

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 492	Date: December 6, 2013
	Change Request 8393

SUBJECT: Additional Updates to Chapter 15 of the Program Integrity Manual (PIM)

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to incorporate several recent provider enrollment policy determinations into Publication 100-08, Chapter 15.

EFFECTIVE DATE: January 7, 2014

IMPLEMENTATION DATE: January 7, 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/Table of Contents
R	15/15.5.4/Practice Location Information
R	15/15.5.5/Owning and Managing Organizations
R	15/15.7.7.7/Contractor Jurisdictional Issues
R	15/15.17/Establishing an Effective Date of Medicare Billing Privileges
R	15/15.19.1/Application Fees
R	15/15.24.9/Revocation Letter Guidance
R	15/15.24.9.1/Model Revocation Letter for Part B Suppliers and Certified Providers and Suppliers
R	15/15.26.3/Additional Home Health Agency (HHA) Review Activities
R	15/15.29/Provider and Supplier Revalidations

III. FUNDING:

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

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is

not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Number	Requirement	Responsibility											
		A/B MAC			D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				Other
		A	B	H H H					F I S S	M C S	V M S	C W F	
	System shall be the “doing business as” name if one is listed.												

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility							
		A/B MAC			D M E M A C	F I	C A R R I E R	R H I	Other
		A	B	H H H					
8393.6	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor’s next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X					

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:
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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) or Contractor Manager, as applicable.

VI. FUNDING

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

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

Section B: For Medicare Administrative Contractors (MACs):

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

Medicare Program Integrity Manual

Chapter 15 - Medicare Enrollment

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- 15.19.1-*Application Fees*
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15.5.4 – Practice Location Information

(Rev. 492, Issued: 12-06-13, Effective: 01-07-14, Implementation: 01-07-14)

Unless specifically indicated otherwise, the instructions in this section 15.5.4 apply to the Form CMS-855A, the Form CMS-855B, and the Form CMS-855I.

The instructions in section 15.5.4.1 apply only to the Form CMS-855A; the instructions in section 15.5.4.2 apply only to the Form CMS-855B; and the instructions in section 15.5.4.3 only apply to the Form CMS-855I.

A. Practice Location Verification

The contractor shall verify that the practice locations listed on the application actually exist. *If a particular location cannot at first be verified, the contractor shall request clarifying information; for instance, the contractor can request that the applicant furnish letterhead showing the appropriate address.*)

The contractor shall also verify that the reported telephone number is operational and connects to the practice location/business listed on the application. (The telephone number must be one where patients and/or customers can reach the applicant to ask questions or register complaints.) The contractor shall match the applicant's telephone number with known, in-service telephone numbers - via, for instance, the Yellow Pages or the Internet - to correlate telephone numbers with addresses. If the applicant uses his/her/its cell phone for their business, the contractor shall verify that this is a telephone connected directly to the business. If the contractor cannot verify the telephone number, it shall request clarifying information from the applicant; the inability to confirm a telephone number may indicate that an onsite visit is necessary. In some instances, a 1-800 number or out-of-state number may be acceptable if the applicant's business location is in another State but his/her/its practice locations are within the contractor's jurisdiction.

In addition:

- If an individual practitioner or group practice: (1) is adding a practice location and (2) is normally required to complete a questionnaire in section 2 of the Form CMS-855I or Form CMS-855B specific to its supplier type (e.g., psychologists, physical therapists), the person or entity must submit an updated questionnaire to incorporate services rendered at the new location.
- Any provider submitting a Form CMS-855A, Form CMS-855B or Form CMS-855I application must submit the 9-digit ZIP Code for each practice location listed.
- *The practice location name entered into the Provider Enrollment, Chain and Ownership System shall be the “doing business as” name if one is listed.*

B. Do Not Forward (DNF)

Unless instructed otherwise in another CMS directive, the contractor shall follow the DNF initiative instructions in Pub. 100-04, chapter 1, section 80.5. Returned paper checks, remittance notices, or EFT payments shall be flagged if returned from the post office or banking institution, respectively, as this may indicate that the provider's “special payment” address (section 4 of the Form CMS-855) or EFT information has changed. The provider should submit a Form CMS-855 or Form CMS-588 request to change this address; if the provider does not have an established enrollment record in the Provider Enrollment, Chain and Ownership System, it must complete an entire Form CMS-855 and Form CMS-588. The Durable Medical Equipment Medicare Administrative Contractors are responsible for obtaining, updating and processing Form CMS-588 changes.

