	
11954.1	Beginning on or after November 1, 2020, contractors shall		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MA C	Shared-System Maintainers				Othe r
		A	B	HH H		FIS S	MC S	VM S	CW F	
	accept the Form CMS-855B to enroll HIT suppliers.									
11954.1.1	MACs shall not process these applications until the regulation finalizes. MACs shall hold these applications and change the receipt date of the application to the date the regulation is implemented.		X							
11954.2	Contractors shall allow a HIT supplier to write the provider/supplier type "Home Infusion Therapy" or "HIT" into the "other" field on the Form CMS-855B until the form has been updated.		X							
11954.3	Contractors shall collect an application fee for HIT applicants.		X							
11954.4	Contractors shall revalidate HIT suppliers on a 5-year cycle.		X							
11954.5	Contractors shall ensure at initial enrollment and revalidation that the HIT		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MA C	Shared-System Maintainers				Othe r
		A	B	HH H		FIS S	MC S	VM S	CW F	
	suppliers are currently and validly accredited as home infusion therapy suppliers by a CMS-recognized HIT supplier accreditation organization.									
11954.5.1	Contractors shall deny the HIT supplier's enrollment if the supplier is not currently and validly accredited as a HIT supplier by a CMS-recognized home infusion therapy supplier accreditation organization.		X							
11954.5.2	Contractors shall enter the HIT supplier's accreditation information in section 2 in PECOS.		X							
11954.5.3	Contractors shall ensure that HIT suppliers submit a copy of their accreditation certification and accreditation approval letter with their application. The document must contain an effective date of		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	accreditation. Contractor shall develop for this information if it is not included with the application.									
11954.6	Contractors shall issue effective dates for billing privileges the later of - (1) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) The date that the supplier first began furnishing services at a new practice location. A retrospective billing date can be issued for up to 30 days prior to the effective date.		X							
11954.7	Contractors shall not issue effective dates or retrospective billing dates that take effect prior to January 1, 2021.		X							
11954.8	Contractors shall screen HIT suppliers as limited risk.		X							
11954.9	By signing the CMS-855B		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MA C	Shared-System Maintainers				Othe r
		A	B	HH H		FIS S	MC S	VM S	CW F	
	application the HIT supplier certifies that they are compliant with § 414.1515 and all provisions of 42 CFR Part 486, subpart I as well as that they meet and will continue to meet the specific requirements for enrollment described in §424.68.									
11954.10	Contractors shall ensure that HIT suppliers completed Section 4D: Rendering Services in Patients Home of the CMS-855B application and shall develop for this information if it is not included with the application.		X							
11954.11	If a HIT supplier has more than one location, Contractors shall create one enrollment record in PECOS but shall issue each location a separate PTAN number.		X							
11954.12	HIT suppliers will have a		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FIS	MC	VM	CW	
	choice of PAR or NON PAR.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11954.13	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.		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): Joseph Schultz, 410-786-2656 or joseph.schultz@cms.hhs.gov , Emmanuelle Calvet, 410-786-3865 or emmanuelle.calvet@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 10 – Medicare Enrollment

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(Rev. 10467; 11-13-20)

[Transmittals for Chapter 10](#)

10.2.2 – Suppliers That Enroll Via the Form CMS-855B

(Rev. 10467; Issued: 11-13-20; Effective: 01-01-21; Implementation: 11-01-20)

A. Ambulatory Surgical Centers (ASCs)

ASCs are a certified supplier type that enroll via the Form CMS-855B.

1. 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 is accredited by a national accrediting body, or licensed by a state agency, that CMS determines provides reasonable assurance that the conditions are met;
- In the case of deemed status through accreditation by a national accrediting body, where state law requires licensure, the ASC complies with state licensure requirements; and
- The ASC authorizes the release to CMS of the findings of the accreditation survey.

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

Note: ASCs can be fixed locations or mobile in nature.

2. Additional Enrollment Information

The contractor shall include any licenses, certifications, and accreditations submitted by ASCs in the enrollment package that is forwarded to the state and/or RO.

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

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

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

3. Ambulatory Surgical Centers (ASCs) and Reassignment

Physicians and non-physician practitioners who meet the reassignment exceptions in 42 CFR §424.80, and Pub. 100-04, chapter 1, sections 30.2.6 and 30.2.7, may reassign their benefits to an ASC.

If a physician or non-physician practitioner wishes to reassign its benefits to an existing (that is, a currently-enrolled) ASC, both the individual and the entity must sign the CMS-855R. However, it is not necessary for the ASC to separately enroll as a group practice in order to receive benefits. It can accept reassignment as an ASC.

4. Ambulatory Surgical Centers (ASCs) - Initial Enrollment

Unlike other supplier types that enroll via the Form CMS-855B, ASCs must receive a State survey and RO approval before they can enroll in Medicare. Accordingly, once it finishes reviewing the supplier's application, the contractor may only make a recommendation for approval to the State. The contractor shall not enroll the supplier until it receives a tie-in notice or approval letter from the RO.

When enrolling the ASC, the contractor shall use the effective date that is indicated on the tie-in notice/approval letter. This is the date from which the supplier can bill for services. See section 15.7.8.4 of Pub. 100-08, Chapter 15 for more information on ASC tie-in notices/approval letters.

5. Ambulatory Surgical Centers (ASCs) Changes of Ownership (CHOWs)

Though ASCs are not mentioned in 42 CFR § 489.18, CMS generally applies the change of ownership (CHOW) provisions of § 489.18 to them. CHOWs involving ASCs are thus handled in accordance with the principles in §489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). Note that the RO – not the contractor – determines whether a CHOW has occurred (unless this function has been delegated).

As discussed in section 10.2.2(A)(5) of this chapter, an ASC must sign a supplier agreement with Medicare prior to enrollment.

6. ASCs and CHOWs

If – pursuant to the CHOW – the seller submits a Form CMS-855B voluntary termination application, the contractor shall contact and explain to the seller that the ambulatory surgical center will not receive any payments until the RO approves the CHOW. (This is because payments must be sent to the seller until the tiein/approval letter is sent). If the seller insists that its application be processed, the contractor shall process it; however, it shall first notify the facility/new owner and explain that payments will cease once the seller's termination is effective.

