CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10672	**Date: March 18, 2021**
	Change Request 12149

SUBJECT: First General Update to Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual (PIM)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to: (1) Incorporate technical and editorial changes into parts of Chapter 10 of Pub. 100-08, PIM; and (2) Address any outstanding policy issues in the Chapter 10 sections included in this CR.

EFFECTIVE DATE: March 12, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 22, 2021

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	10/10.1/Introduction to Medicare Provider Enrollment
R	10/10.1/10.1.1/Definitions
R	10/10.1/10.1.2/Enrolling to Receive Medicare Payment
R	10/10.1/10.1.3/General Summary of Process to Enroll in Medicare
R	10/10.1/10.1.4/General Overview of Medicare Enrollment Application Forms
R	10/10.2/Provider and Supplier Types/Services
R	10/10.2/10.2.1/Certified Providers and Certified Suppliers That Enroll Via the Form CMS-855A
N	10/10.7/10.7.19/Model Approval Letter for Federally Qualified Health Centers (FQHCs)

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: 10672	Date: March 18, 2021	Change Request: 12149

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EFFECTIVE DATE: March 12, 2021
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I. GENERAL INFORMATION

A. Background: The CMS has recently completed transferring the entirety of Chapter 15 of Pub. 100-08 to Chapter 10 of Pub. 100-08. Chapter 10 outlines policies related to Medicare provider enrollment and instructs contractors on the processing of Form CMS-855 provider enrollment applications. This CR -- (1) Incorporates minor technical and editorial changes into parts of Chapter 10; and (2) Addresses several outstanding policy issues in the Chapter 10 sections included in the CR, especially those pertaining to federally qualified health centers (FQHCs). This CR will be the first in a series of CRs that update various portions of Chapter 10 with technical revisions and any necessary policy changes.

Contractors were previously directed to postpone until further notice the implementation of the FQHC instructions in CMS CR 11917 ("Completion of Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08," issued September 18, 2020). CR 11917's FQHC instructions were incorporated into new section 10.2.1(D) in Chapter 10 of Pub. 100-08. The FQHC instructions in this CR supplement and supersede those already in section 10.2.1(D) in chapter 10 of Pub. 100-08. Accordingly, the contractor shall adhere to and implement all instructions in section 10.2.1(D) of Chapter 10 of Pub. 100-08 as described in the manual instructions for this CR notwithstanding the aforementioned postponement, which is no longer in effect.

B. Policy: This CR does not contain any legislative or regulatory policies.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
12149.1	The contractor shall adhere to and implement the instructions in section 10.2.1(D) in Chapter 10 of Pub. 100-08 notwithstanding	X								

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	any previous postponement of the implementation thereof.									
12149.2	Pursuant to section 10.2.1(D)(3)(ii)(G) in Chapter 10 of Pub. 100-08, the contractor shall confirm the applicant's attestation and tribal/urban Indian status if the applicant indicates that it has such status.	X								
12149.3	In its review of an FQHC initial enrollment application, the contractor shall check the Provider Enrollment, Chain and Ownership System to determine whether a rural health clinic is enrolled at the same location.	X								
12149.3.1	The contractor shall adhere to the instructions in section 10.2.1(D)(3)(ii)(H) in Chapter 10 of Pub. 100-08 if it determines (pursuant to Business Requirement (BR) 12149.3) that a rural health clinic is enrolled at the	X								

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	same location as the FQHC applicant.									
12149.4	The contractor shall follow the instructions in section 10.2.1(D)(4)(b) in Chapter 10 of Pub. 100-08 if the Exhibit 177 was signed prior to the effective date listed in the FQHC's enrollment application.	X								
12149.5	The contractor shall follow the instructions in section 10.2.1(D)(4)(b) in Chapter 10 of Pub. 100-08 if it determines that the FQHC's initial enrollment application should be denied.	X								
12149.6	The contractor shall send an approval letter to the FQHC (with a copy of the signed Exhibit 177) if the Provider Enrollment & Oversight Group (PEOG) determines that the FQHC's initial application should be approved.	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12149.7	If BR 12149.6 applies, the contractor shall notify the entities identified in section 10.2.1(D)(6) in Chapter 10 of Pub. 100-08 of the FQHC's approval in the manner described in that section.	X								
12149.8	The contractor shall notify PEOG pursuant to (and in the manner described in) section 10.2.1(D)(7)(iii) in Chapter 10 of Pub. 100-08 if it determines that an FQHC's location change should not be approved.	X								
12149.9	If the contractor determines that the 36-month rule does not apply to a particular home health agency change in majority ownership, the contractor shall (as applicable) process the application as a change of information under 42 CFR § 424.516(e) or as a potential change of ownership under 42 CFR § 489.18.	X		X						

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12149.10	As stated in section 10.2.1(F)(8) in Chapter 10 of Pub. 100-08, the contractor shall exhaust all efforts to obtain the attestation of funds statement before forgoing the attestation requirement.	X		X						
12149.11	The contractor shall use the model letter in section 10.7.19 in Chapter 10 of Pub. 100-08 in the applicable circumstances described in section 10.2.1(D) in Chapter 10 of Pub. 100-08.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

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

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

VI. FUNDING

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

ATTACHMENTS: 0

Medicare Program Integrity Manual
Chapter 10 – Medicare Enrollment
Table of Contents
(Rev. 10672; Issued: 03-18-21)

10.1 – Introduction to Medicare Provider Enrollment

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

This chapter specifies the resources and procedures Medicare *A*dministrative *C*ontractors (MAC) must use to establish and maintain provider and supplier enrollment in the Medicare program. These procedures apply to the MACs and the National Supplier Clearinghouse (NSC) *(hereafter occasionally referred to collectively as simply "the contractor")*, unless contract specifications state otherwise.

10.1.1 – Definitions

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

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

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

Add – For purposes of completing the *Form* CMS-855 *or Form CMS-20134* enrollment *applications*, you are adding enrollment information to your existing *enrollment record* (e.g.*,* practice locations). When adding a practice location*,* an application fee may be required for applicable institutions*.* (For further information, see the term "institutional provider" as defined in 42 CFR § 424.502*, the application fee requirements in 42 CFR § 424.514, and the application fee guidance in section 10.6.14 of this chapter.*)

Administrative *l*ocation means a physical location associated with a Medicare Diabetes Prevention Program (MDPP) supplier's operations from where*: (1)* coaches are dispatched or based*;* and *(2)* MDPP services may or may not be furnished.

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

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

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

Approve/Approval means the enrolling provider or supplier has been determined to be eligible under Medicare rules and regulations to*: (1)* receive a Medicare billing number and be granted Medicare billing privileges*; or (2) enroll to solely order, certify, or refer the items or services described in 42 CFR § 424.507.*

Authorized official (as defined by 42 CFR § 424.502) means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.

Billing agency means an entity that furnishes billing and collection services on behalf of a provider or supplier. A billing agency is not enrolled in the Medicare program. A billing agency submits claims to Medicare in the name and billing number of the provider or supplier that furnished the service or services. In order to receive payment directly from Medicare on behalf of a provider or supplier, a billing agency must meet the conditions described in § 1842(b)(6)(D) of the Social Security Act. (For further information, see CMS Publication *(Pub.)* 100-04, *Claims Processing Manual,* chapter 1, section 30.2.4.)

Change - For purposes of completing the *Form* CMS-855 or CMS-20134 enrollment *applications*, you are replacing existing information with new information (e.g. practice location, ownership) or updating existing information (e.g. change in suite #, telephone #). If you are changing a practice location an application fee is not required.

Change in majority ownership occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a home health agency (HHA) during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sales, stock transfers, mergers, or consolidations). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership. *(See 42 CFR § 424.550(b) for more information on HHA changes of ownership.)*

Change of ownership (CHOW) is defined in 42 CFR § 489.18(a) and generally means, in the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law. In the case of a corporation, the term generally means the merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation. The transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.

CMS-approved accreditation organization means an accreditation organization designated by CMS to perform the accreditation functions/*deeming activities* specified. *(See 42 CFR §§ 488.1 and 488.5 for more information on accrediting organizations.)*

Coach means an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer.

Community setting means a location where the MDPP supplier furnishes MDPP services outside of *its* administrative locations in meeting locations open to the public. A community setting is a location not primarily associated with the supplier where many activities occur, including, but not limited to, MDPP services. Community settings may include, for example, church basements or multipurpose rooms in recreation centers.

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

Delegated official (as defined by 42 CFR § 424.502) means an individual who is delegated by the "Authorized Official" the authority to report changes and updates to the provider/supplier's enrollment record. The delegated official must be an individual with an ownership or control

interest in (as that term is defined in section 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of, the provider or supplier.

Delete/Remove – For purposes of completing the *Form* CMS-855 enrollment *and Form CMS-20134 applications*, you are removing existing enrollment information. If you are deleting or removing a practice location, an application fee is not required.

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to: (1) receive Medicare billing privileges*; or (2) enroll to solely order, certify, or refer the items or services described in 42 CFR § 424.507.*

Effective Date *means* the date on which a provider's or supplier's eligibility was initially established for the purposes of submitting claims for Medicare-covered items and services and*/or* ordering or certifying Medicare-covered items and services. *(*This is not the same as a reactivation effective date.*)*

Eligible coach means an individual who CMS has screened and determined can provide MDPP services on behalf of an MDPP supplier.

Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.

Enrollment application means a paper *Form* CMS-855 or *Form* CMS-20134 enrollment application or the equivalent electronic enrollment process approved by the Office of Management and Budget (OMB).

Final adverse legal action means *the following*:

For purposes of the definition of this term in § 424.502, final adverse action means one or more of the following:

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

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

(3) Revocation or suspension by an accreditation organization;

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

(5) An exclusion or debarment from participation in a federal or state health care program.

For purposes of the reporting requirements on the Form CMS-855 or Form CMS-20134, final adverse action means one or more of the following:

Convictions (as defined in 42 CFR 1001.2) within the preceding 10 years

1. Any federal or state felony conviction(s).
2. Any misdemeanor conviction, under federal or state law, related to: (a) the delivery of an item or service under Medicare or a state health care program, or (b) the abuse or neglect of a patient in connection with the delivery of a health care item or service.

3. Any misdemeanor conviction, under federal or state law, related to the theft, fraud, embezzlement, breach of fiduciary duty, or other financial misconduct in connection with the delivery of a health care item or service.
4. Any misdemeanor conviction, under federal or state law, related to the interference with or obstruction of any investigation into any criminal offence described in 42 C.F.R. section 1001.101 or 1001.201.
5. Any misdemeanor conviction, under federal or state law, related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Exclusions, Revocations, or Suspensions

1. Any current or past revocation, suspension, or voluntary surrender of a medical license in lieu of further disciplinary action.
2. Any current or past revocation or suspension of accreditation.
3. Any current or past suspension or exclusion imposed by the U.S. Department of Health and Human Service's Office of Inspector General (OIG).
4. Any current or past debarment from participation in any Federal Executive Branch procurement or non- procurement program.
5. Any other current or past *f*ederal *s*anctions.
6. Any Medicaid exclusion, revocation, or termination of any billing number.