In situations where a provider is closing his/her/its business and has a termination date (e.g., he/she is retiring), the contractor will likely need to make payments for prior services rendered. Since the practice

location has been terminated, the contractor may encounter a DNF message. If so, the contractor should request the provider to complete the “special payment” address section of the Form CMS-855 and to sign the certification statement. The contractor, however, shall not collect any other information unless there is a need to do so.

C. Remittance Notices/Special Payments

For new enrollees, all payments must be made via EFT. The contractor shall thus ensure that the provider has completed and signed the Form CMS-588 and shall verify that the bank account is in compliance with Pub. 100-04, chapter 1, section 30.2.

If an enrolled provider that currently receives paper checks submits a Form CMS-855 change request – no matter what the change involves – the provider must also submit:

- A Form CMS-588 that switches its payment mechanism to EFT. (The change request cannot be processed until the Form CMS-588 is submitted.) All future payments (excluding special payments) must be made via EFT.
- An updated section 4 that identifies the provider’s desired “special payments” address.

The contractor shall also verify that the bank account is in compliance with Pub. 100-04, chapter 1, section 30.2.

(Once a provider changes its method of payment from paper checks to EFT, it must continue using EFT. A provider cannot switch from EFT to paper checks.)

The “special payment” address may only be one of the following:

- One of the provider’s practice locations
- A P.O. Box
- The provider’s billing agent. The contractor shall request additional information if it has any reason to suspect that the arrangement – at least with respect to any special payments that might be made – may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.
- The chain home office address. Per Pub.100-04, chapter 1, section 30.2, a chain organization may have payments to its providers sent to the chain home office. The legal business name of the chain home office must be listed on the Form CMS-588. The TIN on the Form CMS-588 should be that of the provider.
- Correspondence address

15.5.5 – Owning and Managing Organizations

(Rev. 492, Issued: 12-06-13, Effective: 01-07-14, Implementation: 01-07-14)

(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.

15.7.7.7 – Contractor Jurisdictional Issues

(Rev. 492, Issued: 12-06-13, Effective: 01-07-14, Implementation: 01-07-14)

A. Audit and Claims Contractors

1. Background

For purposes of enrollment via the Form CMS-855A, there are generally two categories of contractors: audit contractors and claims contractors. The audit contractor enrolls the provider, conducts audits, etc. The claims contractor pays the provider’s claims. In most cases, the provider’s audit contractor and claims contractor will be the same. On occasion, though, they will differ. *This* can happen, for instance, with provider-based entities, whereby *the parent provider’s contractor (audit contractor) will process the provider’s enrollment application and a different contractor will pay the provider’s claims (claims contractor).*

Should the audit and claims contractors differ, the audit contractor shall process all changes of information, including all Form CMS-588 changes. The audit contractor shall notify the applicant during the initial enrollment process that all future changes of information must be sent to the audit contractor, not the claims contractor. If the provider inadvertently sends a change request to the claims contractor, the latter shall return the application per section 15.8.1 of this chapter.

2. Process

If the audit contractor approves the Form CMS-855A transaction in question (e.g., initial enrollment), it shall:

(a) Send an e-mail to the claims contractor identifying the specific Form CMS-855A transaction involved and confirming that the information has been updated in the Provider Enrollment, Chain and Ownership System (PECOS). Pertinent identifying information, such as the provider name, CMS Certification Number and National Provider Identifier, *shall* be included *in* the e-mail notification. Any supporting documentation *that contains* personal health information or personally identifiable *information may* still be faxed to the claims contractor.

(b) As applicable, fax or mail a copy of the submitted Form CMS-588 to the appropriate claims contractor.

Upon receipt of the e-mail notification, the claims contractor shall access PECOS, review the enrollment record, and, as needed, update its records accordingly.

The audit contractor shall keep all original copies of Form CMS-855A paperwork and supporting documentation, *including all Form CMS-588s*.

3. Tie-In/Tie-Out Notices and Approval Notices

If the provider's audit contractor and claims contractor are different, the audit contractor shall e-mail or fax a copy of all tie-in/tie-out notices and approval letters it receives to the claims contractor. This is to ensure that the claims contractor is fully aware of the RO's action, as some ROs may only send copies of tie-in/tie-out notices and approval letters to the audit contractor. If the audit contractor chooses, it can simply contact the claims contractor by phone or e-mail and ask if the latter received the tie-in notice.