7. 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

- 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.

8. 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

B. CLIA Labs

CLIA Labs are a certified supplier type that enroll via the Form CMS-855B.

1. 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.

2. Certificates

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

3. CLIA Enrollment

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 state in which testing is performed.
- If a lab is under the same ownership and at the same location as the “main provider,” it generally does not need to enroll separately. The enrolling provider will simply furnish its CLIA number in the practice location section. Conversely, if a lab is an “independent CLIA lab,” it must enroll separately.
- A separate enrollment record need not be created for each CLIA number. For instance, suppose a physician is enrolling in Medicare and has a CLIA number. The contractor need only create a single enrollment record that will encompass the Medicare number and the CLIA number.

4. Procedure to Update CLIA Certificate for an Enrolled CLIA lab

A Medicare-enrolled CLIA lab shall submit the updated CLIA Certificate to its contractor with a CMS-855. The MAC shall update PECOS accordingly, regardless if the provider or supplier is in PECOS.

5. Site Visits of Independent CLIA Labs

a. 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 Pub. 100-

08, Chapter 15, Section 15.19.2.2. 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.

b. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

c. 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 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

6. Integrated CLIA Labs

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

If the lab is not "integrated," the lab must enroll as an independent CLIA lab via the Form CMS-855B application. The contractor shall advise the lab that it must contact the applicable CLIA office; the lab cannot be enrolled until it receives a CLIA number. The contractor shall also ensure that the lab is CLIA-certified and, as applicable, State-licensed.

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

7. 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)

C. Mammography Screening Centers

Mammography Screening Centers are a certified supplier type that enroll via the Form CMS-855B.

1. General Background Information

As defined in 42 CFR § 410.34(a)(2), a screening mammography is a radiologic procedure “furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure.” 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).”

2. Enrollment of Mammography Screening Centers

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. If the supplier fails to submit the FDA certificate within 30 days of the MAC's request the MAC shall follow the rejection instructions within Pub. 100-08, Chapter 15, Section 15.8.2.

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

D. Pharmacies

Pharmacies are a supplier type that enroll via the Form CMS-855B

1. General Background Information

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 MAC, meaning that the pharmacy must enroll with the Part A/B MAC via the Form CMS-855B.

2. Additional Information

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

- Pub. 100-04, Claims Processing Manual, chapter 17

- Pub. 100-02, Benefit Policy Manual, chapter 15, sections 50 through 50.6

E. Portable X-Ray Suppliers (PXRSSs)

PXRSSs are a certified supplier type that enroll via the Form CMS-855B.

1. General Background Information

To qualify as a portable x-ray supplier (PXRSS), an entity must meet the conditions for coverage discussed in 42 CFR § 486.100-110.

A PXRSS can be simultaneously enrolled as a mobile IDTF, though they cannot bill for the same service. A PXRSS requires a State survey, while a mobile IDTF does not (although an IDTF requires a site visit).

A PXRSS does not have a supplier agreement.

2. Enrollment of PXRSSs

a. Initial application

Unlike other supplier types that enroll via the Form CMS-855B, PXRSSs must receive a State survey and RO approval before they can enroll in Medicare. Accordingly, once it finishes reviewing the supplier's application, the contractor may only make a recommendation for approval to the State. The contractor shall not enroll the supplier until it receives a tie-in notice or approval letter from the RO and a follow-up site visit is performed per section 10.2.2(E)(3) of this chapter.

When enrolling the PXRSS, the contractor shall use the effective date that is indicated on the tie-in notice/approval letter. This is the date from which the supplier can bill for services. See section 15.7.8.4 of Pub. 100-08, Chapter 15 for more information on PXRSS tie-in notices/approval letters.

b. Practice Location Information

In order to enroll as a PXRSS, 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 PXRSS 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 PXRSS 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.

3. Site Visits

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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

a. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

b. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

c. Reassignment

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

4. Additional Enrollment Information

The contractor shall include any licenses, certifications, and accreditations submitted by portable x-ray suppliers in the enrollment package that is forwarded to the state and/or RO.

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

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

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

See also Pub. 100-08, Chapter 15, Section 15.19.2.2 for additional PXRS site visit information.

5. PXRS and CHOWs

Though PXRSs are not mentioned in 42 CFR § 489.18, CMS generally applies the change of ownership (CHOW) provisions of § 489.18 to them. CHOWs involving PXRSs are thus handled in accordance with the principles in §489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). Note that the RO – not the contractor – determines whether a CHOW has occurred (unless this function has been delegated).

If – pursuant to the CHOW – the seller submits a Form CMS-855B voluntary termination application, the contractor shall contact and explain to the seller that the portable x-ray supplier will not receive any payments until the RO approves the CHOW. (This is because payments must be sent to the seller until the tie-in/approval letter is sent). If the seller insists that its application be processed, the contractor shall process it; however, it shall first notify the facility/new owner and explain that payments will cease once the seller's termination is effective.

6. 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 – 2424B
- 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 Pub. 100-08, Chapter 15, Section 15.19.2.2 for additional PXRS site visit information.

F. Radiation Therapy Centers (RTCs)

RTCs are a supplier type that enroll via the Form CMS-855B.

1. General Background Information

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.

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

2. Additional Information

For additional background on radiation therapy services, see:

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

G. Suppliers of Ambulance Services

Suppliers of Ambulance Services are supplier types that enroll via the Form CMS855B.

1. General Background Information

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

2. 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 in § 414.605 as follows:

- a. Advanced Life Support, level 1 (ALS1) - Transportation by ground ambulance vehicle, medically necessary supplies and services, and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.
- b. Advanced Life Support, level 2 (ALS2) - Either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the seven ALS procedures specified in § 414.605.
- c. Air Ambulance (Fixed-Wing and Rotary-Wing) (See § 414.605 for specific definitions of fixed-wing and rotary-wing).

d. 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 (EMTBasic).

e. 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.

f. 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.)

