CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12852	**Date: September 27, 2024**
	Change Request 13765

SUBJECT: Fifteenth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to address several provider enrollment topics. These include, but are not limited to -- (1) Stays of enrollment; and (2) Certified provider changes of information.

EFFECTIVE DATE: November 7, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: November 7, 2024

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/10.2/10.2.2.4/Independent Diagnostic Testing Facilities (IDTFs)
R	10/10.4/10.4.9/Stay of Enrollment
R	10/10.6/10.6.1.1.3.2/Step 2 – Post-Initial Review Actions and Scenarios
R	10/10.6/10.6.1.2/Changes of Information – Transitioned Certified Providers and Suppliers
R	10/10.7/10.7.20/Stay of Enrollment Letters

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

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

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II. GENERAL INFORMATION

A. Background: The purpose of this CR is to address several provider enrollment topics. These include but are not limited to -- (1) Stays of enrollment; and (2) Certified provider changes of information.

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

III. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13765.1	The contractor shall observe and adhere to the applicable policy changes outlined in this CR.	X	X	X						NPEAST, NPWEST

IV. PROVIDER EDUCATION TABLE

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

V. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

VI. CONTACTS

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

VII. FUNDING

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

ATTACHMENTS: 0

Medicare Program Integrity Manual
Chapter 10 – Medicare Enrollment

Table of Contents
(Rev. 12852; Issued: 09-27-24)

10.2.2.4 – Independent Diagnostic Testing Facilities (IDTFs)

(Rev. 12852; Issued: 09-27-24; Effective: 11-07-24; Implementation: 11-07-24)

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

A. Introduction

1. General Background

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

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

2. Place of IDTF Service

i. "Indirect IDTFs" – Background

IDTFs generally perform diagnostic tests on beneficiaries in, for instance, a health care facility, physician's office, or mobile setting. The IDTF standards at § 410.33(g) (as well as other provisions in § 410.33) were, in fact, designed for traditional IDTF suppliers that engage in direct or in-person beneficiary interaction, treatment, and/or testing. Yet some health care entities have developed or utilize diagnostic tests that do not require such interaction (hereafter occasionally referenced as "indirect IDTFs"). That is, certain IDTFs perform diagnostic services via computer modeling and analytics, or other forms of testing not involving direct beneficiary interaction. The service is often conducted by a technician who undertakes a computer analysis offsite or at another location at which the patient is not present. The physician then reviews the image to determine the appropriate course of action. In short, these entities generally, though not exclusively, have two overriding characteristics. First, the tests they perform do not involve direct patient interaction, meaning that the test is conducted away from the patient's physical presence and is non-invasive. Second, the test involves off-site computer modeling and analytics.

Despite the comparatively new and innovative forms of testing these entities undertake, they can still qualify as IDTFs (notwithstanding the offsite and indirect nature of the test) so long as they meet the applicable requirements of § 410.33. In the past, however, these entities have often been unable to meet certain IDTF requirements (and thus cannot enroll in Medicare) strictly because of the test's indirect nature. In other words, the types of tests at issue do not fall within the category of those to which several of the standards in § 410.33 were intended to apply (specifically, to in-person procedures).

ii. "Indirect IDTFs" – General Description, Exemptions, and Verification

To account for such technological advances in diagnostic testing, we revised § 410.33 in the CY 2022 Physician Fee Schedule final rule such that **IDTFs that have no beneficiary interaction, treatment, or testing whatsoever at their practice location are wholly exempt from the following requirements in § 410.33(g).**

- § 410.33(g)(6)) - The IDTF must have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF.

- § 410.33(g)(8)) - The IDTF must answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF.

- § 410.33(g)(9)) - The IDTF must openly post the standards outlined in § 410.33(g) for review by patients and the public.

In addition. 42 CFR § 410.33(c) previously stated in full: "Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met." This requirement (now codified in § 410.33(c)(1)) remains intact for IDTFs that perform direct, in-person testing. For indirect IDTFs, however, new § 410.33(c)(2) states that---for services that do not require direct or in-person beneficiary interaction, treatment, or testing---any nonphysician personnel performing the test must meet all applicable state licensure requirements for doing so; if such state licensure requirements exist, the IDTF must maintain documentation available for review that these requirements have been met. If no state licensure requirements for such personnel exist, the contractor need not undertake additional verification activities under § 410.33(c)(2) concerning the technician in question; the contractor shall not establish its own additional certification, credentialing, or similar technician requirements (e.g., federal accreditation) above and beyond the requirements in § 410.33(c)(2).

The only complete or partial exemptions in § 410.33 that apply to indirect IDTFs are those described in this subsection (A)(2) (i.e., § 410.33(c)(2), (g)(6), (g)(8), and (g)(9)).

iii. Synopsis

In sum:

(A) IDTFs that perform direct, in-person testing on beneficiaries must still meet all requirements and standards in 42 CFR § 410.33. Also, the personnel performing these tests must comply with the requirements in § 410.33(c)(1).

(B) Indirect IDTFs need not meet the standards in § 410.33(g)(6), (g)(8), and (g)(9). The personnel performing these tests must comply with the requirements in § 410.33(c)(2) rather than § 410.33(c)(1).

(C) If an IDTF performs both direct and indirect tests:

- It must meet the standards in § 410.33(g)(6), (g)(8), and (g)(9). **An IDTF must exclusively and only perform tests involving no beneficiary interaction, treatment, or testing to be exempt from § 410.33(g)(6), (g)(8), and (g)(9). Thus, even if the overwhelming majority of the IDTF's tests are those described in the previous sentence, the above-mentioned exemptions are inapplicable if the IDTF conducts any tests requiring direct, in-person patient interaction.**

- Personnel performing direct patient interaction tests must meet the requirements of § 410.33(c)(1). Personnel conducting indirect, non-person tests must meet the requirements of § 410.33(c)(2). If a particular technician at an IDTF performs both categories of tests, he or she must meet § 410.33(c)(1)'s requirements for the direct, in-person tests and § 410.33(c)(2)'s requirements for the indirect, non-in-person tests.

(D) The contractor will typically be able to determine during application processing whether the IDTF is an "indirect IDTF." This can be done via, for instance, reviewing: (1) the site

visit results; or (2) the tests reported in Attachment 2 of the Form CMS-855B. In this matter, the contractor shall abide by the following:

- Unless there is evidence that the IDTF only performs indirect tests, the contractor may assume that the supplier is not an "indirect IDTF."
- If the contractor determines that the IDTF performs both indirect and direct tests, it shall follow the instructions described in this subsection (A)(2).

Note that the contractor is not required to submit all potential indirect IDTF applications to PEOG for review or prior approval. The contractor need only contact its PEOG BFL if it: (1) is truly unsure if an indirect IDTF situation is involved; or (2) does not believe the supplier is an indirect IDTF but the supplier states that it is.

B. IDTF Standards

Consistent with 42 CFR § 410.33(g)—and excluding § 410.33(g)(6), (g)(8), and (g)(9) for indirect IDTFs---each IDTF must certify on its Form CMS-855B enrollment application that it meets the following standards and all other requirements:

1. Operates its business in compliance with all applicable federal and state licensure and regulatory requirements for the health and safety of patients (§ 410.33(g)(1)).

- The purpose of this standard is to ensure that suppliers are licensed in the business and specialties being provided to Medicare beneficiaries. Licenses are required by state and/or federal agencies to make certain that guidelines and regulations are being followed and to ensure that businesses are furnishing quality services to Medicare beneficiaries.

- The responsibility for determining what licenses are required to operate a supplier's business is the sole responsibility of the supplier. The contractor is not responsible for notifying any supplier of what licenses are required or that any changes have occurred in the licensure requirements. No exemptions to applicable state licensing requirements are permitted, except when granted by the state.

- The contractor shall not grant billing privileges to any business not appropriately licensed as required by the appropriate state or federal agency. If a supplier is found providing services for which it is not properly licensed, billing privileges may be revoked and appropriate recoupment actions taken.

2. Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and final adverse actions must be reported to the contractor within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days (§ 410.33(g)(2)).