Again, it is imperative that audit and claims contractors effectively communicate and coordinate with each other in all payment-related and program integrity matters involving the provider.

B. Provider Nomination

With respect to provider nomination and changes of contractors, the contractor shall follow the instructions in Pub. 100-04, chapter 1, sections 20 through 20.5.1.

If the contractor receives a request from a provider to change its existing contractor, it shall refer the provider to the RO contact person responsible for contractor assignments.

15.17 – Establishing an Effective Date of Medicare Billing Privileges

(Rev. 492, Issued: 12-06-13, Effective: 01-07-14, Implementation: 01-07-14)

(This section only applies to the following individuals and organizations: physicians; physician assistants; nurse practitioners; clinical nurse specialists; certified registered nurse anesthetists; *anesthesiology assistants*; certified nurse-midwives; clinical social workers; clinical psychologists; registered dietitians or nutrition professionals; and physician and non-physician practitioner organizations (e.g., group practices) consisting of any of the categories of individuals identified in this paragraph.)

A. Background

In accordance with 42 CFR §424.520(d), the effective date for the individuals and organizations identified above is the later of:

- The date the physician filed an enrollment application that was subsequently approved, or
- The date the physician first began furnishing services at a new practice location.

NOTE: The date of filing for Internet-based Provider Enrollment, Chain and Ownership System (PECOS) applications is the date that the contractor received an electronic version of the enrollment application and a signed certification statement submitted via paper or electronically.

B. Retrospective Billing

Consistent with 42 CFR §424.521(a), the individuals and organizations identified above may retrospectively bill for services when:

- The supplier has met all program requirements, including State licensure requirements, and
- The services were provided at the enrolled practice location for up to—

1. 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or

2. 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§5121-5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

The contractor shall interpret the phrase “circumstances precluded enrollment” to mean that the physician, non-physician practitioner, or physician or non-physician practitioner organization meets all program requirements (including State licensure) during the 30-day period before an application was submitted and no final adverse action, as identified in 42 CFR §424.502, precluded enrollment. If a final adverse action precluded enrollment during this 30-day period, the contractor shall only establish an effective billing date the day after the date that the final adverse action was resolved, as long as it is not more than 30 days prior to the date on which the application was submitted.

C. Legal Distinction between Effective Date of Enrollment and retrospective Billing Date

The effective date of enrollment is “the later of the date of filing or the date (the supplier) first began furnishing services at a new practice location.” The retrospective billing date, however, is “up to...30 days prior to (the supplier’s) effective date (of enrollment).” To illustrate, suppose that a non-Medicare enrolled physician begins furnishing services at an office on March 1. She submits a Form CMS-855I initial enrollment application on May 1. The application is approved on June 1. The physician’s effective date of enrollment is May 1, which is the later of: (1) the date of filing, and (2) the date she began furnishing services. The retrospective billing date is April 1 (or 30 days prior to the effective date of enrollment), assuming that the requirements of 42 CFR §424.521(a) are met.

NOTE: However, that the effective date entered into the Provider Enrollment, Chain and Ownership System (PECOS) and the Multi-Carrier System will be April 1 and that claims submitted for services provided before April 1 will not be paid.

15.19.1 – Application Fees

(Rev. 492, Issued: 12-06-13, Effective: 01-07-14, Implementation: 01-07-14)

A. Background

Pursuant to 42 CFR §424.514 - and with the exception of physicians, non-physician practitioners, physician group practices and non-physician group practices – institutional providers that are (1) initially enrolling in Medicare, (2) adding a practice location, or (3) revalidating their enrollment information per 42 CFR §424.515 *(regardless of whether the revalidation application was requested by CMS or voluntarily submitted by the provider or supplier)*, must submit with their application:

- An application fee in an amount prescribed by CMS, and/or
- A request for a hardship exception to the application fee.

This requirement applies to applications that the contractor receives on or after March 25, 2011.

For purposes of this requirement, the term “institutional provider,” as defined in 42 CFR §424.502, means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS- 855B (not including physician and non-physician practitioner organizations), Form CMS-855S or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application. A physician, non-physician practitioner, physician group, or non-physician practitioner group that is enrolling as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) via the Form CMS-855S application must submit the required application fee with its Form CMS-855S form.