3. Ambulance Qualifications

a. Vehicle Design and Equipment

Section 410.41(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 state or local laws.

b. Vehicle Personnel

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

An ALS vehicle, in addition to meeting the BLS vehicle staff requirements described in 42 CFR § 410.41(b)(1), must also have one of the two staff members be certified as a paramedic or an emergency medical technician, by the state or local authority where the services are being furnished, to perform one or more ALS services.

4. 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 requirements 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.

5. Geographic Area: Single Contractor Jurisdiction

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

- Each site at which its vehicles are garaged in section 4A. (The site is considered a practice location for enrollment purposes, including with respect to payment of the application fee.)
- Each site from which its personnel are dispatched in section 4A. (The site is considered a practice location for enrollment purposes, including with respect to payment of the application fee.)

- Its base of operations – which, for ambulance companies, is their primary headquarters – in section 4E. (The supplier can only have one base of operations.)

If the supplier will be furnishing services in more than one contractor jurisdiction, it shall follow the applicable instructions below.

6. Geographic Area: Multiple States

The applicant must list the geographic areas in which it provides services. If the supplier indicates that it provides services:

- In more than one contractor's jurisdiction, it must submit a separate Form CMS-855B to each contractor.
- In more than one state but within the same contractor jurisdiction, the contractor shall review section 10.2.2(G)(6) of this chapter to determine whether a separate enrollment for the additional state is required.

7. Practice Location

For purposes of provider enrollment, the following are considered ambulance “practice locations”:

- A site at which the supplier’s vehicles are garaged
- A site from which the supplier’s personnel are dispatched
- The supplier’s base of operations (i.e., the supplier’s primary headquarters). The supplier can only have one base of operations.

Hence, if an ambulance supplier submits a Form CMS-855B to add to its enrollment record a site at which the supplier’s vehicles are garaged or from which personnel are dispatched, the supplier must pay an application fee.

Consider the following scenarios:

a. The ambulance supplier is enrolling and performing services in multiple states but within only 1 contractor jurisdiction: The supplier would have to list on its Form CMS-855B each city/state/zip code in which it performs services. Its base of operations and all other practice locations would also have to be listed, and all licensure/certification requirements would have to be met for each state in which it performs services. However, separate Form CMS-855B applications for each state would only be required if all 5 conditions described in Pub. 100-08, Chapter 15, Section 15.5.4.1.C are met. (If separate applications are not required, the contractor shall still create a separate Provider Enrollment, Chain and Ownership System (PECOS) record for each state.)

b. The ambulance supplier is enrolling (and has its base of operations) in Contractor Jurisdiction X. Its vehicles perform services in X and in adjacent Contractor Jurisdiction Y: The supplier would have to enroll with X and Y. For its Contractor X CMS-855B, the supplier would have to list all of the data mentioned in

Example (a) above. For its Contractor Y CMS-855B, the supplier would have to (1) list the cities/zip codes in Y in which it performs services, (2) list its Jurisdiction X base of operations and any practice locations in Jurisdiction Y, and (3) meet all licensure/certification requirements for the state(s) in Y in which the supplier performs services.

8. Licensure Information

With respect to licensure:

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

9. Paramedic Intercept Information

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

10. Air Ambulances

Air ambulance suppliers must submit the following:

1. Proof that the air ambulance supplier or its leasing company possesses a valid charter flight license (FAA Part 135 Certificate) for the aircraft being used as an air ambulance. Any of the following constitutes acceptable proof:
 - If the air ambulance supplier or provider owns the aircraft, the owner's name on the FAA Part 135 certificate must be the same as the supplier's or provider's name on the enrollment application.
 - If the air ambulance supplier or provider owns the aircraft but contracts with an air services vendor to supply pilots, training and/or vehicle maintenance, the FAA Part 135 certificate must be issued in the name of the air services vendor. A certification from the supplier or provider must also attest that it has an agreement with the air services vendor and must list the date of that agreement. A copy of the FAA Part 135 Certificate must accompany the enrollment application.
 - If the air ambulance supplier or provider leases the aircraft from another entity, a copy of the lease agreement must accompany the enrollment application. The name of the company leasing the aircraft from that other entity must be the same as the supplier's or provider's name on the enrollment application.

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

In addition:

The contractor shall access the following FAA Web site on a quarterly basis to validate all licenses/certifications of air ambulance operators that are enrolled with the contractor:

- https://www.faa.gov/about/office_org/headquarters_offices/agc/practice_areas/enforcement/reports/
- The contractor shall deny or revoke the enrollment of an air ambulance supplier if the supplier does not maintain its FAA certification or any other applicable licenses.

11. Hospital-Based Ambulances

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

- The ambulance services will appear on the hospital's cost-report; and
- The hospital possesses all licenses required by the State or locality to operate the ambulance service.

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

H. Intensive Cardiac Rehabilitation (ICR)

ICR suppliers are a supplier type that enrolls via the Form CMS-855B.

1. Background

ICR programs must be approved by CMS through the national coverage determination (NCD) process and must meet certain criteria for approval. Individual sites seeking to provide ICR services via an approved ICR program must enroll with their local Medicare contractor as an ICR program supplier.

2. ICR Enrollment

In order to enroll as an Intensive Cardiac Rehab (ICR) site, a supplier must complete a Form CMS-855B, with the supplier type of "Intensive Cardiac Rehabilitation" 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. However, reassignments are not required.

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 232

I. Independent Diagnostic Testing Facilities (IDTFs)

IDTFs are a supplier type that enroll via the Form CMS-855B.

1. General Background Information

An IDTF is a facility that is independent both of an attending or consulting physician's office and of a hospital. However, IDTF general coverage and payment policy rules apply when an IDTF furnishes diagnostic procedures in a physician's office (see 42 Code of Federal Regulations (CFR) 410.33(a)(1)).

Effective for diagnostic procedures performed on or after March 15, 1999, MACs pay for diagnostic procedures under the physician fee schedule when performed by an IDTF. An IDTF may be a fixed location or a mobile entity. It is independent of a physician's office or hospital.

