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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-08 Medicare Program Integrity | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 371 | Date: March 23, 2011 |
| | Change Request 7350 |

NOTE: This instruction is being re-issued to correct Business Requirements references which inadvertently referred to chapter 15, section 17 to chapter 15, section 19. The references have been revised to correctly reflect chapter 15, section 19. The transmittal number, date issued and all other information remain the same.

SUBJECT: Implementation of Provider Enrollment Provisions in CMS-6028-FC

I. SUMMARY OF CHANGES: In the February 2, 2011 edition of the Federal Register, the Centers for Medicare and Medicaid Services (CMS) published a final rule with comment period entitled: “Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers” (CMS-6028-FC). This rule finalized, among other things, provisions related to the: (1) submission of application fees as part of the provider enrollment process, (2) establishment of provider enrollment screening categories, and (3) imposition of a temporary moratorium on the enrollment of new Medicare providers and suppliers of a particular type (or the establishment of new practice locations of a particular type) in a geographic area. This change request implements said provisions.

EFFECTIVE DATE: March 25, 2011

IMPLEMENTATION DATE: March 25, 2011

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 |
|--------------|---|
| N | 15/Table of Contents |
| N | 15/19/Application Fees and Additional Screening Requirements |
| N | 15/19.1/Application Fees |
| N | 15/19.2/Screening Categories |
| N | 15/19.2.1/Background |
| N | 15/19.2.2/Scope of Site Visit |
| N | 15/19.2.3/Changes of Information |
| N | 15/19.2.4/Reactivations |
| N | 15/19.2.5/Movement of Providers and Suppliers into the High Level |
| N | 15/19.3/Temporary Moratoria |
| N | 15/19.4/Tracking |

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
Funding for implementation activities will be provided to contractors through the regular budget process.

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

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

Attachment - Business Requirements

| | | | |
|-------------|------------------|----------------------|----------------------|
| Pub. 100-08 | Transmittal: 371 | Date: March 23, 2011 | Change Request: 7350 |
|-------------|------------------|----------------------|----------------------|

NOTE: This instruction is being re-issued to correct Business Requirements references which inadvertently referred to chapter 15, section 17 to chapter 15, section 19. The references have been revised to correctly reflect chapter 15, section 19. The transmittal number, date issued and all other information remain the same.

SUBJECT: Implementation of Provider Enrollment Provisions in CMS-6028-FC

Effective Date: March 25, 2011

Implementation Date: March 25, 2011

I. GENERAL INFORMATION

A. Background: In the February 2, 2011 edition of the *Federal Register*, the Centers for Medicare and Medicaid Services (CMS) published a final rule with comment period entitled: “Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers” (CMS-6028-FC). This rule finalized, among other things, provisions related to the: (1) submission of application fees as part of the provider enrollment process, (2) establishment of provider enrollment screening categories, and (3) imposition of a temporary moratorium on the enrollment of new Medicare providers and suppliers of a particular type (or the establishment of new practice locations of a particular type) in a geographic area. This change request implements said provisions.

B. Policy: The purpose of this change request is to implement the provider enrollment-related provisions in CMS-6028-FC.

Please note that under 42 CFR §424.518(c)(2)(ii), providers and suppliers in the “high” level of categorical screening are subject to a fingerprint-based criminal background check. This requirement is not being implemented at the current time.