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

3. Maintain a physical facility on an appropriate site. (For purposes of this standard, a post office box, commercial mailbox, hotel, or motel is not an appropriate site. The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.) (§410.33(g)(3)).

- IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.

- The requirements in 42 CFR § 410.33(g)(3) take precedence over the guidelines in section 10.3.1(B)(1)(d) of this chapter pertaining to the supplier's practice location requirements.

- The physical location must have an address, including the suite identifier, which is recognized by the United States Postal Service (USPS).

4. Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—

(i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;

(ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request; and

(iii) Maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers, and provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days. (§ 410.33(g)(4)).

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

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

(ii) Telephone or toll-free telephone numbers available in a local directory and through directory assistance. (§ 410.33(g)(5)).

The requirements in 42 CFR § 410.33(g)(5) take precedence over the guidelines in section 10.3.1(B)(1)(d) of this chapter regarding the supplier's telephone requirements.

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

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

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

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations. (§ 410.33(g)(6))

7. Agree not to directly solicit patients; this includes - but is not limited to - a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients

referred for diagnostic testing by an attending physician who: (a) is furnishing a consultation or treating a beneficiary for a specific medical problem; and (2) uses the results in the management of the beneficiary's specific medical problem. Non-physician practitioners may order tests as set forth in § 410.32(a)(3). (§ 410.33(g)(7))

- By the signature of the authorized official in Section 15 of the Form CMS-855B, the IDTF agrees to comply with 42 CFR § 410.33(g)(7).

- The supplier is prohibited from directly contacting any individual beneficiary for the purpose of soliciting business for the IDTF. This includes contacting the individual beneficiary by telephone or via door-to-door sales.

- There is no prohibition on television, radio, or Internet advertisements, mass mailings, or similar efforts to attract potential clients to an IDTF.

8. Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF. (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) The date the complaint was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision. (§ 410.33(g)(8))

9. Openly post these standards for review by patients and the public. (§ 410.33(g)(9))

10. Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change. (§ 410.33(g)(10))

11. Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers' suggested maintenance and calibration standards. (§ 410.33(g)(11))

12. Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable federal or state licenses or certifications of the individuals performing these services. (§ 410.33(g)(12))

13. Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days. (§ 410.33(g)(13))

14. Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must---

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours. (§ 410.33(g)(14))

15. With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

(i) Sharing a practice location with another Medicare-enrolled individual or organization;

(ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or

(iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. (§ 410.33(g)(15))

16. Enrolls in Medicare for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed-base location. (§ 410.33(g)(16))

17. Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act (§ 410.33(g)(17)) (Section 1861(w)(1) states that the term "arrangements" is limited to arrangements under which receipt of payments by the hospital, critical access hospital, skilled nursing facility, home health agency or hospice program (whether in its own right or as an agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.)

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

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

C. Leasing and Staffing

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

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

D. Sharing of Space and Equipment

As previously noted, the standard in § 410.33(g)(15) states that, with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF cannot: (i) share a practice location with another Medicare-enrolled individual or organization; (ii) lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization; or (iii) share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

If the contractor determines that an IDTF is violating at least one of the three prohibitions in § 410.33(g)(15), the contractor shall revoke the supplier's Medicare billing privileges.

E. Multi-State IDTFs

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

a. Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the states in which it operates; and

b. Operate in compliance with all applicable federal, state, and local licensure and regulatory requirements with regard to the health and safety of patients.

Under § 410.33(e)(2), the point of the actual delivery of service means the place of service on the claim form. When the IDTF performs or administers an entire diagnostic test at the beneficiary's location, the beneficiary's location is the place of service. When one or more aspects of the diagnostic testing are performed at the IDTF, the IDTF is the place of service.

F. One Enrollment per Practice Location

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

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

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

G. Interpreting Physicians

1. Reporting Interpreting Physicians on the Form CMS-855B

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

The contractor shall ensure and document that:

- All listed physicians are enrolled in Medicare

- All interpreting physicians who are reassigning their benefits to the IDTF have the right to do so

- The interpreting physicians listed are qualified to interpret the types of tests (codes) listed. (The contractor may need to contact another contractor to obtain this information.) If the applicant does not list any interpreting physicians, the contractor need not request additional information because the applicant may not be billing for the interpretations; that is, the physicians may be billing for the interpretation themselves.

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

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

2. Changes of Interpreting Physicians

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

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

H. Effective Date of IDTF Billing Privileges

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

(1) The filing date of the Medicare enrollment application that was subsequently approved by the contractor; or

(2) The date the IDTF first started furnishing services at its new practice location.

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

The contractor shall note that if it rejects an IDTF application under 42 CFR § 424.525 and a new application is later submitted, the date of filing is the date the contractor receives the new enrollment application.

If an IDTF undergoes an ownership change that results in a new enrollment (e.g., a new federal tax information number (TIN) results from this change), the contractor should use the transfer of ownership/business date as indicated by the IDTF, instead of establishing a new effective date.

I. IDTF Technicians Must Be Listed on the Form CMS-855B

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

J. IDTF Technician Licensure and Certification Requirements

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

In lieu of requiring a copy of the technician's certification card, the contractor may validate a technician's credentials online via organizations such as the American Registry for Diagnostic Medical Sonography (ARDMS), the American Registry of Radiology Technologists (ARRT), and the Nuclear Medicine Technology Certification Board (NMTCB). If online verification is not available or cannot be made, the contractor shall request a copy of the technician's certification card.

K. IDTF - Changes of Technicians

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

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

L. IDTF Supervising Physicians – General Principles

An IDTF must have one or more supervising physicians who are responsible for:

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

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

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

M. IDTF - Information about Supervising Physicians

The contractor shall ensure and document in PECOS that each supervising physician is: (1) licensed to practice in the state(s) where the diagnostic tests he or she supervises will be performed; (2) Medicare-enrolled; and (3) not currently excluded or debarred. The physician(s) need not necessarily be Medicare-enrolled in the state where the IDTF is

enrolled; moreover, the physician need not be furnishing medical services outside of his/her role as a supervising physician (i.e., he/she need not have his/her own medical practice separate from the IDTF). If the physician is enrolled in another state or with another contractor, however, the contractor shall ensure that he or she is appropriately licensed in that state.

In addition:

- Each physician of the group who actually performs an IDTF supervisory function must be listed.

- If a supervising physician has been recently added or changed, the updated information must be reported via a Form CMS-855B change request. The new physician must have met all of the supervising physician requirements at the time any tests were performed.

- If the contractor knows that a reported supervising physician has been listed with several other IDTFs, the contractor shall check with the physician to determine whether he or she is still acting as supervising physician for these other IDTFs.

- If the supervising physician is enrolling in Medicare and does not intend to perform medical services outside of his/her role as a supervising physician: (1) the contractor shall still send the physician an approval letter (assuming successful enrollment) and issue a PTAN; (2) the physician shall list the IDTF's address as a practice location; and (3) the space-sharing prohibition in 42 CFR § 410.33(g) does not apply in this particular scenario.

N. IDTF - General, Direct, and Personal Supervision

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

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

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

O. IDTF - Attestation Statement for Supervising Physicians

A separate attestation statement must be completed and signed by each supervising physician listed. If Question E2 is not completed, the contractor may assume – unless it has reason to suspect otherwise - that the supervising physician in question supervises for all codes listed in Section 2 of the IDTF attachment. If Question E2 is completed, the contractor shall ensure that all codes listed in Section 2 are covered through the use of multiple supervising physicians.

The contractor no longer needs to contact each supervisory physician *by telephone or otherwise* to verify that the physician: (1) actually exists (e.g., is not using a false or inactive physician number); (2) indeed signed the attestation; and (3) is aware of his or her responsibilities.

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

P. IDTF - Changes of Supervising Physicians

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

If the contractor receives notification from a supervising physician that he/she is no longer supervising tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B change of information. If the IDTF did not have another supervising physician listed on the current application, the IDTF must submit a change of information adding a new supervising physician. If the IDTF does not provide this information, the contractor shall proceed with non-compliance revocation procedures as noted in section 10.4(M) of this chapter.

