CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12356	**Date: November 9, 2023**
	Change Request 13331

SUBJECT: Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08 - Physician Fee Schedule (PFS) Final Rule

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to incorporate into Chapter 10 of Pub. 100-08 certain provider enrollment policies included in the Calendar Year (CY) 2024 PFS final rule.

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 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
N	10/10.1/10.1.1.1/Additional Definitions
N	10/10.2/10.2.3.17/Marriage and Family Therapists (MFTs)
N	10/10.2/10.2.3.18/Mental Health Counselors (MHCs)
R	10/10.2/10.2.6/Medicare Diabetes Prevention Program (MDPP) Suppliers
R	10/10.2/10.2.8/Providers/Suppliers Not Eligible to Enroll
R	10/10.4/10.4.2.1/Denials – General Principles
R	10/10.4/10.4.2.2/Denial Reasons
R	10/10.4/10.4.2.3/Additional Denial Policies
R	10/10.4/10.4.4/Changes of Information
R	10/10.4/10.4.7.2/Revocation Effective Dates
R	10/10.4/10.4.7.3/Revocation Reasons
R	10/10.4/10.4.7.4/Reenrollment Bar
R	10/10.4/10.4.7.5/Additional Revocation Policies
R	10/10.6/10.6.2/Establishing Effective Dates
R	10/10.6/10.6.12/Opting-Out of Medicare
R	10/10.6/10.6.18/Appeals Process
R	10/10.7/10.7.15/Revalidation Notification 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

Pub. 100-08	Transmittal: 12356	Date: November 9, 2023	Change Request: 13331

SUBJECT: Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08 - Physician Fee Schedule (PFS) Final Rule

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 2024

I. GENERAL INFORMATION

A. Background: The CY 2024 PFS final rule, which was placed on display at the Federal Register on November 2, 2023, contains provisions concerning Medicare provider enrollment. These include, but are not limited to, establishing--(1) Several new and revised provider enrollment definitions and denial and revocation reasons; (2) Policies for the enrollment of marriage and family therapists (MFTs) and mental health counselors (MHCs) into the Medicare program; and (3) A new enrollment status labeled a "stay of enrollment." Except for the stay of enrollment provision and the revision to the "authorized official" definition, which CMS will address in separate guidance to the contractors, this CR instructs contractors on the implementation of these regulatory provisions.

The CMS will issue separate guidance to the contractors as to when they may begin accepting enrollment applications from MFTs and MHCs.

Excluding MFT and MHC applications, the instructions in this CR apply to provider enrollment applications received on or after January 1, 2024.

B. Policy: CY 2024 PFS final rule.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13331.1	The contractor shall observe the new definitions listed in Section 10.1.1.1 in Chapter 10 of CMS Pub. 100-	X	X	X						NPEAST, NPWEST

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	08.									
13331.2	The contractor shall follow the instructions in Sections 10.2.3.17 and 10.2.3.18 in Chapter 10 of CMS Pub. 100-08 concerning the enrollment of, respectively, MFTs and MHCs.		X							
13331.3	The contractor shall follow the instructions in Sections 10.4.2.2 and 10.4.2.3 in Chapter 10 of CMS Pub. 100-08 regarding the new and revised denial reasons listed in Section 10.4.2.2.	X	X	X						NPEAST, NPWEST
13331.4	The contractor shall follow the instructions in Section 10.4.7.2 in Chapter 10 of CMS Pub. 100-08 regarding the new revocation effective dates.	X	X	X						NPEAST, NPWEST
13331.5	The contractor shall follow the instructions in Sections	X	X	X						NPEAST, NPWEST

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	10.4.7.3 and 10.4.7.5 in Chapter 10 of CMS Pub. 100-08 regarding the new and revised revocation reasons listed in Section 10.4.7.3.									
13331.6	The contractor shall follow the instructions in Sections 10.4.7.4(D) and 10.6.18(A)(1) in Chapter10 of CMS Pub. 100-08 with respect to reconsiderations, particularly those involving Sections 42 CFR 424.530(a)(18) and 424.535(a)(23).	X	X	X						NPEAST, NPWEST
13331.7	The contractor shall observe the revised practice location reporting timeframes in Section 10.4.4(B) in Chapter 10 of CMS Pub. 100-08.	X	X	X						NPEAST, NPWEST
13331.8	The contractor shall follow the revised instructions in	X	X	X						NPEAST, NPWEST

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Section 10.4.2.1(B) in Chapter 10 of CMS Pub. 100-08 regarding prior approval of denials.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13331.9	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X	X		

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

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

VI. FUNDING

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

ATTACHMENTS: 0

Medicare Program Integrity Manual
Chapter 10 – Medicare Enrollment
Table of Contents
(Rev. 12356; Issued: 11-09-23)

Transmittals for Chapter 10

10.1.1.1 – Additional Definitions
10.2.3.17 – Marriage and Family Therapists
10.2.3.18 – Mental Health Counselors
10.4.7.2 – Revocation Effective Date*s*

10.1.1.1 – Additional Definitions

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

Authorized official (as defined by 42 CFR § 424.502) means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program. For purposes of this definition only, the term "organization" means the enrolling entity as identified by its legal business name and tax identification number.

(This definition of authorized official supersedes that in section 10.1.1 above.)

Indirect ownership interest means as follows:

(1)(i) Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier; or

(ii) Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.

(2) The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership interest in the provider or supplier and need not be reported.

Supplier means (for purposes of 42 CFR Part 424, subpart P) all the following:

(1) The individuals and entities that qualify as suppliers under § 400.202
(2) Physical therapists in private practice
(3) Occupational therapists in private practice
(4) Speech-language pathologists

10.2.3.17 – Marriage and Family Therapists (MFTs)

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Definition and Requirements

Effective January 1, 2024, Medicare covers services furnished by MFTs. An MFT is defined in CFR § 410.53(a)(1)-(3) as an individual who:

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a MFT pursuant to state law of the state in which such individual furnishes the services defined as MFT services;

(2) After obtaining such degree, has performed at least 2 years or 3,000 hours of post-master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as an MFT by the state in which the services are performed.

Under 42 CFR § 410.53(b)(1), MFT services means services furnished by an MFT (as defined in § 410.53(a)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MFT is legally authorized to perform under state law (or the state regulatory mechanism provided by state law) of the state in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as incident to a physician's professional service and must meet the requirements of § 410.53(b)(1).

Per 42 CFR § 410.53(b)(2), MFT services furnished by an MFT to an inpatient of a Medicare-participating hospital are not MFT services for purposes of billing Medicare Part B under the MFT benefit category.

B. Verification

As it does with Medicare supplier types, the contractor shall familiarize itself with the applicable state licensure and associated education requirements for MFTs. This will assist the contractor in ascertaining whether the MFT meets all state requirements.

In verifying the supplier's compliance with:

1. *§ 410.53(a)(1) – Except as stated in the discussion of § 410.53(a)(3) below, the contractor shall require the supplier to submit a copy of their master's or doctor's degree. Whether a master's or, instead, a doctor's degree is required will depend on the applicable state's requirements.*

2. *§ 410.53(a)(2) – Except as stated in the discussion of § 410.53(a)(3) below, the contractor shall require the supplier to submit documentation verifying that they have performed, at a minimum, either 2 years or 3,000 hours of post-master's clinical supervised experience in marriage and family therapy in an appropriate setting, such as a hospital, SNF, private practice, or clinic. (The supplier need only meet the 2-year or the 3,000-hour standard, not both.) Such documentation shall be one of the following:*

   (i) A statement from the provider/supplier at which the MFT performed the services in question (e.g., hospital, clinic) verifying that the MFT performed services at that setting for the required number of years or hours. The statement shall:

      (a) Be on the provider's/supplier's letterhead (e-mail is not acceptable); and

      (b) Be signed by: (1) the provider/supplier supervisor under whom the MFT performed the services; (2) an applicable department head (e.g., chief of psychology) of the provider/supplier; or (3) a current authorized or delegated official of the provider/supplier (i.e., the AO/DO has already been approved as such in the provider/supplier's enrollment record) if the provider/supplier is Medicare-enrolled.

   The statement need not contain standard, boilerplate language. It need only confirm to the contractor's satisfaction that the year or hour requirement was met. Also, the contractor may accept statements from multiple providers/suppliers if the year or hour requirement was met by performing services at more than one setting. For instance, suppose Dr. Smith earned her MFT experience by performing 1,000 hours at Hospital X and 2,000 hours at Hospital Y. The contractor can accept one statement from Hospital X concerning the 1,000 hours and another from Hospital Y regarding the remaining 2,000 hours so long as each statement meets the requirements of subsections (B)(2)(i)(a) and (B)(2)(i)(b) above. Put otherwise, the MFT can combine years and hours from multiple providers/suppliers to meet § 410.53(a)(2).

In addition:

- *A statement from the MFT's current employer that the MFT met the year or time requirement at other settings besides the employer is not acceptable. All statements must be from the provider/supplier in which setting(s) the MFT performed the services. Using our example above, suppose Dr. Smith's supervisor at Hospital X was Dr. Jones. Dr. Jones is no longer with Hospital X, however. Dr. Smith submits a statement from Dr. Jones stating that Dr. Smith performed 1,000 hours of MFT services at Hospital X. This statement cannot be accepted because it is not from Hospital X.*

- *The setting can be any provider/supplier at which MFT services are furnished. It need not be one of the four provider/supplier types listed in § 410.53(a)(2). Moreover, the provider/supplier need not have been (or currently be) enrolled in Medicare at the time the MFT performed the services there.*

OR

(ii) A statement verifying that the MFT meets the year or hour requirements from a: (1) licensing or credentialing body for the state in which the MFT is enrolling; or (2) national MFT credentialing organization. The statement can be signed by any official of the state licensing/credentialing or national credentialing body. It must, however, be on the body's letterhead.

If the MFT fails to furnish the above documentation, the contractor shall develop for it consistent with the instructions in this chapter.

3. *§ 410.53(a)(3) – The contractor shall verify state licensure or certification consistent with existing policies for doing so in this chapter.*

   If the contractor confirms to its satisfaction that the state already requires, as a condition of licensure or credentialing, the MFT to have:

   - *Performed, at a minimum, either 2 years or 3,000 hours of post-master's clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic, the contractor can forgo verifying separate compliance with the § 410.53(a)(2) requirement described above; the MFT need not submit the documentation specified in subsection (B)(2). (This is because the licensure/credentialing already includes the year/hour requirement.)*

   - *A master's or doctor's degree (as applicable), the MFT need not submit a copy of his or her degree nor need the contractor verify that the MFT received said degree.*

C. Additional Information

1. Pre/Post Degree - As indicated above, all 2 years/3,000 hours of clinical supervised experience must have been performed post-degree. Pre-degree experience does not count towards the required time total under § 410.53(a)(2), even if the state permits pre-degree experience to be counted towards meeting state requirements. For example, suppose State X requires 1,000 hours of supervised experience for licensure. The hours can be performed pre-degree or post-degree. Jones, who is licensed by X, performed her 1,000 hours before receiving her degree. Jones cannot apply these hours towards the § 410.53(a)(2) time requirement – even though she is licensed – and must furnish evidence of 2 years/3,000 hours post-degree experience. If, however, Jones had performed 500 hours pre-degree and 500

hours post-degree, she could apply the latter (but not the former) to the § 410.53(a)(2) time requirement.

2. Additional Policies

Like certain other individual practitioners, MFTs may opt-out of Medicare, form groups, reassign their benefits under § 424.80, receive reassigned benefits, and order/certify services to the extent otherwise permitted by law. They will complete the Form CMS-855I to bill for services and be subject to limited-risk screening (except as described in § 424.518(c)(3)).

Until the Form CMS-855I is revised to include MFTs, the MFT shall check the "Undefined Non-Physician Practitioner Specialty" box and state "marriage and family therapist" in the line next thereto.

10.2.3.18 – Mental Health Counselors (MHCs)

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Definitions and Requirements

Effective January 1, 2024, Medicare covers services furnished by MHCs. An MHC is defined in 42 CFR § 410.54(a) as an individual who:

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as an MHC, clinical professional counselor, or professional counselor under the state law of the state in which such individual furnishes the services defined as mental health counselor services;

(2) After obtaining such a degree, has performed at least 2 years or 3,000 hours of post-master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as an MHC, clinical professional counselor, professional counselor, addiction counselor, or alcohol and drug counselor (ADC) by the state in which the services are performed.

Under 42 CFR § 410.54(b)(1), MHC services means services furnished by an MHC (as defined in § 410.54(a)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MHC is legally authorized to perform under state law (or the state regulatory 1417 mechanism provided by state law) of the state in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as incident to a physician's professional service and must meet the requirements of § 410.54.

Per 42 CFR § 410.54(c)(2), MHC services furnished by an MHC to an inpatient of a Medicare-participating hospital are not MHC services for purposes of billing Medicare Part B:

B. Verification

As it does with Medicare supplier types, the contractor shall familiarize itself with the state licensure and associated education requirements for MHCs. This will assist the contractor in ascertaining whether the MHC meets all state requirements.

In verifying the supplier's compliance with:

1. *§ 410.54(a)(1) – Except as stated in the discussion of § 410.54(a)(3) below, the contractor shall require the supplier to submit a copy of their master's or doctor's degree. Whether a master's or, instead, a doctor's degree is required will depend on the applicable state's requirements.*

2. *§ 410.54(a)(2) – Except as stated in the discussion of § 410.54(a)(3) below, the contractor shall require the supplier to submit documentation verifying that they have performed, at a minimum, either 2 years or 3,000 hours of post-master's clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic. (The supplier need only meet the 2-year or the 3,000-hour standard, not both.) Such documentation shall be one of the following:*

   (i) A statement from the provider/supplier at which the MHC performed the services in question (e.g., hospital, clinic) verifying that the MHC performed services at that setting for the required number of years or hours. The statement shall:

      (a) Be on the provider's/supplier's letterhead (e-mail is not acceptable); and

      (b) Be signed by: (1) the supervisor under whom the MHC performed the services; (2) an applicable department head (e.g., chief of psychology) of the provider/supplier; or (3) a current authorized or delegated official of the provider/supplier (i.e., the AO/DO has already been approved as such in the provider/supplier's enrollment record) if the provider/supplier is Medicare-enrolled.

   The statement need not contain standard, boilerplate language. It need only confirm to the contractor's satisfaction that the year or hour requirement was met. Also, the contractor may accept statements from multiple providers/suppliers if the year or hour requirement was met by performing services at more than one setting. For instance, suppose Dr. Smith earned her MHC experience by performing 1,000 hours at Hospital X and 2,000 hours at Hospital Y. The contractor can accept one statement from Hospital X concerning the 1,000 hours and another from Hospital Y regarding the remaining 2,000 hours so long as each statement meets the requirements of subsections (B)(2)(i)(a) and (B)(2)(i)(b) above. Put otherwise, the MHC can combine years and hours from multiple providers/suppliers to meet the requirements in § 410.54(a)(2).

   In addition:

   - *A statement from the MHC's current employer that the MHC met the year or time requirement at other settings besides the employer is not acceptable. All statements must be from the provider/supplier in which setting(s) the MHC performed the services. Using our example above, suppose Dr. Smith's supervisor at Hospital X was Dr. Jones. Dr. Jones is no longer with Hospital X, however. Dr. Smith submits a statement from Dr. Jones stating that Dr. Smith performed 1,000 hours of MHC service at Hospital X. This statement cannot be accepted because it is not from Hospital X.*
   - *The setting can be any provider/supplier at which MHC services are furnished. It need not be one of the four provider/supplier types listed in § 410.54(a)(2). Moreover, the provider/supplier need not have been (or currently be) enrolled in Medicare at the time the MHC performed the services there; or*

   (ii) A statement verifying that the MHC meets the year or hour requirements from a: (1) licensing or credentialing body for the state in which the MHC is enrolling; or (2) national MHC credentialing organization. The statement can be signed by any official of

the state licensing/credentialing or national credentialing body. It must, however, be on the body's letterhead.

If the MHC fails to furnish the above documentation, the contractor shall develop for it consistent with the instructions in this chapter.

3. *§ 410.54(a)(3) – The contractor shall verify state licensure or certification consistent with existing policies for doing so in this chapter.*

   If the contractor confirms to its satisfaction that the state already requires, as a condition of licensure or credentialing, the MHC to have:

   - *Performed, at a minimum, either 2 years or 3,000 hours of clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic, the contractor can forgo verifying separate compliance with the § 410.54(a)(2) requirement described above; the MHC need not submit the documentation specified in subsection (B)(2). (This is because the licensure/credentialing already includes the year/hour requirement.)*

   - *A master's or doctor's degree (as applicable), the MHC need not submit a copy of his or her degree nor need the contractor verify that the MHC received said degree.*

C. Further Information

1. *Addiction Counselors – Addiction counselors and ADCs may enroll as MHCs if they meet the MHC requirements. They cannot, however, enroll as addiction counselors or ADCs.*

2. *Pre/Post Degree – As indicated above, all 2 years/3,000 hours of clinical supervised experience must have been performed post-degree. Pre-degree experience does not count towards the required time total under § 410.53(a)(2), even if the state permits pre-degree experience to be counted towards meeting state requirements. For example, suppose State X requires 1,000 hours of supervised experience for licensure. The hours can be performed pre-degree or post-degree. Jones, who is licensed by X, performed her 1,000 hours before receiving her degree. Jones cannot apply these hours towards the § 410.53(a)(2) time requirement – even though she is licensed – and must furnish evidence of 2 years/3,000 hours post-degree experience. If, however, Jones had performed 500 hours pre-degree and 500 hours post-degree, she could apply the latter (but not the former) to the § 410.53(a)(2) time requirement.*

3. *Additional Policies - Like certain other individual practitioners, MHCs may opt-out of Medicare, form groups, reassign their benefits under § 424.80, receive reassigned benefits, and order/certify services to the extent otherwise permitted by law. They will complete the Form CMS-855I to bill for services and be subject to limited-risk screening (except as described in § 424.518(c)(3)).*

Until the Form CMS-855I is revised to include MHCs, the MHC shall check the "Undefined Non-Physician Practitioner Specialty" box and state "mental health counselor" in the line next thereto.

10.2.6 - Medicare Diabetes Prevention Program (MDPP) Suppliers

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. General Background Information

MDPP is a structured lifestyle intervention that includes dietary coaching, lifestyle intervention, and moderate physical activity, all with the goal of preventing the onset of diabetes in individuals who are pre-diabetic. An entity or individual seeking to furnish MDPP services to Medicare beneficiaries must enroll as an "MDPP supplier" via the Form CMS-20134. Such suppliers must meet the following enrollment requirements:

- Has MDPP preliminary recognition (as defined at 42 CFR § 424.205(c)(1)) or full recognition as determined by the Center for Disease Control and Prevention's (CDC) Diabetes Prevention Recognition Program (DPRP)

- Maintains a valid TIN and NPI at the organizational level

- Passed screening requirements at a high categorical risk level per § 424.518(c) upon initial enrollment and revalidate at the moderate categorical risk level per § 424.518(b) and

- Complies with the supplier standards

MDPP supplier applicants do not require any licensure, accreditation, or certificates to be eligible to enroll as an MDPP supplier. Rather, the CDC administers the curriculum for the MDPP and monitors the organization's fidelity to and success with furnishing the services. Thus, organizations with preliminary or full recognition from the CDC's DPRP indicate that they are prepared to deliver MDPP services.

As a part of the expanded CMMI model, CMS will only accept in-person MDPP suppliers to enroll in Medicare. Though an entity may furnish a select number of virtual MDPP make up sessions to a beneficiary (no more than 4 per beneficiary over the entire period of MDPP services), they would still be considered in-person MDPP suppliers.

B. MDPP Supplier Standards

All MDPP suppliers must comply with MDPP supplier standards to obtain and retain Medicare billing privileges. Consistent with 42 CFR § 424.205(b)(5) and (d), each MDPP supplier must certify on its Form CMS-20134 enrollment application that it meets and will continue to meet the following standards (listed in § 424.205(d)) and all other requirements:

(1) Must have and maintain MDPP preliminary recognition or full CDC DPRP recognition
(2) Must not currently have its billing privileges terminated or be excluded by a state Medicaid agency
(3) Must not permit MDPP services to be furnished by or include on its roster any individual coach who meets the ineligibility criteria in § 424.205(e)(1)
(4) Must maintain at least one administrative location on an appropriate site. All administrative locations, must be reported on their CMS-20134 form and may be subject to site visits. (See § 424.205(d)(4) for more information regarding site requirements.)
(5) Must update the enrollment application within 30 days for any change of ownership, change to the coach roster, *change of practice location (including additions and deletions of locations)*, and final adverse legal action history, and update all other changes within 90 days
(6) Must maintain a primary business telephone that is operating at administrative locations or directly where services are furnished. The associated telephone number must be listed with the name of the business in public view.
(7) Must not convey or reassign a supplier billing number
(8) Must not deny an MDPP beneficiary access to MDPP services during the MDPP benefit period, including conditioning access to MDPP services on the basis of an MDPP beneficiary's weight, health status, or achievement of performance goals (with certain

exceptions described in § 424.205(d)(8)(i))

(9) Must not---nor may other individuals or entities performing functions or services related to MDPP services on the MDPP supplier's behalf---directly or indirectly commit any act or omission, or adopt any policy that coerces or otherwise influences an MDPP beneficiary's decision to begin accessing MDPP services or change to a different MDPP supplier specifically

(10) Must offer an MDPP beneficiary no fewer than the services described in § 424.205(d)(10)

(11) Must disclose detailed information about the MDPP benefit to each beneficiary to whom it furnishes MDPP services before the initial core session is furnished, including the set of services, eligibility requirements, the once-per-lifetime nature of MDPP services, and the standards in § 424.205(d)

(12) Must answer MDPP beneficiaries' questions about MDPP services and respond to MDPP related complaints. An MDPP supplier must implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such action on behalf of the MDPP supplier. This information must be kept at each administrative location and made available to CMS or its contractors upon request

(13) Must maintain a crosswalk file which indicates how participant identifications for the purposes of CDC performance data correspond to corresponding beneficiary health insurance claims numbers or Medicare Beneficiary Identifiers for each MDPP beneficiary. The MDPP supplier must submit the crosswalk file to CMS or its contractor

(14) Must submit performance data for MDPP beneficiaries who attend ongoing maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core benefit

(15) Must allow CMS or its agents to conduct onsite inspections or recordkeeping reviews in order to ascertain the MDPP supplier's compliance with these standards, as well as the documentation requirements outlined § 424.205(g)

The CMS will notify the contractor when an MDPP supplier within its jurisdiction has moved from preliminary or full recognition down to pending and therefore no longer maintains eligibility as an MDPP supplier.