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

Ineligible coach means an individual whom CMS has screened and determined cannot provide MDPP services on behalf of an MDPP supplier.

Institutional provider means – for purposes of the Medicare application fee only - any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and non-physician practitioner organizations), Form CMS–855S, Form CMS-20134, or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application.

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

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

Medicare identification number - For Part A providers, the Medicare identification number is the CMS Certification Number (CCN). For Part B suppliers the Medicare identification number is the Provider Transaction Access Number (PTAN).

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

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

Other eligible professional – as defined in 1848(k)(3)(B) of the Social Security Act – means: (i) a physician; (ii) a practitioner described in section 1842(b)(18)(C); (iii) a physical or occupational therapist or a qualified speech-language pathologist; or (iv) a qualified audiologist (as defined in section 1861(ll)(3)(B)). (For (ii), "practitioner" is defined in section 1842(b)(18)(C) as a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, or registered dietitian or nutrition professional.)

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

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

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

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

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

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

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

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

Reassignment means that an individual physician, non-physician practitioner, or other supplier has granted a Medicare-enrolled provider or supplier the right to receive payment for the physician's, non-physician practitioner's or other supplier's services. (For further information, see § 1842(b)(6) of the Social Security Act, the Medicare regulations at 42 CFR §§424.70 - 424.90, and CMS *Pub.* 100-04, chapter 1, sections 30.2 – 30.2.16.)

Reject/Rejected means that the provider or supplier's enrollment application was not processed due to incomplete information or that additional information or corrected information was not received from the provider or supplier in a timely manner. *(See 42 CFR § 424.525 for more information.)*

Retrospective Billing Privileges means that certain Part B suppliers can bill retrospectively for up to 30 or 90 days prior to their enrollment effective date as described in 42 CFR *§§ 424.520(d) and* 424.521(a).

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

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

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

10.1.2 – Enrolling to Receive Medicare Payment

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

No provider or supplier shall receive payment for services furnished to a Medicare beneficiary unless the provider or supplier is enrolled in the Medicare program. Further, it is essential that each provider and supplier enroll with the appropriate M*edicare* A*dministrative* C*ontractor*. We use the term "enrollment" generally to include activities a provider or supplier undertakes to enroll in the Medicare *p*rogram and maintain enrollment in good standing, which includes, but is not limited to, initially enrolling, revalidating enrollment, and reporting changes of information as described within this chapter.

A. Initial Enrollment

In general, a provider or supplier shall enroll as an initial applicant if it is:

- Initially enrolling in the Medicare *p*rogram or enrolling as a provider or supplier in a new geographic jurisdiction.

- Seeking to reestablish itself in the Medicare program after a voluntary withdrawal from the Medicare *p*rogram, or subsequent to a termination or revocation *of enrollment* based upon any CMS authority under *Title* 42 *of the* CFR.

For additional information, refer to *s*ections of this chapter concerning unique provider and supplier types, the applications that correspond to Medicare enrollment by provider/supplier type and purpose, and a general discussion of enrollment topics.

B. Revalidation

Pursuant to 42 CFR §*§* 424.515, 410.41(c), and 424.57(g), providers and suppliers use the CMS enrollment application process to periodically revalidate the*ir* Medicare enrollment record. *Suppliers of d*urable *m*edical *e*quipment, *p*rosthetics, *o*rthotics, and *s*upplies are required to revalidate every 3 years and all other providers and suppliers every 5 years.

C. Changes of Information

*Consistent with 42 CFR § 424.516, p*roviders and suppliers use the CMS enrollment application process to report changes of information as required to remain in compliance with the requirements to participate in Medicare.

10.1.3 - General Summary of Process to Enroll in Medicare

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

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

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

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

Paper applications can be accessed at the Web site https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html.

PECOS can be accessed at https://pecos.cms.hhs.gov/pecos/login.do.

Web Sites

The contractor must link to CMS' provider/supplier enrollment Web site located at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html?redirect=/MedicareProviderSupEnroll/. The link shall: (1) be available on the contractor's existing provider outreach Web site (which should be an established sub-domain of the contractor's current commercial Web site)*;* and (2) comply with the guidelines stated in the Provider/Supplier Information and Education Web site section (Activity Code 14101) under the Provider Communications Budget and Performance Requirements. Bulletins, newsletters, seminars/workshops and other information concerning provider enrollment issues shall also be made available on the existing provider outreach Web site. All contractor Web sites must comply with section 508 of the Rehabilitation Act of 1973 in accordance with, 36 CFR §1194, and must comply with CMS' Contractor Web site Standards and Guidelines posted on CMS's Web site.

The CMS Provider/Supplier Enrollment Web site, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index?redirect=/MedicareProviderSupEnroll/, furnishes the user with access to provider/supplier enrollment forms, specific requirements for provider/supplier types, manual instructions, frequently asked questions (FAQs), contact information, hot topics, and other pertinent provider/supplier information. The contractor shall not duplicate content already provided at the CMS provider/supplier enrollment Web site and shall not reproduce the forms or establish the contractor's own links to forms. It shall, however, have a link on its Web site that goes directly to the forms section of the CMS provider/supplier enrollment site.

On a quarterly basis (specifically, no later than the 15th day of January, April, July, and October), each contractor shall review and provide updates regarding its contact information shown at URL: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/contact_list.pdf

If the contractor services several *s*tates with a universal address and telephone number, the contractor shall report that information. In situations where no actions are required, a response from the contractor is still required (i.e., the contact information is accurate). In addition, only such information that pertains to provider enrollment activity for the contractor's jurisdiction is to be reported. All updates shall be sent directly via e-mail to the contractor's CMS Provider Enrollment & Oversight Group Business Function Lead.

10.1.4 - General Overview of Medicare Enrollment Application Forms

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

The enrollment applications are available online as well as in paper form:

A. General Overview of Form CMS-855 and CMS-20134

Each *Form* CMS-855 *application* is used to enroll a specific provider or supplier type for a specific purpose.

1. CMS-855A – Medicare Enrollment Application for Institutional Providers

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

2. CMS-855B –Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers

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

3. CMS-855I - Medicare Enrollment Application for Physicians and Non-Physician Practitioners

This application should be completed by physicians and non-physician practitioners who render Medicare Part B services to beneficiaries. (This includes a physician or practitioner who *is*: (1) the sole owner of a professional corporation, professional association, or limited liability company *and* will bill Medicare through this business entity*; or* (2) *a* sole proprietor.) *(See section 10.6.4 of this chapter for more information on the business types discussed in this paragraph.)*

4. CMS-855R - Medicare Enrollment Application for Reassignment of Medicare Benefits

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

5. CMS-855S – Medicare Enrollment Application for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers

This application should be completed by *DMEPOS* suppliers. The National Supplier Clearinghouse (NSC) is responsible for processing this type of enrollment application.

6. CMS-855O – Medicare Enrollment Application for Eligible Ordering, Certifying Physicians, and other Eligible Professionals

This form is used for physicians and other eligible professionals who wish to register in Medicare solely for the purpose of ordering and certifying *the* items and services *described in 42 CFR § 424.507*. These physicians and other eligible professionals do not and will not send claims to a MAC for *any* services they furnish.

7. CMS-20134 – Medicare Enrollment Application for Medicare Diabetes Prevention Program (MDPP) Suppliers

This application should be completed by any supplier organizations that will furnish and bill Medicare Part B for the *MDPP* services furnished to Medicare beneficiaries.

B. General Overview of Additional Enrollment Forms

The following forms or form types are routinely submitted with an enrollment application:

1. CMS-588 – Electronic Funds Transfer (EFT) Authorization Agreement

The *EFT* Agreement authorizes CMS to deposit Medicare payments directly into a provider/supplier's bank account.

For *Form* CMS-855S enrollment, CMS only requires collection of Form CMS-588 with initial enrollment applications.

2. CMS-460 – Medicare Participating Physician or Supplier Agreement

This agreement establishes that the Medicare provider/supplier accepts assignment of the Medicare Part B payment for all services for which the participant is eligible to accept assignment under the Medicare law and regulations and which are furnished while the agreement is in effect. The contractor shall explain to the provider or supplier the purpose of the agreement and how it differs from the actual enrollment process. (This only applies to suppliers that complete the Forms CMS-855B, CMS-855I and CMS-855S.)

3. CMS Standard Electronic Data Interchange (EDI) Enrollment Form

See *CMS Publication 100-04*, Medicare Claims Processing Manual, *c*hapter 24, *s*ections 30 - 30.5 for further information.

4. State-Specific Forms for Certified Provider*s*/*Certified* Supplier*s*

If the applicant is a certified supplier or certified provider, it will need to contact the *s*tate agency for any *s*tate-specific forms and to begin preparations for a *s*tate survey. (This does not apply *to*

those certified entities, such as federally qualified health centers, that do not receive a *s*tate survey.)

10.2 – Provider and Supplier Types/Services

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

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

Provider and supplier specialty codes can be found at *CMS* Publication 100-04, chapter 26, sections 10.8 through 10.8.3.

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

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

A. Community Mental Health Centers

1. General Background Information

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

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

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

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

d. **Screening** for patients being considered for admission to *s*tate mental health facilities.

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

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

- The CMHC arranging for the particular service is authorized by State law to perform the service itself;
- The arranging CMHC accepts full legal responsibility for the service; and
- There is a written agreement between the two entities.

While the CMHC generally has the option to furnish services under arrangement, there is actually an instance where the facility must do so. If the CMHC is located in a State that prohibits CMHCs from furnishing screening services (service *(d)* above), it must contract with another entity to have the latter perform the services. Any such arrangement must be approved by the *CMS Survey & Operations Group (SOG) Locations (formerly CMS Regional Offices and hereafter referenced as "SOG Locations.")* (See *CMS Publication (*Pub.*)* 100-07, State Operations Manual, chapter 2, section 2250 for additional information on core services and arrangements.)

A CMHC must provide mental health services principally to individuals who reside in a defined geographic area (service area); that is, it must service a distinct and definable community.

2. Initial Enrollment and Certification

a. CMHC Conditions of Participation: Federal Regulations That Apply Beginning October 29, 2014

As of October 29, 2014, CMHCs *are* required to meet the conditions of participation outlined in 42 CFR Part 485, subpart J. CMHCs, like many other types of certified providers and certified suppliers, *are* therefore required to undergo a *s*tate survey as part of the certification and enrollment process. The *SOG Location* no longer perform*s* the site visit nor does the CMHC *need to submit the previously-required* attestation statement. Except as otherwise noted in this chapter 10 or in another CMS directive, CMHC initial applications shall – on and after October 29, 2014 - be processed in the same manner as those for all other certified providers.

b. Site Visit - Initials Post Tie-In

The contractor shall order a site visit of the CMHC through the Provider Enrollment, Chain and Ownership System (PECOS) after the contractor receives the tie-in notice (or approval letter) from the *SOG Location* but before the contractor conveys Medicare billing privileges to the CMHC. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with *s*ection*s* 10.6.20(A) and 10.6.20(B) of this chapter; the National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

i. Practice Locations

Each CMHC location must separately and independently meet the CMHC conditions of participation in 42 CFR Part 485, subpart J. Accordingly, a CMHC must separately enroll each of its practice locations. It cannot have multiple locations on a single application.