2. IDTF Standards

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

- a. Operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.
- The purpose of this standard is to ensure that suppliers are licensed in the business and specialties being provided to Medicare beneficiaries. Licenses are required by State and/or Federal agencies to make certain that guidelines and regulations are being followed and to ensure that businesses are furnishing quality services to Medicare beneficiaries.

- The responsibility for determining what licenses are required to operate a supplier's business is the sole responsibility of the supplier. The contractor is not responsible for notifying any supplier of what licenses are required or that any changes have occurred in the licensure requirements. No exemptions to applicable State licensing requirements are permitted, except when granted by the State.
 - The contractor shall not grant billing privileges to any business not appropriately licensed as required by the appropriate State or Federal agency. If a supplier is found providing services for which it is not properly licensed, billing privileges may be revoked and appropriate recoupment actions taken.
- b. Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and final adverse actions must be reported to the contractor within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

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

- c. Maintain a physical facility on an appropriate site. (For purposes of this standard, a post office box, commercial mailbox, hotel, or motel is not an appropriate site. The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.)
- IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.
 - The requirements in 42 CFR §410.33(g)(3) take precedence over the guidelines in 100-08, Chapter 15, Sections 15.5.4 and 15.5.4.2 pertaining to the supplier's practice location requirements.
 - The physical location must have an address, including the suite identifier, which is recognized by the United States Postal Service (USPS).
- d. Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—
- (i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers, at the physical site;
 - (ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request; and

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

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

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

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

The requirements in 42 CFR §410.33(g)(5) take precedence over the guidelines in Pub. 100-08, Chapter 15, Section 15.5.4.A regarding the supplier's telephone requirements.

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

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

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

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

g. Agree not to directly solicit patients; this includes - but is not limited to - a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician who: (a) is furnishing a consultation or treating a beneficiary for a specific medical problem, and (2) uses the results in the management of the beneficiary's specific medical problem. Non-physician practitioners may order tests as set forth in §410.32(a)(3).

- By the signature of the authorized official in section 15 of the Form CMS855B, the IDTF agrees to comply with 42 CFR §410.33(g)(7).
- The supplier is prohibited from directly contacting any individual beneficiary for the purpose of soliciting business for the IDTF. This includes contacting the individual beneficiary by telephone or via door-to-door sales.
- There is no prohibition on television, radio or Internet advertisements, mass mailings, or similar efforts to attract potential clients to an IDTF.

- h. Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF. (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:
- (i) The name, address, telephone number, and health insurance claim number of the beneficiary.
 - (ii) The date the complaint was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.
 - (iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.
- i. Openly post these standards for review by patients and the public.
- j. Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.
- k. Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers' suggested maintenance and calibration standards.
- l. Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.
- m. Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days.
- n. Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must---
- (i) Be accessible during regular business hours to CMS and beneficiaries; and
 - (ii) Maintain a visible sign posting its normal business hours.
- o. Enrolls in Medicare for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed-base location.
- p. Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act. (Section 1861(w)(1) states that the term "arrangements" is limited to arrangements under which receipt of payments by the hospital, critical access hospital, skilled nursing facility, home health agency or hospice program (whether in its own right or as an agent), with respect to

services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.)

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

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

3. Leasing and Staffing

For purposes of the provisions in 42 CFR §410.33, a "mobile IDTF" does not include entities that lease or contract with a Medicare enrolled provider or supplier to provide: (1) diagnostic testing equipment; (2) non-physician personnel described in 42 CFR §410.33(c); or (3) diagnostic testing equipment and non-physician personnel described in 42 CFR §410.33(c). This is because the provider/supplier is responsible for providing the appropriate level of physician supervision for the diagnostic testing.

An IDTF is not required to report equipment that the IDTF is leasing for a period less than 90 days, unless the IDTF is leasing equipment for services that they have not already reported on a CMS-855B IDTF Attachment. For all new services being provided, IDTFs would need to complete a change of information to include the equipment and CPT/HCPCS codes that will be billed. Any accreditation for the services provided would need to be obtained by the IDTF.

4. Sharing of Space and Equipment

Effective January 1, 2008, with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF does not: (i) share a practice location with another Medicare-enrolled individual or organization; (ii) lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization; or (iii) share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. (See 42 CFR §410.33(g)(15).)

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

5. Multi-State IDTFs

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

- a. Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it operates; and
- b. Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.

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

6. IDTF Enrollment Information

Consistent with 42 CFR §410.33(g), each IDTF must certify on its Form CMS-855B enrollment application that it meets the IDTF standards under Section 10.2.2(I)(2) of this Chapter and all other requirements.

7. One Enrollment per Practice Location

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

Each separately enrolled practice location of the IDTF must meet all applicable IDTF requirements. The location's failure to comply with any of these requirements will result in the revocation of its Medicare billing privileges.

If an IDTF adds equipment for diagnostic testing that is mobile in nature, but is fixed permanently to the IDTF's physical location (i.e.: a CT scanner that is mounted in a bus or trailer, but is parked at the IDTF's site for use by the IDTF), a second enrollment is not necessary. This equipment can be listed in the Form CMS-855B along with the services performed on the equipment. In these cases, the MAC shall indicate the use of a fixed mobile unit is in use at the IDTF's site in the site visit request so the site inspector will know to view the fixed mobile equipment as part of the IDTF.

8. Interpreting Physicians

a. Listing Interpreting Physicians

The applicant shall list all physicians for whose diagnostic test interpretations it will bill. This includes physicians who will provide interpretations subject to the antimarkup payment limitation as detailed in CMS Publication 100-04, chapter 1, § 30.2.9 - whether the service is provided to the IDTF on a contract basis or is reassigned.

The contractor shall ensure and document that:

- All listed physicians are enrolled in Medicare
- All interpreting physicians who are reassigning their benefits to the IDTF have the right to do so
- The interpreting physicians listed are qualified to interpret the types of tests (codes) listed. (The contractor may need to contact another contractor to obtain

this information.) If the applicant does not list any interpreting physicians, the contractor need not request additional information because the applicant may not be billing for the interpretations; that is, the physicians may be billing for the interpretation themselves.

