CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 556	**Date: November 26, 2014**
	Change Request 8810

SUBJECT: Revisions to Pub. 100-08, Program Integrity Manual (PIM), Chapter 15

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to add certain provider enrollment policy clarifications to chapter 15 of the PIM.

EFFECTIVE DATE: December 29, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: December 29, 2014

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/15.4.1.3/End-Stage Renal Disease Facilities (ESRDs)
R	15/15.5.5/Owning and Managing Organizations
R	15/15.19.2.1/Background

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

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

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I. GENERAL INFORMATION

A. Background: This change request (CR) adds certain provider enrollment policy clarifications to chapter 15 of the PIM.

B. Policy: This CR adds certain provider enrollment policy clarifications to chapter 15 of the PIM.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8810.1	**NOTE**: The contractor shall observe the policy clarifications in this change request.	X	X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8810.2	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are	X	X	X		

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.					

IV. SUPPORTING INFORMATION

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

"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

15.4.1.3 - End-Stage Renal Disease Facilities (ESRDs)

(Rev.556, Issued: 11- 26-14, Effective: 12- 29-14, Implementation: 12-29-14)

A. Types of ESRD Facilities

ESRD facilities are entities that perform renal services for patients with irreversible and permanent kidney failure. There are several types of ESRD facilities:

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

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

    - The RDC need not furnish transplantation services.

    - An RTC can also be an RDC.

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

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

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

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

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

B. ESRD Survey and Certification

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

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

C. Miscellaneous ESRD Policies

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

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

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

- *ESRDs entities/facilities cannot be mobile.*

D. ESRD Enrollment

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

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

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

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

E. Additional Information on ESRD Facilities

For further data on ESRD facilities, refer to:

- Section §1881 of the Social Security Act

- 42 CFR Part 405, Subpart U

- Pub. 100-07, *State Operations Manual,* chapter 2, section 2270 – 2287B

- Pub. 100-02, *Benefit Policy Manual, chapter 11*

- Pub. 100-04, *Claims Processing Manual*, chapter *8*

15.5.5 – Owning and Managing Organizations

(Rev.556, Issued: 11- 26-14, Effective: 12- 29-14, Implementation: 12-29-14)

(This section only applies to section 5 of the Form CMS-855A and Form CMS-855B. It does not apply to the Form CMS-855I.)

All organizations that have any of the following must be listed in section 5A of the Form CMS-855:

1. A 5 percent or greater direct or indirect ownership interest in the provider.

The following illustrates the difference between direct and indirect ownership:

EXAMPLE: The supplier listed in section 2 of the Form CMS-855B is an ambulance company that is wholly (100 percent) owned by Company A. Company A is considered to be a direct owner of the supplier (the ambulance company), in that it actually owns the assets of the business. Now assume that Company B owns 100 percent of Company A. Company B is considered an indirect owner - but an owner, nevertheless - of the supplier. In other words, a direct owner has an actual ownership interest in the supplier, whereas an indirect owner has an ownership interest in an organization that owns the supplier.

See the instructions for section 5 of the Form CMS-855 for additional information on indirect ownership.

2. Mortgage or security interest

For purposes of enrollment, ownership also includes "financial control." Financial control exists when:

(a) An organization or individual is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the provider or any of the property or assets of the provider, and

(b) The interest is equal to or exceeds 5 percent of the total property and assets of the provider.

All entities with at least a 5 percent mortgage, deed of trust or other security interest in the provider must be reported in section 5. This frequently will include banks, other financial institutions, and investment firms,

3. Any general partnership interest in the provider, regardless of the percentage. This includes: (1) all interests in a non-limited partnership, and (2) all general partnership interests in a limited partnership.

4. For limited partnerships, any limited partnership interest that is 10 percent or greater.

5. Managing control of the provider or supplier

A managing organization is one that exercises operational or managerial control over the provider, or conducts the day-to-day operations of the provider. The organization need not have an ownership interest in the provider in order to qualify as a managing organization. For instance, the entity could be a management services organization under contract with the provider to furnish management services for one of the provider's practice locations.

The organizations referred to above generally fall into one or more of the following categories:

- Corporations
- Partnerships and limited partnerships
- Limited liability companies
- Charitable and religious organizations
- Governmental/tribal organizations

- Banks and financial institutions
- Investment firms
- Holding companies
- Trusts and trustees
- Medical providers/suppliers
- Consulting firms
- Management services companies
- Medical staffing companies
- Non-profit entities

In section 5(A)(2) of the Form CMS-855, the provider must indicate the type(s) of organizational categories the reported entity falls into.

The following principles also apply with respect to section 5:

a. Diagrams – In addition to completing section 5(A):

- The provider must submit an organizational structure diagram/flowchart identifying all of the entities listed in section 5 and their relationships with the provider and each other. (This applies to the Form CMS-855A, CMS-855B and CMS-855S.)

- If the provider is a skilled nursing facility (SNF), it must submit a diagram/flowchart identifying the organizational structures of all of its owners, including those that were not required to be listed in section 5 or 6. This must be submitted in addition to the diagram/flowchart in the previous bullet.