For those suppliers that no longer have a valid recognition level to maintain their MDPP supplier enrollment, the contractor shall take the necessary steps to revoke the supplier's billing privileges.

Violations of the supplier standards are determined as non-compliance and the associated enrolment denial and revocation authorities would apply.

10.2.8 - Providers/Suppliers Not Eligible to Enroll

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

Section 10.2.8 contains a *non-exhaustive* list of individuals and entities that frequently attempt to enroll in Medicare *but are not eligible to enroll as one of the categories listed below. (For instance, an individual cannot enroll as a drug and alcohol rehabilitation counselor.)* If the contractor receives an enrollment application from an individual/entity attempting *to enroll as one of these categories below*, the contractor shall deny the application -- with the exception of entities eligible to enroll using the Form CMS-20134, which is specific to the furnishing of MDPP services. An assisted living facility, for example, that also provides the DPP and is eligible to enroll as an MDPP supplier may enroll

through the CMS-20134; however, this enrollment only pertains to the rendering of MDPP services.

- Acupuncturist
- Assisted Living Facility
- Birthing Center
- Certified Alcohol and Drug Counselor
- Certified Social Worker
- Drug and Alcohol Rehabilitation Counselor
- Hearing Aid Center/Dealer
- Intern (Graduate Medical Education)
- Licensed Alcoholic and Drug Counselor
- Licensed Massage Therapist
- Licensed Practical Nurse
- Licensed Professional Counselor
- Master of Social Work
- Medicare Beneficiaries
- National Certified Counselor
- Naturopath
- Occupational Therapist Assistant
- Physical Therapist Assistant
- Registered Nurse
- Speech and Hearing Center
- State Medicaid Agency (SMA)(SMAs do not have an NPI and are not eligible to enroll in the Medicare program. If an SMA is enrolled or seeks enrollment as a provider or supplier in the Medicare program, the contractor shall deny or revoke its Medicare billing privileges using, respectively, § 424.530(a)(5)(ii) (denials) and § 424.535(a)(5)(ii) (revocations) as the basis.)
- Substance Abuse Facility

10.4.2.1 - Denials – General Principles

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Notification Letters for Denials

If the contractor finds a legal basis for denying an application - and, if applicable under section 10.4.2 et seq., section 10.6.6, or another CMS directive, receives approval from PEOG for said denial - the contractor shall deny the application and notify the provider by letter. Except as stated otherwise in this chapter, the denial letter shall contain:

(i) A legal (i.e., regulatory) basis for each reason for the denial;

(ii) A clear explanation of why the application is being denied, including the facts or evidence that the contractor used in making its determination;

(iii) An explanation of why the provider does not meet the applicable enrollment criteria;

(iv) The appropriate regulatory basis (e.g., 42 CFR § 424.530(a)(1)) for the denial. (The contractor shall not use provisions from this chapter 10 as the basis for denial.)

(v) Procedures for submitting a corrective action plan (CAP, for denials based on 42 CFR § 424.530(a)(1)); and

(vi) Complete and accurate information about the provider's further appeal rights.

In addition, the letter shall follow the format of the applicable model denial letter in section 10.7 et seq. of this chapter.

There is no reenrollment bar for denied applications. Reenrollment bars apply only to revocations.

B. When Prior PEOG Approval of the Denial Necessary

For cases involving 42 CFR § 424.530(a)(3) (Felony Convictions), § 424.530(a)(4) (False or Misleading Information or Application), § 424.530(a)(6) (Existing Overpayment at Time of Application), § 424.530(a)(12) (Revoked Under Different Name, Numerical Identifier, or Business Identity), § 424.530(a)(13) (Affiliation that Poses an Undue Risk), § 424.530(a)(14) (Other Program Termination or Suspension), *§ 424.530(a)(15) (Patient Harm), and § 424.530(a)(17) (False Claims Act Judgments)*, the contractor shall obtain approval of both the denial and the denial letter from PEOG via the ProviderEnrollmentRevocations@cms.hhs.gov mailbox prior to sending the denial letter. The contractor shall also obtain prior PEOG approval of the denial and denial letter if otherwise required to do so in this chapter or another CMS directive (i.e., certain denial situations other than those described in this subsection 10.4.2.1(B) require prior PEOG approval). *(Note that MDPP denials no longer require prior PEOG approval except in cases where such approval is otherwise mandated per this section 10.4.2.1(B) (e.g., MDPP denials under (a)(3), (a)(4), etc.)*

PEOG will notify the contractor of its determination (including, as applicable, whether a reapplication bar under § 424.530(f) is to be imposed) and instruct the contractor as to how to proceed. Absent a CMS instruction or directive to the contrary, the denial letter shall be sent to the provider via certified mail no later than 5 business days after PEOG concludes that the provider's application should be denied. The contractor shall not proceed with finalizing the denial until it receives the aforementioned guidance from PEOG. If this guidance is delayed, the contractor shall carve the impacted application(s) out of its timeliness reporting; the contractor shall document and report the impacted application(s) in its Monthly Status Reports.

C. When Prior PEOG Approval of the Denial Unnecessary – Timeframe for Sending Letter

Absent a CMS instruction or directive to the contrary, the denial letter shall be sent to the provider/supplier via certified mail no later than 5 business days after the contractor determines that the provider's application should be denied.

D. No Denial Recommendation to State

If the applicant is a certified provider or certified supplier and a denial reason is implicated, the contractor need not submit a recommendation for denial to the state/SOG Location. Except as stated otherwise in this chapter, the contractor can simply: (1) deny the application (though, as explained in this chapter, some denials might require prior PEOG approval); (2) close out the PECOS record; (3) send a denial letter to the provider; and (4) copy the state and the SOG Location on said letter.

E. PECOS Entry

All denied applications and all applicable denial reasons shall be entered into PECOS, including fingerprint and non-covered provider or supplier type denials. For non-covered

provider or supplier type denials, the contractor shall select the "Other" specialty/provider/supplier type option and input the type listed on the application.

10.4.2.2 - Denial Reasons

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Denial Reason 1– Not in Compliance with Medicare Requirements (42 CFR § 424.530(a)(1))

"The provider or supplier is determined not to be in compliance with the enrollment requirements in *Title 42* or on the enrollment application applicable to its provider or supplier type, and has not submitted a plan of corrective action as outlined in 42 CFR part 488." Such non-compliance includes, but is not limited to, the following situations:

i. The provider or supplier does not have a physical business address or mobile unit where services can be rendered.

ii. The provider or supplier does not have a place where patient records are stored to determine the amounts due such provider or other person.

iii. The provider or supplier is not appropriately licensed.

iv. The provider or supplier is not authorized by the federal/state/local government to perform the services that it intends to render.

v. The provider or supplier does not meet CMS regulatory requirements for the specialty that it seeks to enroll as. (See section 10.2.8 of this chapter for examples of suppliers that are not eligible to participate.)

vi. The provider or supplier does not have a valid social security number (SSN) or employer identification number (EIN) for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or authorized or delegated official.

vii. The applicant does not qualify as a provider of services or a supplier of medical and health services. (For instance, the applicant is not recognized by any federal statute as a Medicare provider or supplier (see section 10.2.8 of this chapter.)) An entity seeking Medicare payment must be able to receive reassigned benefits from physicians in accordance with the Medicare reassignment provisions in § 1842(b)(6) of the Act (42 U.S.C. 1395u(b)).

viii. The provider or supplier does not otherwise meet general enrollment requirements.

ix. The provider or supplier does not meet standards specific to their supplier type. *(See section 10.4.2.3 for more information.)*

(With respect to (v) above – and, as applicable, (iii), (iv) and (ix) - the contractor's denial letter shall cite the appropriate statutory and/or regulatory citation(s) containing the specific licensure/certification/authorization requirement(s) for that provider or supplier type. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

NOTE: The contractor must identify in its denial letter the exact provision within said statute(s)/regulation(s) with which the provider/supplier is non-compliant.

B. Denial Reason 2– Excluded/Debarred from Federal Program (42 CFR § 424.530(a)(2))

"The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel (such as a billing specialist, accountant, or human resources specialist) furnishing services payable by a federal health care program, of the provider or supplier is—

(i) Excluded from Medicare, Medicaid, or any other federal health care program, as defined in 42 CFR § 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Social Security Act, or

(ii) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement program or activity in accordance with section 2455 of the Federal Acquisition Streamlining Act."

(Unless stated otherwise in section 10.6.6 of this chapter or in another CMS directive, the contractor need not review the OIG exclusion list for any "health care or administrative or management services personnel" who are not otherwise required to be reported on the enrollment application.)

C. Denial Reason 3 – Felony Conviction (42 CFR § 424.530(a)(3))

"The provider, supplier, or any owner, managing employee, managing organization, officer, director, of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR § 1001.2) of a federal or state felony offense that CMS determines to be detrimental to the best interests of the Medicare program and its beneficiaries. Offenses include, but are not limited in scope and severity to:

(i) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(ii) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(iii) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(iv) Any felonies outlined in section 1128 of the Social Security Act."

While a reenrollment bar is established for revoked providers/suppliers, this does not preclude the contractor from denying reenrollment to a provider/supplier that was convicted of a felony within the preceding 10-year period or that otherwise does not meet all of the criteria necessary to enroll in Medicare.

Note that if an MDPP coach meets the above felony requirements, this would not itself warrant a denial of the MDPP supplier under § 424.535(a)(3). This is because the coach, not the MDPP supplier, has the felony conviction. The MDPP supplier could, however, be denied enrollment under § 424.530(a)(1) (non-compliance with enrollment requirements) for having an ineligible coach.

As explained in section 10.6.6 of this chapter, the contractor shall submit all felonies found on Form CMS-855 and CMS-20134 applications to PEOG for review via ProviderEnrollmentRevocations@cms.hhs.gov. (See section 10.6.6 for more information.)

D. Denial Reason 4– False or Misleading Information on Application (42 CFR § 424.530(a)(4))

"The provider or supplier submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program."

E. Denial Reason 5– On-Site Review/Other Reliable Evidence that Requirements Not Met (42 CFR §424.530(a)(5))

"Upon on-site review or other reliable evidence, CMS determines that the provider or supplier:

(i) Is not operational to furnish Medicare-covered items or services; or
(ii) Otherwise fails to satisfy any Medicare enrollment requirement."

F. Denial Reason 6– Existing Overpayment at Time of Application (42 CFR § 424.530(a)(6))

1. Background

Consistent with 42 CFR § 424.530(a)(6), an enrollment application may be denied if the provider, supplier, or owner thereof has an existing Medicare overpayment that is equal to or exceeds a threshold of $1,500 and has not been repaid in full at the time the application was filed. More specifically:

"(A) The enrolling provider, supplier, or owner (as defined in § 424.502) thereof has an existing Medicare debt.

(B) The enrolling provider, supplier, or owner (as defined in § 424.502) thereof was previously the owner of a provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily terminated, involuntarily terminated, or revoked, and all of the following criteria are met:

(1) The owner left the provider or supplier with the Medicare debt within 1 year before or after that provider or supplier's voluntary termination, involuntary termination, or revocation.

(2) The Medicare debt has not been fully repaid.

(3) CMS determines that the uncollected debt poses an undue risk of fraud, waste, or abuse. In making this determination [under § 424.530(a)(6)(ii)], CMS considers the following factors:

(a) The amount of the Medicare debt.

(b) The length and timeframe that the enrolling provider, supplier, or owner thereof was an owner of the prior entity.

(c) The percentage of the enrolling provider, supplier, or owner's ownership of the prior entity.

(d) Whether the Medicare debt is currently being appealed.

(e) Whether the enrolling provider, supplier, or owner thereof was an owner of the prior entity at the time the Medicare debt was incurred."

In addition, a denial of Medicare enrollment under paragraph (a)(6) can be avoided if the enrolling provider, supplier, or owner thereof does either of the following: (1) satisfies the criteria set forth in § 401.607 and agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt; or (2) repays the debt in full.

1. Contractor's Determination of Overpayment

When processing a Form CMS-855A, CMS-855B, CMS-855I, CMS-855S, or CMS-20134 initial or change of ownership application (if applicable), the contractor shall determine – using a system generated monthly listing – whether the provider, supplier, or any owner listed in Section 5 or 6 of the application has an existing or delinquent Medicare overpayment, as described in section 10.4.2.2(F)(1) above and § 424.530(a)(6). If such an overpayment exists, the contractor shall deny the application, using 42 CFR §424.530(a)(6) as the basis. However, prior PEOG approval is required before proceeding with the denial. The contractor shall under no circumstances deny an application under § 424.530(a)(6) without receiving PEOG approval to do so.

2. Examples

Example #1: Dr. X, a sole proprietor, has a $70,000 overpayment. Three months later, he joins Group Y and becomes a 50 percent owner thereof. Group Y submits an initial enrollment application two months thereafter. Group Y's enrollment could be denied because Dr. X is an owner.

Example #2: Dr. John Smith's practice ("Smith Medicine") is set up as a sole proprietorship. He incurs a $50,000 overpayment. He terminates his Medicare enrollment. Six months later, he tries to enroll as a sole proprietorship; his practice is named "JS Medicine." A denial is warranted because § 424.530(a)(6) applies to physicians and the $50,000 overpayment was attached to him as the sole proprietor.

Example #3 - Same scenario as example #2, but assume that his new practice is an LLC of which he is only a 30 percent owner. A denial is still warranted because he is an owner of the enrolling supplier and the $50,000 overpayment was attached to him.

Example #4 - Jane Smith is a nurse practitioner in a solo practice. Her practice ("Smith Medicine") is set up as a closely-held corporation, of which she is the 100 percent owner. Smith Medicine is assessed a $20,000 overpayment. She terminates her Medicare enrollment. Nine months later, she submits a Form CMS-855I application to enroll herself, Jane Smith as a new individual provider. The business will be established as a sole proprietorship. A denial is not warranted because the $20,000 overpayment was attached to Smith Medicine, not to Jane Smith.

In each of these examples, however, denial could be avoided if (1) the party with the overpayment is on a Medicare-approved plan of repayment or (2) the overpayments in question are currently being offset or being appealed.

3. Additional Considerations Involving § 424.530(a)(6)

The contractor shall also observe the following with respect to § 424.530(a)(6):

a. In determining whether an overpayment exists, the contractor need only review its own records; it need not contact other contractors to determine whether the person or entity has an overpayment in those contractor jurisdictions.

b. The instructions in this section 10.4.2.2(F) apply only to (i) initial enrollments and (ii) new owners in a change of ownership.

c. The term "owner" under § 424.502 means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of, the provider or supplier as defined in sections 1124 and 1124A(A) of the Act.

d. If the person or entity had an overpayment at the time the application was filed but repaid it in full by the time the contractor performed the review described in this section 10.4.2.2(F), the contractor shall not deny the application based on § 424.530(a)(6).

G. Denial Reason 7– Medicare or Medicaid Payment Suspension (42 CFR § 424.530(a)(7))

"The provider, supplier or any owning and managing employee or organization of the provider or supplier is currently under a Medicare or Medicaid payment suspension at the time the denial is issued, as defined in § 405.370 through §405.372."

H. Denial Reason 8– Home Health Agency (HHA) Capitalization (42 CFR § 424.530(a)(8))

An HHA submitting an initial application for enrollment:

a. Cannot, within 30 days of a CMS or Medicare contractor request, furnish supporting documentation verifying that the HHA meets the initial reserve operating funds requirement in 42 CFR § 489.28(a); or

b. Fails to satisfy the initial reserve operating funds requirement in 42 CFR § 489.28(a).

I. Denial Reason 9– Hardship Exception Denial and Fee Not Paid (42 CFR § 424.530(a)(9))

"The institutional provider's (as that term is defined in 42 CFR § 424.502) hardship exception request is not granted, and the institutional provider does not submit the required application fee within 30 days of notification that the hardship exception request was not approved."

(This denial reason should only be used when the institutional provider fails to submit the application fee <u>after</u> its hardship request was denied. The contractor shall use § 424.530(a)(1) as a basis for denial when the institutional provider: (a) does not submit a hardship exception request and fails to submit the application fee within the prescribed timeframes; or (b) submits the fee, but it cannot be deposited into a government-owned account.)

J. Denial Reason 10– Temporary Moratorium (42 CFR § 424.530(a)(10))

"The provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium." (This denial reason applies to initial enrollment applications and practice location additions.)

K. Denial Reason 11– DEA Certificate/State Prescribing Authority Suspension or Revocation (42 CFR § 424.530(a)(11))

"1. A physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause; or

2. The applicable licensing or administrative body for any state in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date the physician or eligible professional submits his or her enrollment application to the Medicare contractor."

(Except as otherwise stated in this chapter or in another CMS directive, the contractor need not verify whether an individual's DEA certificate was surrendered in response to a show cause order.)

L. Denial Reason 12 (42 CFR § 424.530(a)(12) - Revoked Under Different Name, Numerical Identifier, or Business Identity)

"The provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired. In making its determination, CMS considers the following factors:

(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 [or CMS-20134] application);
(ii) Geographic location;
(iii) Provider or supplier type;
(iv) Business structure; or
(v) Any evidence indicating that the two parties [the revoked provider/supplier and the newly-enrolling provider/supplier] are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar."

NOTE: With respect to (a)(12), PEOG – rather than the contractor – will make all determinations regarding whether a provider or supplier was revoked under a different name, numerical identifier or business identity.

M. Denial Reason 13 (42 CFR § 424.530(a)(13) - Affiliation that Poses an Undue Risk)

"The provider or supplier has or has had an affiliation under 42 CFR § 424.519 (specifically, the factors listed in 42 CFR § 424.519(f)) that poses an undue risk of fraud, waste, and abuse to the Medicare program."

An affiliation is defined as any of the following:

(i) A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
(ii) A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
(iii) An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of § 424.519 only, sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.
(iv) An interest in which an individual is acting as an officer or director of a corporation.
(v) Any reassignment relationship under § 424.80.

NOTE: With respect to (a)(13), PEOG -- rather than the contractor – will make all determinations regarding whether a provider or supplier has an affiliation per 42 CFR § 424.519 that poses an undue risk of fraud, waste and abuse.

N. Denial Reason 14 (42 CFR § 424.530(a)(14) – Other Program Termination or Suspension)

"(1) The provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a state Medicaid program or any other federal health care program; or (2) the provider or supplier's license is currently revoked or suspended in a state other than that in which the provider or supplier is enrolling."

In determining whether a denial under § 424.530(a)(14) is appropriate, CMS considers the following factors:

a. The reason(s) for the termination, suspension, or revocation;

b. Whether, as applicable, the provider or supplier is currently terminated or suspended (or otherwise barred) from more than one program (for example, more than one state's Medicaid program), has been subject to any other sanctions during its participation in other programs or by any other state licensing boards, or has had any other final adverse actions (as that term is defined in § 424.502) imposed against it; and

c. Any other information that CMS deems relevant to its determination."

NOTE: With respect to (a)(14), PEOG -- rather than the contractor – will make all determinations regarding whether a provider or supplier has a termination or suspension from another program.

O. Denial Reason 15 (42 CFR § 424.530(a)(15) – Patient Harm)

"The physician or other eligible professional has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a denial is appropriate, CMS considers the following factors:

(A) The nature of the patient harm

(B) The nature of the physician's or other eligible professional's conduct

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree: (i) license restriction(s) pertaining to certain procedures or practices; (ii) required compliance appearances before state oversight board members; (iii) license restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge); (iv) administrative/monetary penalties; and (v) formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon."

Section 424.530(a)(15) does not apply to actions or orders pertaining exclusively to either of the following: (i) required participation in rehabilitation or mental/behavioral health programs; or (ii) required abstinence from drugs or alcohol and random drug testing.

NOTE: With respect to (a)(15), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

P. Denial Reason 17 – False Claims Act Judgment (42 CFR § 424.530(a)(17))

"(i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the False Claims Act (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a denial under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502).

(F) Any other information that CMS deems relevant to its determination."

NOTE: With respect to (a)(17), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

Q. Denial Reason 18 – Standard or Condition Violation (42 CFR § 424.530(a)(18))

"(i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d)."

(Similar to current practice with respect to § 424.530(a)(1), the contractor can make denial determinations under § 424.530(a)(18) without prior PEOG approval. The contractor's denial letter shall cite the exact statutory and/or regulatory citation(s) containing the specific standard/condition with which the provider/supplier is non-compliant. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

(See section 10.4.2.3 for more information regarding § 424.530(a)(18).)

10.4.2.3 – Additional Denial Policies

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Post-Denial Submission of Enrollment Application

A denied provider may not submit a new enrollment application until:

(i) If the initial denial was not appealed, the provider's appeal rights have lapsed;

(ii) If the initial denial was appealed, the provider has received notification that the determination was upheld; or

(iii) The reapplication bar has expired, if applicable.

The contractor shall return an application submitted before the aforementioned have occurred.

B. 30-Day Effective Date of Denial

A denial is effective 30 calendar days after the contractor sends its denial notice to the provider.