Q. Desk and Site Reviews

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

- The information listed on Attachment 2 of the Form CMS-855B is correct, verifiable, and in accordance with all IDTF regulatory and enrollment requirements.

- To the extent applicable, the IDTF meets the criteria outlined in sections 10.6.20(A) and 10.6.20(B) of this chapter.

- The IDTF meets the supplier standards in 42 CFR § 410.33.

The contractor shall order the site visit through PECOS. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

R. Mobile Units

Mobile units must list their geographic service areas in Section 4 of the Form CMS-855B. Based on the information furnished therein, the NSVC will generally perform the site visit via one of the following methods: (1) the mobile unit visits the office of the NSVC (or some other agreed-to location) for inspection; (2) the NSVC visits the mobile unit's base of operations to inspect the unit; or (3) the NSVC obtains an advance schedule of the locations at which the IDTF will be performing services and conducts the site visit at one of those locations.

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

- How they will perform these types of supervision on a mobile basis;

- What their responsibilities are; and

- That a patient's physician who is performing direct or personal supervision for the IDTF on their patient should be aware of the prohibition concerning physician self-referral for

testing (in particular, this concerns potentially illegal compensation to the supervisory physician from the IDTF).

S. Addition of Codes

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

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

If the enrolled IDTF (1) originally listed only general supervision codes, (2) was only reviewed for general supervision tests, and (3) now wants to perform tests that require direct or personal supervision, the contractor shall promptly suspend all payments for all codes other than those requiring general supervision. The contractor shall order an NSVC site visit through PECOS. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment); and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

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

T. IDTF That Performs Diagnostic Mammography

If an IDTF performs diagnostic mammography services, it must have a Food and Drug Administration certification to perform the mammography. However, an entity that only performs diagnostic mammography services should not be enrolled as an IDTF. Rather, it should be separately enrolled as a mammography screening center.

U. IDTF Ownership of CLIA Laboratory

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

V. Denials and Revocations for Non-Compliance with IDTF Supplier Standards

Pursuant to 42 CFR §§ 424.530(a)(1)/(18) and 424.535(a)(1)/(23), an IDTF's enrollment may be denied or revoked if it violates any applicable standard in § 410.33(g). The contractor shall abide by the following in such situations:

1. (a)(1) – Prior approval unnecessary

For violations of any of the following supplier standards in § 410.33(g), the contractor shall deny or revoke enrollment under, respectively, §§ 424.530(a)(1) or 424.535(a)(1). Prior

PEOG approval is unnecessary. Corrective action plan (CAP) rights under §§ 424.530(a)(1) or 424.535(a)(1) apply.

- § 410.33(g)(1) through (g)(6) as well as (g)(8) through (17).

2. (a)(1) and (a)(23) – Prior approval unnecessary

For violations of the following supplier standard in § 410.33(g), the contractor shall deny or revoke enrollment under, respectively, §§ 424.530(a)(1) or 424.535(a)(23). Prior PEOG approval is unnecessary. CAP rights under §§ 424.530(a)(1) apply but no CAP rights apply for § 424.535(a)(23) revocations.

- § 410.33(g)(7)

10.4.9 – Stay of Enrollment

(Rev. 12852; Issued: 09-27-24; Effective: 11-07-24; Implementation: 11-07-24)

(In the event of any inconsistency between the instructions in this section 10.4.9 and other instructions in chapter 10, the 10.4.9 instructions take precedence if a stay of enrollment situation is involved.)

A. Background

In the Calendar Year 2024 Physician Fee Schedule final rule (CMS-1784-F), CMS established a new provider enrollment status in 42 CFR § 424.541 labeled a "stay of enrollment." The purpose was to create a CMS action that would be less burdensome on providers/suppliers (hereafter collectively "provider," except as otherwise noted) than a deactivation or revocation. It represents a middle ground between (1) a deactivation and (2) non-action on CMS' part. It gives CMS greater flexibility to take appropriate, fair, and reasonable measures commensurate with the degree of the provider's non-compliance.

A stay of enrollment (or simply "stay") is a preliminary, interim status---prior to any subsequent deactivation or revocation---that would represent, in a sense, a "pause" in enrollment, during which the provider would nonetheless remain enrolled in Medicare. In this vein, CMS would neither formally nor informally treat the stay as a sanction or adverse action for purposes of Medicare enrollment.

Unless CMS explicitly instructs the contractor to do so (such as per section 10.4.9(D) below), the contractor shall not: (i) initiate or impose a stay; or (ii) refer a potential stay case to PEOG if the contractor believes a certain situation it has encountered may warrant one.

B. Regulatory Requirements for Imposition -- Two-Step Test under § 424.541(a)(1)

As outlined in § 424.541(a)(1)(i) and (ii), there are two requirements for a stay's implementation. Specifically, the provider:

- Is non-compliant with at least one enrollment requirement in Title 42; **and**

- Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS-855, Form CMS-20134, or Form CMS-588 change of information or revalidation application (hereafter occasionally and collectively referenced as "the applicable CMS form" or "ACF".)

Examples of how this bright-line, two-pronged test would be met include:

- A provider failed to timely report a change in its address from 10 Smith Street to 20 Smith Street.
- A supplier did not respond to a revalidation request.
- A DMEPOS supplier did not report the deletion of a managing employee.
- A physician did not timely report a change in his/her practice location's zip code.
- An MDPP supplier failed to timely report a change in the address of an organizational owner.
- An IDTF failed to comply with a supplier standard in § 410.33(g) but compliance can be reached by submitting an ACF.

In these illustrations, the provider failed to adhere to a reporting, revalidation, or supplier standard requirement in Title 42 (the first prong of the § 424.541(a)(1) test) but could resume compliance by submitting the applicable CMS form (the second prong). (It is important to understand that if the type of non-compliance involved cannot be corrected via the submission of an ACF, a stay cannot be imposed.) These are merely examples, however, and there are many scenarios in which a stay could apply.

Examples of when the stay of enrollment test would not be met include:

- A provider's owner has been convicted of a felony.
- A physician has lost his/her state medical license.

Although the first prong of the § 424.541(a)(1) test --- non-compliance --- has been met in these situations, the provider cannot correct the non-compliance simply by submitting an ACF.

C. Important Facets of a Stay as Outlined in § 424.541

Section 424.541 also contains the following provisions:

1. Enrollment Status (§ 424.541(a)(2)(i)) – As previously mentioned, the provider remains enrolled in Medicare during the stay.

2. Claims (§ 424.541(a)(2)(ii)):

Per § 424.541(a)(2)(ii)(A) – and except as stated in § 424.541(a)(2)(ii)(B) -- claims submitted by the provider with dates of service within the stay period will be rejected.

Under § 424.541(a)(2)(ii)(B), claims submitted by the provider with dates of service within the stay period are eligible for payment (assuming all other requirements for claim payment are met) if:

- CMS or its contractor determines that the provider has resumed compliance with all Medicare enrollment requirements in Title 42 (§ 424.541(a)(2)(ii)(B)(1)); and
- The stay ends before its original expiration date. (To illustrate, suppose CMS imposes a stay period of 30 days. The claims described in § 424.541(a)(2)(ii)(B) would be payable if the provider resumes compliance on or before the 30th day of the stay.)

To reiterate, the requirements of both § 424.541(a)(2)(ii)(B)(1) and (2) must be met for payments to be made pursuant to § 424.541(a)(2)(ii)(B).

3. Maximum Duration of the Stay (§ 424.541(a)(3)) - A stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter, which is the effective date of the stay. **For purposes of this requirement, the postmark date is the date on which the**

letter is mailed. For instance, suppose the letter is mailed on June 1. The stay period commences on June 1, which is also the stay's effective date.

Again, a stay has a maximum length of 60 days and cannot be extended. Note, however, that CMS can impose a stay of less than 60 days. It is not required that each assigned stay period be 60 days.

4. End-Date of the Stay (§ 424.541(a)(5)) – A stay ends on the earlier of the following dates:

- The date on which CMS or its contractor determines that the provider has resumed compliance with all Medicare enrollment requirements in Title 42, OR
- The day after the imposed stay period expires.