II. BUSINESS REQUIREMENTS TABLE

Use “Shall” to denote a mandatory requirement

| Number | Requirement | Responsibility (place an “X” in each applicable column) | | | | | | | | |
|--------|-------------|---|---|---|---|---|---------------------------|---|---|-------|
| | | A | D | F | C | R | Shared-System Maintainers | | | OTHER |
| | | / | M | I | A | H | | | | |
| | | B | E | | R | H | | | | |
| | | | | | R | I | | | | |
| | | M | M | | I | | F | M | V | C |
| | | A | A | | E | | I | C | M | W |
| | | C | C | | R | | S | S | S | F |
| | | | | | | | S | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|----------|--|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|---------------------------------------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| 7350.1 | If the contractor receives a hardship exception request separately from the paper Form CMS-855 application or the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) certification statement, it shall: (1) return the hardship exception request to the provider, and (2) notify the provider via letter, e-mail or telephone that it will not be considered. | X | | X | X | X | | | | | National Supplier Clearinghouse (NSC) |
| 7350.2 | Upon receipt of a paper Form CMS-855 application (or Internet-based PECOS 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. | X | | X | X | X | | | | | NSC |
| 7350.2.1 | If the application does not fall within any of the categories identified in business requirement 7350.2, the contractor shall process the application as normal. | X | | X | X | X | | | | | NSC |
| 7350.2.2 | If the application falls within any of the categories identified in business requirement 7350.2, the contractor shall 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. | X | | X | X | X | | | | | NSC |
| 7350.2.3 | If the provider has neither paid the fee nor submitted a 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, such a request will not be considered in lieu of the fee. | X | | X | X | X | | | | | NSC |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|--------------|---|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| 7350.2.4 | During the 30-day period described in business requirement 7350.2.3, the contractor shall review each updated Fee Submitter List to determine if the fee has been paid. | X | | X | X | X | | | | | NSC |
| 7350.2.4.1 | If the fee is paid within the 30-day period described in business requirement 7350.2.3, the contractor shall begin processing the application as normal. | X | | X | X | X | | | | | NSC |
| 7350.2.4.2 | If the fee is not paid within the 30-day period described in business requirement 7350.2.3, 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). | X | | X | X | X | | | | | NSC |
| 7350.2.5 | If the provider has paid the fee but has not submitted a hardship exception request, the contractor shall begin processing the application as normal. | X | | X | X | X | | | | | NSC |
| 7350.2.6 | If the provider has submitted a hardship exception request but has not paid the fee, the contractor shall send the request and all documentation accompanying the request to its Provider Enrollment Operations Group (PEOG) liaison. | X | | X | X | X | | | | | NSC |
| 7350.2.6.1 | If PEOG denies the hardship exception request, the contractor shall – during the following 30-day period - review each updated Fee Submitter List to determine if the fee has been paid. | X | | X | X | X | | | | | NSC |
| 7350.2.6.1.1 | If the fee is not paid within the 30-day period described in 7350.2.6.1, 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). | X | | X | X | X | | | | | NSC |
| 7350.2.6.2 | If PEOG approves the hardship exception request, the contractor shall begin processing the application as | X | | X | X | X | | | | | NSC |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|----------|--|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| | normal. | | | | | | | | | | |
| 7350.2.7 | If, at any time during the 30-day periods referred to in business requirements 7350.2.3 and 7350.2.6.1, the provider submits a <u>Pay.gov</u> receipt as proof of payment, the contractor shall begin processing the application as normal. | | | | | | | | | | |
| 7350.2.8 | If the provider has submitted a hardship exception request and has paid the fee, the contractor shall: (1) send the request and all documentation accompanying the request to its PEOG liaison, and (2) begin processing the application as normal. | X | | X | X | X | | | | | NSC |
| 7350.2.9 | 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. | X | | X | X | X | | | | | NSC |
| 7350.3 | If PEOG approves a provider's hardship exception reconsideration request, the contractor shall process the application as normal, or, to the extent applicable: (a) if the application has already been rejected, request that the provider resubmit the application without the fee, or (b) 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. | X | | X | X | X | | | | | NSC |
| 7350.3.1 | If the Administrative Law Judge (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 | X | | X | X | X | | | | | NSC |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|----------|--|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| | the application without the fee. | | | | | | | | | | |
| 7350.3.2 | If the Departmental Appeals Board (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. | X | | X | X | X | | | | | NSC |
| 7350.3.3 | 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 treat this as a non-submission of the fee and follow the instructions in Publication 100-08, Chapter 15, section 19.1(D)(b)(i) or (iii) (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 <u>Pay.gov</u> and shall include the submitted check with the letter. | X | | X | X | X | | | | | NSC |
| 7350.4 | The contractor shall utilize the screening procedures outlined in Publication 100-08, Chapter 15, sections 19.2 through 19.2.5 for applications it receives on or after March 25, 2011. | X | | X | X | X | | | | | NSC |