As stated in 42 CFR § 424.530(c), if the denial was due to adverse activity (e.g., exclusion, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care or administrative or management personnel of the provider or supplier furnishing services payable by a federal health care program, the denial may be reversed (with PEOG approval) if the provider or supplier submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

C. Denials - Changes of Information and Changes of Ownership (CHOWs)

1. Expiration of Timeframe for Reporting Changes

If the contractor denies a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has expired, the contractor shall send an e-mail to the CMS MedicareProviderEnrollment@cms.hhs.gov mailbox notifying PEOG of the denial. PEOG will determine whether the provider's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

2. Timeframe Not Yet Expired

If the contractor denies a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has not yet expired, the contractor shall send the e-mail referenced in subsection (C)(1) above after the expiration of said time period unless the provider has resubmitted the change request/CHOW.

3. Second Rejection, Return, or Denial

If, per subsection (C)(2) above, the provider resubmits the change of information or CHOW application and the contractor either denies it again, returns it, or rejects it, the contractor shall send the e-mail referenced in subsection (C)(1) above regardless of whether the applicable timeframe has expired. PEOG will determine whether the provider's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

D. Reactivations

If the contractor denies a reactivation application, the provider's Medicare billing privileges shall remain deactivated or revoked.

E. Revalidations

If the contractor denies a revalidation application, the contractor shall – unless an existing CMS instruction or directive states otherwise - deactivate the provider's Medicare billing privileges if the applicable time period for submitting the revalidation application has expired. If it has not expired, the contractor shall deactivate the provider's billing privileges after the applicable time period expires unless the provider has resubmitted the revalidation application. If, per the previous sentence, the provider resubmits the application and the contractor denies it again, returns it, or rejects it, the contractor shall - unless an existing CMS instruction or directive states otherwise – revoke the provider's billing privileges, assuming the applicable time period has expired.

F. Appeals of Denials

For information regarding the provider enrollment appeals process, see section 10.6.18 of this chapter.

G. *Use of 424.530(a)(1)*

1. (A)(1) Versus (A)(5)

If a denial is warranted because the provider/supplier's location is vacant, occupied by another party, closed during office hours, etc., or a state survey failure is involved, the contractor shall use § 424.530(a)(5) (rather than § 424.530(a)(1)) as the denial reason. (This applies to both certified and non-certified providers/suppliers.) No CAP rights are therefore involved.

2. (A)(1) Versus (A)(18)

If a denial is warranted due to non-compliance with one of the standards and conditions referenced in § 424.530(a)(18), the contractor shall use § 424.530(a)(18) (rather than § 424.530(a)(1)) as the denial reason. No CAP rights are therefore involved.

10.4.4 – Changes of Information

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. General Information

Unless as stated otherwise in this chapter, the following apply:

(i) The instructions in this section 10.4.4 apply to Part A and Part B enrollments.

(ii) In the event an instruction in sections 10.6.1 et seq. or 10.6.22 et seq. of this chapter contradicts that in this section 10.4.4, the section 10.6.1 et seq. or 10.6.22 et seq. guidance takes precedence (e.g., transitioned certified provider/supplier change of information instructions in section 10.6.1.2 of this chapter).

(iii) Except as otherwise specified in this chapter or another CMS directive, if an enrolled provider/supplier is adding, deleting, or changing information under its existing tax identification number, it must report the change using the applicable Form CMS-855 or

CMS-20134. (Letterhead is impermissible.) The provider/supplier shall: (a) furnish the changed data in the applicable section(s) of the form; and (b) sign and date the certification statement.

(iv) The timeframes for reporting changes are generally addressed in § 424.516.

B. Time Requirements to Report Changes of Information via a Form CMS-855/20134 Application

(For purposes of the regulatory provisions referenced in this section 10.4.4(B) (e.g., § 424.57(c)(2)):

- *A practice location "change" includes location additions, deletions, and relocations.*
- *All practice location changes – regardless of the provider or supplier type involved – must be reported within 30 days of the change.)*

1. Physicians/Non-Physicians/Groups

Pursuant to § 424.516(d), change of information requirements apply to physicians, non-physician practitioners, and physician and non-physician practitioner organizations (i.e., clinic/group practices). These supplier types must report the following changes within 30 days: (1) a change of ownership; (2) adverse legal action; and (3) a change in practice location. All other changes must be reported within 90 days.

2. DMEPOS Suppliers

Per 42 CFR §§ 424.57(c)(2) and 424.516(c), DMEPOS suppliers must report any change to their enrollment information within 30 days.

3. IDTFs

Per 42 CFR §§ 410.33(g)(2) and 424.516(b), IDTFs must report any change in adverse legal actions, ownership, location, and general supervision within 30 days. All other changes must be reported within 90 days.

4. MDPP Suppliers

Per 42 CFR §§ 424.205(d)(5) and 424.516(e), an MDPP supplier must update its enrollment application within 30 days of any change of ownership, *practice location,* change to its coach roster (including due to coach ineligibility or because the coach is no longer an employee, contractor, or volunteer of the MDPP supplier), or change in final adverse action history. All other changes must be reported within 90 days.

5. All Other Provider/Supplier Types

Consistent with 42 CFR § 424.516(e), all other provider/supplier types not specifically referenced in § 424.516(b) through (e) are subject to the following reporting timeframes:

(i) Changes of ownership or control (including changes in authorized official(s) or delegated official(s)); *change of practice location* – 30 days

(ii) All other changes – 90 days

(In addition, and per § 424.516(e)(3), an air ambulance supplier must report a revocation or suspension of its license or certification to the contractor within 30 days of the

revocation/suspension. The following FAA certifications must be reported: (a) specific pilot certifications including, but not limited to, instrument and medical certifications; and (b) airworthiness certification.)

C. Signatories and Notifications

1. Signer Not on Record - If the signer has never been reported in Section 6 of the Form CMS-855 or CMS-20134, Section 6 must be completed in full with information about the individual. (This policy applies regardless of whether the provider/supplier already has a Form CMS-855/20134 on file.) The contractor shall conduct all required validations concerning the individual.

2. Notifications – For changes of information that do not require state agency or SOG Location approval (e.g., Form CMS-855I changes, Form CMS-855B changes not involving ambulatory surgical centers or portable x-ray suppliers, minor Form CMS-855A/B certified provider/supplier changes), the contractor shall:

(i) Furnish written, e-mail, PCV, or fax confirmation to the provider that the change has been made; and

(ii) Document PECOS (per sections 10.3 and 10.6.19 of this chapter) with the date and time the confirmation was made. If, however, the transaction only involves an area code/ZIP code change, the contractor need not send confirmation to the provider that it has processed the change.

3. Confirmation of Change in Practice Location Address

In cases where a provider submits a Form CMS-855 or Form CMS-20134 request to change its practice location address, the contractor shall contact the location currently associated with the provider in PECOS or MCS to verify that the provider/supplier is no longer there and did in fact move.

D. Change in Special Payments Address

Note that the instructions in this subsection (D) are in addition to, and not in lieu of, those in section 10.6.23 and vice versa.

1. Submitted Change - If the provider/supplier submits a change to its special payments address, the contractor shall verify the change by contacting the individual physician/practitioner (Form CMS-855I changes), an authorized or delegated official (Form CMS-855A, Form CMS-855B, and Form CMS-20134 changes), or the contact person listed in Section 13 (for Form CMS-855A, Form CMS-855B, Form CMS-20134, and Form CMS-855I changes). If the contractor cannot reach, as applicable, the individual physician/practitioner or an authorized or delegated official, it shall confirm the change with the contact person.

2. Revalidation - When processing a revalidation application, the contractor shall (unless another CMS directive instructs otherwise) follow the instructions in sections 10.4.4(D) and 10.4.4(C)(3) above, respectively, if the practice location address or special payment address on the application is different from that currently associated with the provider in PECOS or MCS.

E. Provider or Supplier Changing Specialty Type

With the exception of individual physicians and certain situations described in section 10.3 of this chapter, providers and suppliers who wish to change their enrolled provider/supplier type must terminate their current enrollment and submit an initial enrollment application (Screening and an application fee (if applicable) applies for the new enrollment.)

F. Changes Involving Complete Form CMS-855 or CMS-20134 Applications

A provider must submit a complete Form CMS-855 or CMS-20134 application if it (1) submits any change request and (2) does not have an established enrollment record in PECOS. (For purposes of this requirement, the term "change request" includes EFT changes.) It is immaterial whether: (1) the provider or another party (e.g., local government changes street name) was responsible for triggering the changed data; or (2) the signer of the change request or EFT form already has a signature on file with the contractor.

If the contractor receives a change request from a provider that is not in PECOS, the contractor shall develop for the entire application consistent with the procedures described in this chapter (i.e., the contractor shall treat the transaction as a request for additional information). Consistent with existing policies for requesting additional data, the provider has 30 calendar days from the date of the contractor's request to furnish a complete Form CMS-855 or CMS-20134. During this period, the contractor should "hold" (i.e., not process) the change request until the entire application arrives; no L & T record shall be created in PECOS at this point.

If the provider fails to submit a complete application within the aforementioned 30-day period, the contractor shall follow the instructions in section 10.4.1.4.3 of this chapter.

If the provider submits the application, the contractor shall process it in accordance with the instructions in this chapter and all other applicable CMS directives. This includes:

(i) Processing the complete application consistent with the timeframes for initial applications outlined in this chapter.

(ii) Validate all data elements on the Form CMS-855 or CMS-20134 consistent with the instructions in this chapter pertaining to initial applications. The contractor shall not approve the change request until it has verified all data on the complete Form CMS-855 or CMS-20134 consistent with the instructions in this chapter.

(iii) Creating a record in PECOS prior to approving the change request. (The receipt date should be the date on which the complete application was received, not the date on which the initial change request was received.) The transaction should be treated as an initial enrollment in PECOS; internally, the contractor shall treat it as a change of information. As the complete application will presumably incorporate the changed data reported on the original Form CMS-855 or CMS-20134 change request, the contractor shall not take two separate counts (one initial and one change request) for the transaction. (NOTE: Any PECOS 2.0 policies or procedures that are contrary to those in this subparagraph (iii) take precedence over the latter.)

G. Incomplete or Unverifiable Changes of Information

(The contractor shall follow the instructions in this section 10.4.4(G) if it cannot process the submitted change request to completion.)

There can be instances where a provider has an enrollment record in PECOS and submits a change request but: (1) fails to timely respond to the contractor's request for additional or clarifying information; or (2) the changed information cannot be validated. The contractor in

these situations shall reject the change request in accordance with section 10.4.1.4.3 of this chapter. Moreover, if the changed information is of such materiality that the contractor cannot determine whether the provider still meets all enrollment requirements, the contractor shall refer the matter to its PEOG BFL for guidance. Examples include but are not limited to: (i) change in the provider's lone practice location; (ii) change in ownership; or (iii) change in EFT information.

H. Change of EFT Information

(Note that the instructions in this subsection (H) are in addition to, and not in lieu, those in section 10.6.23 and vice versa.)

If the provider submits a Form CMS-588 request to change the bank name, depository routing transit number, or depository account number, the contractor shall contact the individual physician/practitioner (for Form CMS-855I enrollees), an authorized or delegated official on record (for Form CMS-855A, CMS-855B, and Form CMS-20134 enrollees), or the Section 13 contact person on record (for Form CMS-855A, Form CMS-855B, Form CMS-20134 and Form CMS-855I enrollees) to verify the change. If the contractor cannot reach, as applicable, the individual physician/practitioner or an authorized or delegated official, it shall confirm the change with the contact person.

I. Special Instructions for Certified Providers, ASCs, and Portable X-ray Suppliers

1. Timeframe for State Review

In situations where state and/or SOG Location review of the change of information is required (see sections 10.6.1.2 and 10.6.22.1), the contractor may (via any means) advise the provider that it may take several months for the request to be approved.

2. Post-Recommendation Changes

If an applicant submits a change request after the contractor recommends approval of the provider's initial Form CMS-855 application but before the state or SOG Location (as applicable) notifies the contractor that, respectively, it recommends approval of or approves the initial application, the contractor shall process the newly-submitted data as a separate change of information. The contractor shall not take the changed information/corrected pages and, immediately upon receipt, send them directly to the state/SOG Location for incorporation into the existing application.

In entering the change request into PECOS, the contractor shall use the date on which it received the change request in its mailroom as the actual receipt date in PECOS; the contractor shall not use the date on which the contractor received the aforementioned state/SOG Location approval/recommendation. The contractor shall explain the situation in PECOS.

J. Critical Access Hospital (CAH) Addition of New Provider-Based Locations

Regulations found at 42 CFR § 485.610(e)(2) and in the State Operations Manual state that the CAH's provider-based location must meet certain distance requirements from the main campus of another hospital or CAH.

The contractor shall contact the appropriate SOG Location while processing the Form CMS-855A to verify that the CAH's new provider-based location is more than 35 miles (15 miles in the case of mountainous terrain or an area with only secondary roads) from the main

campus of another hospital or CAH. The contractor may not make a recommendation for approval without receiving a response from the SOG Location.

If the SOG Location finds that CAH's new provider-based location meets the distance requirements, the contractor shall continue processing the application normally. If the SOG Location determines that the location does not meet the distance requirements, the contractor shall reject the application and issue to the CAH the applicable rejection letter outlined in section 10.7 et seq.

The SOG Location will provide the CAH with three options if the location does not meet the distance requirements:

1. The CAH keeps the new provider-based location, which will cause an involuntary termination in 90 days (as outlined in the Pub. 100-07, chapter 3, section 3012).
2. The CAH terminates the new provider-based location and continue its enrollment as a CAH.
3. The CAH keeps the new provider-based location but converts to a hospital (as outlined in Pub. 100-07, chapter 2, sections 2256G and 2256H).

For each option, the contractor shall keep the CAH's enrollment in an approved status in PECOS. For Option #1 above, the contractor will receive notice from the SOG Location of the termination, which will lead to revocation of the CAH's enrollment. For Option #2, the CAH's enrollment remains approved and the contractor shall expect no further communication from the SOG Location. If the CAH chooses Option #3 to convert to a hospital, the contractor will receive a Form CMS-855A to terminate the CAH's enrollment and a new Form CMS-855A to enroll as a hospital.

10.4.7.2 – Revocation Effective Dates

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Effective Dates

The contractor shall apply a revocation effective date based upon federal regulations at § 424.535(g). In general, and as discussed below, these dates are either prospective or retroactive.

1. Revocations with Prospective Effective Dates *(§ 424.535(g)(1))*

Except in the situations described in § 424.535(g)(2) and (g)(3) (see subsections (A)(2) and (A)(3) below), the contractor shall use a prospective effective date (i.e., the date that is 30 days after CMS or the CMS contractor mails notice of its determination to the provider).

2. Revocations with Retroactive Effective Dates *(§ 424.535(g)(2))*

Except as stated in § 424.535(g)(3) (see subsection (A)(3) below), the following revocation reasons require a retroactive effective date *per* § 424.535(*g*):

(i) Federal exclusion or debarment - The date of the exclusion or debarment

(ii) Felony conviction - The date of the felony conviction

(iii) State license suspension or revocation - The date of the license suspension or revocation

(iv) Practice location is non-operational - The date on which the provider's or supplier's practice location was no longer operational (per CMS' or the CMS contractor's determination)

(v) State license surrender in lieu of further disciplinary action - The date of the license surrender.

(vi) Termination from a federal health care program other than Medicare (for example, Medicaid) - The date of the termination.

(vii) For revocations based on termination of a provider agreement under 42 CFR Part 489, and as applicable to the type of provider involved, the later of the following:

(A) The date of the provider agreement termination; or
(B) The date that CMS establishes under § 489.55.

(viii) For revocations based on § 424.535(a)(23) (see section 10.4.7.3 below), the effective dates are as follows:

(A) If the standard or condition violation involves the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's federal or state license, certification, accreditation, or MDPP recognition, the effective date is the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

(B) If the standard or condition violation involves a non-operational practice location, the effective date is the date the non-operational status began.

(C) If the standard violation involves a felony conviction of an individual or entity described in § 424.67(b)(6)(i) (which pertains to OTPs), the effective date is the date of the felony conviction.

(D) For all standard violations not addressed in paragraphs (ix)(A) through (C) above, the effective date in § 424.535(g)(1) (see subsection (A)(1) above) applies if the effective date in § 424.535(g)(3) does not.

To illustrate, for a revocation involving a licensure revocation/suspension, the revocation effective date (and the date listed on the revocation letter) shall be the date of the actual license revocation/suspension.

3. *Revocations for Pre-Enrollment Actions (§ 424.535(g)(3))*

If the action that resulted in the revocation occurred prior to the effective date of the provider's or supplier's enrollment, the effective date of the revocation shall be the same as the effective date of enrollment.

Strictly for purposes of applying § 424.535(g)(3) -- and notwithstanding any guidance to the contrary in section 10.6.2 of this chapter – the effective date of enrollment is the date that was established under §§ 424.520 or 424.521, whichever is earlier.

B. Revocations Based Upon More than One Reason

When a revocation involves more than one reason, the contractor shall determine whether any of the grounds require a retroactive effective dates (listed in §§ 424.535(g) and section

10.4.7.2(B) above; if a retroactive date is indeed implicated, the contractor shall apply the appropriate retroactive date.

10.4.7.3 – Revocation Reasons

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

Sections 10.4.7.3(A) through (*W*) list the revocation reasons in 42 CFR § 424.535. Section 10.4.7.3(*X*) discusses extensions of revocations per 42 CFR § 424.535(i).

A. Revocation Reason 1 – Noncompliance (42 CFR § 424.535(a)(1))

"The provider or supplier is determined not to be in compliance with the enrollment requirements in *this Title 42* or in the enrollment application applicable to its provider or supplier type, and has not submitted a plan of corrective action as outlined in 42 CFR Part 488. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter."

(Title 42 includes the principal provider enrollment regulations in 42 CFR Part 424, subpart P; the IDTF enrollment standards in 42 CFR § 410.33; the OTP enrollment standards in 42 CFR § 424.67; etc.)

Noncompliance includes but is not limited to: (1) the provider/supplier no longer has a physical business address or mobile unit where services can be rendered; (2) the provider/supplier does not have a place where patient records are stored to determine the amounts due such provider or other person; and/or (3) the provider/supplier no longer meets or maintains general enrollment requirements. Noncompliance also includes situations when the provider/supplier has failed to pay any user fees as assessed under 42 CFR Part 488.

Other situations (some of which were mentioned in the previous paragraph) in which § 424.535(a)(1) may be used as a revocation reason include, but are not limited to, the following:

- The provider or supplier does not have a physical business address or mobile unit where services can be rendered.
- The provider or supplier does not have a place where patient records are stored to determine the amounts due such provider or other person.
- The provider or supplier is not appropriately licensed.
- The provider or supplier is not authorized by the federal/state/local government to perform the services that it intends to render.
- The provider or supplier does not meet CMS regulatory requirements for the specialty that it is enrolled as.
- The provider or supplier does not have a valid social security number (SSN) or employer identification number (EIN) for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or authorized or delegated official.
- The provider or supplier fails to furnish complete and accurate information and all supporting documentation within 60 calendar days of the provider/supplier's notification from CMS or its contractor to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

(This revocation reason will not apply if CMS has instructed the contractor to use deactivation reason § 424.540(a)(3) in lieu thereof.)

- The provider or supplier does not otherwise meet general enrollment requirements.

(Concerning the last bullet above – and, as applicable, bullets 3, 4 and 5 – the contractor's revocation letter shall cite the appropriate statutory and/or regulatory citation(s) containing the specific licensure/certification/authorization requirement(s) for that provider/supplier type.)

Special Instructions Regarding Certified Providers/Suppliers – The SOG Location may involuntarily terminate a certified provider/supplier if the latter no longer meets CMS requirements, conditions of participation, or conditions of coverage. When this occurs, CMS terminates the provider'/supplier's provider agreement and notifies the contractor thereof. Upon receipt of the CMS notice (and except as otherwise stated in this chapter), the contractor shall follow the revocation procedures in this chapter (including, as applicable, those in section 10.6.6)), using § 424.535(a)(1) as the revocation basis; the contractor shall not process the involuntary termination as a deactivation based upon a voluntary withdrawal from Medicare.

Note that the contractor need not (but certainly may) contact the SOG Location to obtain further details of the termination.

B. Revocation Reason 2 – Provider or Supplier Conduct (42 CFR § 424.535(a)(2))

"The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management personnel furnishing services payable by a federal health care program, of the provider or supplier is:

(i) Excluded from the Medicare, Medicaid, and any other federal health care program, as defined in 42 CFR § 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) Is debarred, suspended, or otherwise excluded from participating in any other federal procurement or non-procurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services non-procurement common rule at 45 CFR part 76."

If the contractor finds an excluded party (and unless section 10.6.6 states otherwise, in which case the latter section takes precedence), the contractor shall notify its PEOG BFL immediately. PEOG will notify the Contracting Officer's Representative (COR) for the appropriate Unified Program Integrity Contractor (UPIC). The COR will, in turn, contact the OIG for further investigation.

C. Revocation Reason 3 – Felony Conviction (42 CFR § 424.535(a)(3))

"The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR §1001.2) of a federal or state felony offense that CMS determines to be detrimental to the best interests of the Medicare program and its beneficiaries. [Under § 424.535(a)(3)(ii),] [o]ffenses include, but are not limited in scope and severity to:

- Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
- Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
- Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.
- Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

[Under § 424.535(a)(3)(iii),] revocations based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses."

The expiration of a reenrollment bar issued pursuant to 42 CFR § 424.535(c) does not preclude CMS or its contractors from denying reenrollment to a provider that (i) was convicted of a felony within the preceding 10-year period or (ii) otherwise does not meet all criteria necessary to enroll in Medicare.