B. Fee

1. Amount

The application fee must be in the amount prescribed by CMS for the calendar year (1) in which the application is submitted (for Internet-based PECOS applications) or (2) of the postmark date (for paper applications). The fee for March 25, 2011 through December 31, 2011 was \$505.00. The fee for January 1, 2014 through December 31, 2014 is \$542.00. Fee amounts for future years will be adjusted by the percentage change in the consumer price index (for all urban consumers) for the 12-month period ending on June 30 of the prior year. CMS will give the contractor and the public advance notice of any change in the fee amount for the coming calendar year.

2. Non-Refundable

Per 42 CFR §424.514(d)(2)(v), the application fee is non-refundable, except if it was submitted with one of the following:

- a. A hardship exception request that is subsequently approved;
- b. An application that was rejected prior to the contractor's initiation of the screening process, or
- c. An application that is subsequently denied as a result of the imposition of a temporary moratorium under 42 CFR §424.570.

(For purposes of (B)(2)(b) above, the term "rejected" includes applications that are returned pursuant to section 15.8.1 of this Chapter.)

In addition, the fee should be refunded if:

- It was not required for the transaction in question (e.g., the provider submitted a fee with its application to report a change in phone number).
- It was not part of an application submission.

3. Format

The provider or supplier must submit the application fee electronically through <https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do>, either via credit card, debit card, or check.

Also, with respect to the application fee requirement:

- The fee is based on the Form CMS-855 application submission, not on how enrollment records are created in PECOS. For instance, suppose a hospital submits an initial Form CMS-855A. In section 2A2 of the application, the hospital indicates that it has a psychiatric unit and a rehabilitation unit. Separate PECOS enrollment records must be created for each unit. However, only one application fee is required because only one Form CMS-855A application was submitted.
- A physician/non-physician practitioner clinic or group practice enrolling via the Form CMS-855B is exempt from the fee even if it is: (1) Tribally-owned/operated, or (2) hospital-owned. However, if a hospital is adding a physician/non-physician practitioner clinic or group practice to its Form CMS-855A enrollment, a fee is required because the hospital is adding a practice location.

C. Hardship Exception

1. Background

A provider or supplier requesting a hardship exception from the application fee must include with its enrollment application a letter (and any supporting documentation) that describes the hardship and why the hardship justifies an exception. If a paper Form CMS-855 application is submitted, the hardship exception letter must accompany the application; if the application is submitted via Internet-based PECOS, the hardship exception letter must accompany the certification statement. Hardship exception letters shall not be considered if they were submitted separately from the application or certification statement, as applicable. If the contractor receives a hardship exception request separately from the application or certification statement, it shall: (1) return it to the provider, and (2) notify the provider via letter, e-mail or telephone that it will not be considered.

2. Criteria for Determination

The application fee generally should not represent a significant burden for an adequately capitalized provider or supplier. Hardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship. The provider must instead make a strong argument to support its request, including providing comprehensive documentation (which may include, without limitation, historical cost reports, recent financial reports such as balance sheets and income statements, cash flow statements, tax returns, etc.).

Other factors that may suggest that a hardship exception is appropriate include the following:

- (a) Considerable bad debt expenses,
- (b) Significant amount of charity care/financial assistance furnished to patients,
- (c) Presence of substantive partnerships (whereby clinical, financial integration are present) with those who furnish medical care to a disproportionately low-income population;
- (d) Whether an institutional provider receives considerable amounts of funding through disproportionate share hospital payments, or
- (e) Whether the provider is enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act).

Upon receipt of a hardship exception request with the application or certification statement, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its Provider Enrollment Operations Group Business Function Lead (PEOG BFL). PEOG has 60 calendar days from the date of the contractor's receipt of the hardship exception request to determine whether it should be approved; during this period, the contractor shall not commence processing the provider's application. PEOG will communicate its decision to the provider and the contractor via letter, after which the contractor shall carry out the applicable instructions in section 19.1(D) below.

If the provider fails to submit appropriate documentation to support its request, the contractor is not required to contact the provider to request it. The contractor can simply forward the request "as is" to its PEOG BFL. Ultimately, it is the provider's responsibility to furnish the necessary supporting evidence at the time it submits its hardship exception request.