| 7350.5 | For providers and suppliers in the "limited" category, the contractor shall (unless Publication 100-08, Chapter 15, section 19.2.5 applies) process initial, revalidation, and new location applications in accordance with existing instructions. | X | | X | X | X | | | | | |
| 7350.6 | For providers and suppliers in the "moderate" level of categorical screening, the contractor shall (unless | X | | X | X | X | | | | | NSC |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|----------|---|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| | Publication 100-08, Chapter 15, section 19.2.5 applies): (1) process initial, revalidation, and new location applications in accordance with existing instructions; and (2) perform a site visit in accordance with Publication 100-08, Chapter 15, sections 19.2 through 19.2.5. | | | | | | | | | | |
| 7350.6.1 | For ambulance suppliers, independent clinical laboratories, physical therapists, and physical therapist groups, the contractor shall conduct a site visit prior to the contractor's final decision regarding the application. | X | | | X | | | | | | |
| 7350.6.2 | For initially enrolling community mental health centers (CMHCs) – and in addition to the site visit that is currently performed for CMHCs - the contractor shall conduct another site visit after receiving the tie-in notice from the regional office but before the contractor conveys Medicare billing privileges to the CMHC. | X | | X | | | | | | | |
| 7350.6.3 | For revalidating CMHCs, the contractor shall conduct a site visit prior to making a final decision regarding the revalidation application. | X | | X | | | | | | | |
| 7350.6.4 | For CMHCs that are adding a new practice location, the contractor shall conduct a site visit of the new location prior to making a recommendation for approval. | X | | X | | | | | | | |
| 7350.6.5 | For initially enrolling comprehensive outpatient rehabilitation facilities (CORFs), hospices and portable x-ray suppliers (PXRSSs), the contractor shall conduct a site visit after receiving the tie-in notice from the regional office but before the contractor conveys Medicare billing privileges to the provider. | X | | X | X | X | | | | | |
| 7350.6.6 | For revalidating CORFs, hospices and PXRSSs, the contractor shall conduct a site visit prior to making a final decision regarding the revalidation application. | X | | X | X | X | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|-----------|--|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| 7350.6.7 | For CORFs, hospices and PXRSSs that are adding a new location, the contractor shall conduct a site visit of the new location prior to making a recommendation for approval. | X | | X | X | X | | | | | |
| 7350.6.8 | For initially enrolling independent diagnostic testing facilities (IDTFs), the contractor shall continue to conduct site visits in accordance with Publication 100-08, Chapter 10, section 4.19.6. | X | | | X | | | | | | |
| 7350.6.9 | For revalidating IDTFs, the contractor shall (prior to making a final decision regarding the revalidation application) conduct a site visit in accordance with Publication 100-08, Chapter 10, section 4.19.6. | X | | | X | | | | | | |
| 7350.6.10 | For revalidating home health agencies (HHAs), the contractor shall conduct a site visit of the HHA prior to making a final decision regarding the revalidation application. | X | | X | | X | | | | | |
| 7350.6.11 | For revalidating suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) – and to the extent that a site visit is not currently required - the contractor shall conduct a site visit of the DMEPOS supplier prior to making a final decision regarding the revalidation application. | | | | | | | | | | NSC |
| 7350.7 | For providers and suppliers in the “high” level of categorical screening, the contractor shall: (1) process initial, revalidation, and new location applications in accordance with existing instructions; and (2) perform a site visit to the extent that this is not already required by CMS. (If a site visit is currently required, the contractor shall continue this activity in accordance with existing instructions.) | X | | X | X | X | | | | | NSC |
| 7350.8 | Changes of information (including additions of practice locations) submitted by providers and suppliers in the “limited” level of categorical screening shall be processed in accordance with | X | | X | X | X | | | | | NSC |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|-----------|--|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
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| | existing instructions. | | | | | | | | | | |
| 7350.9 | With the exception of DMEPOS suppliers, if a provider or supplier in the "moderate" level of categorical screening submits a Form CMS-855 request to add a practice location (including an HHA branch), the contractor shall: (1) process the application in accordance with existing instructions, and (2) conduct a site visit in accordance with Publication 100-08, Chapter 15, sections 19.2 through 19.2.5. | X | | X | X | X | | | | | |
| 7350.10 | With the exception of DMEPOS suppliers and HHAs, if a provider or supplier in the "moderate" level of categorical screening undergoes a change of ownership resulting in a new tax identification number (TIN), the contractor shall: (1) process the application in accordance with existing instructions, and (2) conduct a site visit in accordance with Publication 100-08, Chapter 15, sections 19.2 through 19.2.5. | X | | X | X | | | | | | |
| 7350.10.1 | For ownership changes described in business requirement 7350.10 that must be approved by the regional office under current CMS instructions, the contractor shall perform the site visit after it receives the tie-in notice from the regional office but before the contractor activates the new owner's billing privileges. | X | | X | X | X | | | | | |