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

A Form CMS-855R need not accompany a Form CMS-855B application submitted by an independent diagnostic testing facility (IDTF) that employs or contracts with an interpreting physician.

b. Changes of Interpreting Physicians

If an interpreting physician is being added or changed, the updated information must be reported via a Form CMS-855B change request. The new interpreting physician must have met all of the necessary requirements at the time any tests were performed to perform services as an interpreting physician.

If the contractor receives notification from an interpreting physician that he/she is no longer interpreting tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B change of information to end date the interpreting physician from the enrollment.

9. Effective Date of IDTF Billing Privileges

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

- (1) The filing date of the Medicare enrollment application that was subsequently approved by a MAC; or
- (2) The date the IDTF first started furnishing services at its new practice location.

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

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

If an IDTF undergoes an ownership change that results in a new enrollment in PECOS (a new federal Tax Identification Number is a result of this change), MACs should use the transfer of ownership/business date as indicated by the IDTF, instead of establishing a new effective date.

10. IDTF Technicians Must be Listed on the Form CMS-855B

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

11. IDTF Technicians Licensure and Certification Requirements

All technicians must meet the standards of a state license or state certification at the time of the IDTF's enrollment. The contractor may not grant temporary exemptions from such requirements.

In lieu of requiring a copy of the technician's certification card, the contractor may validate a technician's credentials online via organizations such as the American Registry for Diagnostic Medical Sonography (ARDMS), the American Registry of

Radiology Technologists (ARRT), and the Nuclear Medicine Technology Certification Board (NMTCB). If online verification is not available or cannot be made, the contractor shall request a copy of the technician's certification card.

12. IDTF: Changes of Technicians

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

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

13. IDTF Supervising Physicians – General Principles

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

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

Not every supervising physician has to be responsible for all of these functions. For instance, one supervising physician can be responsible for the operation and calibration of equipment, while another supervising physician can be responsible for test supervision and the qualifications of non-physician personnel. The basic requirement, however, is that all supervising physician functions must be properly met at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervising physicians at different locations. They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

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

14. IDTF: Information about Supervising Physicians

The contractor shall ensure and document that each supervising physician is: (1) licensed to practice in the State(s) where the diagnostic tests he or she supervises will be performed, (2) Medicare-enrolled, and (3) not currently excluded or debarred. The physician(s) need not necessarily be Medicare-enrolled in the State where the IDTF is enrolled; moreover, the physician need not be furnishing medical services outside of his/her role as a supervising physician (i.e., he/she need not have his/her own medical practice separate from the IDTF). If the physician is enrolled in another State or with another contractor, however, the contractor shall ensure that he or she is appropriately licensed in that State.

In addition:

- Each physician of the group who actually performs an IDTF supervisory function must be listed.
- If a supervising physician has been recently added or changed, the updated information must be reported via a Form CMS-855B change request. The new physician must have met all of the supervising physician requirements at the time any tests were performed.
- If the contractor knows that a listed supervising physician has been listed with several other IDTFs, the contractor shall check with the physician to determine whether he or she is still acting as supervising physician for these other IDTFs.
- If the supervising physician is enrolling in Medicare and does not intend to perform medical services outside of his/her role as a supervising physician:
 - The contractor shall still send the physician an approval letter (assuming successful enrollment) and issue a Provider Transaction Access Number
 - The physician shall list the IDTF's address as a practice location
 - The space-sharing prohibition in 42 CFR §410.33(g) does not apply in this particular scenario.

IDTF: General, Direct, and Personal Supervision

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

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

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

IDTF: Attestation Statement for Supervising Physicians

A separate attestation statement must be completed and signed by each supervising physician listed. If Question E2 is not completed, the contractor may assume – unless it has reason to

suspect otherwise - that the supervising physician in question supervises for all codes listed in section 2 of the IDTF attachment. If Question E2 is completed, the contractor shall ensure that all codes listed in section 2 are covered through the use of multiple supervising physicians.

With respect to physician verification, the contractor shall contact each supervisory physician by telephone to verify that the physician: (1) actually exists (e.g., is not using a phony or inactive physician number); (2) indeed signed the attestation; and (3) is aware of his or her responsibilities.

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

IDTF: Changes of Supervising Physicians

If a supervising physician is being added or changed, the updated information must be reported via a Form CMS-855B change request. The new supervising physician must have met all of the necessary requirements at the time any tests were performed to perform services as a supervising physician.

If the contractor receives notification from a supervising physician that he/she is no longer supervising tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B change of information. If the IDTF did not have another supervising physician listed on the current application, the IDTF must submit a change of information adding a new supervising physician. If the IDTF does not provide this information, the MAC shall proceed with non-compliance revocation procedures as noted in Pub. 100-08, Chapter 15, Section 15.27.2.

15. Desk and Site Reviews

All initial and revalidating independent diagnostic testing facility (IDTF) applicants shall receive: (1) a thorough desk review, and (2) a mandatory site visit prior to the contractor's approval of the application. The general purposes of these reviews are to determine whether:

- The information listed on Attachment 2 of the Form CMS-855B is correct, verifiable, and in accordance with all IDTF regulatory and enrollment requirements.
- To the extent applicable, the IDTF meets the criteria outlined in Pub. 100-08, Chapter 15, Section 15.19.2.2.
- The IDTF meets the supplier standards in 42 CFR § 410.33.

The contractor shall order the site visit through the Provider Enrollment, Chain and Ownership System. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

16. Mobile Units

Mobile units are required to list their geographic service areas in section 4 of the Form CMS-855B. Based on the information furnished therein, the NSVC will generally perform the site visit via one of the following methods: (1) the mobile unit visits the office of the NSVC (or some other agreed-to location) for inspection, (2) the NSVC visits the mobile unit's base of

operations to inspect the unit, or (3) the NSVC obtains an advance schedule of the locations at which the IDTF will be performing services and conducts the site visit at one of those locations.