D. Revocation Reason 4 – False or Misleading Information on Application (42 CFR § 424.535(a)(4))

"The provider or supplier certified as ''true'' misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current laws and regulations.)"

E. Revocation Reason 5 - On-Site Review/Other Reliable Evidence that Requirements Not Met (42 CFR § 424.535(a)(5))

"Upon on-site review or other reliable evidence, CMS determines that the provider or supplier:

(i) Is not operational to furnish Medicare-covered items or services; or
(ii) Otherwise fails to satisfy any Medicare enrollment requirement."

F. Revocation Reason 6 - Hardship Exception Denial and Fee Not Paid (42 CFR §424.535(a)(6))

(i) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application; or

(ii) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(iii) Either of the following occurs:

- CMS is not able to deposit the full application amount into a government-owned account; or

- The funds are not able to be credited to the United States Treasury;

(iv) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(v) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

G. Revocation Reason 7 – Misuse of Billing Number (42 CFR § 424.535(a)(7))

"The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers that enter into a valid reassignment of benefits as specified in 42 CFR § 424.80 or a change of ownership as outlined in 42 CFR § 489.18."

H. Revocation Reason 8 – Abuse of Billing Privileges (42 CFR § 424.535(a)(8))

"Abuse of billing privileges includes either of the following:

(i) The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to the following situations:

- Where the beneficiary is deceased.

- The directing physician or beneficiary is not in the state or country when services were furnished.

- When the equipment necessary for testing is not present where the testing is said to have occurred.

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following factors:

- The percentage of submitted claims that were denied during the period under consideration.

- Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502) and the nature of any such actions.

- The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).

- Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination."

(**NOTE**: Concerning (a)(8), PEOG -- rather than the contractor -- will (1) make all determinations regarding whether a provider has a pattern or practice of submitting non-compliant claims; (2) consider the relevant factors; and (3) accumulate all information needed to make such determinations.)

I. Revocation Reason 9 – Failure to Report (42 CFR § 424.535(a)(9))

"The provider or supplier failed to comply with the reporting requirements specified in 42 CFR § 424.516(d) or (e), § 410.33(g)(2), or § 424.57(c)(2) [which pertain to the reporting of changes in adverse actions and practice locations]."

With respect to § 424.535(a)(9) (and except as otherwise stated in section 10.6.6):

- If the provider reports a change in practice location more than 30 days after the effective date of the change, the contractor shall not pursue a revocation on this basis. However, if the contractor independently determines – through an on-site inspection under 42 CFR § 424.535(a)(5)(ii) or via another verification process - that the provider's address has changed but the provider has not notified the contractor thereof within the aforementioned 30-day timeframe, the contractor may pursue a revocation (e.g., seeking PEOG's approval to revoke).

- If an IDTF reports a change in ownership, change of location, change in general supervision or change in adverse legal action more than 30 days after the effective date of the change, the contractor may pursue a revocation on this basis (e.g., seeking PEOG's approval to revoke).

- If a DMEPOS supplier reports a change of information more than 30 days after the effective date of the change, the contractor may pursue a revocation on this basis (e.g., seeking PEOG's approval to revoke).

J. Revocation Reason 10 – Failure to Document or Provide CMS Access to Documentation (42 CFR § 424.535(a)(10))

"The provider or supplier did not comply with the documentation requirements specified in 42 CFR § 424.516(f). A provider that furnishes any covered ordered, certified, referred, or prescribed Part A or B services, items or drugs is required to maintain documentation for 7 years."

K. Revocation Reason 11 - Home Health Agency (HHA) Capitalization (42 CFR § 424.535(a)(11))

"An HHA fails to furnish - within 30 days of a CMS or contractor request - supporting documentation verifying that the HHA meets the initial reserve operating funds requirement found in 42 CFR § 489.28(a)."

L. Revocation Reason 12 – Other Program Termination (42 CFR § 424.535(a)(12))

"The provider or supplier is terminated, revoked, or otherwise barred from participation in a particular State Medicaid Agency or any other federal health care program." Under § 424.535(a)(12)(ii), "Medicare may not revoke [a provider/supplier's Medicare billing privileges] unless and until the provider or supplier has exhausted all applicable appeal rights or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal."

In making its determination, CMS considers the following factors listed in 42 CFR § 424.535(a)(12):

"(A) The reason(s) for the termination or revocation;

(B) Whether the provider or supplier is currently terminated, revoked, or otherwise barred from more than one program (for example, more than one state's Medicaid program) or has been subject to any other sanctions during its participation in other programs; and;

(C) Any other information that CMS deems relevant to its determination."

M. Revocation Reason 13 - Prescribing Authority (42 CFR § 424.535(a)(13))

"(i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked or is surrendered in response to an order to show cause; or

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician's or other eligible professional's ability to prescribe drugs."

N. Revocation Reason 14 – Improper Prescribing Practices (42 CFR § 424.535(a)(14))

"CMS determines that the physician or other eligible professional has a pattern or practice of prescribing Part B or D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both. In making this determination, CMS considers the following factors:

(A) Whether there are diagnoses to support the indications for which the drugs were prescribed;

(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit);

(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses;

(D) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the State or States in which he or she practices, and the reason(s) for the action(s);

(E) Whether the physician or eligible professional has any history of final adverse actions (as that term is defined in § 424.502);

(F) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined);

(G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination; and

(H) Any other relevant information provided to CMS.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors:

(A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority.

(B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration.

(C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications that were not medically accepted - that is, for indications neither approved by the FDA nor medically accepted under section 1860D-2(e)(4) of the Act - and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient."

(**NOTE**: Concerning (a)(14), PEOG -- rather than the contractor -- will (1) make all determinations regarding whether a provider/supplier has a pattern or practice of prescribing Part B or D drugs; (2) consider the relevant factors; and (3) accumulate all information needed to make such determinations.)

O. Revocation Reason 15 – False Claims Act Judgment (42 CFR § 424.535(a)(15))

"(i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the False Claims Act (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted)

(B) The types of provider or supplier actions involved

(C) The monetary amount of the judgment

(D) When the judgment occurred

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502)

(F) Any other information that CMS deems relevant to its determination."

P. **Revocation Reason 1*7* – Debt Referred to the United States Department of Treasury (42 CFR § 424.535(a)(17))**

"The provider or supplier has an existing debt that CMS appropriately refers to the United States Department of Treasury." In determining whether a revocation is appropriate, CMS considers the following factors:

"(i) The reason(s) for the failure to fully repay the debt (to the extent this can be determined);

(ii) Whether the provider or supplier has attempted to repay the debt (to the extent this can be determined);

(iii) Whether the provider or supplier has responded to CMS' requests for payment (to the extent this can be determined);

(iv) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions;

(v) The amount of the debt; and

(vi) Any other evidence that CMS deems relevant to its determination."

(NOTE: *With respect to (a)(17):*

- PEOG – rather than the contractor – will make all determinations regarding whether a provider/supplier has an existing debt that has been referred to the Department of Treasury.

- *This revocation does not apply in cases where:*

  - *The provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or*
  - *The administrative appeals process concerning the debt has not been exhausted or the timeframe for filing such an appeal (at the appropriate level of appeal) has not expired.*

Q. **Revocation Reason 1*8* – Revoked Under a Different Name, Numerical Identifier or Business Identity (42 CFR § 424.535(a)(18))**

"The provider or supplier is currently revoked [from Medicare] under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired." In making its determination, CMS considers the following factors:

"(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 [or CMS-20134] application);

(ii) Geographic location;

(iii) Provider or supplier type;

(iv) Business structure; or

(v) Any evidence indicating that the two parties [the revoked provider or supplier and newly enrolling provider or supplier] are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar."

(NOTE: Concerning (a)(18), PEOG – rather than the contractor – will make all determinations regarding whether a provider/supplier was revoked under a different name, numerical identifier, or business identity.)

R. **Revocation Reason 1*9* – Affiliation that Poses an Undue Risk (42 CFR § 424.535(a)(19))**

1. Specific Reason

"The provider or supplier has or has had an affiliation under 42 CFR § 424.519 that poses an undue risk of fraud, waste and abuse to the Medicare program." In making this determination, CMS considers the following factors listed in 42 CFR § 424.519(f)(1) through (6):

"(1) The duration of the affiliation

(2) Whether the affiliation still exists and, if not, how long ago it ended

(3) The degree and extent of the affiliation

(4) If applicable, the reason for the termination of the affiliation

(5) Regarding the affiliated provider/supplier's disclosable event [under § 424.519(b)]:

(i) The type of disclosable event.

(ii) When the disclosable event occurred or was imposed.

(iii) Whether the affiliation existed when the disclosable event occurred or was imposed.

(iv) If the disclosable event is an uncollected debt: (A) the amount of the debt; (B) whether the affiliated provider or supplier is repaying the debt; and (C) to whom the debt is owed.

(v) If a denial, revocation, termination, exclusion, or payment suspension is involved, the reason for the disclosable event.

(6) Any other evidence that CMS deems relevant to its determination."

2. Definition of Affiliation

For purposes of § 424.519 only, 42 CFR § 424.502 defines "affiliation" as:

- A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.

- A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.

- An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of [§ 424.519 only], sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.

- An interest in which an individual is acting as an officer or director of a corporation.

- Any reassignment relationship under § 424.80."

(NOTE: Concerning (a)(19), PEOG -- rather than the contractor -- will make all determinations regarding whether a provider/supplier has an affiliation per § 424.519 that poses an undue risk of fraud, waste, and abuse.)

***S*. Revocation Reason *20* – Billing from a Non-Compliant Location (42 CFR § 424.535(a)(20))**

"CMS may revoke a provider's or supplier's Medicare enrollment or enrollments, even if all of the practice locations associated with a particular enrollment comply with Medicare enrollment requirements, if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements. In determining whether and how many of the provider/supplier's enrollments (involving the non-compliant location or other locations) should be revoked, CMS considers the following factors [enumerated in § 424.535(a)(20)(i) through (vii)]:

- The reason(s) for and the specific facts behind the location's non-compliance;
- The number of additional locations involved;

- The provider or suppliers possibly history of final adverse actions or Medicare or Medicaid payment suspensions;
- The degree of risk the location's continuance poses to the Medicare Trust Funds;
- The length of time that the location was considered non-compliant;
- The amount that was billed for services performed at or items furnished from the non-compliant location; and,
- Any other evidence that CMS deems relevant to its determination."

(NOTE: Concerning (a)(20), PEOG – rather than the contractor – will make all determinations regarding whether a provider/supplier has performed services or furnished items from a location that did not comply with Medicare enrollment requirements.)

***T*. Revocation Reason *21* – Abusive Ordering, Certifying, Referring, or Prescribing of Part A or B Services, Items or Drugs (42 CFR § 424.535(a)(21))**

"The physician or eligible professional has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements." In making its determination, CMS considers the following factors [enumerated in § 424.535(i) through (ix)]:

- Whether the physician or eligible professional's diagnosis supports the order, certification, referral or prescription in question;
- Whether there are instances where the necessary evaluation of the patient for whom the order, certification, referral or prescription could have not occurred (for example: the patient was deceased or out of state at the time of the alleged office visit);
- The number and types of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state(s) in which he or she practices and the reason(s) for the action(s);
- Whether the physician or eligible professional has any history of final adverse actions (as defined by 42 CFR § 424.502);
- The length of time over which the pattern or practice has continued;
- How long the physician or eligible professional has been enrolled in Medicare;
- The number of type(s) of malpractice suits that have been filed against the physician or eligible professional related to ordering, certifying, referring or prescribing that resulted in a final judgement against the physician or eligible professional or the physician or eligible professional paid a settlement to the plaintiff(s) (to the extent this can be determined);
- Whether any State Medicaid Agency (SMA) or other public health insurance program has restricted, suspended, revoked or terminated the physician's or eligible professional's ability to practice medicine and reason for any such restriction, suspension, revocation or termination; and
- Any other information that CMS deems relevant to its determination.

(NOTE: Concerning (a)(21), PEOG – rather than the contractor – will make all determinations regarding whether a physician or eligible professional has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items, or drugs that is abusive, threatening to the safety of Medicare beneficiaries, or fails to meet Medicare requirements).

***U*. Revocation Reason *22* – Patient Harm (42 CFR § 424.535(a)(22))**

The physician or other eligible professional has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization

(IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation is appropriate, CMS considers the following factors [enumerated in § 424.535(a)(22)(i)(A) through (E)):

(A) The nature of the patient harm.

(B) The nature of the physician's or other eligible professional's conduct.

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by the state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(i) License restriction(s) pertaining to certain procedures or practices.

(ii) Required compliance appearances before State medical board members.

(iii) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(iv) Administrative or monetary penalties.

(v) Formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician/other eligible professional's conduct and the degree of harm thereto or impact upon."

(Per 42 CFR § 424.535(a)(22)(ii), paragraph (a)(22) does not apply to actions or orders pertaining exclusively to either of the following:

- Required participation in rehabilitation or mental/behavioral health programs; or
- Required abstinence from drugs or alcohol and random drug testing.)

V. Revocation Reason 23 – Standard or Condition Violation (42 CFR § 424.535(a)(23))

"(i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d)."

***W*. Extension of Revocation**

If a provider's Medicare enrollment is revoked under § 424.535(a), CMS may revoke any and all of the provider's Medicare enrollments, including those under different names, numerical identifiers or business identities and those under different types. In determining whether to revoke a provider's other enrollments, CMS considers the following factors:

(i) The reason for the revocation and the facts of the case;

(ii) Whether any final adverse actions have been imposed against the provider or supplier regarding its other enrollments;

(iii) The number and type(s) of other enrollments; and

(iv) Any other information that CMS deems relevant to its determination.

10.4.7.4 – Reenrollment Bar

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

If any inconsistency exists between an instruction in this section 10.4.7.4 and a directive in section 10.6.6, the latter instruction takes precedence. In addition, the contractor shall adhere to any instruction in section 10.6.6 that addresses a reenrollment bar matter not discussed in section 10.4.7.4.

A. Background

As stated in 42 CFR § 424.535(c), if a provider/supplier has their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10 years, depending on the severity of the basis for revocation. In addition, CMS may impose a reenrollment bar of up to 20 years if the provider/supplier is being revoked from Medicare for the second time.

Per § 424.535(c), the reenrollment bar does not apply if the revocation: (i) is based on § 424.535(a)(1); and (ii) stems from a provider/supplier's failure to respond timely to a revalidation request or other request for information. If both of these conditions are met, no reenrollment bar will be applied.

The contractor shall update PECOS to reflect that the individual cannot participate in Medicare for the applicable length of the reenrollment bar. Except as otherwise stated in this chapter, PEOG (rather than the contractor) determines reenrollment bars that exceed 3 years.

In addition, CMS may add up to 3 more years to the provider/supplier's reenrollment bar if it determines that the provider/supplier is attempting to circumvent its existing reenrollment bar.

B. Establishment of Length

The following serves merely as general, non-binding guidance regarding the establishment of the length of reenrollment bars. It is crucial to note that every situation must and will be judged on its own merits, facts, and circumstances. It should not be assumed that a particular timeframe will always be applied to a specific revocation reason in all cases. CMS retains the discretion to apply a reenrollment bar period that is different from that indicated below (though which in no case will be greater than 10 to 20 years).

- § 424.535(a)(1) *and (23)* (Noncompliance) -- For licensure issues, 1 year if no billing after loss of license
- § 424.535(a)(6) (Grounds Related to Screening) – 1 year
- § 424.535(a)(11) (Initial Reserve Operating Funds) – 1 year

The following revocation reasons will receive reenrollment bar lengths per CMS discretion:

- *§ 424.535(a)(15) (False Claims Act Judgments)*
- § 424.535(a)(17) (Debt Referred to the United States Department of Treasury)
- § 424.535(a)(18) (Revoked Under a Different Name, Numerical Identifier or Business Identity)
- § 424.535(a)(19) (Affiliation that Poses an Undue Risk)
- § 424.535(a)(20) (Billing from a Non-Compliant Location)
- §424.535(a)(21) (Abusive Ordering, Certifying, Referring, or Prescribing of Part A or B Services, Items or Drugs)
- § 424.535(a)(22) (Patient Harm) will receive reenrollment bar lengths per CMS' discretion.

C. Applicability of Bar

In general, and unless stated otherwise above, any reenrollment bar at a minimum applies to: (1) all practice locations under the provider's PECOS or legacy enrollment record; and (2) any effort to reestablish any of these locations (i) at a different address and/or (ii) under a different business or legal identity, structure, or TIN. If the contractor receives an application and is unsure whether a revoked provider is attempting to reestablish a revoked location, it shall contact its PEOG BFL for guidance. Instances where the provider might be attempting to do so include - but are not limited to – the following:

SCENARIO 1 - John Smith was the sole owner of Group Practice X, a sole proprietorship. Six months after X was revoked under § 424.535(a)(9), the contractor receives an initial application from Group Practice Medicine, LLC, of which John Smith is the sole owner/member.

SCENARIO 2 - Jack Jones and Stan Smith were 50 percent owners of World Home Health Agency, a partnership. One year after World Home Health was revoked under § 424.535(a)(7), the contractor receives an initial application from XYZ Home Health, a corporation owned by Jack Jones and his wife, Jane Jones.

SCENARIO 3 - John Smith was the sole owner of XYZ Medical Supplies, Inc. XYZ's lone location was at 1 Jones Street. XYZ's billing privileges were revoked after it was determined that the site was non-operational. Nine months later, the contractor receives an initial application from Johnson Supplies, LLC. The entity has two locations in the same city in which 1 Jones Street is located. John Smith is listed as a 75 percent owner.

D. Discussing Provider Enrollment Appeals Process in Revocation Letter

(If a conflict exists between the instructions in this section 10.4.7.4(D) and those in either (i) those in section 10.6.18 or (ii) the language in the applicable model letter in section 10.7 et seq., the guidance in section 10.6.18 or the model letter takes precedence.)

In the revocation letter, the contractor shall include information concerning the provider's appeal rights. The following table summarizes where the provider must send a corrective action plan (CAP) and/or reconsideration request.

	CAP requests should be sent to:		Reconsideration request should be sent to:	
Revocation Regulation	**Institutional***	**Non-institutional**	**Institutional***	**Non-Institutional**
424.535(a)(1) related to an enrollment requirement (i.e., 425.516)	Alone or in combination: CMS	MAC	CMS	MAC
424.535(a)(1) Licensure	CAP rights (to CMS)	CAP rights (to the MAC)	CMS	MAC
424.535(a)(2) Exclusion	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(2) Debarment	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(3)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(4)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(5)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(6)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(7)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(8)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(8)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(9)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(10)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(11)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(12)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(13)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(14)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(15)	*No CAP rights*	*No CAP rights*	*CMS*	*CMS*
424.535(a)(17)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(18)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(19)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(20)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(21)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(22)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(23)	*No CAP rights*	*No CAP rights*	*MAC*	*MAC*

* Institutional providers:

- Ambulance Service Suppliers
- Ambulatory Surgery Centers
- CLIA Labs
- Community Mental Health Centers
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals
- End Stage Renal Disease (ESRDs)
- Federally Qualified Health Centers (FQHCs)
- Histocompatibility Laboratories
- Home Health Agencies
- *Home Infusion Therapy Suppliers*
- Hospices
- Hospitals and Hospital Units
- Independent Diagnostic Testing Facilities (IDTFs)

- Intensive Cardiac Rehabilitation
- Indian Health Service Facility
- Mammography Screening Centers
- Mass Immunization/Flu Roster Billers
- Medicare Diabetes Prevention Programs (MDPPs)
- Opioid Treatment Centers (OTPs)
- Organ Procurement Organizations (OPOs)
- Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)
- Pharmacies
- Portable X-Ray Suppliers (PXRSs)
- Radiation Therapy Centers
- Rehabilitation Services
- Religious Non-Medical Health Care Institutions (RNCHIs)
- Rural Health Clinics (RHCs)
- Skilled Nursing Facilities (SNFs)

CMS defines "institutional provider" in 42 CFR § 424.502 to mean any provider/supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (except physician and non-physician practitioner organizations), or Form CMS-855S, or the associated Internet-based PECOS enrollment application. (Note that MDPP suppliers no longer fall within this regulatory definition of institutional provider. Per 42 CFR § 424.205(b)(5), the provider enrollment application fee is inapplicable to all MDPP suppliers that submit a Form CMS-20134 enrollment application. Solely for purposes of appeal submissions, however, MDPP suppliers are included in the bulleted list above.)

10.4.7.5 – Additional Revocation Policies

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. ***Use of § 424.535(a)(1)***

1. (A)(1) Versus (A)(5)

If a revocation is warranted because the provider/supplier's location is vacant, occupied by another party, closed during office hours, etc., or a state survey failure is involved, the contractor shall use § 424.535(a)(5) (rather than § 424.535(a)(1)) as the revocation reason. (This applies to both certified and non-certified providers/suppliers.) No CAP rights are therefore involved.

2. (A)(1) Versus (A)(23)

If a revocation is warranted due to non-compliance with one of the standards and conditions referenced in § 424.535(a)(23), the contractor shall use § 424.535(a)(23) (rather than § 424.535(a)(1)) as the revocation reason. No CAP rights are therefore involved.

B. **Submission of Claims for Services Furnished Before Revocation**

Per 42 CFR § 424.535(h), a revoked provider or supplier (other than a home health agency (HHA)) must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter. A revoked HHA must submit all claims for items and services within 60 days after the later of: (1) the effective date of the revocation, or (2) the date that the HHA's last payable episode ends.

Nothing in § 424.535(h) impacts the requirements of 42 CFR § 424.44 regarding the timely filing of claims.

C. Reporting Revocations/Terminations to the State Medicaid Agencies and Children's Health Program (CHIP)

(If the instructions in this section 10.4.7.5(*C*) conflict with those in another CMS directive, the latter takes precedence.)