For purposes of § 424.541(a)(5) ONLY:

++ **The term "has resumed compliance" means the provider has submitted the ACF that CMS requested the provider to submit in the stay notification letter**. (See section 10.4.9(C)(5)(f) below for more information.) To illustrate, assume a provider receives a stay notification letter on March 1 because the provider had failed to timely report an address change via the Form CMS-855B. The letter requests the provider to submit this ACF. The provider does so on March 10. The stay thus ends on March 10. Note that the contractor need not have begun processing the ACF for a stay to be lifted. Even if the application is later returned, rejected, or denied, the stay ceases on the date the application is submitted.

++ For paper ACFs, the ACF is considered "submitted" on the date the contractor receives the ACF (e.g., in its mailroom).

5. Additional Considerations

a. Adverse Action - A stay is not considered an adverse legal action of any kind.

b. Deactivations and Revocations - **CMS always reserves the right to impose:**

(i) **A deactivation or revocation instead of a stay, even in cases of minor non-compliance. It should not be assumed that a stay will always be the first step in such situations**.

(ii) **A deactivation prior to the expiration of the stay, in which case the deactivation ends the stay**

c. Multiple Stays and Extensions – CMS will neither extend a stay period beyond 60 days nor apply a subsequent stay based on the same non-compliance (e.g., the provider failed to reach compliance within the imposed/assigned stay period (e.g., within 15 days), so CMS immediately applies another stay). Yet CMS may impose a stay multiple times against the provider for separate instances of non-compliance (e.g., one stay in June 2024, another stay in December 2025, and so forth).

d. Timeliness – Normal timeliness standards (as outlined in section 10.5 of this chapter) and processing alternatives (outlined in chapter 10) apply when the contractor is processing the ACF.

e. Applicable Forms and Transactions – As stated in § 424.541(a)(1), the types of ACFs for stay purposes are the Form CMS-855A, Form CMS-855B, Form CMS-855I, Form CMS-855S, Form CMS-20134, Form CMS-855O (though the CMS-855O will not involve claim submissions, retroactive payments, etc.), and Form CMS-588. The applicable transactions are limited to changes of information and revalidations. For purposes of the

stay, however, the term "changes of information" can include, at CMS' discretion, reassignment situations under the Form CMS-855I.

f. Compliance – Except as stated or instructed otherwise by CMS, and strictly and solely for purposes of lifting/ending a stay, compliance under §§ 424.541(a)(2)(ii)(B)(1) and (a)(5) is reached when the provider submits the ACF. **Once the stay expires, though, compliance under Title 42 is only resumed consistent with existing policies (e.g., the contractor approves the change of information).**

g. Ordering/Certifying – A stay has no effect on a physician/practitioner's ability to order/certify/refer/prescribe services, items, or drugs.

h. Stay Periods – Except as instructed otherwise by CMS, all assigned stay periods for revalidation non-responses (see subsection (D)(1) below) will be 30 days (rather than 60 days). For the PEOG-directed stays described in subsection (D)(2) below, PEOG will notify the contractor of the assigned stay period for that specific case.

6. General Stay Process for Revalidations

In general – and subject to the more specific scenarios described in section 10.4.9(D)(1) -- the stay process will work as follows in situations where the provider fails to submit a revalidation application in response to a CMS/contractor revalidation request:

Implementing the Stay - Within 10 days after the expiration of the period in which the provider had to submit the revalidation application, the contractor shall: (a) send to the provider via regular mail the letter identified in section 10.7.20(A); and (b) switch the PECOS status to "Approved – Stay of Enrollment" effective the date the letter is mailed.

Removing the Stay if the Provider Submits the Revalidation Application During the Stay - Within 10 days after the revalidation application is submitted, the contractor shall change the PECOS status to "Approved – Remove Stay of Enrollment."

Failure to Respond During the Allotted Timeframe – Within 10 days of the allotted timeframe described below, the contractor shall deactivate the provider in accordance with CMS directives.

(This also includes the contractor turning on and turning off claim rejection edits as warranted (e.g., implementing the edits when the stay is imposed).)

Note that the above general process will be largely similar in cases where CMS directs the contractor to impose a stay in a specific case, the principal exception being the timeframe for contractor action in certain situations. These cases are addressed in subsections (D)(2)(a) through (D)(2)(c) below.

D. Case Studies

This section 10.4.9(D) contains more detailed scenarios addressing how the stay process will typically operate and the contractor's required activities therein. (Except as otherwise indicated, all days are calendar days.)

1. Non-Response to Revalidation Request

These scenarios assume the provider (Smith Health Care) failed to submit the requested revalidation application within the required revalidation timeframe (RRT) – the last day of which, for purposes of our examples, is February 27.

Scenario A – Revalidation Application Submitted During Stay Period and Is Approved

Step 1 –No later than 10 days after the expiration of the RRT, the contractor shall: (a) send to Smith via regular mail the letter identified in section 10.7.20(A); and (b) switch the PECOS status to "Approved – Stay of Enrollment" effective the date the letter is mailed. Thus, if the letter is mailed March 5, the PECOS status should be changed effective March 5, which will be the effective date of the stay. This means Smith has until April 4 (or 30 days) to submit the revalidation application. Claims for services furnished beginning March 5 to the end of the stay will be rejected except as stated in § 424.541(a)(2)(ii)(B).

(If the contractor receives the revalidation application from Smith after the RRT expires but before it mails the stay notification letter, the contractor can process the application as normal without imposing a stay.)

Step 2 – Smith submits the revalidation application on March 16.

Step 3 – No later than 10 days after the revalidation application is submitted, the contractor shall change the PECOS status to "Approved – Remove Stay of Enrollment" effective on the submission date (March 16 if the application was submitted via PECOS). Claims for services furnished between March 5 and March 16 (i.e., the duration of the stay) are therefore payable.

Step 4 – The contractor processes the revalidation application to approval and takes all standard actions related thereto (e.g., sends approval letter, switches PECOS record to "Approved"). No further action needed.

Scenario B – Revalidation Application Not Submitted at All

Assume that Step 1 is the same as Step 1 in Scenario A.

Step 2 – Smith fails to submit the revalidation application by April 4, the last day of the stay period. The contractor need take no action regarding the lifting of the stay (e.g., notifying the provider of the stay's cessation).

Step 3 – Within 10 days of the April 4 date (i.e., by April 14), the contractor shall: (a) change the PECOS status to "Deactivated" effective the day after the RRT expired (or February 28); and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

Note that the deactivation effective date is retroactive to the date of the non-compliance (again, February 28), or the date by which Smith was required to submit the revalidation application to CMS. This means that even though the stay was lifted effective April 5 and claims furnished on or after that date are thus payable, this will effectively be negated by the retroactive deactivation in a manner akin to how retroactive deactivations currently operate.

Due to the provider's failure to submit the application during the stay period, claims for services furnished during the stay (March 5 – April 4) are not payable.

Scenario C – Revalidation Application Submitted During the Stay but Is Rejected

Assume Steps 1, 2, and 3 are the same as Steps 1, 2, and 3 in Scenario A.

Step 4 – The contractor determines that the revalidation application should be rejected.

Step 5 – The contractor shall:

- Process the rejection consistent with existing procedures.
- Within 10 days of sending the rejection letter, the contractor shall: (a) change the PECOS status to "Deactivated" effective the day after the RRT expired (or February

28); and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

Scenario D – Revalidation Application Not Submitted During the Stay but Is Submitted After the Stay Period Expires

Assume Step 1 is the same as Step 1 in Scenario A. (Note that the stay expired on April 4.)

Step 2 - Smith submits the revalidation application on April 7.
Step 3

Step 3A - If the contractor receives the revalidation application before it mails the deactivation letter (as described in Step 3 of Scenario B), the contractor can process the application as normal without imposing a deactivation.

Step 3B – If the contractor receives the revalidation application after it mails the deactivation letter, it shall process the application as a reactivation application.

Scenario E *- Contractor Imposes Stay for Failure to Submit Requested Revalidation Application and Provider Then Submits COI Rather Than Revalidation. Here, the contractor:*

(i) Shall not remove the stay. This is because the COI is not an ACF --- that is, it does not address the cause of the stay, which is the failure to submit a revalidation application.