If a CMHC is changing *its* physical location, the contractor shall order a site visit of the new/changed location through PECOS after the contractor receives notice of approval from the *SOG Location* but before *it* switches the provider's enrollment record to "Approved." This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with *s*ection*s* 10.6.20(A) and 10.6.20(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.

ii. Revalidation Site Visits

If the CMHC submits a Form CMS-855A revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with *s*ection 10.6.20 of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

***3*. CMHC 40 Percent Rule**

a. Background

Effective October 29, 2014, under § 485.918(b)(1) a CMHC must provide at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Social Security Act*; this is* measured by the total number of CMHC clients treated by the CMHC for whom services are not paid for by Medicare, divided by the total number of clients treated by the CMHC in the applicable timeframe.

Pursuant to this requirement, a CMHC is required to submit to CMS a certification statement provided by an independent entity (such as an accounting technician). The document must certify that *t*he entity has reviewed the CMHC's client care data for:

- Initial enrollments: The CMHC meets the 40 percent requirement for the prior 3 months.

- Revalidations: The CMHC meets the 40 percent requirement for each of the intervening 12-month periods between initial enrollment and revalidation.

The statement must be submitted as part of any initial enrollment or revalidation (including off-cycle revalidations).

When processing *the application*, the contractor shall abide by the following:

i. Contractor Does Not Receive the Certification

If the contractor does not receive the certification with the Form CMS-855*, t*he contractor shall develop for the certification as it would with any other form of required supporting documentation. If the CMHC fails to submit the certification within the applicable time period, the contractor shall follow the instructions in *s*ection 10.4(H)(2) of this chapter.

ii. Contractor Receives the Certification

If the contractor receives the certification with the Form CMS-855 or timely receives the certification as part of a development request*, t*he contractor shall review the certification to ensure that it complies with § 485.918(b)(1) and the provisions of this section 10.2.1(A). If the certification is compliant, the contractor shall continue processing the application; if the certification is not compliant, the contractor shall deny the application or, if it chooses, develop for a revised certification.

Sections *10.2.1(A)(3)(a)(i)* and *(ii)* above do not apply if the contractor determines that the Form CMS-855 can be returned under *s*ection 10.4(H)(1) of this chapter.

If the contractor exceeds applicable timeliness standards due to the instructions in this section 10.2.1(A), the contractor shall accordingly document the provider file consistent with section 10.6.19(H) of this chapter.

iii. Special Guidelines

The following *additional* guidelines *concerning certification* apply:

*(1) As previously indicated, a*n appropriate official of the certifying entity must sign the document. (Notarization is not required unless CMS requests it.) Such persons may include accounting technicians, CEOs, officers, directors, etc.

(2) The certification should be on the certifying entity's letterhead or should otherwise indicate that the document is clearly from the entity.

(3) The contractor shall include the certification in the recommendation package it sends to the state agency.

Unless CMS instructs the contractor otherwise, the appropriate denial bases for failing to comply with § 485.918(b)(1) are §§ 424.530(a)(1) and 485.918(b)(1). The appropriate revocation bases are §§ 424.535(a)(1) and 485.918(b)(1). In cases involving the latter, CMS will determine the appropriate re-enrollment bar length under § 424.535(c) and will notify the contractor thereof.

4. For more information on CMHCs, refer to:

- *Section 1861(ff) of the Social Security Act*
- *42 CFR §§ 410.2, 410.43, and 410.110*
- *Pub. 100-07, chapter 2, sections 2250 - 2251F*

B. Comprehensive Outpatient Rehabilitation Facilities (CORFs)

1. General Background Information

A CORF is a facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients by or under the supervision of a physician. Specific examples of such services include:

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

(* Services that the CORF must provide)

In addition:

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

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

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

2. Enrollment Information

a. Offsite Locations

Notwithstanding the "single fixed location" language cited in subsection *(B)(1)* above, there may be isolated cases where the *SOG Location* permits a CORF to have an offsite location. This typically arises if the CORF wants to provide physical therapy, occupational therapy, or speech language pathology services away from the primary location. (This is permitted under 42 CFR § 485.58(e)(2)). The offsite location would not necessarily be separately surveyed but would be listed as a practice location on the CORF's Form CMS-855A application.

b. Site Visits

i. Initial application – If a CORF submits an initial application, the contractor shall order a site visit through PECOS after the contractor receives the tie-in notice (or approval letter) from the *SOG Location* but before the contractor conveys Medicare billing privileges to the *CORF*. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with *s*ection*s* 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

ii. Revalidation – If a CORF submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with *s*ection*s* 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

iii. New/changed location - If a CORF is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with *s*ection*s* 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the change of information application prior to the completion of the NSVC's site visit and the contractor's review of the results.

3. Additional Information

For more information on CORFs, refer to:

- Section 1861(cc) of the Social Security Act
- 42 CFR Part 485, Subpart B
- Pub. 100-07, chapter 2
- Pub. 100-07, Appendix K
- Pub. 100-02, *Benefit Policy Manual,* chapter 12

C. End-Stage Renal Disease Facilities (ESRDs)

1. General Background Information

ESRD facilities are entities that p*rovide* renal services *and related care* for patients with irreversible and permanent kidney failure. As ESRD facilities are technically "suppliers," they sign a supplier agreement rather than a provider agreement. Even if the ESRD facility is a hospital unit, it signs an agreement that is separate and distinct from the hospital's agreement. ESRD entities/facilities cannot be mobile.

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

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

2. Types of ESRD Facilities

Pub. 100-07, chapter 2, section 2272 lists several classifications of ESRD facilities. They are summarized as follows:

i. Hospital-Based ESRD Facility

A hospital-based ESRD facility is a separately certified ESRD facility that (1) is an outpatient department of a hospital and (2) meets the ESRD conditions of coverage at 42 CFR Part 494. A hospital-based ESRD facility is owned and administered by a hospital or critical access hospital and is physically located on the hospital campus. If a hospital operates multiple separately certified hospital-based ESRD facilities, each separate ESRD facility must have its own CMS certification number (CCN) and be separately enrolled.

A hospital-based ESRD facility is discussed at 42 CFR § 413.174(c) and meets the criteria listed therein (e.g., ESRD facility and hospital have a common governing body and are financially integrated). Hospital-based ESRD facilities are assigned CCNs from the 2300-2499 series.

ii. Satellite Renal Dialysis Facility (Hospital-Based)

A satellite renal dialysis facility is a hospital-owned and hospital-administered ESRD facility but is not located on the campus of the hospital. A single hospital may have several satellite renal dialysis facilities. Each satellite facility: (1) is separately certified and surveyed; (2) must

independently meet the ESRD conditions of coverage; (3) is assigned its own CCN; and (4) be separately enrolled. Satellite renal dialysis facilities (hospital-based) are assigned CCNs in the 3500-3699 series.

iii. Independent Renal Dialysis Facility

An independent renal dialysis facility is any ESRD facility that does not meet the definition of a hospital-based renal dialysis facility or satellite renal dialysis facility as described in the paragraphs above. An independent renal dialysis facility may be physically located on a hospital campus, but it is not owned and/or administered by the hospital. Independent renal dialysis facilities are assigned CCNs in the 2500-2899 series and are individually enrolled.

iv. Special Purpose Renal Dialysis Facility (SPRDF) (§ 494.120)

This type of renal disease facility is temporarily certified to furnish dialysis at special locations on a short-term basis (i.e., up to 8 months in any 12 month period) to a group of dialysis patients who would otherwise be unable to obtain treatment in the geographical area. The SOG Location must clearly specify the limited nature of the SPRDF certification, the time period covered by the certification, and the automatic termination of payment on the last day of the certification period in its notifications. The special locations for SPRDF fall into two categories:

(A) Vacation Camps - Vacation camps serve dialysis patients temporarily residing there. A vacation camp SPRDF would allow campers to receive hemodialysis at the camp site, avoiding interruption of the camping experience. Vacation camps may be approved for the duration of the camp but up to a maximum of 8 months in any 12-month period.

(B) Emergency Circumstance SPRDFs - These locations are set up to provide dialysis services to those ESRD patients who would otherwise be unable to obtain such services in their geographical area as a result of a natural or man-made disaster or a need for a greater capacity to dialyze patients who may have been evacuated from another location. The CMS SOG Location may extend the time period in emergency SPRDF approvals, where necessary, beyond the standard eight-month period based upon the termination of the emergency condition.

SPRDFs are assigned CCNs in the 3700-3799 series when owned and administered by a hospital and in the 2900-2999 series for independent facilities; they are individually enrolled.

***3*. ESRD Enrollment**

An ESRD facility is separately and individually certified and does not have any branch, multiple, or parent locations. As such, each type of ESRD facility/location must independently and separately enroll as such via the Form CMS-855A; multiple sites cannot be listed on a single application.

*T*he Form CMS-855A does not distinguish between the different types of ESRD facilities. If an enrolled *ESRD facility* wants to *change to another type of ESRD facility or expand/add ESRD stations*, the provider *therefore* need not submit a Form CMS-855A change of information (*e.g., an ESRD station does not qualify as a practice location on the Form CMS-855A). However, the SOG Location may issue a tie-in notice or approval letter to the contractor as notification of the change. Also, the ESRD facility shall contact the state and the SOG Location to see if it must submit other documents or undergo other reviews pursuant to the change in ESRD type.*

***4*. ESRD Survey and Certification**

The standard CMS survey and certification form used for ESRDs is the Form CMS-3427. *For more information on this form, see Pub. 100-07, chapter 2, section 2247B.*

***5*. Site Visits**

Site visits for ESRDs are performed during the survey and certification process by the state agency.

6. For further information on ESRD facilities, refer to:

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

D. Federally Qualified Health Centers (FQHCs)

1. Statutory Background

Section 4161(a)(2) of OBRA '90 (P.L. 101-508) amended §1861(aa) of the Act and established FQHC services as a benefit under the Medicare program effective October 1, 1991. The statutory requirements that entities must meet to be considered an FQHC for Medicare purposes are at §1861(aa)(4) of the Act. Regulations establishing the FQHC benefit and outlining *the* Conditions for Coverage for FQHCs were published on June 12, 1992, in the Federal Register (57 FR 24961) and became effective on the date of publication. These regulations were amended on April 3, 1996 (61 FR 14640). Section 13556 of OBRA 1993 (P.L. 103-66) amended §1861(aa) of the Act by adding outpatient health programs or facilities operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act, as entities eligible to participate in Medicare as FQHCs.