Section 6401(b)(2) of the Patient Protection and Affordable Health Care Act (i.e., the Affordable Care Act) was enacted on March 23, 2010. It requires that CMS establish a process for making available to each State Medicaid Plan or Child Health Plan the name, NPI, and other identifying information regarding any revoked or denied Medicare provider/supplier. Accordingly, CMS provides a monthly revoked and denied provider list to all contractors via the Share Point Ensemble site.

The contractor shall:

- Access this list on the 5th day of each month via the Share Point Ensemble site

- Review the monthly revoked and denied provider list for the names of Medicare providers revoked and denied in PECOS

- Document any appeal actions a provider/supplier may have submitted after the provider/supplier's revocation or denial

- Update the last three columns on the tab named "Filtered Revocations" of the spreadsheet for every provider/supplier revocation or denial

The contractor shall not make any other modifications to the format of this form or its contents.

The following are the only authorized entries to be made on the report:

Appeal Submitted:
Yes - (Definition: An appeal has been received. (This includes either a CAP or Reconsideration request or notification of an ALJ or DAB action.))
No - (Definition: No appeal of any type has been submitted)

Appeal Type:
CAP
Reconsideration
ALJ
DAB

Appeal Status:
Under Review
Revocation Upheld
Revocation Overturned
Denial Upheld
Denial Overturned
CAP accepted
CAP denied
Reconsideration Accepted
Reconsideration Denied

If a contractor is reporting that no appeal has been submitted, the appeal type and status columns will be noted as N/A.

If an appeal action has been submitted to PEOG for certified providers/suppliers, the contractor shall access the PEOG appeals log via the Share Point Ensemble site to determine the appeal status to include on the spreadsheet.

The contractor shall submit their completed reports by the 20th of each month to the CGI Share Point Ensemble site.

D. Opting-Out after Revocation

Revoked suppliers cannot order, certify, or prescribe Part A or B services, items, or drugs to Medicare beneficiaries if they opt-out of Medicare after revocation. For example, if Dr. Thompson is Medicare-revoked, he cannot opt-out and order back and knee orthoses for his patients.

E. Overpayments Based Upon Revocations

The contractor shall commence procedures to collect overpayment after the timeframe for the appeal of the revocation has expired or within 10 days of the final appeal determination at the first level of appeal. Overpayments are processed in accordance with 42 CFR Part 405, subpart C.

If a revocation has a prospective effective date, the contractor shall assess an overpayment back to the date that is the more recent of the following:

- The date when Medicare claims are determined to be ineligible for payment; or

- The date that is within 4 years from the date of the initial claim determination or redetermination for good cause as defined in 42 CFR § 405.986 (42 CFR § 405.980).

The date when Medicare claims are determined to be ineligible for payment may, but will not always, match the inactive date of the enrollment as reflected in PECOS and in MCS or FISS. Again, in determining an overpayment, the contractor shall use the starting date upon which claims are ineligible for reimbursement, not the date the enrollment is inactive according to PECOS and MCS or FISS.

In accordance with 42 CFR § 424.565, if a physician, non-physician practitioner, physician organization, or non-physician practitioner organization fails to comply with the reporting requirements specified in 42 CFR § 424.516(d)(1)(ii), the contractor may assess an overpayment back to a date that is the more recent of the following:

- The date of the final adverse action or change in practice location; or

- The date that is within 4 years from the date of the initial claim determination or redetermination for good cause as defined in 42 CFR § 405.986 (42 CFR § 405.980).

F. Other Sources of Potential Bases for Revocations

When CMS instructs the contractor to take revocation action, PEOG communicates such direction; neither the UPIC, the state agency, CMS Field Office, nor CMS Regional Office (RO) (including SOG Location) personnel can direct a contractor to revoke a provider/supplier. However, some of these entities may refer a potential revocation to PEOG. This section 10.4.7.5(E) discusses the operational aspects of these referrals.

1. UPICs

a. Background

If, through its investigations, the UPIC believes that a particular provider/supplier's Medicare billing privileges should be revoked, it shall develop a case file - including the reason(s) for revocation and the data described in subsection (E)(1)(b) below - and submit the file and all supporting documentation to PEOG.

PEOG will review the case file and:

- Return the case file to UPIC for additional development, or
- Consider approving the UPIC's recommendation for revocation.

If PEOG approves the revocation recommendation, PEOG will: (1) instruct the applicable contractor to revoke the provider/supplier; and (2) notify the applicable contracting officer's representative (COR).

If the contractor receives a direct request from a UPIC to revoke a provider/supplier, it shall refer the matter to its PEOG BFL if it is unsure whether the UPIC received prior PEOG approval of the revocation.

b. Contents of Request

The revocation request shall contain the following information:

- Provider/supplier name; administrative location(s); community setting(s), if applicable type (e.g., DMEPOS supplier); Provider Transaction Access Number (PTAN); National Provider Identifier (NPI); applicable Medicare Administrative Contractor

- Name(s), e-mail address(es), and phone number(s) of investigators

- Tracking number

- Provider/supplier's billing status (Active? Inactive? For how long?)

- Whether the provider/supplier is a Fraud Prevention System provider/supplier

- Source/Special Project

- Whether the provider/supplier is under a current payment suspension

- Legal basis for revocation

- Relevant facts

- Application of facts to revocation reason

- Any other notable facts

- Effective date (per 42 CFR § 424.535(g))

- Supporting documentation

- Photos (which should be copied and pasted within the document)

2. CMS Field Office or RO Revocations

If a CMS Field Office (FO) or (RO) believes that Revocation Reason 8 (see 42 CFR § 424.535(a)(8) is appropriate in a certain case), the FO/RO will develop a case file - including the reason(s) for revocation - and submit the file and all supporting documentation to PEOG. The case file must include the name, all known identification numbers (including the NPI and associated PTAN(s)), and locations of the provider/supplier, as well as detailed information to substantiate the revocation action.

If PEOG concurs with the FO/RO's revocation recommendation, PEOG will: (1) instruct the contractor to revoke the provider/supplier; and (2) accordingly notify the FO/RO.

(See section 10.4.3 of this chapter for information on the contractor's responsibilities concerning involuntary terminations received from the SOG Location.)

3. OIG Identified Revocations

PEOG is responsible for actions based on HHS OIG Identified revocations.

G. MDPP Supplier Revocation for Use of an Ineligible Coach

1. Background

Section 424.205(h)(1)(v) established a new revocation reason for MDPP suppliers. It permits revocation if the MDPP supplier knowingly permitted an ineligible coach to furnish MDPP services to beneficiaries, despite being previously removed from the MDPP supplier's roster through a CAP.

If a contractor or UPIC suspects this scenario, it shall develop a case file - including the revocation reason(s) - and submit the file and all supporting documentation to PEOG. The contractor shall provide PEOG with the information described in section 10.4.7.5(E)(1)(b).

PEOG will review the case file and:

- Return the case file to the contractor for additional development, or

- Consider approving the contractor's recommendation for revocation.

If PEOG approves the revocation recommendation, PEOG will: (1) instruct the contractor to revoke the provider/supplier; and (2) notify the applicable COR.

If the contractor receives a direct request from a UPIC to revoke a provider/supplier, it shall refer the matter to its PEOG BFL if it is unsure whether the UPIC received prior PEOG approval of the revocation.

2. Effective Dates

An MDPP supplier revoked under § 424.205(h)(1)(v) does not have CAP rights. The revocation becomes effective 30 days after the contractor sends notice of the revocation.

3. Reenrollment Bar

As stated in § 424.205(h), if an MDPP supplier has its billing privileges revoked, it is barred from participating in Medicare from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10 years, depending on the severity of the basis for revocation.

10.6.2 – Establishing Effective Dates

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

In reviewing this section 10.6.2, it is important that the contractor keep in mind the distinctions between: (1) the date of enrollment/approval; (2) the effective date of billing privileges under 42 CFR § 424.520(d); and (3) the date from which the supplier may retrospectively bill for services under § 424.521(a).

(Note that the date of receipt of a PECOS application is the date on which the contractor received it, not the date on which the application required the contractor's manual intervention per section 10.3.)

A. Date of Enrollment/Approval

This section 10.6.2(A) does not apply to the application of § 424.535(g)(3). See section 10.4.7.2(A)(3) for more information.

For suppliers other than ambulatory surgical centers and portable x-ray suppliers, the date of enrollment is the date the contractor approved the application. The enrollment date cannot be made retroactive. To illustrate, suppose a practitioner met all the requirements needed to enroll in Medicare (other than the submission of a Form CMS-855I) on January 1. He submits his Form CMS-855I to the contractor on May 1, and the contractor approves the application on June 1. The date of enrollment is June 1, not January 1.

B. Establishing Effective Dates of Billing Privileges for Certain Suppliers Under 42 CFR § 424.520(d)

1. Applicability

This section 10.6.2(B) applies to the following individuals and organizations:

a. Physicians; physician assistants; nurse practitioners; audiologists; clinical nurse specialists; certified registered nurse anesthetists; anesthesiology assistants; certified nurse- midwives; clinical social workers; clinical psychologists; independently billing psychologists, registered dietitians or nutrition professionals; physical therapists; occupational therapists; speech-language pathologists; *mental health counselors; marriage and family therapists;* and physician and non-physician practitioner organizations (e.g., group practices) consisting of any of the categories of individuals identified above.

b. Ambulance suppliers

c. Part B hospital departments

d. CLIA labs

e. Opioid treatment programs.

f. Mammography centers

g. Mass immunizers/pharmacies

h. Radiation therapy centers

i. Home infusion therapy suppliers

(See 42 CFR §§ 424.520(d)(2) and 424.521(a)(2) for the regulatory listing of these providers/suppliers.)

2. Background

In accordance with 42 CFR § 424.520(d)(1), the effective date of billing privileges for the individuals and organizations identified in § 424.520(d)(2) (and section 10.6.2(B)(1) above) is the later of:

(i) The date the supplier filed an enrollment application that was subsequently approved, or

(ii) The date the supplier first began furnishing services at a new practice location.

NOTE: The date of filing for Form CMS-855 applications is the date on which the contractor received the application, regardless of whether the application was submitted via paper or Internet-based PECOS.

3. Retrospective Billing Under 42 CFR § 424.521(a)

Consistent with 42 CFR § 424.521(a)(1), the individuals and organizations identified in § 424.521(a)(2) (and section 10.6.2(B)(1) above) may retrospectively bill for services when:

(i) The supplier has met all program requirements, including state licensure requirements; and

(ii) The services were provided at the enrolled practice location for up to—

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

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

The contractor shall interpret the aforementioned phase "circumstances precluded enrollment" to mean that the supplier meets all program requirements (including state licensure) during the 30-day period before an application was submitted and no final adverse action (as that term is defined in § 424.502) precluded enrollment. If a final adverse action precluded enrollment during this 30-day period, the contractor shall only establish an effective billing date the day after the date that the final adverse action was resolved--so long as it is not more than 30 days prior to the date on which the application was submitted.

If the contractor believes that the aforementioned Presidentially-declared disaster exception may apply in a particular case, it shall contact its CMS Provider Enrollment & Oversight Group Business Function Lead for a determination on this issue.

4. Summarizing the Distinction Between Effective Date of Billing Privileges and Retrospective Billing Date

As already discussed, the effective date of billing privileges is "the later of the date of filing or the date (the supplier) first began furnishing services at a new practice location." The retrospective billing date, however, is "up to…30 days prior to (the supplier's) effective date (of enrollment)." To illustrate, suppose that a non-Medicare enrolled physician begins furnishing services at an office on March 1. She submits a Form CMS-855I initial enrollment application on May 1. The application is approved on June 1 (which, as discussed in section 10.6.2(A) above, is the date of enrollment). The physician's effective date of billing privileges is May 1, which is the later of: (1) the date of filing, and (2) the date she began furnishing services. The retrospective billing date is April 1 (or 30 days prior to the effective date of billing privileges), assuming that the requirements of 42 CFR § 424.521(a) are met. The effective date entered into PECOS and the Multi-Carrier System will be April 1; claims submitted for services provided before April 1 will not be paid.

C. Effective Date of Reassignment

Per 42 CFR § 424.522(a), the effective date of the reassignment is 30 days before the Form CMS-855R is submitted if all applicable requirements during that period were otherwise met. The contractor shall apply this policy in the following manner:

1. Form CMS-855R submitted as "stand-alone" without Form CMS-855I – The effective date in § 424.522(a) applies to the reassignment unless the effective date that the supplier listed on the Form CMS-855R is later than what the § 424.522(a) date is, in which case the Form CMS-855R-listed effective date controls.

2. Form CMS-855R submitted with Form CMS-855I either simultaneously or as part of development (e.g., physician only submits Form CMS-855I and contractor develops for Form CMS-855R) – The contractor shall apply the Form CMS-855I effective date (per 42 CFR §§ 424.520(d) and 424.521(a)) to the Form CMS-855R. When one or both of these forms requires the contractor to develop for information – and for purposes of establishing the §§ 424.520(d)/424.521(d) effective date -- the contractor may apply the receipt date of the first application that is submitted as complete (i.e. no further development is necessary).

3. Form CMS-855R submitted with Form CMS-855B either simultaneously or as part of development – The contractor shall apply the Form CMS-855B effective date (per 42 CFR §§ 424.520(d) and 424.521(a)) to the Form CMS-855R. When one or both of these forms requires the contractor to develop for information – and for purposes of establishing the §§ 424.520(d)/424.521(d) effective date -- the contractor may apply the receipt date of the first application that is submitted as complete (i.e. no further development is necessary).

Notwithstanding the foregoing, the contractor shall apply the 90-day retroactive billing period referenced in subsection 10.6.2(B)(3)(ii)(B) above to the Form CMS-855R submissions described in this subsection (C) in the event of a Presidentially-declared disaster under the Stafford Act).

D. Effective Date for Certified Providers and Certified Suppliers

Note that 42 CFR § 489.13 governs the determination of the effective date of a Medicare provider agreement or supplier approval for health care facilities that are subject to survey and certification. Section 489.13 has been revised to state that: (1) the date of a Medicare provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met; and (2) such requirements include the contractor's review and verification of an application to enroll in Medicare.

E. Effective Date for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Per § 424.57(b), DMEPOS suppliers must meet, among other requirements, the following conditions in order to be eligible to receive payment for a Medicare-covered item:

(1) The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities.)

(2) The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.

The contractor shall indicate the supplier's status as approved in PECOS upon the contractor making the determination the supplier meets all of the supplier standards found at § 424.57(c). The date the supplier was approved in PECOS shall be the supplier's effective date.

F. Form CMS-855O Effective Dates

Notwithstanding any other instruction in the chapter to the contrary, the effective date of a Form CMS-855O enrollment per 42 CFR § 424.522 is the date on which the Medicare contractor received the Form CMS-855O application if all other requirements are met --- meaning the Form CMS-855O was processed to approval.

G. Effective Date for Medicare Diabetes Prevention Program (MDPP) Suppliers

In accordance with 42 CFR § 424.205(f), the effective date of billing privileges for MDPP suppliers is the later of:

- The date the supplier filed an enrollment application that was subsequently approved,
- The date the supplier filed a corrective action plan that was subsequently approved by a Medicare contractor, or
- The date the supplier first began furnishing services at a new administrative location that resulted in a new enrollment record or Provider Transaction Access Number. (For PECOS applications, see section 10.3 of this chapter for information about what constitutes an enrollment record in PECOS.)

Under no circumstances should an effective date for billing privileges be prior to April 1, 2018. For any Form CMS-20134 submitted prior to April 1, 2018 and subsequently approved, the contractor shall note April 1, 2018 as the MDPP supplier's effective date, even if this date is in the future.

NOTE: The date of filing for paper Form CMS-20134 applications is the date on which the contractor received the application. For Internet-based PECOS applications, the date of filing is the date that the contractor received an electronic version of the enrollment application and a signed certification statement submitted via paper or electronically.

H. Future Effective Dates

If the contractor cannot enter an effective date into PECOS because the provider/supplier, its practice location, etc., is not yet established, the contractor may use the authorized official's date of signature as the temporary effective date. Once the provider/supplier and the effective date are established (e.g., notification from the state is received), the contractor shall change the effective date in PECOS.

10.6.12 – Opting-Out of Medicare

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

Physicians and practitioners are typically required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. They are also not permitted to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished. However, certain types of physicians and practitioners may "opt-out" of Medicare. A physician or practitioner who opts-out is not required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare-covered services. Medicare does not pay anyone for services (except for certain emergency and urgent care services) furnished by an opt-out physician or practitioner. Instead, opt-out physicians and practitioners sign private contracts with beneficiaries. Please refer to CMS Pub. 100-02, Chapter 15, sections 40 - 40.39 for more information regarding the maintenance of opt-out affidavits and the effects of improper billing of claims during an opt-out period.

The instructions in this section 10.6.12 address the contractor's processing of opt-out affidavits. (See Pub. 100-02, chapter 15, section 40.8 for private contract definitions and requirements.)

A. Who May Opt-Out of Medicare

Only the following physicians and practitioners (sometimes collectively referenced as "eligible practitioners" in this section) can "opt-out" of Medicare:

Physicians who are:

- Doctors of medicine or osteopathy,
- Doctors of dental surgery or dental medicine,
- Doctors of podiatry, or
- Doctors of optometry who are legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the state in which such function or action is performed.

Non-physician practitioners who are

- Physician assistants,
- Nurse practitioners,
- Clinical nurse specialists,
- Certified registered nurse anesthetists,
- Certified nurse midwives,
- Clinical psychologists,
- Clinical social workers,
- Registered dietitians or nutrition professionals who are legally authorized to practice by the state and otherwise meet Medicare requirements,
- *Mental health counselors, or*
- *Marriage and family therapists*

(Organizations are not permitted to opt-out of Medicare.)

This means that neither the eligible practitioner nor the beneficiary submits the bill to Medicare for services performed. Instead, the beneficiary pays the eligible practitioner out-of-pocket and neither party is reimbursed by Medicare. In fact, a private contract is signed between the eligible practitioner and the beneficiary that states, in essence, that neither can receive payment from Medicare for the services performed. (The contract, though, must be signed before the services are provided so the beneficiary is fully aware of the eligible practitioner's opt-out status.) Moreover, the eligible practitioner must submit an affidavit to Medicare expressing his/her decision to opt-out of the program. The contractor's provider enrollment unit must process these affidavits.

Eligible practitioners who opt-out of Medicare are not the same as non-participating physicians/suppliers. The latter are enrolled in Medicare and choose on a claim-by-claim basis whether they want to accept assignment unless the service can only be paid on an assignment-related basis as required by law (e.g., for drugs, ambulance services, etc.). Non-participating physicians/suppliers must therefore comply with Medicare's mandatory claim submission, assignment, and limiting charge rules. Opt-out eligible practitioners, on the other hand, are excused from the mandatory claim submission, assignment, and limiting charge rules, though **only** when they maintain compliance with all of the requirements for opting out.

In an emergency care or urgent care situation, an eligible practitioner who has opted-out may treat a Medicare beneficiary with whom he or she does not have a private contract. In those circumstances, the eligible practitioner must complete a Form CMS-855 application.

B. Requirements for an Opt-out Affidavit

1. Affidavit Contents

As stated in Pub. 100-02, chapter 15, section 40.9, the affidavit shall state that, upon signing the affidavit, the eligible practitioner agrees to the following requirements:

- Except for emergency or urgent care services, during the opt-out period the eligible practitioner will provide services to Medicare beneficiaries only through private contracts, but for their provision under a private contract, would have been Medicare-covered services;

- The eligible practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the eligible practitioner permit any entity acting on the eligible practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary;

- During the opt-out period, the eligible practitioner understands that he/she may receive no direct or indirect Medicare payment for services that the eligible practitioner furnishes to Medicare beneficiaries with whom the eligible practitioner has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan;

- An eligible practitioner who opts out of Medicare acknowledges that, during the opt-out period, the eligible practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the eligible practitioner's services, directly or on a capitated basis;

- On acknowledgment by the eligible practitioner to the effect that, during the opt- out period, the eligible practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the eligible practitioner has entered into;

- Acknowledge that the eligible practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the eligible practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom the eligible practitioner has not previously privately contracted) without regard to any payment arrangements the eligible practitioner may make;

- With respect to an eligible practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;

- Acknowledge that the eligible practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services;

- Identify the eligible practitioner sufficiently so that the Medicare contractor can ensure that no payment is made to the eligible practitioner during the opt-out period; and

- Be filed with all MACs that have jurisdiction over claims the eligible practitioner would otherwise file with Medicare; the initial two-year opt-out period will begin the date on which the affidavit meeting the requirements of 42 C.F.R. § 405.420 is signed, provided the affidavit is filed within 10 days after the eligible practitioner signs his or her first private contract with a Medicare beneficiary.

(See Pub. 100-02, chapter 15, section 40.9 for more information on the requirements of opt-out affidavits. See also section 10.6.12(B)(5) below for acceptable opt-out formats.)

The contractor shall review initial opt-out affidavits to ensure that they contain the following information about the eligible practitioner in order to create an affidavit record in PECOS:

- Full name (first, middle and last),
- Birthdate,
- Address and telephone number,
- License information and
- NPI (if one has been obtained), and
- SSN (if no NPI has been issued, though note that this cannot be an individual tax identification number (ITIN)).

If, in order to create a PECOS affidavit record, the contractor needs to obtain data that is missing from an affidavit, it may (1) obtain this information from other sources (such as the state license board) or (2) contact the eligible practitioner only **one time** directly. The contractor shall **not** use Internet-based PECOS or the Form CMS-855 to secure the data from the eligible practitioner, for the eligible practitioner **is not** enrolling in Medicare. If the eligible practitioner is requested to submit missing information to permit the processing of the affidavit and fails to do so within 30 days, the contractor shall reject the opt-out affidavit.