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

- How they will perform these types of supervision on a mobile basis;
- What their responsibilities are; and
- That a patient's physician who is performing direct or personal supervision for the IDTF on their patient should be aware of the prohibition concerning physician self-referral for testing (in particular, this concerns potentially illegal compensation to the supervisory physician from the IDTF).

17. Addition of Codes

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

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

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

In the situations described in the two previous paragraphs, the contractor shall not approve the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

18. IDTF That Performs Diagnostic Mammography

If an independent diagnostic testing facility (IDTF) performs diagnostic mammography services, it must have a Food and Drug Administration (FDA) certification to perform the mammography. However, an entity that only performs diagnostic mammography services

should not be enrolled as an IDTF. Rather, it should be separately enrolled as a mammography screening center.

19. IDTF Ownership of CLIA Laboratory

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

J. Home Infusion Therapy (HIT) Suppliers

Home Infusion Therapy (HIT) suppliers are a supplier type that enroll via the Form CMS-855B.

1. General Background Information

Section 5012 of the 21st Century Cures Act (“the Cures Act”) (Pub. L. 114-255), which amended sections 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit. The Medicare home infusion therapy services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries.

Section 1861(iii)(3)(D)(i) of the Act defines a “qualified home infusion therapy supplier” as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. A qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by an organization designated by the Secretary; and meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage (MA) plans under Part C and in the private sector.

2. HIT Supplier Eligibility and Enrollment Requirements

An entity who wishes to furnish HIT services to Medicare beneficiaries must enroll as a HIT provider. Such providers must meet the following requirements:

- Obtain and maintain a valid TIN and NPI at the organizational level.*
- The home infusion therapy supplier must be currently and validly accredited as such by a CMS-recognized home infusion therapy supplier accreditation organization in order to enroll and remain enrolled in Medicare. The CMS-recognized home infusion therapy supplier accreditation organizations include the Joint Commission (TJC), the Utilization Review Accreditation Commission (URAC), the*

Accreditation Commission for Health Care (ACHC), the Community Health Accreditation Partner (CHAP), the National Association Boards of Pharmacy (NABP), and the Compliance Team (TCT).

- *The home infusion therapy supplier must submit a copy of its accreditation certification and accreditation approval letter with its application. The home infusion therapy supplier must submit a document that contains an effective date of accreditation.*
- *The home infusion therapy supplier must be compliant with § 414.1515 and all provisions of 42 CFR Part 486, subpart I in order to enroll and maintain Medicare enrollment.*
- *The home infusion therapy supplier must certify via the CMS-855B application that the home infusion therapy supplier meets and will continue to meet the specific requirements for enrollment described in §424.68 and Part 424, subpart P.*
- *Prospective (newly enrolling) home infusion therapy suppliers must pass application screening upon initial enrollment and revalidate at a limited categorical risk level per § 424.518(a).*
- *Pay an application fee at initial enrollment, revalidation and when adding a practice location.*
- *The home infusion therapy supplier is required to enroll in each state in which they have an accredited practice location. Suppliers do not need to enroll in states in which they do not have accredited practice locations. Suppliers may provide services in patients' homes across state borders as long as they are appropriately licensed. HIT suppliers must be appropriately licensed in each state in which they provide infusion therapy services in patients' homes. HIT suppliers will complete Section 4D: Rendering Services in Patients Home of the CMS-855B application to report all locations where health care services are rendered in patients' homes. This includes locations across state borders.*
 - *For example, if the HIT supplier has two accredited practice locations in Arkansas and is providing home infusion therapy services in patients' homes in Arkansas and in Oklahoma then the HIT supplier only needs to enroll in Arkansas. If this same HIT supplier wishes to add another accredited practice location in Texas, the HIT supplier would need to submit an enrollment application to enroll in Texas.*

10.6.15 – Risk-Based Screening

(Rev. 10467; Issued: 11-13-20; Effective: 01-01-21; Implementation: 11-01-20)

A. Risk Based Screening Categories

1. Risk-Based Screening Categories - Background

Consistent with 42 CFR § 424.518, newly-enrolling and existing providers and suppliers will, beginning on March 25, 2011, be placed into one of three levels of categorical screening: limited, moderate, or high. The risk levels denote the level of the contractor's screening of the provider when it initially enrolls in Medicare, adds a new practice location, or revalidates its enrollment information.

2. Limited Risk Screening Category

The "limited" level of categorical screening consists of the following provider and supplier types:

- Physicians
- Non-physician practitioners other than physical therapists
- Physician group practices
- Non-physician group practices other than physical therapist group practices
- Ambulatory surgical centers
- Competitive Acquisition Program/Part B Vendors
- End-stage renal disease facilities
- Federally qualified health centers
- Histocompatibility laboratories
- *Home infusion therapy suppliers*
- Hospitals (including critical access hospitals, Department of Veterans Affairs hospitals, and other federally-owned hospital facilities.
- Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act
- Mammography screening centers
- Mass immunization roster billers
- Organ procurement organizations
- Outpatient physical therapy/outpatient speech pathology providers enrolling via the Form CMS-855A
- Pharmacies that are newly enrolling or revalidating via the Form CMS-855B application
- Radiation therapy centers
- Religious non-medical health care institutions
- Rural health clinics
- Skilled nursing facilities

For providers and suppliers in the "limited" category, the contractor shall (unless section 10.6.15(A)(1) of this chapter applies) process initial, revalidation, and new location applications in accordance with existing instructions.