2. Requirements

FQHCs furnish services such as those performed by physicians, nurse practitioners, physician assistants, clinical psychologists, *certified nurse-midwives*, and clinical social workers. This also includes certain preventive services like prenatal services, immunizations, blood pressure checks, hearing screenings and cholesterol screenings. (See Pub. 100-02, chapter 13 for more information). *To participate in the Medicare program, applicants seeking initial enrollment as an FQHC must submit a Form CMS-855A application to the appropriate Medicare Administrative Contractor (MAC).* Even though they complete the Form CMS-855A application, FQHCs are considered Part B certified suppliers *and are paid Part B benefits for FQHC services*.

FQHCs are not required to obtain a state survey. *However, FQHCs still must meet all applicable state and local requirements and submit all applicable licenses. Typically, the Health Resources*

and Services Administration (HRSA) will verify such state/local compliance by asking the FQHC to attest that it meets all state/local laws.

FQHCs can be located in a rural or urban area that is designated as either a health professional shortage area or an area that has a medically underserved population.

For purposes of Medicare enrollment, an FQHC is defined as an entity that has entered into an agreement with CMS to meet Medicare program requirements under 42 CFR *§* 405.2434(a), *and (as outlined in Pub. 100-07, chapter 9, exhibit 179):*

- Is receiving a grant under *§* 330 of the Public Health Service (PHS) Act;
- Is receiving funding under a contract with the recipient of a *§* 330 grant, and meets the requirements to receive a grant under § 330 of the PHS Act;
- Is an FQHC "Look-Alike" *(*i.e., HRSA), has notified *it that it* meets the requirements for receiving a *§* 330 grant, even though it is not actually receiving such a grant*)*;
- Was treated by CMS as a comprehensive federally funded health center as of January 1, 1990; or
- Is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under *T*itle V of the Indian Health Care Improvement Act.

3. Initial FQHC Applications

i. Contractor Review and Required Documents

In contrast to both past practice and the process that is normally followed with other certified provider/certified supplier types, the contractor does not make a recommendation for approval to the state/SOG Location for FQHC applications. Instead, the contractor will either approve or deny the application *at the contractor level pursuant to the instructions in this section.*

The following documents must be included *with* the *FQHC's completed Form CMS-855A* application*:*

- *One* signed and dated copy of the attestation statement (Exhibit 177). In order to attest to being in compliance, the facility must be open and operating when the attestation is signed. Since FQHCs must sign an agreement stipulating that they will comply with § 1861(aa)(4) of the Act and specific FQHC regulations, this statement serves as the Medicare FQHC *benefit (or provider/supplier)* agreement when it is also signed and dated by PEOG. *(See Pub. 100-07, chapter 2, section 2826B.)*

- HRSA Notice of Grant Award or FQHC Look-Alike Designation that includes an address for the site of the applicant which matches the practice location reported on the Form *CMS-*855A. *A Notice of Grant Award by HRSA verifies that the applicant qualifies as a FQHC grant recipient; the FQHC Look-Alike Designation Memo from HRSA verifies look-alike status.*

- Form CMS-588*;* Electronic Funds Transfer (EFT) Authorization Agreement.

- Clinical Laboratory Improvement Act (CLIA) Certificate (if applicable). Facilities that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings is considered a laboratory and must meet CLIA requirements. These facilities must apply and obtain a certificate from the

CLIA program that corresponds to the complexity of tests performed. Certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. One example would be facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostics test. *Pub. 100-07, c*hapter 6, *s*ection 6002 provides additional details regarding laboratories and laboratory tests NOT subject to CLIA requirements. It is the *FQHC's* responsibility to review the CLIA requirements and obtain a CLIA certificate if needed. *Neither t*he *contractor* nor CMS determin*es* whether the FQHC *needs to* obtain and submit a CLIA certificate.

- Copy of *s*tate *l*icense (if applicable).

ii. General Processing Concepts

(A) Practice Locations - An FQHC cannot have multiple sites or practice locations. Each location must be separately enrolled and will receive its own *CCN*.

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

(C) Date on Exhibit 177 - The contractor shall ensure *that* the date *on which* the Exhibit 177 was signed *is* on or after the date the FQHC *listed* as *its* effective date *on the Form CMS-855A application*. *If the Exhibit 177 was signed prior to the listed effective date, the contractor shall follow the instructions in section (D)(5)(b) below;* the FQHC should be providing services in order to meet the regulations noted in Exhibit 177.

(D) Date Application Complete - When reviewing an initial FQHC application, the contractor shall verify the date on which the FQHC's application was complete. To illustrate, assume that the FQHC submitted an initial application on March 1. Two data elements were missing*, so* the contractor requested additional information. The two elements were submitted on March 30. The contractor shall therefore indicate the March 30 date in its approval letter as the effective date of the FQHC.

(E) Site Visits - Site visits for FQHCs are performed by HRSA prior to enrollment.

(F) Contractor Jurisdiction - Except for tribal and Urban Indian FQHCs, a freestanding FQHC that is initially enrolling is assigned to the Medicare Administrative Contractor (MAC) that covers the state in which the FQHC is located. An initially enrolling tribal or Urban Indian FQHC is assigned to the Jurisdiction H MAC.

(G) Tribal/Urban Indian Organizations – Certain outpatient health programs or facilities may be operated by a tribe or tribal organization or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act. The contractor shall confirm the applicant's attestation and tribal/urban Indian status if the FQHC indicates on the application that it has such status; several means are available:

- *The applicable Indian Health Service (IHS) web link at https://www.ihs.gov/locations/. The contractor can search for the facility by clicking on the "Find Health Care" sub-link https://www.ihs.gov/findhealthcare/?CFID=15011511&CFTOKEN=36378825 or downloading the Excel complete listing of HIS facilities. (These are the highly recommended means of verification.)*

- *Contacting (1) the IHS directly, (2) contacting the applicable SOG Location, or (3) the contractor's PEOG BFL.*

(H) Potential RHC Relationship – On occasion, a rural health clinic (RHC) may seek to convert to an FQHC. (A facility cannot be both an RHC and an FQHC.) Accordingly, in its review of an initial FQHC application, the contractor shall check PECOS to determine whether an RHC is enrolled at the same location. If one is, the contractor shall refer the matter to MedicareProviderEnrollment@cms.hhs.gov. In doing so, the contractor shall furnish to PEOG (1) the names, NPIs, and shared address of the RHC and FQHC, and (2) a copy of all information submitted with the FQHC application; the e-mail's subject line shall state: "RHC & FQHC shared address".

4. Initial FQHC *Applications - Determination*

a. Approval

*The c*ontractor shall contact PEOG via email at MedicareProviderEnrollment@cms.hhs.gov *if it believes* that the FQHC's *initial* application *should* be approved. The contractor shall provide to *PEOG: (1)* a copy of the draft approval letter *(see section 10.7.19 of this chapter for a model FQHC approval letter); (2) the Form* CMS-855A application or PECOS Application Data Report (ADR) and all supporting documentation*; (3) a* copy of the FQHC's HRSA documentation*;* and *(4)* Exhibit 177.

While awaiting PEOG's final determination---and beginning on the date following the sending of the aforementioned e-mail---the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's decision. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

b. Denial

If the contractor believes that the FQHC's application should be denied, the contractor shall: (1) notify the applicant of the denial using the appropriate model letter guidance in section 10.7.8 of this chapter; and (2) copy the SOG Location and, as applicable, HRSA's Bureau of Primary Health Care or the Indian Health Service on the letter consistent with the instructions in this chapter. If the contractor is uncertain as to whether a denial is warranted or what the appropriate denial ground under 42 CFR 424.530(a) should be, it may contact its PEOG BFL for guidance.

5. Post-PEOG Review and Response to Contractor

If PEOG determines (based on the information the contractor furnished) that the FQHC's application should be approved, PEOG will:

- *Assign the CCN, which will be part of the 1800-1989 series*

- *Assign the effective date, which will be the date the FQHC application was considered complete by the contractor*

- *Make any necessary revisions to the draft approval letter*

- *Sign and date the attestation using the completion date, which is also the effective date (Exhibit 177)*

- *E-mail all of the foregoing documents and data to the contractor, at which point the aforementioned processing time clock resumes.*

6. Post-Approval Contractor Action

If PEOG notifies the contractor that the FQHC's application should be approved, the contractor shall send the approval letter to the FQHC with a copy of the signed Exhibit 177. (The contractor shall also (1) copy the appropriate SOG Location and HRSA's Bureau of Primary Health Care or the Indian Health Service (as applicable) on the letter via mail, e-mail, or fax; and (2) send a copy of the signed Exhibit 177 to the appropriate SOG Location via any of the foregoing three means.)

***7*. Location Changes**

i. Verification

If *an* FQHC is changing *the* physical location of an existing *site*, the *FQHC must submit the following documentation (as applicable to that FQHC) to the contractor:*

- *For § 330 grantees, a* Notice of Grant Award approving the physical location change *and the new address; or*
- *For look-alikes, an updated letter from HRSA approving the physical location change and listing the new address.*

(Consistent with the instructions in this chapter, the contractor shall develop for this documentation with the FQHC if the latter fails to submit it.)

For tribal/Urban Indian organizations, the contractor may confirm the new location via the IHS website or by contacting IHS. (See section (D)(3)(ii)(G) above for the web link.)

In all cases, the new address listed on the notice of grant award, IHS website, etc., must match that listed on the Form CMS-855A change request. If it does not, the contractor shall develop with the FQHC for clarification consistent with the instructions in this chapter.

ii. Approval

If approving the location change, the contractor does not issue a recommendation of approval to the *SOG Location, notwithstanding any instruction to the contrary in this chapter*; rather, the contractor shall approve the location change in PECOS and issue an approval letter to the FQHC. The contractor shall send the *SOG Location a copy of* the approval letter of the change via e-mail. *Beginning on March 15, 2021,* tie-in *notices* will *not* be issued for address change*s*.

iii. Denial

If the contractor does not approve the location change (*i.e.,* the FQHC *is* no longer *located* in a shortage area, *the FQHC fails to submit the applicable HRSA supporting documentation after contractor development (discussed above)*, or another reason is *implicated*), the contractor *shall*

refer the matter to PEOG at ProviderEnrollmentRevocations@cms.hhs.gov consistent with all applicable instructions in this chapter and other CMS directives. (The referral shall include, at a minimum, the FQHC's LBN and NPI as well as a brief explanation of the situation and the reason for referral.) PEOG will review the matter and instruct the contractor on how to proceed.