D. Receipt

Upon receipt of a paper application (or, if the application is submitted via Internet-based PECOS, upon receipt of a certification statement) from a provider or supplier that is otherwise required to submit an application fee, the contractor shall first determine whether the application is an initial enrollment, a revalidation, or involves the addition of a practice location. If the application does not fall within any of these categories, the contractor shall process the application as normal. If it does fall within one of these categories, the contractor shall undertake the following:

- a. Determine whether the provider has: (1) paid the application fee via Pay.gov, and/or (2) included a hardship exception request with the application or certification statement.
- b. If the provider:
 - i. Has neither paid the fee nor submitted the hardship exception request, the contractor shall send a letter to the provider notifying it that it has 30 days from the date of the letter to pay the application fee via Pay.gov, and that failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations). The letter shall also state that because a hardship exception request was not submitted with the original application, CMS will not consider granting a hardship exception in lieu of the fee.

During this 30-day period, the contractor shall determine whether the fee has been paid via Pay.gov. If the fee is paid within the 30-day period, the contractor may begin processing the application as normal. If the fee is not paid within the 30-day period, the contractor shall reject the application (initial enrollments and new locations) under 42 CFR §424.525(a)(3) or revoke the provider's Medicare billing privileges under 42 CFR §424.535(a)(6) (revalidations).

If, at any time during this 30-day period, the provider submits a Pay.gov receipt as proof of payment, the contractor shall begin processing the application as normal.

- ii. Has paid the fee but has not submitted a hardship exception request, the contractor shall begin processing the application as normal.
- iii. Has submitted a hardship exception request but has not paid a fee, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG BFL. If PEOG:
 - a. Denies the hardship exception request, it will notify the provider in the decision letter (on which the contractor will be copied) that the application fee must be paid within 30 calendar days from the date of the letter. During this 30-day period, the contractor shall determine whether the fee has been submitted via Pay.gov. If the fee is not paid within 30 calendar days, the contractor shall deny the application (initial enrollments and new locations) pursuant to 42 CFR §424.530(a)(9) or revoke the provider's Medicare billing privileges under 42 CFR §424.535(a)(6) (revalidations).

If, at any time during this 30-day period, the provider submits a Pay.gov receipt as proof of payment, the contractor shall begin processing the application as normal.

- b. Approves the hardship exception request, it will notify the provider of such in the decision letter (on which the contractor will be copied). The contractor shall begin processing the application as normal.

- iv. Has submitted a hardship exception request and has paid a fee, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG BFL. As the fee has been paid, the contractor shall begin processing the application as normal.

In all cases, the contractor shall not begin processing the provider's application until: (1) the fee has been paid, or (2) the hardship exception request has been approved.

E. Year-to-Year Transition

There may be isolated instances where, at the end of a calendar year, an institutional provider pays the fee amount for that year (Year 1), yet the submission date (for Internet-based PECOS applications) or the application postmark date (for paper applications) falls in the beginning of the following year (Year 2). Assuming that Year 2's fee is higher than Year 1's, the provider will be required to pay the Year 2 fee. The contractor shall not begin processing the application until the entire fee amount has been paid. Accordingly, the contractor shall (1) send an e-mail to its PEOG BFL requesting a full refund of the fee and including any pertinent documentation in support of the request, and (2) send a letter to the provider notifying it that it has 30 days from the date of the letter to pay the correct fee amount (i.e., the Year 2 amount) via Pay.gov, and that failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations). The letter shall also state that because a hardship exception request was not submitted with the original application, CMS will not consider granting a hardship exception in lieu of the fee.

During this 30-day period, the contractor shall determine whether the correct fee has been paid via Pay.gov. If it has been, the contractor may begin processing the application as normal. If it is not paid within the 30-day period, the contractor shall reject the application (initial enrollments and new locations) under 42 CFR §424.525(a)(3) or revoke the provider's Medicare billing privileges under 42 CFR §424.535(a)(6) (revalidations).

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

F. Appeals of Hardship Determinations

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

1. If the provider is dissatisfied with PEOG's decision to deny a hardship exception request, it may file a written reconsideration request with PEOG within 60 calendar days from receipt of the notice of initial determination (e.g., PEOG's denial letter). The request must be signed by the individual provider or supplier, a legal representative, or any authorized official within the entity. Failure to file a reconsideration request within this timeframe is deemed a waiver of all rights to further administrative review.

The reconsideration request should be mailed to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment Operations Group
7500 Security Boulevard
Mailstop: AR 18-50
Baltimore, MD 21244-1850

Notwithstanding the filing of a reconsideration request, the contractor shall still carry out the post-hardship exception request instructions in subsections (D)(b)(iii)(a) and (iv) above, as applicable. A reconsideration request, in other words, does not stay the execution of the instructions in section 19.1(D) above.