| 7350.10.2 | For ownership changes described in business requirement 7350.10 that do not require regional office approval under current CMS instructions, the contractor shall perform the site visit prior to making its final decision regarding the application. | X | | X | X | X | | | | | |
| 7350.10.3 | For HHAs undergoing a change in majority ownership, the contractor shall – consistent with Publication 100-08, Chapter 15, section 15.26.1 – | X | | X | | X | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|-----------|---|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| | determine whether the provisions of 42 CFR §424.550(b)(1) and (2) apply. | | | | | | | | | | |
| 7350.10.4 | For HHAs reporting an ownership change that is not a change in majority ownership as that term is defined in §424.502, the contractor shall process the change in accordance with existing instructions. | X | | X | | X | | | | | |
| 7350.10.5 | For HHAs seeking to reactivate their Medicare billing privileges, the contractor shall process the application under the "moderate" level of categorical screening. (A site visit will be necessary prior to the reactivation of the provider's billing privileges.) | X | | X | | X | | | | | |
| 7350.10.6 | Unless specified otherwise in Publication 100-08, Chapter 15, sections 19.2 through 19.2.5, all other changes of information for providers and suppliers in the moderate level of categorical screening shall be processed in accordance with existing instructions. | X | | X | X | X | | | | | NSC |
| 7350.11 | The contractor shall process reactivation applications submitted by providers and suppliers in the "limited" level of categorical screening in accordance with existing instructions. | X | | X | X | X | | | | | NSC |
| 7350.11.1 | The contractor shall process reactivation applications submitted by providers and suppliers in the "moderate" level of categorical screening (including existing DMEPOS suppliers and HHAs) in accordance with the screening procedures for this category. (A site visit will therefore be necessary prior to the contractor's final decision regarding the application.) | X | | X | X | X | | | | | NSC |
| 7350.11.2 | The contractor shall process reactivation applications submitted by providers and suppliers in the "high" level of categorical screening in accordance with the screening procedures for this category. (A site visit will therefore be necessary prior to the contractor's final decision regarding the application.) | X | | X | X | X | | | | | NSC |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|-----------|---|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| 7350.12 | Upon receipt of an initial, revalidation, or new location application from a provider or supplier that otherwise falls within the limited or moderate screening category (and after the appropriate fee has been paid, etc.), the contractor shall determine whether the provider or supplier is on the bi-monthly "high" screening list described in Publication 100-08, Chapter 15, section 19.4. | X | | X | X | X | | | | | NSC |
| 7350.12.1 | If the provider is on the bi-monthly "high" screening list, the contractor shall process the application using the procedures in the "high" screening category. | X | | X | X | X | | | | | NSC |
| 7350.12.2 | If the provider is not on the bi-monthly "high" screening list, the contractor shall process the application in accordance with existing instructions. | X | | X | X | X | | | | | NSC |
| 7350.13 | If the contractor receives an initial or new location application from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the procedures in the "high" screening category. | X | | X | X | X | | | | | NSC |
| 7350.14 | As a moratorium will not apply to an application for which an approval or a recommendation for approval has been made as of the effective date of the moratorium (even if the contractor has not yet formally granted Medicare billing privileges), the application can continue to be processed to completion. | X | | X | X | X | | | | | NSC |
| 7350.15 | As a moratorium will apply to an application that is pending as of the effective date of the moratorium and for which the contractor has not yet made a final approval/denial decision or recommendation for approval, the contractor shall deny said application, using CFR §424.535(a)(10) as the basis. | X | | X | X | X | | | | | NSC |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---------|---|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| 7350.16 | As a moratorium will apply to an application that the contractor receives on or after the effective date of the moratorium, the contractor shall deny said applications, using CFR §424.535(a)(10) as the basis. | X | | X | X | X | | | | | NSC |
| 7350.17 | The contractor shall submit the data referred to in Publication 100-08, Chapter 15, section 19.4 to its Provider Enrollment Operations Group liaison no later than the 15 th day of each month, with the first report due on May 15, 2011. | X | | X | X | X | | | | | NSC |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---------|--|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-----------|
| | | A / B | D M E | F I | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTH ER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| 7350.18 | A provider education article related to this instruction will be available at http://www.cms.hhs.gov/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 site 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 your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community | X | | X | X | X | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | |
|--------|--|---|-------------|--------|---------------------------------|-------------|------------------------------|-------------|-------------|-------------|
| | | A / B | D M E | F I | C A R R I E R | R H I | Shared-System Maintainers | | | |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F |
| | in billing and administering the Medicare program correctly. | | | | | | | | | |