While awaiting PEOG's final determination---and beginning on the date following the sending of the aforementioned e-mail---the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's decision. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

8. Revocations and Other Transactions

Except as otherwise stated or required by CMS, the contractor shall continue to adhere to the applicable instructions in this chapter and all other CMS directives regarding:

- *Potential FQHC revocations and referrals (including sending the referral/information to the appropriate PEOG mailbox)*
- *Changes of ownership*
- *Changes of information*
- *Revalidations*
- *Reactivations*

***9*. Complaint Investigations**

CMS *SOG Locations* investigate complaints *that* raise credible allegations of *an FQHC's* noncompliance with health and safety standards found at 42 CFR 405 Subpart X, and 42 CFR 491 Subpart A *(*except for 42 CFR *§* 491.3*)*. *The contractor shall* refer such complaints to the *SOG Location that has jurisdiction over the* FQHC.

***10.* For additional general information on FQHCs, refer to:**

- Section 1861(aa)(3-4) of the Social Security Act
- 42 CFR Part 491 and 42 CFR Part 405*, subpart X*
- Pub. 100-07, chapter 2, sections 2825 – 2826H
- Pub. 100-07, *chapter 9*, *e*xhibit*s 177 and* 179
- *Admin Info 21 06-ALL – Transitioning FQHC Certification Enrollment Performed by the CMS SOG (Standard Operating Procedures attached)*
- Pub. 100-04, chapter 9
- Pub. 100-02, chapter 13

For *additional* information on the appropriate contractor jurisdictions for incoming FQHC enrollment applications, see Pub. 100-04, chapter 1, section 20 *as well as Pub. 100-07, chapter 9, exhibit 179.*

E. Histocompatibility Laboratories

1. General Background Information

A histocompatibility laboratory does "matching" tests in preparation for procedures such as kidney transplants, bone marrow transplants, and blood platelet transfusions. It is the only type of laboratory that must submit a Form CMS-855A application. Each histocompatibility lab must meet all applicable requirements in 42 CFR Part 493 (see 42 CFR § 493.1 in particular) and undergo a *s*tate survey.

2. Additional Information

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

F. Home Health Agencies (HHAs)

1. General Background Information

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

Like most certified providers, HHAs receive a *s*tate survey (or a survey from an approved accrediting organization) to determine compliance with *f*ederal, *s*tate, and local laws) and must sign a provider agreement.

2. Site Visit Requirements

See *s*ection*s* 10.6.20(A) and 10.6.20(B) of this chapter for more information on HHA site visit requirements.

3. HHA Components

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

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

Branch – A branch *office* is a location or site *from which an HHA provides services within a portion of the total* geographic area *served by* the parent *agency. The branch office is part of the HHA and is located sufficiently close to the parent agency so that it shares administration, supervision, and services with the parent agency on a daily basis. The branch office is not required to independently meet the conditions of participation as an HHA; the branch* can *thus be* listed as practice locations on the main provider's Form CMS-855A. Though the branch receives a 10-digit CCN identifier, it bills under the parent HHA's CCN.

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

4. Out-of-State HHA *Operations*

Pub. 100-07, chapter 2, section 2184 states that when an HHA provides services across state lines:

- *It must be certified by the state in which its CCN is based.*

- *The involved states must have a written reciprocal agreement permitting the HHA to provide services in this manner. In those states that have a reciprocal agreement, HHAs are not required to be separately approved in each state; consequently, they would not have to obtain a separate Medicare provider agreement/number in each state. HHAs residing in a state that does not have a written reciprocal survey agreement with a contiguous state are precluded from providing services across state lines; the HHA must establish a separate parent agency in the state in which it wishes to provide services.*

- *A CMS approved branch office may be physically located in a neighboring state if the state agencies responsible for certification in each state approve the operation.*

See section 10.3.1(A)(1)(d)(iii) of this chapter for additional information regarding the enrollment of out-of-state HHA locations.

5. Verification of HHA Sites

HHAs are not permitted to share a practice location address. If the contractor receives an application from an HHA that has the same general practice location address as another enrolled (or enrolling) HHA and the contractor has reason to suspect that the HHAs may be concurrently operating out of the same suite or office, the contractor shall notify the *NSVC* of this at the time the contractor orders the required site visit through PECOS. If the site visit uncovers two HHAs operating within the same practice location address, the contractor shall deny/reject the application for enrollment.

6. Nursing Registries

If the HHA checks "yes" in *S*ection 12B of the Form CMS-855A, the contractor shall ensure that the information furnished about the HHA nursing registry is accurate. (A nursing registry is akin to a staffing agency, whereby a private company furnishes nursing personnel to hospitals, clinics, and other medical providers.)

7. HHA Ownership Changes

a. Background

Effective January 1, 2011, and in accordance with 42 CFR § 424.550(b)(1), if there is a change in majority ownership of an HHA by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead:

- Enroll in the Medicare program as a new (initial) HHA under the provisions of § 424.510, and

- Obtain a *s*tate survey or an accreditation from an approved accreditation organization.

For purposes of § 424.550(b)(1), a "change in majority ownership" (as defined in 42 CFR § 424.502) occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA during the 36 months following the HHA's initial enrollment into

the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sales, stock transfers, mergers, or consolidations). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.

b. **Exceptions**

There are several exceptions to § 424.550(b)(1). Specifically, the requirements of § 424.550(b)(1) do not apply if:

- The HHA has submitted 2 consecutive years of full cost reports. (For purposes of this exception, low utilization or no utilization cost reports do not quality as full cost reports.)

- The HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

- The HHA is changing its existing business structure – such as from a corporation, a partnership (general or limited), or a *limited liability company (*LLC*)* to a corporation, a partnership (general or limited) or an LLC - and the owners remain the same.

- An individual owner of the HHA dies.

In addition, § 424.550(b)(1) does not apply to "indirect" ownership changes.

c. Timing of 36-Month Period

As indicated earlier, the provisions of 42 CFR § 424.550(b)(1) and (2) *(*as enacted in "CMS-6010-F, Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices; Final Rule"*)* *became* effective January 1, 2011. This means these provisions impact only those HHA ownership transactions whose effective date is on or after January 1, 2011. However, the provisions can apply irrespective of when the HHA first enrolled in Medicare. Consider the following illustrations:

- Example 1 – Smith HHA initially enroll*ed* in Medicare effective July 1, 2009. Smith under*went* a change in majority ownership effective September 1, 2011. The provisions of § 424.550(b)(1) appl*ied* to Smith because it underwent a change in majority ownership within 36 months of its initial enrollment.

- Example 2 – Jones HHA initially enroll*ed* in Medicare effective July 1, 2007. Jones under*went* a change in majority ownership effective February 1, 201*9*. Section 424.550(b)(1) d*id* not apply to this transaction because it occurred more than 36 months after Jones's initial enrollment. Suppose, however, *that* Jones under*went* another change in majority ownership effective February 1, 20*20*. Section 424.550(b)(1) appl*ied* to this transaction because it took place within 36 months after Jones's most recent change in majority ownership (i.e., on February 1, 201*9*).

- Example *3* – Davis HHA initially enroll*ed* in Medicare effective July 1, *2012*. It under*went* its first change in majority ownership effective *December* 1, 201*5*. This change *was*

not affected by §424.550(b)(1) because it occurred more than 36 months after Davis's initial enrollment. Davis under*went* another change in majority ownership effective July 1, 201*9*. This change, too, *was* unaffected by § 424.550(b)(1), *for* it occurred more than 36 months after the HHA's most recent change in majority ownership (i.e., on *December* 1, 201*5*). Davis under*went* another majority ownership change on July 1, 20*20*. This change *was* impacted by § 424.550(b)(1), since it occurred within 36 months of the HHA's most recent change in majority ownership (i.e., on July 1, 201*9*).

d. Determining the 36-Month Rule's *Applicability*

If the contractor receives a Form CMS-855A application reporting an HHA ownership change (and unless a CMS instruction or directive states otherwise), it shall undertake the following steps:

Step 1 – Change in Majority Ownership

The contractor shall determine whether a change in direct majority ownership has occurred. Through its review of the transfer agreement, sales agreement, bill of sale, etc., the contractor shall verify whether:

- The ownership change was a direct ownership change and not a mere indirect ownership change, and

- The change involves a party assuming a greater than 50 percent ownership interest in the HHA.

Assumption of a greater than 50 percent direct ownership interest can generally occur in one of three ways. First, an outside party that is currently not an owner can purchase more than 50 percent of the business in a single transaction. Second, an existing owner can purchase an additional interest that brings its total ownership stake in the business to greater than 50 percent. For instance, if a 40 percent owner purchased an additional 15 percent share of the HHA, this would constitute a change in majority ownership. This is consistent with the verbiage in the aforementioned definition of "change in majority ownership" regarding the "cumulative effect" of asset sales, transfers, etc. Another example of a change in majority ownership would be if a 50 percent owner obtains any additional amount of ownership (regardless of the percentage) and hence becomes a majority owner; thus, for instance, if a 50 percent owner were to acquire an additional .001 percent ownership stake, he or she becomes a majority owner and the transaction involves a change in majority ownership.

If the transfer does not qualify as a change in majority ownership, the contractor can process the application normally *(which will typically be as a change of information under 42 CFR § 424.516(e))*. If it does qualify, the contractor shall proceed to Step 2:

Step 2 – 36-Month Period

The contractor shall determine whether the effective date of the transfer is within 36 months after the effective date of the HHA's (1) initial enrollment in Medicare or (2) most recent change in majority ownership. The contractor shall verify the effective date of the reported transfer by reviewing a copy of the transfer agreement, sales agreement, bill of sale, etc., rather than relying upon the date of the sale as listed on the application. It shall also review its records – and, if necessary, request additional information from the HHA – regarding the effective date of the HHA's most recent change in majority ownership, if applicable.

If the effective date of the transfer does not fall within either of the aforementioned 36-month periods, the contractor may process the application normally*; specifically, the contractor shall, as applicable and depending upon the facts of the case, process the application as a change of information under 42 CFR § 424.516(e) or as a potential change of ownership under 42 CFR § 489.18.*

If the transfer's effective date falls within one of these *36-month* timeframes, the contractor shall proceed to Step 3.

Step 3 – Applicability of Exceptions

If the contractor determines that a change in majority ownership has occurred within either of the above-mentioned 36-month periods, the contractor shall determine whether any of the exceptions in § 424.550(b)(2) apply. As alluded to earlier, the exceptions are as follows:

i. The HHA has submitted 2 consecutive years of full cost reports.

A. For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports. *(See* 42 CFR § 413.24(h) for a definition of low Medicare utilization.*)*

B. The cost reports must have been: (1) consecutive, meaning that they were submitted in each of the 2 years preceding the effective date of the transfer*;* and (2) accepted by the contractor.

ii. The HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

iii. The HHA is changing its existing business structure – such as from a corporation, a partnership (general or limited), or an LLC to a corporation, a partnership (general or limited) or an LLC - and the owners remain the same.