These diagrams/flowcharts must be submitted for initial enrollments, revalidations, Form CMS-855 reactivations, and upon any contractor request.

b. Percentage of Interest (section 5(B)) – The provider need not:

- Disclose a percentage of managerial control

- Submit documentation verifying the percentage of ownership, partnership interest or security/mortgage interest, unless the contractor requests it.

c. Section 2 - Any entity listed as the provider in section 2 of the Form CMS-855 need not be reported in section 5A. The only exception involves governmental entities, which must be identified in section 5A even if they are already listed in section 2.

d. Governmental and Tribal Organization Letter - For governmental and tribal organizations, the letter referred to in the Form CMS-855 instructions for section 5 must be signed by an appointed or elected official of the governmental or tribal entity who has the authority to legally and financially bind the governmental or tribal entity to the laws, regulations, and program instructions of Medicare. This governmental or tribal official is not required to be an authorized official, or vice versa.

e. Non-Profit Organizations - Many non-profit organizations are charitable or religious in nature, and are operated and/or managed by a Board of Trustees or other governing body. The actual name of the Board of Trustees or other governing body must be listed in section 5A of the Form CMS-855. The provider must submit a copy of its 501(c)(3) approval notification for non-profit status. If it does not possess such documentation but nevertheless claims it is a non-profit entity, the provider may submit any other documentation that supports its claim (e.g., written documentation from the State).

Governmental and tribal entities need not submit a copy of a 501(c)(3) if it is otherwise obvious to the contractor that the entity is a governmental or tribal entity. The contractor can assume that the governmental or tribal entity is non-profit.

f. IRS CP-575 - Owning/managing organizations need not furnish an IRS CP-575 document unless requested by the contractor (e.g., the contractor discovers a potential discrepancy between the organization's reported legal business name and tax identification number.

g. Documentation – Proof of ownership, managerial control, security interest, etc., need not be submitted unless the contractor requests it. This also means that articles of incorporation, partnership agreements, etc., need not be submitted absent a contractor's request.

h. Partnerships – Only partnership interests in the enrolling provider need be disclosed in section 5. Partnership interests in the provider's indirect owners need not be reported. However, if the partnership interest in the indirect owner results in a greater than 5 percent indirect ownership interest in the enrolling provider, this indirect ownership interest would have to be disclosed in section 5.

i. Disregarded Entities – In general, a "disregarded entity" is a term the IRS uses for an LLC that – for federal tax purposes only – is effectively indistinguishable from its single owner/member. The LLC's income and expenses are shown on the owner's personal tax return. The LLC itself does not pay taxes.

If an enrolling provider claims that it is a disregarded entity, the contractor need not obtain written confirmation of this from the provider notwithstanding the instruction in section 17 of the Form CMS-855 that such confirmation is required. As a disregarded entity does not receive a CP-575 form from the IRS confirming its legal business name (LBN) and tax identification number (TIN), the contractor may accept from the enrolling provider any government form (such as a W-9) that lists its LBN and TIN. *The disregarded entity's LBN and TIN shall be listed in section 2B1 of the Form CMS-855.*

15.19.2.1 – Background

(Rev.556, Issued: 11- 26-14, Effective: 12- 29-14, Implementation: 12-29-14)

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

A. Limited

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

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

For providers and suppliers in the "limited" category, the contractor shall (unless section 15.19.2.5 of this chapter applies) process initial, revalidation, and new location applications in accordance with existing instructions.

B. Moderate

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

- Ambulance service suppliers

- Community mental health centers (CMHCs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Hospice organizations
- Independent clinical laboratories
- Independent diagnostic testing facilities
- Physical therapists enrolling as individuals or as group practices
- Portable x-ray suppliers (PXRSs)
- Revalidating home health agencies (HHAs)
- Revalidating DMEPOS suppliers

For providers and suppliers in the "moderate" level of categorical screening, the contractor shall (unless section 15.19.2.2 of this chapter or another CMS directive applies):

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

2. Except for revalidating DMEPOS suppliers, order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) in accordance with sections 2(a) through (e) below. The site visit, which the National Site Visit Contractor (NVSC) will perform, is to ensure that the supplier is in compliance with CMS's enrollment requirements. Unless stated otherwise in this chapter, the scope of the site visit will be consistent with section 15.19.2.2.

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

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

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

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

   b. CMHCs

      - Initial application - In addition to the site visit discussed in section 15.4.1.1(B)(1) of this chapter, the contractor shall order a site visit after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the CMHC. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

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

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

c. CORFs, hospices and PXRSs

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

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

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

d. IDTFs

- Initial applications – The NSVC will conduct site visits of initially enrolling IDTFs consistent with section 15.4.19.6 of this chapter.

- Revalidations - The NVSC will conduct site visits of revalidating IDTFs (prior to the contractor's final decision regarding the revalidation application) consistent with section 15.4.19.6 of this chapter.

- Code Changes – The NSVC will conduct site visits for IDTF code changes as specified in section 15.4.19.6(B) of this chapter.

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

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

C. High

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

- Newly enrolling DMEPOS suppliers
- Newly enrolling HHAs *(including HHAs that must submit an initial enrollment application pursuant to § 424.550(b)(1))*

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

1. The contractor shall process the application in accordance with existing instructions; and

2. The NSVC will perform a site visit for newly enrolling HHAs. (The NSC will perform a site visit for newly enrolling DMEPOS suppliers.) For initially enrolling HHAs, the contractor shall order a site visit via PECOS after the contractor receives the tie-in notice or approval letter from the RO but before the contractor switches the provider's enrollment record to "Approved." The contractor shall

not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

NOTE:

- Enrolled DMEPOS suppliers that are adding another location will be classified as "high" for screening purposes. (See section *15.*19.2.3 below for information regarding DMEPOS changes of ownership and tax identification number (TIN) changes.)

- Newly-enrolling HHA sub-units fall within the "high" level of categorical screening.

- The addition of a new HHA branch falls within the "moderate" level of categorical screening. The contractor shall order a site visit of the location through PECOS after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." This is to ensure that the provider is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

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