3. Moderate Risk Screening Category

The "moderate" level of categorical screening consists of the following provider and supplier types:

- Ambulance service suppliers

- Community mental health centers (CMHCs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Hospice organizations
- Independent clinical laboratories
- Independent diagnostic testing facilities
- Physical therapists enrolling as individuals or as group practices
- Portable x-ray suppliers (PXRSSs)
- Newly Enrolling Opioid Treatment Program (OTP) that were SAMSHA certified prior to October 24, 2018
- Revalidating home health agencies (HHAs)
- Revalidating DMEPOS suppliers
- Revalidating MDPP suppliers
- Revalidating OTP providers

For providers and suppliers in the “moderate” level of categorical screening, the contractor shall (unless section 10.6.15(A)(4) of this chapter or another CMS directive applies):

Process initial, revalidation, and new location applications in accordance with existing instructions; and

Except for revalidating DMEPOS suppliers, order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) in accordance with sections 2(a) through (e) below. The site visit, which the National Site Visit Contractor (NSVC) will perform, is to ensure that the supplier is in compliance with CMS’s enrollment requirements. Unless stated otherwise in this chapter, the scope of the site visit will be consistent with section 10.6.15(A)(4).

a. Ambulance suppliers, independent clinical laboratories, physical therapists, and physical therapist groups

i. Initial application

If the supplier submits an initial application, the contractor shall order a site visit. The contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the NSVC’s site visit and the contractor’s review of the results.

ii. Revalidation

If the supplier submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC’s site visit and the contractor’s review of the results.

iii. New Location

The contractor shall order a site visit of the location. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC’s site visit and the contractor’s review of the results.

b. CMHCs

i. Initial application

In addition to the site visit discussed in section 10.2.1(A)(1)(b) of this chapter, the contractor shall order a site visit after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing

privileges to the CMHC. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

ii. Revalidation

If the CMHC submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

iii. New location

The contractor shall order a site visit of the location after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

c. CORFs, hospices and PXRSS

i. Initial application

If the provider/supplier submits an initial application, the contractor shall order a site visit after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the provider/supplier. The contractor shall not convey Medicare billing privileges to the provider/supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.

ii. Revalidation

If the provider/supplier submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

iii. New location

The contractor shall order a site visit of the location after the contractor receives notice of approval from the RO but before the contractor switches the provider/supplier's enrollment record to "Approved." The contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

d. IDTFs

i. Initial applications

The NSVC will conduct site visits of initially enrolling IDTFs consistent with section 10.2.2(O)(15) of this chapter.

ii. Revalidations

The NSVC will conduct site visits of revalidating IDTFs (prior to the contractor's final decision regarding the revalidation application) consistent with section 10.2.2(I)(15) of this chapter.

iii. IDTF Code Changes

The NSVC will conduct site visits for IDTF code changes as specified in section 10.2.2(I)(17) of this chapter.

e. Revalidating HHAs

If an HHA submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

f. Revalidating DMEPOS suppliers

The National Supplier Clearinghouse (NSC) shall conduct a site visit of the DMEPOS supplier prior to making a final decision regarding the revalidation application.

g. Revalidating MDPP Suppliers

If an MDPP supplier submits a revalidation application, the contractor shall order a site visit. The Contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

h. Revalidating OTP Providers

If an OTP provider submits a revalidation application, the contractor shall order a site visit. The Contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

4. High Risk Screening Category

a. Newly Enrolling Providers/Suppliers Assigned to the High Risk Screening Category

Pursuant to 42 CFR § 424.518, the "high" level of categorical screening consists of the following provider and supplier types:

- Newly enrolling DMEPOS suppliers
- Newly enrolling HHAs (including HHAs that must submit an initial enrollment application pursuant to § 424.550(b)(1))
- Newly enrolling MDPP suppliers
- Newly enrolling OTP providers that were SAMSHA certified after October 24, 2018

For providers and suppliers in the "high" level of categorical screening:

- i. The contractor shall process the application in accordance with existing instructions;
- ii. The NSVC will perform a site visit for newly enrolling HHAs. (The NSC will perform a site visit for newly enrolling DMEPOS suppliers.) For initially enrolling HHAs, the contractor shall order a site visit via PECOS after the contractor receives the tie-in notice or

approval letter from the RO but before the contractor switches the provider's enrollment record to "Approved."

iii. Newly enrolling HHAs and DMEPOS suppliers are also required to undergo fingerprint-based criminal background checks. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of fingerprinting and the contractor's review of the results; and

iv. The contractor shall, upon switching the provider's or supplier's enrollment record to "Approved," enter the provider's risk category as "moderate" into PECOS.

NOTE:

- Enrolled DMEPOS suppliers that are adding another location will be classified as "high" for screening purposes. (See section 10.6.15(B)(5) below for information regarding DMEPOS changes of ownership and tax identification number (TIN) changes.)
- Newly-enrolling HHA sub-units fall within the "high" level of categorical screening.
- The addition of a new HHA branch falls within the "moderate" level of categorical screening. The contractor shall order a site visit of the location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." This is to ensure that the provider is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 10.6.15(B)(5) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

This is the only site visit of the new HHA branch that must be performed prior to the record being switched to "Approved."

- The addition of a new MDPP supplier administrative location that does not result in a new PTAN does not require an additional site visit. Any additional MDPP supplier administrative location that results in a new PTAN, either due to being in a new jurisdiction or because of a new CDC organizational code, the contractors shall order a site visit of the location through PECOS. This is to ensure that the provider is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

5. Elevating Existing Providers and Suppliers into the High Risk Screening Category

Under §424.518(c)(3), CMS may adjust a particular provider or supplier's screening level from "limited" or "moderate" to "high" if any of the following occur:

- a. CMS imposes a payment suspension on a provider or supplier at any time within the last 10 years;
- b. The provider or supplier:

- i. Has been excluded from Medicare by the Office of Inspector General; or
 - ii. Had its billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by:
 - Enrolling as a new provider or supplier; or
 - Obtaining billing privileges for a new practice location
 - iii. Has been terminated or is otherwise precluded from billing Medicaid
 - iv. Has been excluded from any Federal health care program
 - v. Has been subject to any final adverse action (as defined in §424.502) within the previous 10 years.
- c. CMS lifts a temporary moratorium for a particular provider or supplier type, and a provider or supplier that was prevented from enrolling based on the moratorium applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

CMS makes available to the contractor on a bi-monthly basis a list of current and former Medicare providers and suppliers within the contractor's jurisdiction that meet any of the criteria in subsection (1) or (2) above. Upon receipt of an initial or revalidation application from a provider or supplier that otherwise falls within the limited or moderate screening category (and after the appropriate fee has been paid, etc.), the contractor shall determine whether the provider or supplier is on the bi-monthly "high" screening list. If the provider or supplier is not on said list, the contractor shall process the application in accordance with existing instructions. If the provider or supplier is on the list, the contractor shall process the application using the procedures in the "high" screening category unless the provider is on the list solely because he/she/it was revoked for failing to timely respond to a revalidation request. If such is the case, the contractor shall contact its CMS Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL) for guidance as to how the situation should be handled.