A. If the HHA is undergoing a change in business structure other than those which are specifically mentioned in this exemption (e.g., corporation to an LLC), the contractor shall contact its *PEOG Business Function Lead (*BFL) for guidance.

B. For the exemption to apply, the owners must remain the same.

iv. An individual owner of the HHA dies – regardless of the percentage of ownership the person had in the HHA.

***e*. Determination**

If the contractor concludes that one of the aforementioned exceptions applies (and unless a CMS instruction or directive states otherwise), it may process the application normally*; specifically, the contractor shall, as applicable and depending upon the facts of the case, process the application as a change of information under 42 CFR § 424.516(e) or as a potential change of ownership under 42 CFR § 489.18.*

If no exception applies, the contractor shall refer the case to its PEOG BFL for review. Under no circumstances shall the contractor *apply the 36-month rule to the HHA and require an initial enrollment based thereon* without the prior approval of PEOG. If PEOG agrees with the

contractor's determination, the contractor shall send a letter to the HHA notifying it that, as a result of § 424.550(b)(1), the HHA must:

- Enroll as an initial applicant; and

- Obtain a new state survey or accreditation *survey* after it has submitted its initial enrollment application and the contractor has made a recommendation for approval to the *s*tate/*SOG Location*.

As the new owner must enroll as a new provider, the contractor shall also deactivate the HHA's billing privileges if the sale has already occurred. The effective date of the deactivation shall be the date the HHA is notified that it must enroll as an initial applicant. If the sale has not occurred, the contractor shall alert the HHA that it must submit a Form CMS-855A voluntary termination application.

Providers and/or their representatives (e.g., attorneys, consultants) shall contact their local MAC with any questions concerning (1) the 36-month rule in general and (2) whether the rule and/or its exceptions apply in a particular provider's case.

f. Additional Notes

The contractor is advised of the following:

i. If the contractor learns of an HHA ownership change by means other than the submission of a *Form* CMS-855A application, it shall notify its PEOG BFL immediately.

ii. If the contractor determines, under Step 3 above, that one of the § 424.550(b)(2) exceptions applies, the ownership transfer still qualifies as a change in majority ownership for purposes of the 36-month clock. To illustrate, assume that an HHA initially enrolled in Medicare effective July 1, 2010. It under*went* a change in majority ownership effective February 1, 2012. The contractor determined that the transaction was exempt from § 424.550(b)(1) because the HHA submitted full cost reports in the previous 2 years. On February 1, 2014, the HHA under*went* another change in majority ownership that did not qualify for an exception. The HHA *thus had to* enroll as a new HHA under § 424.550(b)(1) because the transaction occurred within 36 months of the HHA's most recent change in majority ownership - even though the February 2012 change was exempt from § 424.550(b)(1).

8. Capitalization

a. Background

Effective January 1, 2011, and pursuant to 42 CFR §*§* 489.28(a) and 424.510(d)(9), an HHA entering the Medicare program - including a new HHA resulting from a change of ownership if the change of ownership results in a new provider number being issued - must have available sufficient funds *(known as* initial reserve operating funds*)* at (1) the time of application submission and (2) all times during the enrollment process, to operate the HHA for the three-month period after *the Medicare contractor conveys* billing privileges (exclusive of actual or projected accounts receivable from Medicare). This means that the HHA must also have available sufficient initial reserve operating funds during the 3-month period following the conveyance of Medicare billing privileges.

b. Points of Review

At a minimum, the contractor shall verify that the HHA meets the required amount of capitalization:

- Prior to making its recommendation for approval;

- After a recommendation for approval is made but before the *SOG Location* review process is completed;

- After the *SOG Location* review process is completed but before the contractor conveys Medicare billing privileges to the HHA; and

- During the 3-month period after the contractor conveys Medicare billing privileges to the HHA

For initial applications, the contractor shall verify that the HHA meets all of the capitalization requirements addressed in 42 CFR § 489.28. (Note that capitalization need not be reviewed for revalidation, reactivation applications*, and changes of ownership that do not require a new/initial enrollment under § 424.550(b)*.) The contractor may request from the *HHA* any and all documentation deemed necessary to perform this task.

The HHA must submit proof of capitalization within 30 calendar days of *the contractor's request* to do so. Should the HHA fail to furnish said proof and billing privileges have not yet been conveyed, the contractor shall deny the HHA's application pursuant to § 424.530(a)(8)(i) or (ii), as applicable. If billing privileges have been conveyed, the contractor shall revoke the HHA's billing privileges per § 424.535(a)(11).

Should the contractor *deem* it necessary to verify the HHA's level of capitalization more than once within a given period *(*e.g., more than once between the time a recommendation is made and the completion of the RO review process*),* the contractor shall seek approval from its *PEOG BFL*.

c. Determining Initial Reserve Operating Funds

Initial reserve operating funds are sufficient to meet the requirement of 42 CFR § 489.28(a) if the total amount of such funds is equal to or greater than the product of the actual average cost per visit of *three* or more similarly situated HHAs in their first year of operation (selected by CMS for comparative purposes) multiplied by the number of visits projected by the HHA for its first 3 months of operation--or 22.5 percent (one fourth of 90 percent) of the average number of visits reported by the comparison HHAs--whichever is greater.

The contractor shall determine the amount of the initial reserve operating funds *by* using reported cost and visit data from submitted cost reports for the first full year of operation from at least *three* HHAs that the contractor serves that are comparable to the HHA seeking to enter the Medicare program. Factors to be used in making this determination shall include:

- Geographic location and urban/rural status;
- Number of visits;
- Provider-based versus free-standing status; and
- Proprietary versus non-proprietary status.

The adequacy of the required initial reserve operating funds is based on the average cost per visit of the comparable HHAs, by dividing the sum of total reported costs of the HHAs in their first year of operation by the sum of the HHAs' total reported visits. The resulting average cost per visit is then multiplied by the projected visits for the first 3 months of operation of the HHA seeking to enter the program, but not less than 90 percent of average visits for a 3-month period for the HHAs used in determining the average cost per visit.

d. Proof of Operating Funds

*As described further in section 10.2.1(F)(8)(e) and (g) below, t*he HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For purpose*s* of *the capitalization requirement*, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial 3-month period for which the initial reserve operating funds are required does not qualify *as* meeting the initial reserve operating funds requirement. Examples of cash equivalents for purpose*s* of *the capitalization requirement* are Treasury bills, commercial paper, and money market funds.

As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS may later require the HHA to furnish*: (1)* another attestation from the financial institution that the funds remain available*; and/or (2)* documentation from the HHA that any cash equivalents remain available until a date when the HHA will have been surveyed by the *s*tate agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds constitutes non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

e. Borrowed Funds

i. General Information

If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA. *As part of this, and except as stated in section 10.2.1(F)(8)(e)(ii) below, the HHA must (at a minimum) furnish: (1)* a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds*; and (2)* an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds*; this could* includ*e* furnishing an attestation from a financial institution or other source *(*as may be appropriate*)* to establish that such funds will remain available until a date when the HHA will have been surveyed by the *s*tate agency or by an approved accrediting organization.

ii. Inability to Obtain Attestation Statements

Several national bank chains are no longer providing attestation statements, which are necessary under 42 CFR § 489.28(d), to verify the existence of capitalization funds for HHAs. Accordingly, the contractor may accept a current bank statement unaccompanied by an

attestation from an officer of the bank or other financial institution if the HHA cannot secure the attestation. All efforts must be exhausted, however, to obtain the attestation of funds statement before the contractor can forgo this requirement. In no circumstances shall the MAC instruct the HHA to obtain a different bank that will provide an attestation statement. All other documents listed in section 10.2.1(F)(8) must be obtained if required.

f. Line of Credit

If the HHA chooses to support the availability of a portion of the initial reserve operating funds with a line of credit, it must provide CMS with a letter of credit from the lender. CMS later may require the HHA to furnish an attestation from the lender that the HHA, upon its certification into the Medicare program, continues to be approved to borrow the amount specified in the letter of credit.

g. Documents

As part of ensuring the prospective HHA's compliance with the capitalization requirements, the contractor shall obtain the following from the *HHA*:

- A document outlining the *HHA*'s projected budget – preferably, a full year's budget broken out by month

- A document outlining the number of anticipated visits - preferably a full year broken out by month

- An attestation statement from an officer of the HHA defining the source of funds

- Copies of bank statements, certificates of deposits, etc., supporting that cash is available (must be current)

- *Except as stated in section 10.2.1(F)(8)(e)(ii) above, a* letter from *an* officer of the bank attesting that funds are available

- If available, audited financial statements

The contractor shall also ensure that the capitalization information in *S*ection 12 of the *Form* CMS-855A is provided.

***9*. Additional HHA Review Activities**

As stated in section 10.2.1(F)(*8*) of this chapter, the contractor must verify that a newly enrolling HHA has the required amount of capitalization after the *CMS* RO review process is completed but before the contractor conveys Medicare billing privileges to the HHA. Accordingly, the HHA must submit proof of capitalization during this "post-*SOG Location*" period.

To confirm that the HHA is still in compliance with Medicare enrollment requirements prior to the issuance of a provider agreement *and conveyance of Medicare billing privileges*, the contractor during the post-*SOG Location* review period *shall* ensure that each entity and individual listed in sections 2, 5 and 6 of the HHA's Form CMS-855A application is again reviewed against the Medicare Exclusion Database (MED) and the System for Award Management (SAM) (formerly the General Services Administration (GSA) Access Management

System). This activity applies: (1) regardless of whether the HHA is provider-based or freestanding*;* and (2) only to initial enrollments.

The capitalization and MED/SAM re-reviews described above shall be performed once the *SOG Location* notifies the contractor via e-mail that the *SOG Location*'s review is complete. (Per sections 10.6.20(A) and 10.6.20(B) of this chapter, a site visit will be performed after the contractor receives the tie-in/approval notice from the *SOG Location* but before the contractor conveys Medicare billing privileges to the HHA.) If:

a. The HHA is still in compliance (e.g., no owners or managing employees are excluded*/debarred;* capitalization is met):

i. The contractor shall notify the *SOG Location* of this via e-mail. The notice shall specify the date on which the contractor completed the aforementioned reviews.

ii. The *SOG Location* will: (1) CCN*;* (2) sign a provider agreement*;* and (3) send a tie-in notice or approval letter to the contractor. Per section 10.6.1(B) of this chapter, the contractor shall complete its processing of the tie-in notice/approval letter within 45 calendar days of receipt (during which time a site visit will be performed).

iii. Upon receipt of *SOG Location*'s notification, *the* contractor will perform *the* capitalization reviews discussed in section 10.2.1(F)(*8*) and *MED*/SAM reviews discussed in *s*ection 10.2.1(F)(*9*) of this chapter.

b. The HHA is not in compliance (e.g., capitalization is not met):

i. The contractor shall deny the application in accordance with the instructions in this chapter and issue appeal rights. (The denial date shall be the date on which the contractor completed its follow-up capitalization and *MED*/SAM reviews.)

ii. Notify the *SOG Location* of the denial via e-mail. (PEOG, not the *SOG Location*, will handle any *corrective action plan (*CAP*)* or appeal related to the contractor's denial.)

iii. Upon receipt of *SOG Location*'s notification, *the* contractor will perform capitalization reviews discussed in section 10.2.1(F)(*8*) and *MED*/SAM reviews discussed in section 10.2.1(F)(*9*) of this chapter.