2. Opting-Out and Ordering/Certifying/Referring

If an eligible practitioner who wishes to opt-out elects to order/certify/refer Medicare items or services, the contractor shall develop for the following information (if not provided on the affidavit):

- NPI (if one is not contained on the affidavit voluntarily);

- Date of birth, and;

- SSN (if not contained on the affidavit, though it cannot be an ITIN).

If this information is requested but not received, the eligible practitioner's affidavit can still be processed; however, he/she cannot be listed as an ordering/certifying/referring provider.

3. Adverse Actions

The contractor shall review the List of Excluded Individuals and Entities (LEIE) and the System for Award Management (SAM) for all eligible practitioners who submit opt-out affidavits. Excluded eligible practitioners may opt-out of Medicare but cannot order certify/refer.

As noted in 42 CFR § 405.425(i) and (j), individuals who are revoked from Medicare cannot order, certify, or refer Part A or B services or items to Medicare beneficiaries if they opt-out of Medicare after revocation.

4. No Dual Status

a. Form CMS-855O - Eligible practitioners cannot be enrolled via the Form CMS-855O and actively opted-out simultaneously. Prior to processing an initial Form CMS-855O or opt-out affidavit submission, therefore, the contractor shall confirm that an approved Form CMS-855O enrollment or valid opt-out affidavit does not exist in PECOS. If an approved enrollment or affidavit indeed exists, the contractor shall return the pending application.

b. Form CMS-855I – A Form CMS-855I enrollment can simultaneously exist with a valid opt-out affidavit **only** if the Form CMS-855I is to bill for emergency services. If a Form CMS-855I is received **and** an opt-out affidavit is active, the contractor shall contact the eligible practitioner (via any means) to clarify if he/she submitted the application to solely bill for emergency services provided to a beneficiary. If so, the application shall be processed via normal procedures. If not, the application may be returned. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

An eligible practitioner who has opted out of Medicare need not also enroll via the Form CMS-855O if he/she wishes to order/refer/certify (e.g., providing the necessary information on his/her affidavit per this section 10.6.12).

5. Acceptable Opt-Out Affidavit Formats

The contractor may provide a sample opt-out affidavit form for eligible practitioners to complete. The opt-out affidavit form must provide spaces for the eligible practitioners to furnish their personal information.

Eligible practitioners may also create their own affidavit. If he/she elects to do so, he/she should include information found in section 10.6.12(B)(1) to ensure timely processing of the opt-out affidavit.

The contractor and eligible practitioners may use the information below as an opt-out affidavit form.

I, {Enter Physician/Non-Physician Practitioner Name}, being duly sworn, depose and say:

- Opt-out is for a period of two years. At the end of the two year period, my opt-out status will automatically renew. If I wish to cancel the automatic extension, I understand that I must notify my Medicare Administrative Contractor (MAC) in writing at least 30 days prior to the start of the next two-year opt-out period.

- Except for emergency or urgent care services (as specified in the Medicare Benefit Policy Manual Publication 100-02, Chapter 15 §40.28), during the opt-out period I will provide services to Medicare beneficiaries only through private contracts that meet the criteria of §40.8 for services that, but for their provision under a private contract, would have been Medicare-covered services.

- I will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will I permit any entity acting on my behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in § 40.28.

- During the opt-out period, I understand that I may receive no direct or indirect Medicare payment for services that I furnish to Medicare beneficiaries with whom I have privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under Medicare Advantage.

- I acknowledge that during the opt-out period, my services are not covered under Medicare and that no Medicare payment may be made to any entity for my services, directly or on a capitated basis.

- I acknowledge and agree to be bound by the terms of both the affidavit and the private contracts that I have entered into during the opt-out period.

- I acknowledge and understand that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by myself during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom I have not previously privately contracted) without regard to any payment arrangements I may make.

- I acknowledge that if I have signed a Part B participation agreement, that such agreement terminates on the effective date of this affidavit.

- I acknowledge and understand that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of §40.28 apply if I furnish such services.

- I have identified myself sufficiently so that the MAC can ensure that no payment is made to me during the opt-out period. If I have already enrolled in Medicare, I have included my Medicare PTAN, if one has been assigned. If I have not enrolled in Medicare, I have included the information necessary to opt-out.

- I will file this affidavit with all MACs who have jurisdiction over claims that I would otherwise file with Medicare and the initial two- year opt-out period will begin the date the affidavit meeting the requirements of 42 C.F.R. §405.420 is signed, provided the affidavit is filed within 10 days after the physician/practitioner signs his or her first private contract with a Medicare beneficiary.

Eligible practitioners should also be encouraged to include the following information (to complete an affidavit record in PECOS): NPI; Medicare Identification Number (if issued); SSN (not an ITIN); date of birth; specialty; e-mail address; any request to order/certify/refer.

C. Effective Date of an Opt-Out Period

As noted in Pub. 100-02, chapter 15, section 40.17, eligible practitioners receive effective dates based on their participation status.

1. Eligible Practitioners Who Have Never Enrolled In Medicare

Eligible practitioners need not enroll prior to opting-out of Medicare. If a non-enrolled eligible practitioner submits an opt-out affidavit, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

2. Non-Participating Practitioners

If an eligible practitioner who is a non-participating provider decides to terminate his/her active Medicare billing enrollment and instead opt-out of Medicare, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

3. Participating Practitioners

If an eligible practitioner who is a participating provider (one who accepts assignment for all their Medicare claims) decides to terminate his/her active Medicare billing enrollment and opt-out of Medicare, the effective date of the opt-out period begins the first day of the next calendar quarter. Per 42 CFR § 405.410(d), an eligible practitioner may opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in 42 CFR § 405.420 is submitted to the applicable contractor(s) at least 30 days before the beginning of the selected calendar quarter. (The contractor shall, however, add 5 calendar days to the 30-day period to allow for mailing.) An opt-out affidavit must therefore be submitted at least 30 days before the first day of the calendar quarter in order to receive January 1, April 1, July 1 or October 1 as the effective date. If the opt-out affidavit is submitted within 30 days prior to January 1, April 1, July 1 or October 1, the effective date would be the first day of the next calendar quarter. (For example, an enrolled participating eligible practitioner's opt-out affidavit was submitted on December 10. The eligible practitioner's effective date could not be January 1, for the affidavit was not submitted at least 30 days prior to January 1. The effective date would be April 1.) The eligible practitioner would need to remain enrolled as a participating supplier until the end of the next calendar quarter so that claims can be properly submitted until the opt-out period begins.

4. Opt-Out After Enrollment

(This section 10.6.12(C)(4) applies notwithstanding any instruction to the contrary in this chapter.)

If an enrolled physician or eligible practitioner is now opting-out, the existing PECOS enrollment record shall be end-dated the same day as the affidavit effective date.

D. Emergency and Urgent Care Services

If an eligible practitioner who has opted-out provides emergency or urgent care services, he/she must apply for enrollment via the Form CMS-855I. Once he/she receives his/her PTAN, he/she must submit the claim(s) for any emergency or urgent care service furnished. The contractor shall contact its PEOG BFL for additional guidance when this type of

situation arises. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

E. Termination of an Opt-Out Affidavit

As noted in Pub. 100-02, chapter 15, section 40.35, an eligible practitioner who has not previously opted-out may terminate his/her opt-out period early. However, he/she must submit written notification thereof (with his/her signature) no later than 90 days after the effective date of the initial 2-year opt-out period. To properly terminate an affidavit, moreover, the eligible practitioner must:

1. Not have previously opted-out of Medicare (the eligible practitioner cannot terminate a renewal of his/her opt-out);
2. Notify all the MACs that the eligible practitioner has filed an affidavit no later than 90 days after the effective date of the affidavit;
3. Notify all beneficiaries (or their legal representation) with whom the eligible practitioner entered into private contracts of the eligible practitioner's decision to terminate his/her opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period and;
4. Refund to each beneficiary with whom the physician or practitioner has privately contracted all payments collected in excess of the Medicare limiting charge or deductibles and coinsurance.

For eligible practitioners who were previously enrolled to bill Medicare for services, the contractor shall reactivate the eligible practitioner's enrollment record in PECOS and reinstate his/her PTAN as if no opt-out affidavit existed. The eligible practitioner may bill for services provided during the opt-out period.

For eligible practitioners who were not previously enrolled to bill Medicare for services, the contractor shall remove the affidavit record from PECOS; this will help ensure that the eligible practitioner can submit the appropriate application(s) (via PECOS or paper Form CMS-855 for individual and/or reassignment enrollment) in order to establish an enrollment record in PECOS and thus bill for services rendered during the opt-out period.

F. Opt-Out Period Auto-Renewal and Cancellation of the Opt-Out Affidavit

1. General Policies

Eligible practitioners who initially opted-out or renewed an affidavit on or after June 16, 2015 need not submit a renewal of their affidavit. The opt-out will be automatically renewed for another 2-year period. Yet if the eligible practitioner decides to cancel his/her opt-out, he/she must submit a written notice to each contractor to which he or she would file claims (absent the opt-out) not later than 30 days before the end of the current 2 year opt-out period.

If the eligible practitioner decides to enroll in Medicare after his/her opt-out is canceled, he/she must submit a Form CMS-855I application. The effective date of enrollment, however, cannot be before the cancellation date of the opt-out period. (For example, suppose an eligible practitioner submits a cancellation of her opt-out to end the period on March 31, which is two years from the eligible practitioner's opt-out affidavit effective date. Her requested effective date of enrollment cannot be before April 1.)

If the eligible practitioner submits a cancellation request within 30 days of the end of the current opt-out period or after the opt-out period automatically renews, the contractor shall return the cancellation request to the eligible practitioner and provide appeal rights.

2. Auto-Renewal Report and Opt-Out Renewal Alert

The contractor shall issue an Opt-Out Renewal Alert Letter (found in section 10.7.14(E) of this chapter) to any eligible practitioner whose opt-out period is set to auto-renew. For this purpose, CMS will provide a monthly opt-out report to all contractors via the Share Point Ensemble site. The contractor shall access the report monthly through the Share Point Ensemble site. The contractor shall also review the opt-out report for opted-out eligible practitioners that will auto-renew in the next three-and-a-half months. In addition, the contractor shall issue an Auto-Renewal Alert Letter to eligible practitioners at least 90 days prior to the auto-renewal date; the eligible practitioner will thus have at least 60 days prior to the date a cancellation notice must be submitted to cancel the current opt-out.

The Opt-out Auto-Renewal Alert Letter will provide (1) the date on which the current opt-out period will be auto renewed and (2) the date by which the eligible practitioner will need to submit a cancellation request. The letter will also furnish the eligible practitioner appeal rights if he/she fails to submit a cancellation request and the opt-out renews.

The contractor shall (1) complete the Opt-Out Renewal Alert Letter Report to include the date the Alert Letter was issued, (2) post its reports no later than the 15th of the following month to the Share Point Ensemble site, and (3) email its PEOG BFL when the report has been posted.

If an opted-out eligible practitioner submits a Form CMS-855I and/or a CMS-855R without submitting a cancellation request of his or her opt-out, the contractor shall develop for the cancellation notice. Once the cancellation notice is received, the contractor shall then process the application(s).

If the eligible practitioner submits a cancellation request within 30 days of the end of the current opt-out period or after the opt-out period automatically renews, the contractor shall return the cancellation request to the eligible practitioner and provide appeal rights using the Late Cancellation Request return letter. In addition, if the eligible practitioner submits a cancellation request more than 90 days prior to the auto-renewal date, the contractor shall return the cancellation request to the eligible practitioner using the Cancellation Request Received Too Early return letter.

G. Failure to Properly Cancel or Terminate Opt-Out

Eligible practitioners who fail to properly cancel or terminate their opt-out may appeal the decision to continue (1) the auto-renewal of the opt-out or (2) the eligible practitioner's initial opt-out period.

Opt-out approval letters include appeal rights for eligible practitioners who initially opt-out and fail to properly terminate the opt-out within 90 days of the approval.

10.6.18 – Appeals Process

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Review Procedures for Determinations that Affect Participation in the Medicare Program

1. Background

This review process of initial determinations applies to all providers and suppliers and ensures that all current and prospective providers and suppliers receive a fair and full

opportunity to be heard. With the implementation of the appeals provision of Section 936 of the Medicare Prescription Drug Modernization and Improvement Act (MMA), all providers and suppliers that wish to appeal will be given the opportunity to request Administrative Law Judge (ALJ) review of a reconsideration decision within the Civil Remedies Division of the Departmental Appeals Board (CRD DAB). Providers and suppliers may thereafter seek review of the ALJ decision in the Appellate Division of the Departmental Appeals Board (DAB) and may then request judicial review in Federal District Court.

For purposes of this chapter, in accordance with 42 C.F.R. § 498.3, an initial determination includes: (1) the denial of enrollment in the Medicare program; (2) the revocation of a provider's or supplier's Medicare billing privileges; and (3) the effective date of participation in the Medicare program.

Any corrective action plan (CAP) or reconsideration request that purports to challenge an enrollment action other than the initial determinations identified above (including inclusion on the CMS Preclusion List and Opt-Out Status) shall be forwarded to CMS at ProviderEnrollmentAppeals@cms.hhs.gov for review within 10 business days of the date of receipt. The Medicare Administrative Contractor (MAC) shall take no action on the provider's or supplier's information on its enrollment record regarding an appeal submission for revocations forwarded to CMS for processing unless otherwise instructed by the Provider Enrollment and Oversight Group (PEOG).

A provider or supplier dissatisfied with the initial determinations referenced above, may challenge the determination. All properly submitted requests shall be reviewed at the enrollment level. As a result, if one letter attempts to challenge the initial determination for a group enrollment in addition to individual practitioner enrollment(s), each enrollment shall receive a separate decision. All submissions shall be processed in the order in which they are received. All CAPs and/or reconsideration requests will be reviewed by an individual separate and apart from the individual involved in the implementation of the initial determination.

Depending on the regulatory authority under which an initial determination is issued, providers and suppliers may be entitled to submit a CAP and/or a reconsideration request. A CAP is a plan that allows a provider or supplier an opportunity to demonstrate compliance with all applicable Medicare requirements by correcting the deficiencies (if possible) that led to the initial determination, specifically either the denial of enrollment into the Medicare program under 42 C.F.R. § 424.530(a)(1) or the revocation of Medicare billing privileges pursuant to 42 C.F.R. § 424.535(a)(1). While CAPs may only be submitted in response to a denial under 42 C.F.R. § 424.530(a)(1) or a revocation under 42 C.F.R. § 424.535(a)(1), all initial determinations allow for the submission of a reconsideration request. A reconsideration request allows the provider or supplier an opportunity to demonstrate that an error was made in the initial determination at the time the initial determination was implemented. In contrast to a CAP, a reconsideration request does not allow a provider or supplier the opportunity to correct the deficiencies that led to the initial determination.

Any CAPs and/or reconsideration requests received in response to initial determinations involving the following, either in whole or in part, shall be forwarded to CMS for review within 10 business days of the date of receipt. The CAP and/or reconsideration request shall be sent to the PEOG Provider Enrollment Appeals inbox at ProviderEnrollmentAppeals@cms.hhs.gov.

- All CAPs and reconsideration requests for certified providers/suppliers (as defined in Sections 10.2.1 and 10.2.2 of this chapter) and institutional providers/suppliers which have been revoked (as defined in Section 10.4(M)(2)(e) of this chapter);

- CAPs and reconsideration requests for Independent Diagnostic Testing Facilities;

- CAPs and reconsideration requests for Medicare Diabetes Prevention Programs (MDPP);

- CAPs and reconsideration requests for Opioid Therapy Programs (OTPs);

- Reconsideration requests for enrollment denials pursuant, in whole or in part, to 42 C.F.R. § 424.530(a)(2), (3), (6), (11), (12), (13), (14), *(15), and (17)*

- Reconsideration requests for revocations pursuant, in whole or in part, to 42 C.F.R. § 424.535(a)(2), (3), (4), (7), (8), (10), (12), (13), (14), *(15),* (17), (18), (19), (20), (21), *and* (22)*;*

- Requests for reversals of denials pursuant to 42 C.F.R. § 424.530(c) and/or revocations pursuant to 42 C.F.R. § 424.535(e);

- Reconsideration requests for revocations pursuant, in whole or in part, to 42 C.F.R. § 424.535(j);

- Reconsideration requests challenging the addition of years to an existing re-enrollment bar;

- Reconsideration requests challenging whether an individual or entity other than the provider or supplier that is the subject of the second revocation was the actual subject of the first revocation;

- Reconsideration requests challenging an individual or entity being included on the CMS Preclusion List as defined in § 422.2 or § 423.100; and

- Reconsideration requests regarding opt-out status.

(NOTE: As indicated in section 10.4.7.4(D) of this chapter – and notwithstanding any other instruction to the contrary in this chapter (including in this section 10.6.18(A)(1)) -- the MAC shall make all reconsideration determinations for denials under § 424.530(a)(18) and revocations under § 424.535(a)(23).)

If the provider or supplier is denied enrollment or has its Medicare billing privileges revoked, under 42 C.F.R. § 424.530(a)(1) or 42 C.F.R. § 424.535(a)(1), (5), (9), in conjunction with any denial or revocation reason(s) listed above, those CAPs and/or reconsideration requests should also be forwarded to CMS at ProviderEnrollmentAppeals@cms.hhs.gov for review within 10 business days of the date of receipt and the determination will be rendered by CMS. If the provider or supplier only submits a CAP for the noncompliance portion of any initial determinations listed above, the CAP must be sent to CMS at ProviderEnrollmentAppeals@cms.hhs.gov for review within 10 business days of the date of receipt, even if the provider or supplier does not submit a reconsideration request. The MAC shall not process the CAP if it is required to be forwarded to CMS. If the provider or supplier later submits a reconsideration request, the reconsideration request must also be sent to CMS at ProviderEnrollmentAppeals@cms.hhs.gov within 10 business days of the date of receipt.

All CAPs and reconsideration requests received by the MACs that are not specifically identified above as being required to be forwarded to CMS for review, shall be processed and a decision rendered by the MACs. However, CMS may exercise its discretion to review any CAP and/or reconsideration request and issue a decision regardless of the basis for the initial determination.

(**NOTE:** This includes all CAPs and reconsideration requests for DMEPOS suppliers that fit the criteria identified above. In addition, as also indicated above, CAPs may only be submitted for denials pursuant to 42 C.F.R. § 424.530(a)(1) and revocations pursuant to 42 C.F.R. § 424.535(a)(1). However, in the event a CAP is submitted for revocations pursuant, in whole or in part, to 42 C.F.R. § 424.535(a)(2), (3), (4), (7), (8), (10), (12), (13), (14), *(15),* (17), (18), (19), (20), (21), or (22) the submission should still be forwarded to CMS within 10 business days of the date of receipt to the PEOG Provider Enrollment Appeals inbox at ProviderEnrollmentAppeals@cms.hhs.gov.)

PEOG shall notify the MAC via email when it receives a CAP and/or reconsideration request for a provider or supplier that has not been previously forwarded to PEOG by the MAC. The MAC shall not take any action on a provider or supplier's information on its enrollment record if there is a CAP and/or reconsideration request pending for a revocation action unless otherwise instructed by PEOG. The MAC shall email ProviderEnrollmentAppeals@cms.hhs.gov with any inquiries, questions, or requests.

All documentation related to CAPs and reconsideration requests (including, but not limited to, the decisions) shall be saved in PDF format. The date on the CAP and reconsideration request decisions should be the same date as the date the decision is issued to the provider/supplier/representative.

2. Reopening and Revising CAP and Reconsideration Determinations

Once a CAP and/or reconsideration decision is issued, the MAC shall not reopen and revise a CAP and/or reconsideration decision without PEOG's prior approval, even if the MAC rendered the CAP or reconsideration decision independently. The MAC shall send all requests to reopen and revise a CAP and/or reconsideration decision to ProviderEnrollmentAppeals@cms.hhs.gov and await further instruction before taking any action regarding the CAP and/or reconsideration decision.

3. Requests to the MACs

The MAC shall work with and provide PEOG and the Office of General Counsel (OGC), when applicable, all necessary documentation related to any and all CAPs, reconsideration requests, ALJ appeals, DAB appeals, or requests for judicial review.

The following are examples of information the MAC may be asked to provide. This is not an exhaustive list.

- A copy of the initial determination letter**;**
- A chronological timeline outlining: (1) the processing of applications; (2) the date they began providing services at the newest assigned location; and (3) if there were development requests;
- The hearing officer's decision as well as the provider or supplier's CAP and/or reconsideration request;

- A complete copy of all application Form CMS-855s, and any supporting documentation submitted with the provider or supplier's application;

- All background information and investigative data the hearing officer used to make their decision. Including any on-site visit reports; the MAC's recommendation for administrative action based on the on-site visit;

- Contact information for the person(s) who signed both the revocation and reconsideration decision letters.

The MAC shall supply PEOG or OGC with all requested documentation within 5 business days of receipt of the request, unless requested sooner.

All requested documentation shall be provided in PDF format (if possible) and saved with a file name that identifies the content of the document.

If a CAP and/or reconsideration decision requires the MAC to take action on a provider's or supplier's enrollment, such as reinstating the provider's or supplier's enrollment to an active status, the MAC shall complete all updates to the provider's or supplier's enrollment within 10 business days of the date the CAP and/or reconsideration decision is issued unless additional documentation is needed to update the enrollment. If a CAP or reconsideration decision requires the provider or supplier to submit further information before the enrollment can be updated, such as an enrollment application, the MAC shall allow 30 calendar days for the provider or supplier to submit the necessary information. The MAC shall complete all updates to the provider's or supplier's enrollment within 10 business days of the date of receipt of the additional information/documentation. If the provider or supplier does not submit the necessary information within 30 calendar days, the MAC shall contact PEOG by emailing ProviderEnrollmentAppeals@cms.hhs.gov for further instruction.