With respect to subsection (3) above, if the contractor receives an initial or new location application from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the procedures in the "high" screening category.

B. Risk Based Screening: Changes of Information and Ownership

1. Limited

Changes of information (including additions of practice locations) submitted by providers and suppliers in the "limited" level of categorical screening shall be processed in accordance with existing instructions.

2. Moderate and High

Unless otherwise specified in this chapter or in another CMS directive, this section 10.6.15(B)(2) applies to providers and suppliers in the "moderate" or "high" level of categorical screening.

3. Addition of Practice Location

With the exception of suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), if a provider or supplier submits a Form CMS-855 request to add a practice location (including a home health agency (HHA) branch):

- The contractor shall process the application in accordance with existing instructions, and
- A site visit shall be performed consistent with section 10.6.15(A) above.

(As explained earlier, a DMEPOS supplier that is adding a new practice location falls within the “high” screening category.)

4. Change of Location

a. DMEPOS Suppliers

If a DMEPOS supplier reports a change in the physical location of an existing practice location, the National Supplier Clearinghouse shall perform a site visit.

b. Non-DMEPOS Suppliers

If a provider or non-DMEPOS supplier reports a change in the physical location of an existing practice location, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) in accordance with the following:

c. Ambulance service suppliers, independent clinical laboratories, independent diagnostic testing facilities, physical therapists enrolling as individuals or group practices – The contractor shall order a site visit of the changed location prior to the contractor’s final decision regarding the application. This is to ensure that the location is in compliance with CMS’s enrollment requirements. The scope of the site visit will be consistent with section 10.6.15(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not make its final decision regarding the application prior to the completion of the NSVC’s site visit and the contractor’s review of the results.

d. Community mental health centers, comprehensive outpatient rehabilitation facilities, hospices, portable x-ray suppliers, HHAs - The contractor shall order a site visit of the changed location after the contractor receives notice of approval from the RO but before the contractor switches the provider/supplier’s enrollment record to “Approved.” This is to ensure that the location is in compliance with CMS’s enrollment requirements. The scope of the site visit will be consistent with section 10.6.15(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider’s enrollment record to “Approved” prior to the completion of the NSVC’s site visit and the contractor’s review of the results.

For purposes of this requirement:

- A change of location includes situations in which the provider/supplier is switching suite numbers or floors within a building. A site visit is required.
- If the provider/supplier’s physical location is not changing (e.g., the provider’s street name is changing but its actual office space is not), no site visit is required.

5. Change of Ownership

With the exception of DMEPOS suppliers and HHAs, if a provider or supplier undergoes a change of ownership resulting in a new tax identification number (TIN), the contractor shall:

- a. Process the application in accordance with existing instructions, and
- b. Order a site visit through PECOS in accordance with the following:
 - For ownership changes that must be approved by the RO under current CMS instructions, the site visit shall be ordered and performed after the contractor receives notice of approval from the RO but before the contractor switches the provider/supplier's enrollment record to an "Approved" status. The contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.
 - For ownership changes that do not require RO approval under current CMS instructions, the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.
 - A DMEPOS supplier that is:
 - Undergoing a change of ownership with a change in TIN falls within the "high" screening category.
 - Undergoing a change of ownership with no change in TIN falls within the "moderate" screening category.
 - Undergoing a change in TIN with no change in ownership falls within the "moderate" screening category.

With respect to HHAs:

- For HHAs undergoing a change in majority ownership, the contractor shall – consistent with section 10.2.1(F)(8) of this chapter – determine whether the provisions of 42 CFR §424.550(b)(1) and (2) apply. If the contractor determines that a change in majority ownership has occurred and that none of the exceptions in §424.550(b)(2) apply, the HHA must enroll as a new entity, in which case the newly-enrolling HHA will be placed into the "high" level of categorical screening. If the contractor determines that an exception does apply, the transaction will be subject to the "moderate" level of categorical screening; a site visit will be necessary.
- In addition, if: (1) the contractor determines that one of the exceptions to the 36-month rule applies, and (2) the ownership change is one that requires a recommendation for approval to the RO, the contractor shall ensure that its recommendation letter specifies:
 - That the transaction qualifies as a change in majority ownership
 - The particular exception that applies.
- For HHAs reporting an ownership change that is not a change in majority ownership as that term is defined in §424.502, the contractor shall process the change in accordance with existing instructions. A site visit is not necessary.

- For HHAs seeking to reactivate their Medicare billing privileges, the transaction shall be processed under the “moderate” level of categorical screening. A site visit will be necessary prior to the reactivation of the provider’s billing privileges.

6. All Other Changes of Information

All other changes of information for providers and suppliers in the moderate or high level of categorical screening shall be processed in accordance with existing instructions.

C. Risk Based Screening – Reactivations

1. Form CMS-855 Reactivations

a. Limited

Form CMS-855 reactivation applications submitted by providers and suppliers in the “limited” level of categorical screening shall be processed in accordance with existing instructions.

b. Moderate

Form CMS-855 reactivation applications submitted by providers and suppliers in the “moderate” level of categorical screening – including existing home health agencies and suppliers of durable medical equipment, prosthetics, orthotics and suppliers (DMEPOS) – shall be processed in accordance with the screening procedures for this category. A site visit will therefore be necessary prior to the contractor’s final decision regarding the application.

c. High

Form CMS-855 reactivation applications submitted by providers and suppliers in the “high” level of categorical screening shall be processed in accordance with the screening procedures for this category. A site visit will therefore be necessary prior to the contractor’s final decision regarding the application.