10. Recommendation Before New HHA Location Established

If an HHA is adding a branch or changing the location of its main location or an existing branch, the contractor may make a recommendation for approval to the *s*tate/*SOG Location* prior to the establishment of the new/changed location (notwithstanding any other instruction in this chapter to the contrary). If the contractor opts to make such a recommendation prior to the establishment of the new/changed location, it shall note in its recommendation letter that the HHA location has not yet moved or been established.

1*1*. Additional Information

For more information on HHAs, refer to:

- Sections 1861(o) and 1891 of the Social Security Act
- 42 CFR Part 484

- 42 CFR § 489.28 (capitalization)
- Pub. 100-07, chapter 2
- Pub. 100-04, chapter 10
- Pub. 100-02, chapter 7

G. Hospices

1. General Background Information

A hospice is a public agency or private organization or subdivision of either of these that is primarily engaged in providing a comprehensive set of services such as the assessment and management of pain. Typically, the need for services is identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

2. Enrollment Information

a. Multiple Practice locations

Hospices are not precluded from having multiple practice locations if permitted by the *SOG Location*. If the *SOG Location* disapproves an additional practice location, the location must seek Medicare approval as a separate hospice with its own enrollment and provider agreement. (See Pub. 100-07, chapter 2, section 208*8* for the policies regarding multiple hospice locations.)

b. Site Visits

i. Initial application – If a hospice submits an initial application, the contractor shall order a site visit through PECOS after the contractor receives the tie-in notice (or approval letter) from the *SOG Location* but before the contractor conveys Medicare billing privileges to the hospice. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with *s*ection 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

ii. Revalidation – If a hospice submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with *s*ection*s* 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

iii. New/changed location - If a hospice is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS after the contractor receives notice of approval from the *SOG Location* but before the contractor switches the provider's enrollment record to "Approved." This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with *s*ection*s* 10.6.20(A) and 10.6.20(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.

3. Additional Information:

For more information on hospices, refer to:

- Sections 1861(u) and 1861(dd) of the Social Security Act
- 42 CFR Part 418
- Pub. 100-07, chapter 2, sections 2080 – 2089
- Pub. 100-04, chapter 11
- Pub. 100-02, chapter 9

H. Hospitals and Hospital Units

1. General Background Information

Hospitals and hospital units are a provider type that enrolls via the Form CMS-855A. An exception to this is when the hospital is requesting enrollment to bill for practitioner services for hospital departments, outpatient departments, outpatient locations, and/or hospital clinics; in this circumstance, a new Form CMS-855B enrollment application is required.

2. Enrollment Information

a. Swing-Bed Designation

A “swing-bed” hospital is one that is approved by CMS to furnish post-hospital skilled nursing facility (SNF) services. That is, hospital (or critical access hospital (CAH)) patients’ beds can “swing” from furnishing hospital services to providing SNF care without the patient necessarily being moved to another part of the building. It receives a separate survey and certification from that of the hospital. Thus, if swing-bed designation is terminated, the hospital still maintains its certification. In addition, the hospital is given an additional CCN to bill for swing-bed services. (The third digit of the CCN will be the letter U, W, Y or Z.)

In general, and as stated in 42 CFR § 482.58, in order to obtain swing-bed status the hospital must, among other things: (1) have a Medicare provider agreement; (2) be located in a rural area; and (3) have fewer than 100 non-newborn or intensive care beds. Swing-bed hospitals, therefore, are generally small hospitals in rural areas where there may not be enough SNFs, and the hospital is thus used to furnish SNF services.

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

Additional data on “swing-bed” units can be found in Pub. 100-07, chapter 2, sections 2036 – 2040.

b. Psychiatric and Rehabilitation Units

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

c. Multi-Campus Hospitals

A multi-campus hospital (MCH) has two or more hospital campuses operating under one CCN. The MCH would report its various units/campuses as practice locations on the Form CMS-855A. For additional information on multi-campus hospitals, see Pub. 100-07, chapter 2, section 2024.

d. Physician-Owned Hospitals

As defined in 42 CFR § 489.3, a physician-owned hospital *(POH)* means any participating hospital (as defined in 42 CFR §489.24) in which a physician or an immediate family member of a physician has an ownership or investment interest in the hospital. The ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital. (This definition does not include a hospital with physician ownership or investment interests that satisfy the requirements at 42 CFR § 411.356(a) or (b).)

Section 2(A)(4) of the Form CMS-855A asks the applicant to identify whether it is a physician-owned hospital. If the applicant indicates in *S*ection 2(A)(2) that it is a hospital, it must complete *S*ection 2(A)(4). Applicants that are not hospitals need not complete *S*ection 2(A)(4).

At this time, POHs are not required to submit a completed *Form* CMS-855POH or a completed Attachment 1 of the *Form* CMS-855A. As stated in the March 12, 2015 announcement in MLN Connects Provider eNews, CMS has extended the deadline for the POH Initial Annual Ownership/Investment Report due to concerns about the accuracy of the data collected in the report. Future instruction regarding the reporting of POH ownership and investment will be provided on the CMS physician self-referral website.

e. Critical Access Hospitals

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

f. Hospital Addition of Practice Location

In situations where a hospital is adding a practice location, the contractor shall notify the provider in writing that its recommendation for approval does not constitute approval of the facility or group as provider-based under 42 CFR § 413.65.

If the contractor makes a recommendation for approval of the provider's request to add a hospital unit, the contractor shall forward the package to the *s*tate agency as described in this chapter.

g. Transplant *Programs*

For purposes of Medicare enrollment, a hospital transplant *program* is treated similarly to a hospital sub-unit. If the hospital wishes to add a transplant *program*, it must check the "other" box in *S*ection 2A2 of the *Form* CMS-855A, write "transplant *program*" on the space provided,

and follow the standard instructions for adding a sub-unit. Unless CMS indicates otherwise, the contractor shall process the application in the same manner it would the addition of a hospital sub-unit; however, no separate enrollment in PECOS need be created for the transplant center.

3. Other Enrollment Procedures

Regarding Section 4 of the Form CMS-855A, *the* hospital must list all addresses where it - and not a separately enrolled provider or supplier it owns or operates, such as a nursing home - furnishes services. The *hospital's* primary practice location should be the first location identified in *S*ection 4A and the contractor shall treat it as such – unless there is evidence indicating otherwise. **NOTE**: Hospital departments located at the same address as the main facility need not be listed as practice locations on the Form CMS-855A.

If an enrolled hospital seeks to add a rehabilitation, psychiatric, or swing-bed unit, it should submit a Form CMS-855 change of information request and not an initial enrollment application.

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

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

5. Form CMS-855B Applications Submitted by Hospitals

a. Group Practices

If an entity is enrolling via the Form CMS-855B as a hospital-owned clinic/physician practice, the contractor shall contact the applicant to determine whether the latter will be billing any of the listed locations as provider-based. If the applicant will not be billing as provider-based, the contractor shall process the application normally. If, however, the applicant will bill as provider-based, the contractor shall notify the applicant that the hospital must report any changed practice locations to its contractor via the Form CMS-855A.

If the supplier is enrolling as a hospital department (under the "Clinic/Group Practice" category on the Form CMS-855B) or an existing hospital department is undergoing a change of ownership (CHOW), the contractor shall only issue the necessary billing numbers upon notification that a provider agreement has been issued – or, in the case of a CHOW, the provider agreement has been transferred to the new owner. If, however, the supplier is enrolling as a group practice that is merely owned by a hospital (as opposed to being a hospital department), *the contractor need not* wait until the provider agreement is issued before conveying billing privileges to the group.

b. Individual Billings

Assume an individual physician works for a hospital and will bill for services as an individual (i.e., not as part of the hospital service/payment). However, he/she wants to reassign these benefits to the hospital. The hospital will need to enroll with the contractor via the Form CMS-855B (e.g., as a hospital department, outpatient location).

I. Indian Health Services (IHS) Facilities

1. General Background Information

For purposes of provider enrollment only, there are several types of IHS facilities: (1) those that are wholly owned and operated by the *IHS;* (2) facilities owned by the IHS but tribally operated*;* and (3) facilities wholly owned and operated by a tribe, though under the general IHS umbrella. When an IHS facility wishes to enroll with the Part A contractor, it may check *in Section 2A of the Form CMS-855A* either (a) "Indian Health Services Facility" or (b) the specific provider type it is. For instance, if an IHS hospital is involved, the provider may check "Indian Health Services Facility" or "Hospital" on the application - or perhaps both. Even if it only checked "Hospital," the LBN or DBA Name will typically contain some type of reference to Indian Health Services. The contractor will therefore know that an IHS facility *is involved*.

The overwhelming majority of IHS facilities on the Part A side are either hospitals, SNFs, *CAHs,* or *ESRD* facilities. The contractor processes IHS applications in the same manner (and via the same procedures) as it would with a hospital, SNF, etc. (This also applies to procedures for PECOS entry.)

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

2. Enrollment Information

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

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

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

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

The Affordable Care Act (Pub. L 111-148) amended Section 221 of the Indian Health Care Improvement Act *such that l*icensed health professionals employed by a tribal health program *are*, if licensed in any *s*tate, *exempt* from the licensing requirements of the *s*tate in which the tribal program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act (ISDEAA) (25 U.S.C. 450, et seq.). Pursuant to this statutory provision, *therefore,* any physician or practitioner need only be licensed in one *s*tate – regardless of whether that *s*tate is the one in which the practitioner practices – if he or she is employed by a tribal health program performing services as permitted under the ISDEAA (see Pub. 100-04, chapter 19, section 10 for definitions).

The contractor shall apply this policy when processing applications from these individuals. In terms of the effective date of Medicare billing privileges, the contractor shall continue to apply the provisions of 42 CFR §*§* 424.520(d) and *424.521(a)* and section 10.*6.2* of this chapter.

4. Additional Information

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

J. Organ Procurement Organizations (OPOs)

1. General Background Information

An OPO is an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs. *An OPO must have been certified as a qualified OPO by CMS under 42 U.S.C. 273(b) and § 486.303 to be eligible for designation. In order to be certified as a qualified OPO, an OPO must have received a grant under 42 U.S.C. 273(a) or have been certified or re-certified by the Secretary within the previous four years as being a qualified OPO. Under the statute, no new OPOs can enroll into the Medicare program*

2. Re-certification

An OPO *is designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. Re-certification must occur not more frequently than once every 4 years. The SOG Location is responsible for conducting the re-certification surveys every 4 years; the OPO* must sign a *new* provider agreement (Form CMS-576A) and participate in the Organ Procurement and Transplantation Network. (See CMS Pub. 100-07, chapter 2, sections 2810 and 2811.)