(ii) Shall follow the instructions in section 10.4.5.1(C) of Chapter 10 with respect to the COI submission.

(iii) Shall develop for a revalidation application via any written means (e.g., e-mail but not telephone). The provider shall have 30 additional days from the date the contractor received the COI to submit the revalidation application. In no circumstance, however, shall this latter revalidation timeframe exceed 60 days from the effective date of the stay. To illustrate, suppose the stay's effective date is June 1. The contractor receives the COI on July 2 before it proceeds to a deactivation. (See Scenario D of section 10.4.9(D)(1).) The provider has until July 31 (rather than August 1) to submit the revalidation application.

2. PEOG-Directed Stays

The situations in this subsection (D)(2) only apply when PEOG directs the contractor via e-mail to impose a stay. Except as otherwise instructed, the contractor need not notify PEOG that it has imposed the stay, whether the provider submitted the ACF, whether and when a deactivation was imposed, etc.

a. Ownership Discrepancies

PEOG may notify the contractor via e-mail to apply a stay against a particular provider due to incorrect enrollment information pertaining to ownership; the provider must correct this data by submitting an ACF. In such cases, the contractor shall follow the general stay procedures, steps, and scenarios outlined in subsection (D)(1) above except as follows:

- Step 1 of Scenarios A, B, C, and D - Within **5** days of receiving this e-mail, the contractor shall: (a) send to the provider via regular mail the letter identified in section 10.7.20(B); and (b) switch the PECOS status to "Approved – Stay of Enrollment" effective the date the letter is mailed.

- Step 3 of Scenarios B and D - Within **5** days after the expiration of the 30-day stay period, the contractor shall: (a) change the PECOS status to "Deactivated" effective the date the stay notification letter was mailed; and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

- Step 5 of Scenario C - Within **5** days of sending the rejection letter, the contractor shall: (a) change the PECOS status to "Deactivated" effective the date the stay notification letter was mailed; and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

- Step 3B of Scenario D - If the contractor receives the ACF after it mails the deactivation letter, it shall request the submission of or develop for a reactivation application.

To illustrate the first three exceptions, suppose the contractor receives an e-mail from PEOG on August 1 directing it to impose a stay on Provider X because X's ownership data is incorrect. If this were a revalidation situation, the contractor would have 10 days (or until August 11) to complete Step 1. Here, however, the contractor must complete Step 1 by August 6.

Now assume the contractor finishes Step 1 on August 4. The stay begins that day and ends on September 3. Provider X fails to submit the ACF during that period. The contractor must complete Step 3 by September 8 (rather than September 13). If X timely submitted the ACF but the contractor rejects it and sends the rejection letter on September 20, the contractor must complete Step 5 of Scenario C by September 25.

In sum, the only material differences between the general procedures in subsections (D)(1) and (D)(2)(a) are:

- The timeframes for contractor action (10 days vs. 5 days)
- (D)(1) addresses revalidations --- for which no prior notification from PEOG is needed to impose a stay --- whereas (D)(2)(a) applies only to ownership discrepancies and requires said notification from PEOG.
- In (D)(1) cases, any deactivation effective date is retroactive to the day after the RRT's expiration. For (D)(2)(a) situations, the deactivation effective date is retroactive to the date of the stay notification letter.

b. Immediate Imposition

Situations could occur when PEOG directs the contractor via e-mail to immediately impose a stay. Here, and except if PEOG directs otherwise:

- Step 1 of Scenarios A, B, C, and D - Within **1 business day** of receiving this e-mail, the contractor shall: (a) send to the provider via regular mail the letter identified in section 10.7.20(B); and (b) switch the PECOS status to "Approved – Stay of Enrollment" effective the date the letter is mailed.

- Step 3 of Scenarios B and D - Within **1 business day** after the expiration of the 30-day stay period, the contractor shall -- (a) Change the PECOS status to "Deactivated" effective the date the stay notification letter was mailed; and (b) Take all other measures normally associated with a deactivation (e.g., send deactivation letter).

- Step 5 of Scenario C - Within **1 business day** of sending the rejection letter, the contractor shall: (a) change the PECOS status to "Deactivated" effective the date the stay notification letter was mailed; and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

- Step 3B of Scenario D - If the contractor receives the ACF after it mails the deactivation letter, it shall request the submission of or develop for a reactivation application.

Aside from the above timeframes, the contractor shall follow the general procedures, steps, and scenarios outlined in subsection (D)(1) above.

c. All Other PEOG-Directed Stays

For all PEOG-directed stays other than those described in subsections (D)(2)(a) and (b), the following apply:

- As with revalidations, the contractor has 10 days to undertake the actions described in Steps 1, 3 (Scenarios B and D), and 5 (Scenario C).

- Step 3B of Scenario D - If the contractor receives the ACF after it mails the deactivation letter, it shall request the submission of or develop for a reactivation application.

d. Additional Case Studies Where PEOG Directs a Stay

This subsection (D)(2)(d) identifies certain scenarios in which PEOG may direct a stay and how the contractor should handle the situation. These scenarios are in addition to, and not in lieu of, others that are addressed in section 10.4.9(D).

(i) ACF Received Before the Stay's Imposition

Assume CMS instructs the contractor to impose a stay in Instance (D)(2)(a), (b), or (c) above. Before the contractor mails the stay notification letter to the provider, however, the contractor receives the ACF (as the term ACF is defined/explained in this section 10.4.9). Here:

1. *The contractor shall not impose the PEOG-directed stay and shall instead process the ACF normally (including development as needed).*
2. *Notwithstanding the language in the opening paragraph of subsection (D)(2) regarding PEOG notification, the contractor shall inform its PEOG BFL via e-mail that the stay was not implemented and why. This e-mail shall be sent no later than 7 calendar days after the contractor received the ACF.*

(ii) ACF Submitted During the Stay

Assume Scenario (D)(2)(d)(i) above but further assume that the provider submits the ACF after the stay is implemented. Here, the contractor shall generally follow Step 3 in Scenario A of subsection (D)(1) – specifically: (1) change the PECOS status to "Approved – Remove Stay of Enrollment" effective on the submission date; and (2) process the ACF normally (including development as needed).

If the ACF is approved, the contractor shall generally follow Step 4 in Scenario A of subsection (D)(1).

If the ACF is rejected, the contractor shall follow Step 5 in Scenario C of subsection (D)(1) (though -- as applicable depending on the type of stay involved (e.g., ownership discrepancy) -- modified as described in subsection (D)(2)(a), (b), or (c)) Note that in Step 5, the stay does not go back into effect when the application is rejected and then remain intact until the originally assigned stay period (e.g., 30 days) expires. Rather, the contractor (as described in Step 5) shall proceed to a deactivation without reimposing the stay.

(iii) Contractor Receives COI Before Mailing the Stay Notification Letter

(a) The submitted COI is an ACF, meaning -- as explained in section 10.4.9(B) -- it can remedy the non-compliance in question via the form submission. Here:

(1) The contractor shall not impose the stay and shall instead process the ACF normally (including development as needed).

(2) Notwithstanding the language in the opening paragraph of subsection (D)(2) regarding PEOG notification, the contractor shall inform its PEOG BFL via e-mail that the stay was not implemented and why. This e-mail shall be sent no later than 7 calendar days after the contractor received the ACF.

*(b) The submitted COI is **not** an ACF. Here:*

(1) The contractor shall impose the stay as directed, using the procedures outlined in section 10.4.9.

(2) The contractor shall develop the COI for the information that will remedy the non-compliance (i.e., the missing/deficient/incorrect ACF data that triggered the stay directive). This means the ACF information, to the maximum extent possible, should be furnished on/via the COI and not through a separate ACF submission. However, the contractor shall accept and process the ACF if it is submitted separate from the COI; in this situation, the contractor shall merge the COI and ACF into a single submission. Note that the processing time clock does not stop when developing the COI for the ACF data.

(3) In its stay notification letter – which, for purposes of this scenario, will also constitute a development letter -- the contractor shall request that the provider update its COI with the ACF. (The specific verbiage lies within the contractor's discretion.) If the COI itself also requires development (e.g., data is incorrect), the letter shall also explain the information to be added, remedied, etc.