4. Timing of CAP and Reconsideration Request Submissions

A provider or supplier who wishes to submit a CAP must file its request in writing within 35 calendar days of the date of the initial determination. A provider or supplier who wishes to submit a reconsideration request must file its request in writing within 65 calendar days of the date of the initial determination. The date on which CMS or the MAC receives the submission is considered to be the date of filing. See section D below for information on calculating timely submissions.

The mailing and email address for all CAPs and reconsideration requests to be rendered by CMS identified in section 10.6.18(A) is:

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

Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review, and may result in the dismissal of any untimely submitted reconsideration request. The time limit may be extended if good cause for late filing is shown. Good cause may be found when the record clearly shows or the party alleges and the

record does not negate that the delay in filing was due to circumstances outside of the provider's or supplier's control such as the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

If a reconsideration request is not timely filed, as required in 42 C.F.R. § 498.22, CMS will make a determination as to whether good cause exists. If a MAC receives an untimely CAP and/or reconsideration request that it believes is entitled to a good cause exception related to untimeliness, the hearing officer must request approval from PEOG by emailing ProviderEnrollmentAppeals@cms.hhs.gov with an explanation as to why good cause is believed to exist before making a finding of good cause or taking any other action regarding the CAP and/or reconsideration request. The MAC shall not take action on the CAP and/or reconsideration request until it receives a response from CMS regarding the good cause exception request.

5. Time Calculations

Per 42 C.F.R. § 498.22(b)(3), the date of receipt of an initial determination is presumed to be 5 calendar days after the date on the initial determination notice unless there is a showing that it was, in fact, received earlier or later.

A CAP must be received by the MAC or CMS within 35 calendar days of the date of the initial determination. A reconsideration request must be received by the MAC or CMS within 65 calendar days of the date of the initial determination. If the 35th day (for a CAP) or 65th day (for a reconsideration request), falls on a weekend, or Federally recognized holiday, the CAP and/or reconsideration request shall be considered timely filed if received on the next business day. In the case of an email submission of a CAP and/or reconsideration request, the filing date is presumed to be the date of receipt of the email. Consider the following example:

An initial determination letter is dated April 1. The provider is presumed to have received the initial determination on April 6. The provider submits a CAP and/or reconsideration request by mail that is received on June 10, 65 calendar days after April 6. This is considered timely because it is presumed that the provider did not receive the initial determination letter until April 6.

It is the provider or supplier's responsibility to timely update its enrollment record to reflect any changes to the provider or supplier's enrollment information, including its correspondence address. Failure to timely update a correspondence address or other address included in the enrollment record does not constitute an "in fact" showing that an initial determination letter was received after the presumed date of receipt.

6. Signatures

A CAP and/or reconsideration request must be submitted in the form of a letter that is signed by the individual provider, supplier, the authorized or delegated official, or a properly appointed representative, as defined in 42 C.F.R. § 498.10. If the representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier. This statement is sufficient to constitute notice. If the representative is not an attorney, the provider or supplier must file written notice of the appointment of a representative with the contractor. This notice of appointment must be signed by the

individual provider or supplier, or the authorized or delegated official. The signature need not be original and can be electronic.

Authorized or delegated officials for groups cannot sign and submit a CAP and/or reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

(**NOTE:** The provider or supplier's contact person (as listed in section 13 of the Form CMS-855) does not qualify as a "representative" for purposes of signing a reconsideration request without the requisite appointment statement and signature by the individual provider or supplier.)

If the CAP and/or reconsideration request is not appropriately signed or if a statement from the attorney or written notice of representation is not included in the submission, the MAC shall send a development request for a proper signature or the missing statement/written notice (using the applicable model letter) before dismissing the CAP and/or reconsideration request. The MAC shall allow 15 calendar days from the date of the development request letter for the CAP and/or reconsideration request submitter to respond to the development request.

If the CAP and/or reconsideration request submission is not appropriately signed and no response is timely received to the development request (if applicable), the MAC shall dismiss the CAP and/or reconsideration request using the applicable model dismissal letter.

7. Representative for CAP and/or Reconsideration Request

Per 42 C.F.R. § 498.10, a provider or supplier may appoint as its representative any individual that is not disqualified or suspended from acting as a representative in proceedings before the Secretary of the Department of Health and Human Services or otherwise prohibited by law to engage in the appeals process. If this individual is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative. If the representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with CMS or the MAC. Once a representative has been properly appointed, the representative may sign and/or submit a CAP, reconsideration request, request for reversal, or a request for good cause exception on behalf of the provider or supplier.

8. Submission of Enrollment Application while a CAP and/or Reconsideration Request is Pending/Submission Timeframe has not Expired

If a provider or supplier's enrollment application is denied, the provider or supplier must wait until the time period in which to submit a CAP and/or reconsideration request has ended before submitting a new enrollment application, change of information, or provides any additional information to update their enrollment record. If the MAC receives an enrollment application, change of information, or additional information to update a provider's or supplier's enrollment record prior to the conclusion of the time period in which to submit a CAP and/or reconsideration request, the MAC shall return the application unless the application is received as part of the provider's or supplier's CAP and/or reconsideration request submission. The MAC shall not modify the enrollment record of a provider or supplier that currently has a pending CAP and/or reconsideration request for revocations or is still within the submission time period for denials unless instructed by CMS to do so. Any applications received while the provider or supplier is in a revoked status should be returned to the provider or supplier and not processed pursuant to Section 10.4(H)(1).

B. Corrective Action Plans (CAPs)

1. Background

A CAP is a plan that allows a provider or supplier an opportunity to demonstrate compliance by correcting the deficiencies (if possible) that led to the initial determination. CAPs may only be submitted in response to enrollment denials pursuant to 42 C.F.R. § 424.530(a)(1) and revocation of Medicare billing privileges pursuant to 42 C.F.R. § 424.535(a)(1).

2. Requirements for CAP Submission

CAP submission:

(a) Must contain, at a minimum, verifiable evidence that the provider or supplier is in compliance with all applicable Medicare requirements;

(b) Must be received within 35 calendar days from the date of the initial determination (see section 10.6.18(A)(4) for clarification on timing). The contractor shall accept a CAP via hard-copy mail, email, and/or fax;

(c) Must be submitted in the form of a letter that is signed by the individual provider or supplier, the authorized or delegated official that has been reported within your Medicare enrollment record, or a properly appointed representative;

(d) Should include all documentation and information the provider or supplier would like to be considered in reviewing the CAP.

(e) For denials, the denial must be based on 42 C.F.R. § 424.530(a)(1);

i. For denials based on multiple grounds of which one is § 424.530(a)(1), the CAP may only be accepted with respect to § 424.530(a)(1), but not with respect to the other grounds. If the provider or supplier submits a CAP that does not comply with this paragraph, the MAC shall address this in the acknowledgement email or letter sent to the provider or supplier using the model acknowledgement letter (If multiple grounds are involved of which one is § 424.530(a)(1), the MAC shall:

A. Only consider the portion of the CAP pertaining to § 424.530(a)(1). The other denial bases may only be reviewed as a reconsideration.

(f) For revocations, the revocation must be based on 42 C.F.R. § 424.535(a)(1);

i. Consistent with § 405.809, CAPs for revocations based on grounds other than § 424.535(a)(1) shall not be accepted.

A. For revocations based on multiple grounds of which one is § 424.535(a)(1), the CAP may be accepted with respect to 424.535(a)(1), but not with respect to the other grounds. If the provider or supplier submits a CAP that does not comply with this paragraph, the MAC shall address this in the acknowledgment email or letter sent to the provider or supplier using the model acknowledgment letter. (If multiple grounds are involved of which one is § 424.535(a)(1), the MAC shall:

1. Only consider the portion of the CAP pertaining to § 424.535(a)(1). The other revocation bases may only be reviewed as a reconsideration.

3. Receipt Acknowledgment of CAP

If the MAC receives an acceptable CAP for a provider or supplier, the MAC shall use the model acknowledgment letter to email (if a valid email address is available) and send a hard-copy letter to the address included on the CAP submission letter or if no address is listed on the CAP submission letter, then the return address on the envelope from which the CAP was submitted within 14 calendar days of the date of receipt of the CAP, informing the provider, supplier, or its representative that a CAP decision will be rendered within 60 calendar days of the date of receipt of the CAP. If no address is listed in the CAP, then an acknowledgment letter should be sent to the correspondence address on the provider's or supplier's enrollment record.

If the provider's or supplier's CAP cannot be accepted due to untimeliness, an improper signature (including a failure to respond to development for the required statement or signed declaration from a representative), or any other reason, the MAC shall **not** send the provider or supplier an acknowledgment email or letter. Instead, the MAC shall dismiss the CAP using the applicable model dismissal letter.

4. Dismissing a CAP

A CAP shall be dismissed when the provider or supplier does not have the right to submit a CAP for the initial determination, or when the provider or supplier submitted the CAP improperly or untimely (see Section 10.6.18(B)(2)). As a result, the CAP shall not be reviewed. The MAC shall use the model dismissal letter when dismissing a CAP. All unacceptable CAPs shall be dismissed as soon as possible.

If a provider or supplier concurrently submits a CAP and reconsideration request, but the initial determination being appealed does not afford CAP rights or the CAP submission is untimely, the MAC shall dismiss the CAP using the No CAP Rights Dismissal Model Letter or Untimely CAP Dismissal Model Letter and review the reconsideration request in accordance with the instruction in Section 10.6.18(C).

5. CAP Analysis

The MAC shall only review the CAP as it relates to denial of enrollment pursuant to 42 C.F.R. § 424.530(a)(1) or a revocation of billing privileges pursuant to § 424.535(a)(1). The MAC must determine whether or not the information and documentation submitted with the CAP establishes that the provider or supplier has demonstrated compliance with all applicable Medicare rules and requirements by correcting the deficiency that led to the initial determination. If the MAC finds that the CAP corrects the deficiency that led to the initial determination, then the MAC shall overturn the initial determination as it relates to the denial reasons under 42 C.F.R. § 424.530(a)(1) or revocation under 42 C.F.R. § 424.535(a)(1). If the denial of enrollment is overturned completely, the MAC shall continue processing the previously denied enrollment application in accordance with standard processing procedures. If the revocation is overturned completely, the MAC shall reinstate the provider's or supplier's enrollment to an approved status based on the date the provider or supplier came into compliance. Consider the following example:

Example 1: A provider or supplier is denied enrollment under 42 C.F.R. § 424.530(a)(1) or revoked under 42 C.F.R. § 424.535(a)(1) because its required license has been suspended. The provider timely submits a CAP in which it provides evidence that its licensure has been reinstated and is currently active. After confirming the status of current licensure, the MAC should render a favorable CAP decision because the provider or supplier has corrected the licensure issue that led to enrollment denial or revocation.

If the provider or supplier submitted a CAP for reasons in addition to 42 C.F.R. §

424.535(a)(1), the MAC shall include in the decision letter that the CAP was reviewed only in regards to the 42 C.F.R. § 424.535(a)(1) basis.

If the provider or supplier does not submit information that establishes compliance with all applicable Medicare rules and requirements by correcting the deficiency that led to the initial determination, the MAC need not contact the provider or supplier for the missing information or documentation. The MAC shall instead deny the CAP. Under 42 C.F.R. § 405.809(a)(2), with respect to the revocation basis, the supplier has only one opportunity to correct all deficiencies that served as the basis of its revocation through a CAP.

6. Processing and Approval of CAPs

The time to submit a reconsideration request continues to run even though the MAC has received a CAP and is reviewing the CAP. Therefore, the time period in which to submit a reconsideration request does not stop once a CAP is received and while the CAP is being reviewed. The provider or supplier must submit a reconsideration request within 65 days of the date of the initial determination, even if a CAP is timely submitted and accepted.

The hearing officer shall issue a written decision within 60 calendar days of the date of receipt of the accepted CAP. The hearing officer shall email and mail a hard copy of the CAP decision to the provider or supplier or the individual that submitted the CAP, unless an email address is unavailable or the email is returned, then only a hard copy letter shall be mailed to the return address on the reconsideration request/envelope or the mailing address on the provider's/supplier's enrollment record if no return address is included on the reconsideration request. The MAC should also send the CAP decision letter via fax if a valid fax number is available.

If the MAC approves a CAP, it shall notify the provider or supplier by issuing a favorable decision letter following the applicable model CAP letter. The MAC shall continue processing the enrollment application under standard processing timelines or restore billing privileges (as applicable) within 10 business days of the date of the CAP decision or the date of receipt of additional documentation, if needed.

For denials – and unless stated otherwise in another CMS directive or instruction – the effective date is the later of either the date of the filing of the enrollment application or the date on which services were first rendered. Consider the following examples:

a. Denials

A physician's initial enrollment application is denied on March 1, 2018. The physician submits a CAP showing that, as of March 20th, the physician was in compliance with all Medicare requirements. If the MAC or CMS approves the CAP, the effective date of for the physician's Medicare billing privileges should be March 20th, as that is the day on which the physician came into compliance with all Medicare requirements. The 30-day retrospective billing provision should not be applied in this situation because the rule assumes that the provider was in compliance with Medicare requirements during the 30-day period. This was not the case here. The physician was not in compliance with all Medicare requirements until March 20.

b. Revocations

A physician's medical license is suspended on June 1st. The physician's Medicare enrollment is revoked under 42 C.F.R. § 424.535(a)(1) on June 15th. The physician then submits a CAP showing that, as of July 1st, the physician is currently licensed. If the MAC or CMS approves the CAP, the effective date for reactivation of the physician's Medicare billing privileges

should be July 1st as that is the day on which physician came into compliance with all Medicare requirements. The 30-day retrospective billing provision does not be apply in this situation.

The MAC shall ensure that the applicable CMS Regional Office is notified of the outcome of any CAP decision that involves the revocation of Medicare billing privileges for a certified provider or supplier.

If additional information/documentation is needed prior to reinstating the provider or supplier, the MAC shall document these next steps in their CAP decision letter. The MAC shall not reinstate the provider's or supplier's enrollment until the requested information is received and processed. If the additional information/documentation is not received within 30 calendar days of the date of the CAP decision letter, the MAC shall contact the provider or supplier via the applicable model letter to again request the additional information/documentation within 10 calendar days of not receiving a response. If no response is received within 30 calendar days of the second request for additional information/documentation, the MAC shall contact ProviderEnrollmentAppeals@cms.hhs.gov within 10 calendar days for further instruction.

7. Withdrawal of CAP

The provider, supplier, or the individual who submitted the CAP may withdraw the CAP at any time prior to the mailing of the CAP determination. The withdrawal of the CAP must be postmarked prior to the CAP determination date. The request to withdraw the CAP must be made in writing, signed, and filed with the MAC or CMS. If the MAC receives a request to withdraw a CAP, it shall send a letter or e-mail to the provider or supplier acknowledging receipt of the request to withdraw the CAP and advising that the request has been dismissed, utilizing the applicable model letter.

8. Concurrent Submission of CAP and Reconsideration Request

If a provider or supplier submits a CAP and a reconsideration request concurrently in response to any denial of enrollment under 42 C.F.R. § 424.530(a)(1) or any revocation of billing privileges under 42 C.F.R. § 424.535(a)(1), the MAC shall first process and make a determination regarding the CAP, only as it relates to the denial and/or revocation under 42 C.F.R. § 424.530(a)(1) or 42 C.F.R. § 424.535(a)(1). If the MAC renders a favorable decision as it relates to 42 C.F.R. § 424.530(a)(1) or 42 C.F.R. § 424.535(a)(1), the MAC shall only render a reconsideration decision on the remaining authorities not addressed by the favorable CAP decision. Processing timelines still apply.

If a CAP and a reconsideration request (see Section 10.6.18(B)(8)below) are submitted concurrently, the MAC shall coordinate the review of the CAP and reconsideration request to ensure that the CAP is reviewed and a decision rendered before a reconsideration decision is rendered (if the initial determination is not resolved in its entirety by the CAP decision).

If the CAP is approved and resolves the basis for the initial determination in its entirety, the model CAP decision letter shall be sent to the provider or supplier with a statement that the reconsideration request will not be evaluated because the initial determination has been overturned. If the CAP decision does not fully resolve the initial determination or results in a gap in the provider's or supplier's billing privileges, the MAC shall also process the reconsideration request.

If the CAP is denied:

- There are no further appeal rights; therefore, the CAP decision cannot be

appealed. As a result, do not include further appeal rights for a CAP only decision.

- The MAC shall notify the provider or supplier of the denial of the CAP via the applicable CAP model letter.

- The provider or supplier may continue with the appeals process if it has filed a reconsideration request or is preparing to submit such a request and has not exceeded the timeframe in which to do so.

- The reconsideration request, if properly submitted, shall be processed.

C. Reconsideration Requests

1. Background

A reconsideration request allows the provider or supplier an opportunity to demonstrate that an error was made in the initial determination at the time the initial determination was implemented. In contrast to a CAP, a reconsideration request does not allow a provider or supplier the opportunity to correct the deficiencies that led to the initial determination.

2. Requirements for Reconsideration Request Submission

a. Must contain, at a minimum, state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement;

b. Must be received within 65 calendar days from the date of the initial determination (see Section 10.6.19(A)(4) for clarification on timing). The contractor shall accept a reconsideration request via hard-copy mail, email, and/or fax;

c. Must be submitted in the form of a letter that is signed by the individual provider or supplier, the authorized or delegated official that has been reported within your Medicare enrollment record, or a properly appointed representative;

d. Should include all documentation and information the provider or supplier would like to be considered in reviewing the reconsideration request;

3. Receipt Acknowledgement of Reconsideration Request

Upon receipt of a properly submitted reconsideration request, the MAC shall send an email (if a valid email address is available) and hard-copy letter, to the individual that submitted the reconsideration request to acknowledge receipt of the reconsideration request using the applicable model acknowledgment letter within 14 calendar days of the date of receipt of the reconsideration request. The MAC shall send a hard-copy letter to the address listed in the reconsideration request submission or the return address listed on the reconsideration request submission envelope if no address is included on the reconsideration request letter. If no address is listed in the reconsideration request or on the envelope, then an acknowledgment letter should be sent to the correspondence address on the provider's or supplier's enrollment record. In the acknowledgment letter/email (if applicable), the MAC shall advise the requesting party that the reconsideration request will be reviewed and a determination will be issued within 90 calendar days from the date of receipt of the reconsideration request. The MAC shall include a copy of the acknowledgment letter and email (if applicable) in the reconsideration file. If the reconsideration should have been submitted to CMS, the MAC shall not send the provider or supplier an acknowledgment email or letter. Instead, the MAC shall forward the appeal to CMS within 10 business days of the date of receipt of the

reconsideration request (as specified in Section 10.6.18(A)(1)).

If the provider's or supplier's reconsideration request cannot be accepted due to untimeliness, an improper signature (including a failure to respond to development for the required statement or signed declaration from a representative, or any other reason), the MAC shall not send the provider or supplier an acknowledgment email or letter. Instead, the MAC shall dismiss the reconsideration request using the applicable model dismissal letter.

4. Reconsideration Determination

The MAC shall review all documentation in the record relevant to the initial determination and issue a written determination within 90 calendar days of the date of receipt of the accepted reconsideration request.

A proper reconsideration request must be received by the MAC or CMS within 65 calendar days of the date of the initial determination. Refer to Section 10.6.18(A)(4) for receipt date determinations. However, consistent with 42 C.F.R. § 498.24(a), the provider or supplier, may submit corrected, new, or previously omitted documentation or other facts in support of its reconsideration request at any time prior to the reconsideration decision being issued. The hearing officer must determine whether an error was made in the initial determination at the time the initial determination was implemented, based on all of the evidence presented. This includes:

- The initial determination itself,
- The findings on which the initial determination was based,
- The evidence considered in making the initial determination, and
- Any other written evidence submitted under § 498.24(a), taking into account facts relating to the status of the provider or supplier subsequent to the initial determination.

If the appealing party has additional information that it would like the hearing officer to consider during the reconsideration or, if necessary, an administrative law judge (ALJ) to consider during a hearing, the party must submit that information with its request for reconsideration. This is the party's only opportunity to submit information during the administrative appeals process; the party will not have another opportunity to do so unless an ALJ specifically allows the party to do so under 42 C.F.R. § 498.56(e).

5. Issuance of Reconsideration Determination

The hearing officer shall issue a written decision within 90 calendar days of the date of receipt of the accepted reconsideration request. The hearing officer shall email and mail a hard copy of the reconsideration decision to the provider or supplier or the individual that submitted the reconsideration request, unless an email address is unavailable or the email is returned, then only a hard copy letter should be mailed to the return address on the reconsideration request/envelope or the mailing address on the provider's/supplier's enrollment record if no return address is included on the reconsideration request. The MAC should also fax the CAP decision letter if a valid fax number is available. The reconsideration letter shall follow the applicable model letter and include:

- The regulatory basis to support each reason for the initial determination;
- A summary of the documentation that the provider or supplier provided,

as well as any additional documentation reviewed as part of the reconsideration process;

- The re-stated facts and findings, including the regulatory basis for the action as determined by the contractor in its initial determination;

- A clear explanation of why the hearing officer is upholding or overturning the initial determination in sufficient detail for the provider or supplier to understand the hearing officer's decision and, if applicable, the nature of the provider's or supplier's deficiencies. This explanation should reference the specific regulations and/or sub-regulations supporting the decision, as well as any documentation reviewed;

- If applicable, an explanation of how the provider or supplier does not meet the Medicare enrollment criteria or requirements;

- Further appeal rights, regardless of whether the decision is favorable or unfavorable, procedures for requesting an ALJ hearing, and the addresses to which the written appeal must be mailed or e-mailed. Further appeal rights shall only be provided for reconsideration decisions. There are no further appeals rights related to CAP decisions; and

- Information the provider or supplier must include with its appeal (name/legal business name; supplier number (if applicable); tax identification number/employer identification number (TIN/EIN); NPI; and a copy of the reconsideration decision).