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

- (a) Conducted by a PEOG staff person who was independent from the initial decision to deny the hardship exception request.
- (b) Based on PEOG's review of the original letter and documentation submitted by the provider.

Upon receipt of the reconsideration, PEOG will send a letter to the provider or supplier to acknowledge receipt of its request. In its acknowledgment letter, PEOG will advise the requesting party that the reconsideration will be conducted and a determination issued within 60 days from the date of the request.

If PEOG denies the reconsideration, it will notify the provider of this via letter, with a copy to the contractor. If PEOG approves the reconsideration request, it will notify the provider of this via letter, with a copy to the contractor, after which the contractor shall process the application as normal, or, to the extent applicable:

- i. If the application has already been rejected, request that the provider resubmit the application without the fee, or
- ii. If Medicare billing privileges have already been revoked, reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

Corrective Action Plans (CAPs) may not be submitted in lieu of or in addition to a request for reconsideration of a hardship exception request denial.

2. If the provider is dissatisfied with the reconsideration determination regarding the application fee, it may request a hearing before an Administrative Law Judge (ALJ). Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

If the ALJ reverses PEOG's reconsideration decision and approves the hardship exception request, and the application has already been rejected, the contractor – once PEOG informs it of the ALJ's decision - shall notify the provider via letter, e-mail or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

3. If the provider is dissatisfied with the ALJ's decision, it may request Board review by the Departmental Appeals Board (DAB). Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

If the DAB reverses the ALJ's decision and approves the hardship exception request, and the application has already been rejected, the contractor - once PEOG informs it of the DAB's decision - shall notify the provider via letter, e-mail or telephone that it may resubmit the application without the fee. If the provider's

Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

To the extent permitted by law, a provider or supplier dissatisfied with a DAB decision may seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.

G. Miscellaneous

The contractor shall abide by the following:

1. Paper Checks Submitted Outside of Pay.gov – As stated earlier, all payments must be made via Pay.gov. Should the provider submit an application with a paper check or any other hard copy form of payment (e.g., money order), the contractor shall not deposit the instrument. It shall instead treat the situation as a non-submission of the fee and follow the instructions in (D)(b)(i) or (iii) above (depending on whether a hardship exception request was submitted). When sending the applicable letter requesting payment within 30 days, the contractor shall explain that all payments must be made via Pay.gov, stamp the submitted paper check "VOID," and include the voided paper check with the letter.
2. Practice Locations – DMEPOS suppliers, federally qualified health centers (FQHCs), and independent diagnostic testing facilities (IDTFs) must individually enroll each site. Consequently, the enrollment of each site requires a separate fee. For **all other providers and suppliers** (except physicians, non-physician practitioners, and physician and non-physician practitioner groups, none of which are required to submit the fee), a fee must accompany any application that adds a practice location. (This includes the addition of a hospital unit – such as a psychiatric unit – in section 4 of the Form CMS-855A.) If multiple locations are being added on a single application, however, only one fee is required. The fee for providers and suppliers other than DMEPOS suppliers, FQHCs, and IDTFs is based on the application submission, not the number of locations being added on a single application.
3. Other Application Submissions – A provider or supplier need not pay an application fee if the application is:
 - Reporting a change of ownership via the Form CMS-855B or Form CMS-855S. (For providers and suppliers reporting a change of ownership via the Form CMS-855A, the ownership change does not necessitate an application fee if the change does not require the provider or supplier to enroll as a new provider or supplier.)
 - Reporting a change in tax identification number (whether Part A, Part B, or DMEPOS).
 - Requesting a reactivation of the provider's Medicare billing privileges *unless the provider had been deactivated for failing to respond to a revalidation request, in which case the resubmitted application constitutes a revalidation (not a reactivation) application, hence requiring a fee.*
 - Changing the physical location of an existing practice location (as opposed to reporting an additional/new practice location).

The application fee requirement is separate and distinct from the site visit requirement and risk categories discussed below. Physicians, non-physician practitioners, physician groups and non-physician practitioner groups are exempt from the application fee even if they fall within the "high" level of categorical screening per section 15.19.2.5 of this chapter. Similarly, physical therapists enrolling as individuals or group practices need not pay an application fee even though they fall within the "moderate" level of categorical screening and are subject to a site visit.