(4) Consistent with current policy (assuming the designated stay period (e.g., 30 days) has not expired), the stay ends on the date the provider submits the ACF – either via an update to the COI or as a separate submission.

(5) Final determination

- *If the submitted ACF data cannot be approved (irrespective of whether the COI data can), the contractor shall proceed to a deactivation consistent with the instructions in subsection (D)(2). The COI data will ostensibly be captured via the provider's reactivation application.*
- *If the submitted ACF data can be approved but the COI information cannot, the contractor shall contact its PEOG BFL for guidance on how the matter should be handled.*

E. Returns

In any situation where the contractor determines the submitted ACF – be it a revalidation, COI, etc. -- should be returned, the contractor shall treat the matter as it would a rejected ACF. (See Steps 4 and 5 of Scenario C of subsection (D)(1).)

F. Other Scenarios

The contractor may encounter stay situations not explicitly identified in subsection (D) above. In such situations, the contractor shall -- to the maximum extent possible -- still follow the general processes and basic steps outlined in the (D)(1) and (2) scenario(s) most applicable to the case the contractor is handling. If the contractor nonetheless needs additional guidance, it shall contact its PEOG BFL for guidance.

G. Letters

The contractor shall send all stay notification letters via hard-copy mail and via e-mail (if a valid email address is available); the contractor should also send the notice via fax if a valid fax number is available. All notifications shall be saved in PDF format, **and all notification letters shall be mailed on the same date listed on the letter.**

H. Rebuttals

See section 10.4.9.1 of this chapter for information concerning rebuttals of stays of enrollment.

I. NPE and DME MAC Interaction

The NPEs and the DME MACs shall interact, coordinate, and communicate with each other in stay situations consistent with CMS instructions and in instances generally akin to those involving deactivations. This could include, for example:

- The NPE notifying the applicable DME MAC of the imposition or lifting of a stay and any subsequent deactivation.
- Upon being informed of a stay by the NPE, the DME MAC holding payment for services furnished during the stay period.

J. Stay Expires – Deactivation Effective Date

To reiterate, if a stay expires and a deactivation immediately follows, the deactivation effective date is the date on which the provider first became non-compliant. This is consistent with the guidance in section 10.4.9(D).

K. Removal of A/R Code

As indicated in section 10.4.9, the contractor shall remove the stay of enrollment (e.g., A/R 350 or the Part A PARM) from the provider's file upon:

- *Deactivation of the enrollment if the provider did not submit an ACF during the stay period.*
- *Submission of the ACF after the stay period has ended but prior to deactivation.*

(Other situations when the stay should be lifted are addressed in section 10.4.9.)

10.6.1.1.3.2 – Step 2 – Post-Initial Review Actions and Scenarios

(Rev. 12852; Issued: 09-27-24; Effective: 11-07-24; Implementation: 11-07-24)

After the contractor completes the tasks in section 10.6.1.1.3.1, several results are possible. These are discussed below. Should the contractor encounter a scenario not addressed herein, it may contact its PEOG BFL for guidance. As a reminder, nothing in section 10.6.1.1.3.2 prohibits the contractor from returning or rejecting the application if otherwise permitted to do so per this chapter.

A. Scenarios

1. The contractor ascertains that the transaction falls within the scope of § 489.18 and that the new owner has accepted assignment – If there are no apparent grounds for denying the application (e.g., the new owner has a felony conviction, false information was submitted, a newly reported chief executive officer is excluded), the contractor shall make a recommendation for approval to the state consistent with existing practice and via existing means. (This includes sending recommendations via hard copy mail if the state only accepts this method of transmission.) If a denial ground exists, however, the contractor shall refer the

matter to its PEOG BFL for guidance before submission to the state, notwithstanding any other instruction in this chapter to the contrary. The contractor should include an explanation of the ground(s) it believes exists for the denial (including the regulatory citation).

(For Form CMS-855B CHOW applications: Note that an approval recommendation can be made (and must be treated as a CHOW) notwithstanding the general rule that a TIN change constitutes an initial enrollment; in other words, the reporting rules regarding CHOWs/assignments in this particular situation take precedence over the "change of TIN" principle.)

2. The contractor ascertains that the transaction falls within the scope of § 489.18 but the new owner has not accepted assignment – The contractor shall:
(a) return the application; and (b) notify the new owner in the return letter that it must submit the following within 30 days from the date of the return letter: (i) an initial Form CMS-855 application to enroll as a new provider; and (ii) a voluntary termination application for the existing provider. If the new owner fails to do so within 30 days of the request, the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter. PEOG will review the matter and respond to the contractor.

3. The contractor ascertains that the transaction does not fall within the scope of § 489.18 (e.g., stock transfer), regardless of whether the new owner accepted assignment - This qualifies as an ownership change under 42 CFR § 424.516 rather than a CHOW under § 489.18. The contractor shall: (a) return the application; and (b) notify the provider in the return letter that it must submit a Form CMS-855 application to report the ownership change within 30 days of the return letter. If the provider fails to do so, the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter.

(The only exception to the policies in the previous paragraph is if (1) the submission is a Form CMS-855B and (2) the § 424.516 ownership change also involves a change of TIN. In this scenario, the contractor shall: (a) return the application; and (b) notify the supplier in the return letter that it must submit the following within 30 days from the date of the return letter: (i) an initial Form CMS-855B application to enroll as a new supplier; and (ii) a voluntary termination application. If the supplier fails to do so, the contractor shall contact its PEOG BFL the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter.

B. Referral to State

If the contractor believes that a recommendation for approval per section 10.6.1.1.3.2(A)(1) is warranted, it shall send a recommendation letter to the state (with a copy to the accreditation organization (AO), if applicable). The letter shall follow the format of existing model CHOW recommendation letters in section 10.7 et seq. of this chapter. (Neither the SOG Location nor PEOG need be copied on the letter.) The CHOW package shall: (1) be sent to the state in a manner consistent with existing and past practice; and (2) contain all the applicable documents described in section 10.6.1.1.3.1(A)(iii) above. (For instance, the package must include, among other things, the CMS-377 for ASC and the CMS-3427 for ESRD facilities.)

(For hospital CHOWs, the contractor shall also note in either the recommendation letter or the accompanying e-mail whether the hospital currently has any active sub-units reported in PECOS (e.g., psychiatric unit, transplant program)).

The state will: (1) review the package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the

contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the provider, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

10.6.1.2 – Changes of Information – Transitioned Certified Providers and Suppliers

(Rev. 12852; Issued: 09-27-24; Effective: 11-07-24; Implementation: 11-07-24)

(Until further notice from CMS, the instructions in this section 10.6.1.2 apply only to certified provider and certified supplier types that have officially "transitioned" as part of the transition of various certification activities from the SOG Location to the states, the contractors, and PEOG. These provider/supplier types include SNFs, HHAs, CMHCs, CORFs, FQHCs, Part A OPT/OSP providers, ASCs, PXRSs, hospitals, hospices, and ESRD facilities. The contractor shall continue to use the existing change of information instructions--now in section 10.6.22.1 of this chapter--for all non-transitioned certified provider/supplier types.

When executing the instructions in this section 10.6.1.2, the contractor can disregard directives that obviously do not apply to the transitioned provider/supplier type in question (e.g., references to hospitals).

All references to the SOG Location (formerly the "RO") in this section 10.6.1.2 refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

The instructions in this section 10.6.1.2 address the handling of changes of information involving certified providers and certified suppliers. With the transition of certain functions from the SOG Locations to the contractors and the Provider Enrollment & Oversight Group (PEOG), the processing instructions for these changes of information are slightly different from previous guidance. In particular: (1) the SOG Locations will be much less involved in the process; (2) tie-in and tie-out notices will no longer be issued; (3) the contractor will be responsible for finalizing changes previously requiring SOG Location approval; and (4) recommendations of approval will be made to (and reviewed by) the state agency (hereafter occasionally referenced simply as "state") only and not the SOG Location.