3. Change in Control/Ownership or Service Area

OPOs can undergo a change in control or ownership or service area (§ 486.310). The merger of one OPO into another or the consolidation of one OPO with another is considered a change in control or ownership. The OPO must notify CMS before implementing a change in ownership or control or a change in its service area. The OPO must provide the SOG Location with information that is specific to the board structure of the new organization, as well as operating budgets, financial information and other documentation that the SOG Location determines to be necessary. The OPO must also submit a revised Form CMS-855 to the MAC for review and a recommendation of approval from the SOG Location. When the SOG Location receives notification of a prospective change in control or ownership for a designated OPO, the SOG Location must determine (based upon the documents and information submitted) that the operation of the OPO will continue uninterrupted during and following the change. For any change of ownership or control, a new CMS Form-576 must be signed.

The instructions in the previous paragraph are in addition to, and not in lieu of, those pertaining to changes of ownership and referrals to SOG Locations in sections 10.6 and 10.6.1 of this chapter.

4. Additional Information

For more information on OPOs, refer to:

- Section 1138 of the Social Security Act
- 42 CFR § 486.301 - § 486.3*60*

- Pub. 100-07, chapter 2, sections 2810 – 2821

For guidance on the appropriate contractor jurisdiction for incoming OPO applications, see CMS Pub. 100-04, chapter 1, section 20. Note that a hospital-based OPO must enroll separately, be separately certified, and sign its own provider agreement.

K. Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)

1. General Background Information

Physical therapists and speech pathologists provide therapy targeting a person's ability to move and perform functional activities in their daily lives typically inhibited by illness or injury. Care is typically coordinated by therapists in conjunction with a physician and is based on an agreed upon plan of care.

2. Enrollment Information

a. Providers of OPT/OSP Services

*As explained in Pub. 100-07, chapter 2 section 2292, t*here are three types of *organizations that may qualify as providers of OPT and OSP services under 42 CFR Part 485, Subpart H: clinics, public health clinics, and rehabilitation agencies. However, rehabilitation agencies are the only organizations that are currently enrolled as a Medicare provider with a CCN. The primary purpose of a rehabilitation agency is to improve or rehabilitate an injury or disability and to tailor a rehabilitation program to meet the specific rehabilitation needs of each patient referred to the agency. A rehabilitation agency must provide, at a minimum, physical therapy and/or speech language pathology services to address those needs of the patients. Social/vocational services are no longer a requirement.*

Note that:

- If an OPT/OSP provider elects to convert to a CORF, it must meet the CORF conditions of coverage and participation. An initial Form CMS-855A enrollment application, *s*tate survey, and CMS *program* approval are also required.

- Only those *OTP/OSP providers covered under 42 CFR Part 485, Subpart H that furnish* OPT/OSP services *(as listed above)* have provider agreements under 42 CFR § 489.2. Part B physician groups – the supplier type that most people normally associate with the term "clinics" – do not have *certified* provider or *certified* supplier agreements.

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

b. Extension Locations

As discussed in Pub. 100-07, chapter 2, section*s 2298 and* 2298A, an OPT/OSP provider can*, in certain instances,* furnish services from locations other than its primary site. (The provider must designate one location as its primary location *on the Form CMS-855A*, however.) These sites are called extension locations. *An extension location is defined at 42 CFR § 485.703 as "a location or site from which a rehabilitation agency provides services within a portion of the total*

geographic area served by the primary site. The extension location is part of the agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency." Per Pub. 100-07, chapter 2, section 2298A, only rehabilitation agencies are permitted to have extension locations. The clinics operated by physicians and public health clinics are not permitted extension locations. These two providers must provide outpatient therapy services at their Medicare approved location.

An OPT/OSP provider may also furnish therapy services in a patient's home or in a patient's room in a SNF. *(See Pub. 100-07, chapter 2, section 2300. Note that when the OPT provides services away from the primary site or extension location(s), this is referred to as "off-premises activity" at other locations. Section 2300 (referenced) above discusses such activities.)* Because the*se* are not considered extension locations, neither the home nor the patient's room need be listed as a practice location on the provider's Form CMS-855A. (See Pub. 100-07, chapter 2, section 2298B.)

If an OPT/OSP provider wants to add an extension site, a *Form CMS-855A* change of information request should be submitted.

There is no prohibition against an organization operating on the premises of a supplier (e.g., physician or chiropractor) or another provider as long as they are not operating in the same space at the same time. (See Pub. 100-07, chapter 2, section 2304.)

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

- Section 1861(p) of the Social Security Act
- 42 CFR Part 485, subpart H
- Pub. 100-07, chapter 2, sections 2290 – 230*8*
- Pub. 100-07, Appendix E

L. Religious Non-Medical Health Care Institutions (RNCHIs)

1. General Background Information

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

CMS's Boston *Northeast SOG Location (in coordination with the CMS Central Office)* has primary responsibility over the approval and certification of RNHCIs. RNHCIs are not certified by the *s*tate but must meet all of the conditions of coverage outlined in 42 CFR §403.720 as well as all conditions of participation. *(See* 42 CFR §§ 403.730 through 403.746 *regarding RNCHI conditions of participation.)* For purposes of provider enrollment, the three most important conditions are that the provider:

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

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

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

(See Pub. 100-07, chapter 2, section 2054.1 for additional conditions.)

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

2. Additional Information

For more information on RNCHIs, refer to:

- Section 1861(ss)(1) of the Social Security Act
- 42 CFR Part 403, subpart G
- Pub. 100-07, chapter 2, sections 2054, 2054.1, 2054.1A and 2054.1*B*
- Pub. 100-04, chapter 3, sections 170 - 180
- Pub. 100-02, chapter 1, sections 130 – 130.4.2

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

M. Rural Health Clinics (RHCs)

1. General Background Information

An RHC is a facility located in a rural area designated as a shortage area and is neither a rehabilitation agency nor a facility primarily for the care and treatment of mental diseases. It must meet all other requirements of the RHC regulations at 42 CFR Part 491, subpart A. RHCs:

- Are considered to be Part B certified suppliers even though they enroll in Medicare via the Form CMS-855A.

- *Are defined in section 1861(aa)(2) of the Social Security Act as facilities that are engaged primarily in providing services that are typically furnished in an outpatient clinic.*

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

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

- *Can be freestanding or provider-based. (As stated in Pub. 100-07, p*rovider-based RHCs are an integral and subordinate part of a hospital (including a critical access hospital (CAH), skilled nursing facility (SNF), or a home health agency (HHA)).

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

Note that a facility cannot be simultaneously enrolled as an FQHC and an RHC. Though there are similarities between these two supplier types, there are key differences as well. *For instance,* FQHCs can service rural or urban regions. *To be eligible for certification as an RHC, however, a clinic must be located in a non-urbanized area, as determined by the U.S. Census Bureau, and in an area designated or certified within the previous 4 years by the Secretary of Health and Human Services (HHS), in any one of the four types of shortage area designations that are accepted for RHC certification. (See Pub. 100-02, chapter 13, sections 10.1 and 20.) Also: (1)* RHCs are surveyed by the *s*tate *while* FQHCs are not; and (2) FQHCs furnish preventive services *while* RHCs do not.

2. Additional Information

For more information on RHCs, refer to:

- Section 1861(aa)(1-2) of the Social Security Act
- 42 CFR Part 491, subpart A
- Pub. 100-07, chapter 2, sections 2240 – 2249
- Pub. 100-04, chapter 9
- Pub. 100-02, chapter 13

For guidance on the appropriate contractor jurisdictions for incoming RHC applications, refer to Pub. 100-04, chapter 1, section 20.

N. Skilled Nursing Facilities (SNFs)

1. General Background Information

As stated in Pub. 100-07, chapter 7, section 7004.*2*, a SNF is a facility that:

- Is primarily engaged in providing to residents skilled nursing care and related services for residents who require medical or nursing care; or
- Is primarily engaged in providing to residents skilled rehabilitation services for the rehabilitation of injured, disabled, or sick persons; *while the care and treatment of mental*

disease is not the primary action of SNFs, the ability to provide appropriate resources and support for these beneficiaries is necessary;

- Has in effect a transfer agreement (meeting the requirements of §1861(1) of the Social Security Act with one or more hospitals having agreements in effect under § 1866 of the Social Security Act); and
- Meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of §1819 of the Social Security Act.

The transfer agreement mentioned above need not be submitted with the SNF's Form CMS-855A enrollment application; the *s*tate and/or *SOG Location* will verify that the agreement exists.

Like other certified providers, SNFs receive a *s*tate survey and sign a provider agreement. SNFs cannot have multiple practice locations *under one Form CMS-855A enrollment.*

2. SNF Distinct Parts

A SNF can be a separate institution or a "distinct part" of an institution. The term "distinct part" means an area or portion of an institution (e.g., a hospital) that is certified to furnish SNF services. The hospital and the SNF distinct part will each receive a separate *CCN*. Also:

- A hospital may have only one SNF distinct part.
- "Distinct part" designation is not equivalent to being "provider-based."

A SNF distinct part unit must enroll separately (i.e., it cannot be listed as a practice location on the hospital's Form CMS-855A), be separately surveyed, and sign a separate provider agreement. (Note how this is different from "swing-bed" units, which do not enroll separately and do not sign separate provider agreements.)

3. Additional Information

For more information on SNFs, refer to:

- Section 1819 of the Social Security Act
- Pub. 100-07, chapter 7
- Pub. 100-02, chapter 8

10.7.19 – Model Approval Letter for Federally Qualified Health Centers (FQHCs)

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

This section 10.7.19 contains an FQHC model approval letter that contractors shall use as directed in section 10.2.1(D) of this chapter. This letter takes precedence over all other letters in section 10.7 et seq. that pertain to approval of certified providers and certified suppliers. The contractor shall continue to use existing certified provider/supplier model letters for all other FQHC transactions (e.g., revalidations).

FQHC Approval Letter

[Month, Day, Year]

[FQHC Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [FQHC],

[Insert Contractor] has approved your enrollment as a federally qualified health center (FQHC).

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Location Address	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)/CMS Certification Number (CCN)	
PTAN/CCN Effective Date	
Medicare Year-End Cost Report Date	

Included with this letter is a copy of your "Attestation Statement for Federal Qualified Health Center" (Exhibit 177), which CMS has signed.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes to, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- *Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.*
- *State the issues or findings of fact with which you disagree and the reasons for disagreement.*
- *Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.*
  - *If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.*
  - *If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.*
  - *Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.*

Providers and suppliers may:

- *Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.*
- *Include an email address if you want to receive correspondence regarding your appeal via email.*

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Compliance & Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]