4. Non-Payment of the Fee - If the application is rejected or denied due to non-payment of the fee, the contractor shall:

- Enter the application into PECOS, with the receipt date being the date on which the contractor received the application in its mailroom.
- Indicate in PECOS that a developmental request was made.
- Switch the enrollment record to a “denied” or “rejected” status (*as applicable*) per section 15.19.1(D).
- Notify the applicant of the rejection or denial in accordance with section 15.19.1(D).

15.24.9 – Revocation Letter Guidance

(Rev. 492, Issued: 12-06-13, Effective: 01-07-14, Implementation: 01-07-14)

- The contractor must submit one or more of the 12 Primary Revocation Reasons as found in x.x.x into the appropriate section on the specific Revocation Letter. Only the CFR citation and a short heading shall be cited for the primary revocation reason.
- The contractor may submit a Specific Revocation Reason, as appropriate. The Specific Revocation Reason should state sufficient details so it is clear as to why the provider or supplier is being denied.
- Specific Revocation Reasons may contain a combination of the following items:
 - A specific regulatory (CFR) citation.
 - Dates (of actions, suspensions, convictions, receipt of documents, etc.)
 - Actions
- Exclusions and sanctions – the following two sentences should be REMOVED for all revocation letters that DO NOT involve an exclusion or sanction action:

You may not appeal through this process the merits of any exclusion by another federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the federal agency that took the action.

- Corrective Action Plan language – For revocation reasons #2 (§424.535(a) (2)), #3 (§424.535(a) (3)), and #5 (§424.535(a) (5)), the provider or supplier shall not be given the option of submitting a corrective action plan. Therefore, the following language must be REMOVED from the letter:

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The CAP request must be signed by the authorized or delegated official within the entity. CAP requests should be sent to:

**(Organization)
(Address)
(City), ST (Zip)**

- Certified Providers and Suppliers language

- If the provider is NOT CERTIFIED the following adjustments need to be made on the letter.

The following sentence needs to be removed:

Pursuant to 42 CFR §424.535(b), this action will also terminate your corresponding provider agreement.

The Corrective Action Plan (CAP) must be sent to the Contractor's address.

- If the provider is CERTIFIED, the following adjustments need to be made on the letter.

The Corrective Action Plan must be sent to CMS at the following address:

**Centers for Medicare and Medicaid Services
Provider Enrollment Operations Group
7500 Security Blvd.
Mailstop: AR-18-50
Baltimore MD 21244-1850**

- National Supplier Clearinghouse - Revocation Letters - adjustments
 - If a response to the developmental letter was submitted, insert the following section:

The Supplier Audit and Compliance Unit (SACU) reviewed and evaluated the documents you submitted in response to the developmental letter dated [date]. This letter allowed you to demonstrate your full compliance with the durable medical equipment, prosthetics & orthotics standards (DMEPOS) supplier standards and/or to correct the deficient compliance requirement(s).
 - If a response to the developmental letter was NOT submitted, insert the following section:

The Supplier Audit and Compliance Unit (SACU) has not received a response to the developmental letter sent to you on [date]. This letter allowed you to demonstrate your full compliance with the durable medical equipment, prosthetics & orthotics standards (DMEPOS) supplier standards and/or to correct the deficient compliance requirement(s)
 - If a fee payment was NOT paid in response to a developmental letter denying a hardship exception (42 CFR §424.535(a) (6)), insert the following section:

The National Supplier Clearinghouse has not received a response to the developmental letter sent to you on [date] informing you that the request for a hardship exception for the required application fee was denied. The notification afforded you the opportunity to pay the mandatory application fee for processing your enrollment application and an appeal period which you did not select.
 - If a fee payment was NOT paid in response to a developmental letter notifying the provider or supplier that the application fee was not paid at the time of initial application, (42 CFR §424.535(a)(6)), insert the following section:

The National Supplier Clearinghouse has not received a response to the developmental letter sent to you on [date] informing you that the application

fee was not paid at the time you filed the CMS 855S enrollment application. The 30 day notification afforded you the opportunity to pay the mandatory application fee for processing your enrollment application.

- Final Adverse Action - language
 - If a contractor determines that a Final Adverse Action has NOT occurred, the following section should be removed:

Finally, in accordance with 42 CFR §424.565, [Contractor name] is assessing an overpayment in the amount of [insert dollar amount] because the physician or non-physician practitioner continued to furnish services to Medicare beneficiaries after a final adverse action precluded enrollment in the Medicare program.
 - **NOTE:** As stated in 42 CFR §424.565, Medicare contractors should assess an overpayment back to January 1, 2009, not the date of the final adverse action if the adverse action occurred prior to January 1, 2009.
- For IDTF and DMEPOS providers and suppliers, each regulatory citation needs to be listed along with the specific regulatory language. For IDTF, the standards are found in 42 CFR §410.33(g) 1 through 17. For DMEPOS providers and suppliers, the standards are found in 42 CFR §424.57© 1 through 30.