Except as stated otherwise:

(1) Any provider-specific instructions in section 10.2.1 et seq. of this chapter pertaining to changes of information (e.g., relocation of a federally qualified health clinic site; addition or deletion of an OPT/OSP extension site) take precedence over those in this section 10.6.1.2.

(2) Any instructions pertaining to ownership changes in section 10.6.1.1 et seq. of this chapter take precedence over those in this section 10.6.1.2.

(3) Any instructions pertaining to voluntary terminations of entire enrollments and/or provider agreements in section 10.6.1.3 of this chapter take precedence over those in this section 10.6.1.2.

(4) Any instructions in this section 10.6.1.2 concerning the voluntary termination of a branch, sub-unit, or other practice location that does not involve the termination of the entire enrollment and/or provider agreement take precedence over those in section 10.6.1.3. For instance, suppose a certified provider's Form CMS-855A enrollment has three practice

locations and/or sub-units. The provider is voluntarily terminating one of them. Here, the contractor shall use the instructions in section 10.6.1.2 when processing this transaction. Now assume that a provider is of a type that must individually and separately enroll each location. The provider has three separately enrolled locations with three separate provider agreements. The provider seeks to terminate one of these locations. Since this will involve the termination of an individual/entire enrollment and corresponding provider agreement, the instructions in section 10.6.1.3 apply.

A. Changes of Information Requiring Recommendation to the State

1. Types

The following Form CMS-855 transactions require an approval recommendation to (and review by) the state prior to approval:

- Addition or relocation/change of outpatient physical therapy/outpatient speech pathology extension site
- Addition of HHA branch
- Addition or deletion of a prospective payment system (PPS)-excluded psychiatric unit, rehabilitation unit, or transplant program.
- Addition or deletion of swing-bed approval (see Section 2A2 of the Form CMS-855A)
- Conversion of a hospital from one type to another (e.g., acute care to psychiatric)
- Addition, deletion, or relocation of a hospice practice location
- *Addition, deletion, or relocation of a CMHC practice location*
- *Addition, deletion, or relocation of a CORF practice location*
- Addition, change, and/or relocation of a hospital practice location when a survey of the new site may be required. (If the contractor is uncertain as to whether the state will perform a survey, it may (1) contact the state for guidance or (2) make the referral based on the contractor's experience with these types of changes and with the practices of the state in question. Note that a survey often may be required if the location is shifting outside of the existing geographic area.)
- Addition of PXRS practice location

2. Initial Contractor Review and Recommendation

The contractor shall process the change request consistent with the instructions in this chapter (e.g., verification of data, developing for missing or conflicting data). If the contractor determines that the change/addition should be approved, it shall send the appropriate recommendation letter (see section 10.7 et seq.) to the state with all applicable documentation that the contractor currently sends in such situations. The SOG Location need not be copied on the letter.

Nothing in this section 10.6.1.2(A)(2):

- Prohibits the contractor from returning or rejecting the application if grounds for doing so exist.

- Supersedes any applicable requirement for performing a site visit (including the timing of such visits).

3. State Review and Contractor Receipt of Recommendation

The state will review the recommendation of approval, the application, and any other pertinent information. If the state decides to perform a survey, it will do so and notify the contractor thereof.

a. State Recommends Approval

If the state concludes that the change/addition should be approved, it will make a recommendation to this effect to the contractor, typically via a Form CMS-1539 and/or similar confirming documentation. No later than 5 business days after receipt of the recommendation, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov containing general identifying data about the provider (including LBN, NPI, CCN, specialty, facility name and address), a copy of the Form CMS-1539 (or other similar documentation evidencing the state's approval recommendation, if available), the draft provider approval letter, and a description of the change to be made. If, to the contractor's knowledge, a new CCN is required, the name and address of the new entity requiring the CCN should be furnished along with the effective date. If a termination is involved (e.g., HHA branch), the contractor shall include the old CCN and the termination date in the e-mail.

Once PEOG responds to the contractor, the latter may finalize its processing of the application (e.g., sending copies of the provider notification of approval to the state and, if applicable, accrediting organization; switching the PECOS record from "approval recommended" to "approved").

b. State Does Not Recommend Approval

If the state does not recommend approval, the contractor shall refer the matter to MedicareProviderEnrollment@cms.hhs.gov for guidance. The e-mail to him/her shall contain (1) the identifying data described in (3)(a) above; (2) a copy of the notification from the state declining to recommend approval; and (3) any other information the contractor deems pertinent. PEOG will review the matter and furnish the contractor additional instructions, which the contractor shall follow.

4. Additional Policies

a. Post-Recommendation Inquiries - Once the contractor has made its recommendation for approval to the state, any inquiry the contractor receives from the provider regarding the status of its change request shall be referred to the state.

b. Pending State Recommendation - So as not to keep the PECOS record in "approval recommended" status interminably, if the contractor does not receive the state's recommendation after 120 days, it may contact the state to see if its recommendation is forthcoming. The contractor may contact the state every 30 days thereafter to ascertain the recommendation's status.

c. State Practice - The PECOS record should not be switched to "Approved" until the contractor receives the state's approval recommendation. However, if the contractor knows that the state in question generally does not review this type of transaction, the contractor need not send the transaction to the state and shall instead follow the instructions in section 10.6.1.2(B) below.

B. Post-Approval State Notification Required

Form CMS-855 changes that do not mandate a recommendation to the state but do require post-approval correspondence with PEOG and the state (and, if applicable, the accrediting organization) include:

- Except as described in section 10.6.1.2(A), deletions/voluntary terminations of practice locations or hospital subunits. (Note that this scenario is different from cases where the provider is voluntary terminating its enrollment as a whole (per section 10.6.1.3 of this chapter) rather than simply terminating a single location or subunit within its enrollment.)

- LBN, TIN, or "doing business as name" changes that do not involve a CHOW.

- Except as described in section 10.6.1.2(A), address changes that generally do not require a survey of the new location.

- Addition, change, and/or relocation of a hospital practice location (including physician/practitioner group practice locations) for which a survey is not required.

- Deletion of an OPT/OSP extension site or practice location.

- Ownership changes that involve neither a 42 CFR § 489.18 CHOW nor a § 424.550(b) exempt or non-exempt change in HHA majority ownership (e.g., a 15 percent owner of a hospice sells her ownership stake).

The contractor shall:

(1) Inform PEOG, the state, and the AO (if appropriate) of the changed information (via any mechanism it chooses, including copying PEOG/state/AO on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction. Such notice to the PEOG/state/AO shall specify the type of information that is changing. (Prior PEOG approval of the change is not required, though PEOG will update applicable national database as needed.)

(2) Switch the PECOS record to "Approved."

C. All Other Changes of Information

1. General Principle

For all Form CMS-855 change requests not identified in section 10.6.1.2(A)(1) and (B) above (and except as stated in subsection (C)(2) below), the contractor shall: (1) notify the provider via letter, fax, e-mail, or telephone that the change has been made; and (2) switch the PECOS record to "Approved." The contractor need not notify the state, SOG Location, or PEOG of the change.

2. FQHCs

If an FQHC is adding, deleting, or changing a Section 13 contact person , the contractor shall send an approval letter via e-mail and copy the MedicareProviderEnrollment@cms.hhs.gov mailbox (with "FQHC COI" in the subject line) thereon. (Aside from this exception, all other instructions in subsection (C)(1) apply to this scenario.) See section 10.2.1.4(D) of this chapter for more information on FQHC changes of information.

D. Revalidations, Reactivations, and Complete Form CMS-855 Applications

1. When Referral Required - In situations where the provider submits a (1) Form CMS-855 reactivation, (2) Form CMS-855 revalidation, or (3) full Form CMS-855 as part of a change of information (i.e., the provider has no enrollment record in PECOS), the contractor shall make a recommendation to the state and switch the PECOS record to "approval recommended" only if the application contains new/changed data falling within one of the categories in section 10.6.1.2(A)(1). For instance, if a revalidation application reveals a new hospital psychiatric unit that was never reported to CMS via the Form CMS-855, the contractor shall make a recommendation to the state and await the state's approval recommendation before switching the record to "Approved." In this situation, the contractor should forward the application to the state with a note explaining that the only matter the state needs to consider is the new hospital unit.