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|--|
| | |

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

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

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

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

Funding for implementation activities will be provided to contractors through the regular budget process.

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 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.

Medicare Program Integrity Manual

Chapter 15 - Medicare Enrollment

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(Rev.371, 03-23-11)

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15.19.1 – Application Fees

(Rev.371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

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, 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. Note that 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 in which the application is submitted. The fee for March 25, 2011 through December 31, 2011 is \$505.00. 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 [Pay.gov](https://www.pay.gov), either via credit card, debit card, or check. Note that CMS will send to the contractor on a regular basis a listing of providers and suppliers (the "Fee Submitter List") that have paid an application fee via [Pay.gov](https://www.pay.gov).

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 for Calendar Year 2011 is \$505 and 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 (PEOG) liaison. 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.

Note that 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 liaison. 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. The contractor can verify payment of the application fee by checking:

- Whether the provider has included with its application or certification statement a Pay.gov receipt as proof of payment, and/or*
- The Fee Submitter List*

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 review each updated Fee Submitter List to 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).

Note that 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 liaison. 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 review each updated Fee Submitter List to determine if the fee has been submitted via [Pay.gov](https://www.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](https://www.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 liaison. 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. 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
Provider Enrollment Operations Group
7111 Security Boulevard
Baltimore, MD 21244*

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.

- a. 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.**

Note that 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.

F. 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. 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*

15.19.2 – Screening Categories

(Rev.371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

15.19.2.1 – Background

(Rev.371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

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.

The contractor shall utilize the screening procedures outlined below for applications it receives on or after March 25, 2011.

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*
- *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 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 (PXRSSs)*
- *Revalidating home health agencies (HHAs)*
- *Revalidating DMEPOS suppliers*

For providers and suppliers in the “moderate” level of categorical screening, the contractor shall (unless section 19.2.2 of this Chapter applies):

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

- *Perform a site visit in accordance with the following:*
 - *Ambulance suppliers, independent clinical laboratories, physical therapists, and physical therapist groups* – *The contractor shall conduct a site visit prior to the contractor’s final decision regarding the application.*
 - *CMHCs*
 - *Initial applications - In addition to the site visit that is currently performed, the contractor shall conduct another site visit after receiving the tie-in notice from the regional office 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.*
 - *Revalidations – The contractor shall conduct a site visit prior to making a final decision regarding the revalidation application.*
 - *New location – The contractor shall conduct a site visit of the new location prior to making a recommendation for approval.*
 - *CORFs, hospices and PXRSSs* -
 - *Initial applications - The contractor shall conduct a site visit after receiving the tie-in notice from the regional office but before the contractor conveys Medicare billing privileges to the provider. This is to ensure that the provider is still in compliance with CMS’s enrollment requirements.*
 - *Revalidations – The contractor shall conduct a site visit prior to making a final decision regarding the revalidation application.*
 - *New location – The contractor shall conduct a site visit of the new location prior to making a recommendation for approval.*
 - *IDTFs*
 - *Initial applications – The contractor shall conduct site visits of initially enrolling IDTFs in accordance with Pub. 100-08, Chapter 10, section 4.19.6.*
 - *Revalidations - The contractor shall conduct site visits of revalidating IDTFs (prior to making a final decision regarding the revalidation application) in accordance with Pub. 100-08, Chapter 10, section 4.19.6.*
 - *Revalidating HHAs* – *The contractor shall conduct a site visit of the HHA prior to making a final decision regarding the revalidation application.*