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is revoked based on a condition of participation, then the applicant or enrolled entity must submit a reconsideration or corrective action plan with CMS.

15.24.9.1 – Model Revocation Letter for Part B Suppliers and Certified Providers and Suppliers

(Rev. 492, Issued: 12-06-13, Effective: 01-07-14, Implementation: 01-07-14)

[Month] [day], [year]

[Provider/Supplier Name]

[Address]

[City] ST [Zip]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [Provider/Supplier Name]:

Your Medicare privileges are being revoked effective [Date of revocation] for the following reasons:

xx CFR §xxx.(x) [heading]

[Specific reason]

xx CFR §xxx.(x) [heading]

[Specific reason]

(For certified providers and certified suppliers only: Pursuant to 42 CFR §424.535(b), this action will also terminate your corresponding (provider or supplier) agreement.)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The CAP request must be signed and dated by the authorized or delegated official within the entity. CAP requests should be sent to:

[Name of MAC]

[Address]

[City], ST [Zip]

or

[Centers for Medicare & Medicaid Services]

[Provider Enrollment Operations Group]

[7500 Security Blvd.]

[Mailstop: AR-18-50]

[Baltimore, MD 21244-1850]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The reconsideration must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration that you believe may have a bearing on the decision. The reconsideration must be signed and dated by the authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

The reconsideration request should be sent to:

[Name of MAC]
[Address]
[City], ST [Zip]

Pursuant to 42 CFR §424.535(c), [Contractor name] is establishing a re-enrollment bar for a period of [Insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.26.3 – Additional Home Health Agency (HHA) Review Activities

(Rev. 492, Issued: 12-06-13, Effective: 01-07-14, Implementation: 01-07-14)

As stated in section 15.26.2(B)(3) of this chapter, the contractor must verify that a newly enrolling HHA has the required amount of capitalization after the regional office (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-RO review” period.

To confirm that the HHA is still in compliance with Medicare enrollment requirements prior to the issuance of a provider agreement, the contractor shall also – during the post-RO review period 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 RO notifies the contractor via e-mail that the RO’s review is complete. (Per sections 15.4.1.6 and 15.19.2.2 of this chapter, a site visit will be performed after the contractor receives the tie-in/approval notice from the RO 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, capitalization is met):
 1. The contractor shall notify the RO of this via e-mail. The notice shall specify the date on which the contractor completed the aforementioned reviews.
 2. The RO will: (1) issue a CMS Certification Number (CCN), (2) sign a provider agreement, and (3) send a tie-in notice or approval letter to the contractor. Per *section 15.7.7.2.1 of chapter 15*, 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).

- b. **The HHA is not in compliance** (e.g., capitalization is not met):
 1. 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.)*
 2. *Notify the RO of the denial via e-mail. (PEOG, not the RO, will handle any CAP or appeal related to the contractor’s denial.)*

While, therefore, the process of enrolling certified suppliers and certified providers other than *HHAs* *remains* the same (i.e., recommendation is made to State/RO, after which the RO sends tie-in notice to contractor, etc.), the HHA process *contains* additional steps – specifically, Steps 4 and 5, as outlined below:

1. Contractor processes incoming HHA application and either (1) denies application, or (2) recommends approval to State/RO.
2. State performs survey (if applicable) and makes recommendation to RO.
3. If State recommends approval and RO concurs, RO will – instead of issuing CCN, signing provider agreement and sending tie-in notice/approval letter to contractor at this point, as is done with other certified provider and certified supplier applications – notify contractor that its review is complete.
4. Upon receipt of RO’s notification, contractor will perform capitalization and *MED/SAM* reviews

discussed in sections 15.26.2 and 15.26.3 of this chapter.

5. Once contractor completes its review, it will notify RO as to whether HHA is still in compliance with enrollment requirements.

15.29 - Provider and Supplier Revalidations

(Rev. 492, Issued: 12-06-13, Effective: 01-07-14, Implementation: 01-07-14)

The contractor shall follow existing CMS guidance with respect to the processing of revalidation applications.