2. No Referral Required - If the application contains new/changed data falling within one of the categories in section 10.6.1.2(B), the contractor can switch the PECOS record to "Approved." It shall also inform the state of the changed information (via any mechanism it chooses, including copying the state on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction.

E. Unsolicited Notifications from State

If the contractor receives notice of a provider's change of information from the state but the provider never submitted the required Form CMS-855 change request to the contractor, the contractor shall: (1) alert the state of the situation; and (2) contact the provider and have it complete and submit the change request. However, if the data in question is not collected on the Form CMS-855, the contractor need not make this request.

F. Special ESRD Instructions

Notwithstanding any other contrary instruction in this chapter, if an ESRD change of information application results in the issuance of a new or additional CCN, the contractor shall copy the ESRD Network on the approval letter it sends to the provider. The contact information for the ESRD Network can be found at https://esrdnetworks.org/membership/esrd-networks-contact-information/.

G. Clock Stoppages and Processing Alternatives

While awaiting PEOG's reply on any matter in this section 10.6.1.2 in which the contractor is required to refer a matter to PEOG - and beginning on the date following the sending of the e-mail referenced therein - the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's final response. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

In addition, nothing in this section 10.6.1.2 negates other permissible clock stoppages and processing alternatives outlined in this chapter that can apply to the applications addressed in this section 10.6.1.2.

10.7.20 – Stay of Enrollment Letters

(Rev. 12852; Issued: 09-27-24; Effective: 11-07-24; Implementation: 11-07-24)

This section 10.7.20 contains letters that contractors shall use in stay of enrollment situations. Note that the contractor may remove language from the letter that obviously does not apply to the provider/supplier type in question (e.g., reassignment language in a letter pertaining to an

HHA under a stay).

A. Imposition of Stay of Enrollment Notification Letter – Revalidation Non-Response

Stay of Enrollment

[month] [day], [year]

[Provider/Supplier
Name] [Address]
[City], [State] [Zip
Code]

Dear [Provider/Supplier Name],

Pursuant to 42 CFR § 424.541, we are placing a stay on your Medicare enrollment record effective [insert day of letter's issuance] because you have not responded to our revalidation request of [date revalidation request letter sent]. Your revalidation was due on [inset date].

During this stay, claims for services and items you furnish during this period will be rejected. However, this does not affect your Medicare participation agreement or any of its conditions, and you remain enrolled in the Medicare program.

Every [three or five years], CMS requires you to revalidate your Medicare enrollment record information. Failure to submit a revalidation application within 30 days of this notice may result in a deactivation of your Medicare enrollment. If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN; however, you will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

What record needs revalidating

[Name] | **NPI** [NPI] | **PTAN** [PTAN]

Reassignments:

[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]

<Repeat for other reassignments>

The CMS lists the records that need revalidating at:

go.cms.gov/MedicareRevalidation

How to resume your payments:

- **Revalidate your Medicare enrollment record**, through https://pecos.cms.hhs.gov/pecos/login.do or [Form CMS-855 or Form CMS-20134].

- **Online:** PECOS is the fastest option. If you don't know your username or password, PECOS offers ways to retrieve them. Our customer service can also help you by phone at 866-484- 8049.
- **Paper:** Download the right version of [form CMS-855 or Form CMS-20134] for your situation at cms.gov. We recommend getting proof of receipt for your mailing. Mail to [contractor address].

If you have a fee due, use PECOS to pay. If you feel you qualify for a hardship waiver, mail us a request on practice letterhead with financial statements, application form, and certification.

Rebuttal Rights:

If you believe that this determination is not correct, you may rebut the stay of enrollment as indicated in 42 C.F.R. § 424.541(b). The rebuttal must be received in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this stay of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. (Delete next sentence if letter is related to a DMEPOS supplier's enrollment.) Authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative who is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider's or supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she has the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal request.

The provider's or supplier's failure to submit a rebuttal that is both timely and fully compliant with all the requirements above constitutes a waiver of all rebuttal rights.

The rebuttal should be sent to the following:

[For non-DMEPOS:

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

OR, as applicable

Name and address of MAC

For DMEPOS:

Chags Health Information Technology LLC
P.O. Box 45266
Jacksonville, FL 32232]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

If you need help:

Visit **go.cms.gov/MedicareRevalidation**

Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,

[Name]
[Title]
[Company]

B. Imposition of Stay Notification Letter – All Situations Other than Section 10.7.20(A)

Stay of Enrollment

[month] [day], [year]

[Provider/Supplier
Name] [Address]
[City], [State] [Zip
Code]

Dear [Provider/Supplier Name],

Pursuant to 42 CFR § 424.541, we are placing a stay on your Medicare enrollment record effective [day of letter's issuance] because [provide explanation, such as "you did not report a new managing employee within 30 days of the change as required under 42 CFR § 424.516 (or 42 CFR § 424.57(c)(2) for DMEPOS suppliers)" or "your current ownership information on file with Medicare is incorrect"].

> [Example of supporting facts and rationale: [ABC, Inc.'s Medicare 855 enrollment record reflects that Jane Doe is the owner, authorized official, director and managing employee of Argo Medical Supplies & Services, Inc. However, CMS has found information on the New York Secretary of State which reveals that John Doe is listed as manager effective October 11, 2023. A manager (which meets the definition of managing employee, per 42 C.F.R. § 424.502) is required to be reported on the 855S enrollment record.]]

During this stay, claims for services and items you furnish during this period will be rejected. However, this does not affect your Medicare participation agreement or any of its conditions, and you remain enrolled in the Medicare program.

[In order to maintain enrollment in the Medicare program, you must submit a CMS 855 Change of Information Application. Failure to do so by [today's date + 30] may result in a deactivation or revocation of your Medicare enrollment. If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN; however, you will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

What record needs to be updated.

[Name] | **NPI** [NPI] | **PTAN** [PTAN]

[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]

How to resume your payments:

- **Online:** PECOS is the fastest option. If you don't know your username or password, PECOS offers ways to retrieve them. Our customer service can also help you by phone at 866-484- 8049.
- **Paper:** Download the right version of [form CMS-855 or Form CMS-20134] for your situation at cms.gov. We recommend getting proof of receipt for your mailing. Mail to [contractor address].

If you have a fee due, use PECOS to pay. If you feel you qualify for a hardship waiver, mail us a request on practice letterhead with financial statements, application form, and certification.

Rebuttal Rights:

If you believe that this determination is not correct, you may rebut the stay of enrollment as indicated in 42 C.F.R. § 424.541(b). The rebuttal must be received in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this stay of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. (Delete next sentence if letter is related to a DMEPOS supplier's enrollment.) Authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider's or supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she has the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal request.

The provider's or supplier's failure to submit a rebuttal that is both timely and fully compliant with all the requirements above constitutes a waiver of all rebuttal rights.

The rebuttal should be sent to the following:

[For non-DMEPOS:

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

OR, as applicable

Name and address of MAC

For DMEPOS:

Chags Health Information Technology LLC
P.O. Box 45266
Jacksonville, FL 32232]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Name]
[Title]
[Company]

C. Moot Rebuttal Because Stay Lifted

(The contractor shall use this letter in response to a stay rebuttal submission that is moot because the stay has been lifted.)

Stay of Enrollment

[month] [day], [year]

[Provider/Supplier Name] [Address] [City], [State] [Zip Code]

Dear [Provider/Supplier Name],

This letter is in response to the stay of enrollment rebuttal submission, on behalf of [Provider/Supplier Name] received on [Date]. On [Date], [Contractor Name], received [insert type of CMS application submitted, such as "application to revalidate [Provider/Supplier Name's] enrollment", "[Provider/Supplier Name's] change of information request to report a [new managing employee]", or similar language describing the application submission that lifted the stay] and the stay of enrollment has been lifted. Therefore, the issue set forth in the stay of enrollment rebuttal submission is no longer actionable. As a result, this issue is moot and a determination will not be made in regards to the stay of enrollment rebuttal submission.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Name]
[Title]
[Company]