- *Revalidating DMEPOS suppliers – The contractor 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*

For providers and suppliers in the “high” level of categorical screening, the contractor shall:

- *Process initial, revalidation, and new location applications in accordance with existing instructions; and*
- *Perform a site visit to the extent that this is not already required by CMS. If a site visit is currently required, the contractor shall continue this activity in accordance with existing instructions.*

(NOTE: Enrolled DMEPOS suppliers that are adding another location will be classified as “high” for screening purposes. In addition, newly-enrolling HHA sub-units fall within the “high” level of categorical screening.)

See section 19.2.3 below for information regarding DMEPOS changes of ownership and TIN changes.

15.19.2.2 - Scope of Site Visit

(Rev.371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

A. DMEPOS Suppliers and IDTFs

As stated above, site visits of DMEPOS suppliers and IDTFs shall continue to be conducted in accordance with existing CMS instructions and guidance.

B. Other Provider and Supplier Types

For all provider and supplier types – other than DMEPOS suppliers and IDTFs – that are subject to a site visit in accordance with this section, the contractor shall perform such visits using the procedures outlined in sections 20 and 20.1 of this Chapter. This includes the following:

- *Documenting the date and time of the visit, and including the name of the individual attempting the visit;*

- *Photographing the provider or supplier's business for inclusion in the provider/supplier's file. All photographs should be date/time stamped;*
- *Fully documenting observations made at the facility, which could include facts such as: (a) the facility was vacant and free of all furniture; (b) a notice of eviction or similar documentation is posted at the facility, and (c) the space is now occupied by another company;*
- *Writing a report of the findings regarding each site verification; and*
- *Including a signed declaration stating the facts and verifying the completion of the site verification. (The sample declaration identified in section 20.1 of this Chapter is recommended.)*

In terms of the extent of the visit, the contractor shall determine whether the following criteria are met:

- *The facility is open*
- *Personnel are at the facility*
- *Customers are at the facility (if applicable to that provider or supplier type)*
- *The facility appears to be operational*

This will require the site visitor(s) to enter the provider or supplier's practice location/site, rather than simply conducting an external review.

If any of the 4 elements listed above are not met, the contractor shall, as applicable - and using the procedures outlined in Pub. 100-08, Chapters 10 and 15 - deny the provider's enrollment application pursuant to §424.530(a)(5)(i) or (ii), or revoke the provider's Medicare billing privileges under §424.535(a)(5)(i) or (ii).

15.19.2.3 – Changes of Information

(Rev.371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

1. Limited

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

2. Moderate

a. Addition of Practice Location

With the exception of DMEPOS suppliers, if a provider or supplier in the “moderate” level of categorical screening submits a Form CMS-855 request to add a practice location (including an HHA branch), the contractor shall: (1) process the application in accordance with existing instructions, and (2) conduct a site visit in accordance with the instructions in section 19.2.1(B) above.

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

b. Change of Ownership

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

(1) Process the application in accordance with existing instructions, and

(2) Conduct a site visit in accordance with the following:

- For ownership changes that must be approved by the regional office under current CMS instructions, the site visit shall be performed after the contractor receives the tie-in notice from the regional office but before the contractor activates the new owner’s billing privileges.*
- For ownership changes that do not require regional office approval under current CMS instructions, the site visit shall be performed prior to the contractor’s final decision regarding the application.*

A DMEPOS supplier that is:

- Undergoing a change of ownership with a change in TIN falls within the “high” screening category.*
- Undergoing a change of ownership with no change in TIN falls within the “moderate” screening category.*
- Undergoing a change in TIN with no change in ownership falls within the “moderate” screening category.*

With respect to HHAs:

- *For HHAs undergoing a change in majority ownership, the contractor shall – consistent with section 15.26.1 of this Chapter – determine whether the provisions of 42 CFR §424.550(b)(1) and (2) apply. If the contractor determines that a change in majority ownership has occurred and that none of the exceptions in §424.550(b)(2) apply, the HHA must enroll as a new entity, in which case the newly-enrolling HHA will be placed into the “high” level of categorical screening. If the contractor determines that an exception does apply, the transaction will be subject to the “moderate” level of categorical screening; a site visit will be necessary.*
- *For HHAs reporting an ownership change that is not a change in majority ownership as that term is defined in §424.502, the contractor shall process the change in accordance with existing instructions. A site visit is not necessary.*
- *For HHAs seeking to reactivate their Medicare billing privileges, the transaction shall be processed under the “moderate” level of categorical screening. A site visit will be necessary prior to the reactivation of the provider’s billing privileges.*

c. All Other Changes of Information

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

3. High

Unless otherwise specified in sections 19.2.1 through 19.2.5, no changes of information will be subject to the “high” level of categorical screening.

15.19.2.4 – Reactivations

(Rev.371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

A. Limited

Reactivation applications submitted by providers and suppliers in the “limited” level of categorical screening shall be processed in accordance with existing instructions.

B. Moderate

Reactivation applications submitted by providers and suppliers in the “moderate” level of categorical screening – including existing DMEPOS suppliers and HHAs – shall be processed in accordance with the screening procedures for this category. A site visit will therefore be necessary prior to the contractor’s final decision regarding the application.

C. High

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

15.19.2.5 – Movement of Providers and Suppliers into the High Level (Rev.371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

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

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

CMS intends to send to the contractor on a bi-monthly basis a list of current and former Medicare providers and suppliers within the contractor’s jurisdiction that meet any of the criteria in subsection (1) or (2) above. Upon receipt of an initial, revalidation, or new location

application from a provider or supplier that otherwise falls within the limited or moderate screening category (and after the appropriate fee has been paid, etc.), the contractor shall determine whether the provider or supplier is on the bi-monthly “high” screening list. If the provider or supplier is, the contractor shall process the application using the procedures in the “high” screening category. If the provider or supplier is not on said list, the contractor shall process the application in accordance with existing instructions

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

15.19.3 – Temporary Moratoria

(Rev.371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

Under §424.570(a), CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. In general, a moratorium will not apply to:

- Reactivations*
- Revalidations*
- A change in practice location*
- A change of ownership (with the exception of situations in which an HHA must enroll as a new HHA in accordance with 42 CFR §424.550(b), in which case the new application is treated as an initial enrollment and is therefore subject to the moratorium)*
- Any other change in the provider or supplier’s enrollment information*

The announcement of a moratorium will be made via the Federal Register, though the contractor will also be separately notified of the moratorium. For initial and new location applications involving the affected provider and supplier type, the moratorium:

- Will not apply to applications for which an approval or a recommendation for approval has been made as of the effective date of the moratorium, even if the contractor has not yet formally granted Medicare billing privileges. Such applications can continue to be processed to completion.*
- Will apply to applications that are pending as of the effective date of the moratorium and for which the contractor has not yet made a final approval/denial decision or recommendation for approval. The contractor shall deny such applications, using §424.535(a)(10) as the basis.*
- Will apply to applications that the contractor receives on or after the effective date of the moratorium, and for as long as the moratorium is in effect. The contractor shall deny such applications, using §424.535(a)(10) as the basis.*

If a particular moratorium is lifted, all applications pending with the contractor as of the effective date of the moratorium's cessation are no longer subject to the moratorium and may be processed. However, consistent with §424.518(a)(3), such applications shall be processed in accordance with the "high" level of categorical screening. In addition, any initial application received from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the "high" level of categorical screening.

15.19.4 – Tracking

(Rev.371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

In April 2011, PEOG will send to each contractor an Excel spreadsheet that the contractor shall complete and submit to its PEOG liaison via e-mail no later than the 15th day of each month. The first report will be due on May 15, 2011. The spreadsheet will contain data elements such as, but not limited to:

- Number of enrolled providers and suppliers in each risk category, broken down by provider/supplier sub-type (e.g., hospital, HHA)*
- Amount of fees collected (i.e., fees that were cleared), broken down by provider and supplier type*