Example 1: If a provider or supplier submits a reconsideration request in response to a revocation pursuant to 42 C.F.R. § 424.535(a)(5), the MAC shall review the initial determination, the enrollment application preceding the site visit, the site investigation report(s), the reconsideration request and supporting documentation, as well as any other relevant information, to determine if an error was made in the implementation of the initial determination (e.g., if an error was made during the site visit, or the site visit was conducted at the wrong location.) If the MAC finds that an error was made during the site visit, which found the provider or supplier to be non-operational, the MAC shall order an additional site visit. If an additional site visit is ordered, the MAC shall await the findings of the site investigator, via the site visit report, before issuing a reconsideration decision. If the site visit report finds the provider or supplier to be operational then the MAC shall overturn the revocation of the provider's or supplier's Medicare billing privileges as it relates to 42 C.F.R. § 424.535(a)(5) using the applicable model letter.

If the MAC overturns the initial determination, the MAC shall reinstate the provider's or supplier's billing privileges to an approved status as of the effective date determined in the reconsidered determination or continue processing the enrollment application (as applicable). Unless otherwise instructed by PEOG, the MAC shall only send the favorable reconsideration decision to the provider or supplier, authorized or delegated official, or its representative at the return address included on the reconsideration request. The reconsideration decision is sufficient for providing notice to the provider or supplier of the enrollment action being taken. All enrollment updates shall be completed within 10 business days of the date the reconsideration decision was issued or the date of receipt of additional documentation, if needed.

For initial enrollments, the effective date of Medicare billing privileges is based on the date

the provider or supplier is found to be in compliance with all Medicare requirements or the receipt date of the application – subject, of course, to any applicable retrospective billing provisions. (See Section 10.6.2 of this chapter for more information.) The MAC shall use the receipt date of the reconsideration request as the receipt date entered in the Provider Enrollment, Chain and
Ownership System (PECOS). For DMEPOS suppliers, the effective date is the date awarded by the *applicable contractor*.

The MAC shall ensure that the applicable CMS Regional Office is notified of the outcome of any reconsideration decision that involves the revocation of Medicare billing privileges for a certified provider or supplier.

If additional information/documentation is needed prior to reinstating the provider or supplier, the MAC shall document these next steps in their reconsideration decision letter. The MAC shall not reinstate the provider's or supplier's enrollment until the requested information is received and processed. If the additional information/documentation is not received within 30 calendar days of the date of the reconsideration decision letter, the MAC shall contact the provider or supplier via the applicable model letter to again request the additional information/documentation within 10 calendar days of not receiving a response. If no response is received within 30 calendar days of the second request for additional information/documentation, the MAC shall contact ProviderEnrollmentAppeals@cms.hhs.gov within 10 calendar days for further instruction.

6. Withdrawal of Reconsideration Request

The provider, supplier, or the individual who submitted the reconsideration request may withdraw the reconsideration request at any time prior to the mailing of the reconsideration decision. The withdrawal of a reconsideration request must be postmarked prior to the reconsideration decision date. The request to withdraw the reconsideration request must be made in writing, signed, and filed with the MAC or CMS. If the MAC receives a request to withdraw a reconsideration request, it shall send a letter or e-mail to the provider or supplier acknowledging receipt of the request to withdraw the reconsideration request and advising that the request has been dismissed, utilizing the applicable model letter.

7. Requests for Reversal under 42 C.F.R. § 424.530(c)/424.535(e)

Under 42 C.F.R. § 424.530(c)/424.535(e), a provider or supplier may request reversal of a denial of enrollment or revocation of billing privileges if the denial or revocation was due to adverse activity (sanction, exclusion, or felony) against an *owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program.* The revocation may be reversed, at the discretion of CMS, if the provider or supplier terminates and submits proof that it has terminated its business relationship with the individual or *organization* against whom the adverse action is imposed within *15* days of the *revocation* determination. *(For reversal of denials, the timeframe within 30 days of the denial notification.)* Information that may provide sufficient proof includes, but is not limited to, state corporate filings, IRS documentation, sales contracts, termination letters, evidence of unemployment benefits, board governance documents, and payroll records.

If the MAC receives a CAP and/or reconsideration request from a provider or supplier to reverse or rescind a denial or enrollment or revocation due to the termination of the business relationship between the provider or supplier and the individual against whom the adverse action is imposed, the MAC shall not take any action. The MAC shall forward the CAP and/or reconsideration request to ProviderEnrollmentAppeals@cms.hhs.gov within 10

business days of receipt. The MAC shall not take any action pursuant to the request until further instruction is provided by CMS.

8. Not Actionable CAPs and Reconsideration Requests

If the issue in the initial determination is resolved prior to a CAP and/or reconsideration decision being rendered, the basis of the initial determination may become moot and the CAP and/or reconsideration request will be not actionable. The MAC will be notified if an action has been taken that would render a CAP and/or reconsideration request not actionable as CMS would contact the MAC to rescind the revocation or reinstate the provider or supplier's Medicare billing privileges. If the MAC receives such a notification, then the MAC shall review to determine if a CAP and/or reconsideration request has become not actionable. If so, the MAC shall send a hard copy letter should be mailed to the return address on the CAP or reconsideration request, as well as the provider's or supplier's correspondence address using the applicable not actionable model letter. The MAC shall also send an email if a valid email address is available. The MAC may also send via fax if a valid fax number is available. The MAC shall attach a copy of the letter informing the provider or supplier of the enrollment action which led to the CAP and/or reconsideration request becoming not actionable. If there is a scenario not captured in the not actionable model letter and the MAC believes a CAP and/or reconsideration request has become not actionable, the MAC should email ProviderEnrollmentAppeals@cms.hhs.gov for guidance.

9. Requesting Guidance Related to CAPs and Reconsideration Requests

If the MAC encounters a situation that is not addressed by these instructions, the MAC shall contact the ProviderEnrollmentAppeals@cms.hhs.gov inbox for guidance before taking any action.

D. Further Appeal Rights for Reconsidered Determinations

1. Administrative Law Judge (ALJ) Hearing

The CMS or a provider or supplier dissatisfied with a reconsidered determination is entitled to review by an ALJ with the CRD DAB. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. To request final ALJ review, the provider or supplier must file an appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision. A provider or supplier may file an appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, the provider or supplier must first register a new account by:

(a) Clicking Register on the DAB E-File home page;
(b) Entering the information requested on the "Register New Account" form; and
(c) Clicking Register Account at the bottom of the form. If the provider or supplier has more than one representative, each representative must register separately to use DAB E-File on his/her/its behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, a provider or supplier may file an appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen; and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form. More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E-File Procedures link on the File New Appeal Screen for CRD appeals.

Pursuant to 42 C.F.R. § 405.809(a)(2), a provider or supplier may not appeal an adverse determination for a CAP, if one was made.

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

Upon receipt of a request for an ALJ hearing, an ALJ at the CRD DAB will issue a letter by certified mail to the supplier, CMS and the OGC acknowledging receipt of an appeals request and detailing a scheduled pre-hearing conference. The OGC will assign an attorney to represent CMS during the appeals process; he/she will also serve as the DAB point of contact. Neither CMS nor the Medicare contractor are required to participate in the pre-hearing conference, but should coordinate among themselves and the OGC attorney prior to the pre-hearing to discuss any issues. The MAC shall work with and provide the OGC attorney with all necessary documentation. This includes compiling and sending all relevant case material to the OGC attorney upon the latter's request within 5 calendar days of said request.

Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS. If CMS agrees to settle a provider enrollment appeal, CMS will notify the contractor of appropriate next steps (e.g., changing the effective date of billing privileges or reinstating a provider's billing privileges). This may result in PEOG providing specific instructions to the contractor to modify model letter language to appropriately notify the provider of changes to its enrollment status, revocation effective date, or effective date of billing privileges.

If an ALJ decision is rendered that overturns and/or modifies the initial determination establishing an effective date, revocation or denial of billing privileges, or remands a case back to CMS, this may also result in PEOG providing specific instructions to the contractor to draft and issue a revised reconsideration decision and/or modify the model letter language to appropriately notify the provider or supplier of changes to its enrollment status, revocation effective date, or effective date of billing privileges.

The MAC shall complete all steps associated with the settlement or ALJ decision no later than 10 business days from the date it received PEOG's specific instructions.

2. Departmental Appeals Board (DAB) Hearing

The CMS or a provider/supplier dissatisfied with the ALJ hearing decision may request a Board review by the DAB. Such a request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a DAB review is deemed to be a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented orally to the DAB, a transcript will be prepared and made available to any party upon request.

When CMS receives a decision or order from the DAB, as appropriate, PEOG will notify the MAC of appropriate next steps (i.e., changing an effective date or reinstating a provider's billing privileges). This may also result in PEOG providing specific instructions to the contractor to draft and issue a revised reconsideration decision and/or modify the model letter language to appropriately notify the provider of changes to its enrollment status, revocation effective date, or effective date of billing privileges.

The MAC shall complete all steps associated with the DAB decision no later than 10 business days from the date it received PEOG's specific instructions.

3. Judicial Review

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

E. External Monthly Reporting Requirements for CAPs and Reconsideration Requests

Using the provider enrollment appeals reporting template, the MAC shall complete all columns listed for all appeal submissions except those submissions that are referred to CMS for processing (CAPs and reconsideration requests). No column shall be left blank. If the contractor is unable to complete all columns for a given appeal submission, the contractor shall contact ProviderEnrollmentAppeals@cms.hhs.gov within five business days of discovery to seek further guidance.

The response in column A labelled, "Initial Determination Type," shall be one of the following:

- **Denial:** CAP or Reconsideration Request that challenges the denial of a Medicare enrollment application pursuant to 42 C.F.R. § 424.530(a)(1)-(1*8*).

- **Revocation:** CAP or Reconsideration Request that challenges the revocation of Medicare billing privileges or provider/supplier number pursuant to 42 C.F.R. § 424.535(a)(1)-(2*3*).

- **Effective Date:** Reconsideration request that challenges an initial determination that establishes an effective date of participation in the Medicare program, including the effective date of reactivation after deactivation.

- **Other:** CAP or reconsideration request that does not fall under the three categories listed above. If other is listed, an explanation shall be provided in the "Comments" column N and "N/A" in column G.

The response in Column L labelled, "Final Decision Result," shall be one of the following (If

a final decision has not been issued, the column shall read as “In Process.” If the appeal submission is referred to CMS for processing then the appeal should not be included on the MAC Monthly Appeals Report

1. Not Actionable: Appeal is no longer actionable (moot) because the basis for the initial determination has been resolved. (Ex: Fingerprints have received a passed designation, initial determination has been reopened and revised).

2. Favorable (to provider/supplier): MAC has determined that an error was made in the implementation of the initial determination. Therefore, the initial determination was overturned and the enrollment record has been placed in approved status, the effective date modified, or application processing has continued.

3. Unfavorable (to provider/supplier): MAC upholds the initial determination resulting in the enrollment remaining in a revoked or denied status, or the effective date remaining the same.

4. Dismissed: The appeal does not meet the appeal submission requirements. (Ex: incorrect signature, untimely, not appealable, etc.)

5. Rescinded: MAC has received instruction from CMS to rescind the initial determination and return the enrollment record to an approved status.

6. Withdrawn: Provider/supplier has submitted written notice of its intent to withdraw its appeal (CAP or reconsideration request).

The response in Column M labelled, “Date Final Decision Issued,” shall be “In Process” if a final decision has not been issued at the time the monthly report is sent to CMS.

The response in Column K labelled, “Date Receipt Acknowledgement Sent to Provider/Supplier/Legal Representative,” shall be “Not yet sent” if a receipt acknowledgement email/letter has not been sent to the provider/supplier/legal representative at the time the monthly report is sent to CMS. The response shall be “N/A” if a receipt acknowledgement email/letter is not required for that case.
The response in Column F labelled, “MAC (Including Jurisdiction),” shall be in one of the following formats:

1. **CGS**
2. **FCSO**
3. **NGS JK**
4. **NGS J6**
5. **Palmetto JM**
6. **Palmetto JJ**
7. **NSC**
8. **WPS J8**
9. **WPS J5**

10. Noridian JE

11. Noridian JF

12. Novitas JL

13. Novitas JH

The response in Column G, "Regulatory Authority (As identified on initial determination)," shall be in the following format (the authorities will need to be modified based on the type of initial determination):

- For Effective Date appeal: 424.520;
- For Denial appeal with only one authority cited in the initial determination: 424.530(a)(1-1*8*);
- For Denial appeal with multiple authorities cited in the initial determination: 424.530(a)(1-1*8*)(1-1*8*)
- For Revocation appeal with only one authority cited in the initial determination: 424.535(a)(1-2*3*)
- For Revocation appeal with multiple authorities cited in the initial determination: 424.535(a)(1-2*3*)(1-2*3*).
- For Other appeal: N/A with an explanation in the Comments column N.

The reports shall be sent to CMS via email at ProviderEnrollmentAppeals@cms.hhs.gov no later than the 15th of each month; the report shall include the prior month's appeal submissions, as well as outcomes for all submissions previously received that were not yet completed and reported to CMS (e.g., the February report shall cover all January CAPs/reconsideration requests). All submissions shall remain on the monthly report until a final outcome/decision has been reported to CMS. If this day falls on a weekend or a holiday, the report must be submitted the following business day.

10.7.15 –Revalidation Notification Letters

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Revalidation Letter – Non-DMEPOS Supplier

REVALIDATION

[month] [day], [year]

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

Dear [Provider/Supplier Name],

Every five years, CMS requires you to revalidate your Medicare enrollment record. You need to update or confirm all the information in your record, including your practice locations and reassignments.

We need this from you by **[Due date, as Month dd yyyy]**. If we don't receive your response by then, we may stop your Medicare billing privileges.

If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN, however will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

What record needs revalidating by [Due date, as Month dd yyyy]

[Name] | **NPI** [NPI] | **PTAN** [PTAN]
Reassignments: <Only include this title if the record has any reassignments>
[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]
<Repeat for other reassignments>

CMS lists the records that need revalidating at go.cms.gov/MedicareRevalidation.

What you need to do

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. For more on fees and exceptions, search cms.gov for "CR 7350" or "Fee Matrix".

A new Electronic Funds Transfer (EFT) Authorization Form (CMS-588) is only required to be submitted as part of your revalidation package if: (1) you have no Form CMS-588 on file with Medicare at all; or (2) you are changing any of your existing Form CMS-588 data. The current version of the form can be found at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS588.pdf.

If you need help

Visit go.cms.gov/MedicareRevalidation
Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]

B. Revalidation Letter – DMEPOS Supplier

REVALIDATION

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

Dear [Provider/Supplier Name],

Every three years, CMS requires you to revalidate your Medicare enrollment record. You need to update or confirm all the information in your record, including your practice location.

We need this from you by [Due date, as Month dd yyyy]. If we do not receive your response by then, we may stop your Medicare billing privileges.

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 by [Due date, as Month dd yyyy]
[Name] | NPI [NPI] | PTAN [PTAN]
[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]

The CMS lists the records that need revalidating at go.cms.gov/MedicareRevalidation.

What you need to do

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

- **Online:** PECOS is the fastest option. If you do not 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-855S] 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. For more on fees and exceptions, search cms.gov for "CR 7350" or "Fee Matrix".

A new Electronic Funds Transfer (EFT) Authorization Form (CMS-588) is only required to be submitted as part of your revalidation package if: (1) you have no Form CMS-588 on file with Medicare at all; or (2) you are changing any of your existing Form CMS-588 data.

The current version of the form can be found at http://www.cms.gov/Medicare/CMSForms/CMS-Forms/Downloads/CMS588.pdf.

If you need help

Visit go.cms.gov/MedicareRevalidation
Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]

C. Revalidation Letter – CHOW Scenario Only

[month] [day], [year]

PROVIDER/SUPPLIER NAME
ADDRESS 1, ADDRESS 2
CITY STATE ZIP CODE

NPI:
PTAN:

Dear Provider/Supplier Name:

THIS IS A PROSPECTIVE PROVIDER ENROLLMENT REVALIDATION REQUEST

IMMEDIATELY SUBMIT AN UPDATED
PROVIDER ENROLLMENT PAPER APPLICATION 855 FORM TO VALIDATE YOUR ENROLLMENT INFORMATION

In accordance with Section 6401 (a) of the Patient Protection and Affordable Care Act, all new and existing providers must be reevaluated under the new screening guidelines. Medicare requires all enrolled providers and suppliers to revalidate their enrollment information every five years (reference 42 CFR §424.515). To ensure compliance with these requirements, existing regulations at 42 CFR §424.515(d) provide that the Centers for Medicare & Medicaid Services (CMS) is permitted to conduct off-cycle revalidations for certain program integrity purposes. Upon the CMS request to revalidate its enrollment, the provider/supplier has 60 days from the post mark date of this letter to submit complete enrollment information.

You previously submitted a change of ownership (CHOW) application that is currently being reviewed by the State Agency. Since your application has not been finalized, please validate that we have the most current information on file. Any updated information received since your initial submission will be forwarded to the State Agency for their final determination.

Providers and suppliers can validate their provider enrollment information using the paper application form. To validate by paper, download the appropriate and current CMS-855 Medicare Enrollment application from the CMS Web site at https://www.cms.gov/MedicareProviderSupEnroll/. Mail your completed application and all required supporting documentation to the [insert contractor name], at the address below.

[Insert application return address]

A new Electronic Funds Transfer (EFT) Authorization Form (CMS-588) is only required to be submitted as part of your revalidation package if (1) you have no Form CMS-588 on file with Medicare at all; or (2) you are changing any of your existing Form CMS-588 data. The current version of the form can be found at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS588.pdf.

If additional time is required to complete the validation applications, you may request one 60-day extension, which will be added onto the initial 60 days given to respond to the request. The request may be submitted in writing from the individual provider, the Authorized or Delegated Official of the organization or the contact person and addressed to the MAC(s).

The request should include justification of why a 60-day extension is needed. The request may also be made by contacting your MAC(s), via phone.

Physicians, non-physician practitioners and physician and non-physician practitioner organizations must report a change of ownership, any adverse legal action, or a change of practice location to the MAC within 30 days. All other changes must be reported within 90 days. For most but not all other providers and suppliers, changes of ownership or control, including changes in authorized official(s), must be reported within 30 days; all other changes to enrollment information must be made within 90 days. *For all provider and supplier types, any change of practice location (including practice location additions, deletions, and relocations) must be reported within 30 days.*

Failure to submit complete enrollment application(s) and all supporting documentation within 60 calendar days of the postmark date of this letter may result in your Medicare billing privileges being deactivated and your CHOW not being processed. We strongly recommend you mail your documents using a method that allows for proof of receipt.

If you have any questions regarding this letter, please call [contractor telephone number will be inserted here] between the hours of [contractor telephone hours will be inserted here] or visit our Web site at [insert Web site] for additional information regarding the enrollment process or the [insert application type].

Sincerely,
[Your Name]
[Title]

D. Large Group Revalidation Notification Letter

[month] [day], [year]

PROVIDER/SUPPLIER GROUP NAME
ADDRESS 1, ADDRESS 2
CITY STATE ZIP CODE

NPI:
PTAN:

Dear Provider/Supplier Group Name:

THIS IS **NOT** A PROVIDER ENROLLMENT REVALIDATION REQUEST

This is to inform you that a number of physicians and/or non-physician practitioners reassigning all or some of their benefits to your group have been selected for revalidation. For your convenience, a list of those individuals is attached. A revalidation notice will be sent to the physician or non-physician practitioner within the next seven months. They will need to respond by the revalidation due date provided for each provider. It is the responsibility of the physician and/or non-physician practitioner to revalidate all their Medicare enrollment information and not just that associated with the reassignment to your group practice.

In accordance with Section 6401 (a) of the Patient Protection and Affordable Care Act, all new and existing providers must be reevaluated under the new screening guidelines. Medicare requires all enrolled providers and suppliers to revalidate their enrollment information every five years (reference 42 CFR §424.515). To ensure compliance with these requirements, existing regulations at 42 CFR §424.515(d) provide that the Centers for

Medicare & Medicaid Services (CMS) is permitted to conduct off-cycle revalidations for certain program integrity purposes.

Physicians and non-physician practitioners can revalidate by using either Internet-based PECOS or submitting a paper CMS-855 enrollment application. Failure to submit a complete revalidation application and all supporting documentation within 60 calendar days may result in the physician or non-physician practitioner's Medicare billing privileges being deactivated. As such, your group will no longer be reimbursed for services rendered by the physician or non-physician practitioner.

If you have any questions regarding this letter, please call [contractor telephone number will be inserted here] between the hours of [contractor telephone hours will be inserted here] or visit our Web site at [insert Web site] for additional information regarding the revalidation process.

Sincerely,

[Your Name]
[Title]

E. Revalidation Pend Letter

PAYMENT HOLD

[month] [day], [year]

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

Dear [Provider/Supplier Name],

We are holding all payments on your Medicare claims, because you haven't revalidated your enrollment record with us. This does not affect your Medicare participation agreement, or any of its conditions.

Every [three or five years], CMS requires you to revalidate your Medicare enrollment record information. You need to update or confirm all the information in your record, including your practice locations and reassignments.

Failure to respond to this notice will result in a possible 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 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>

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.

If you need help

Visit **go.cms.gov/MedicareRevalidation**
Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]

F. Revalidation Deactivation Letter

STOPPING BILLING PRIVILEGES

[month] [day], [year]

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

Dear [Provider/Supplier Name],

Your Medicare billing privileges are being deactivated effective [Month] [DD], [YYYY], pursuant to 42 C.F.R. § 424.540(a)(3) because you have not timely revalidated your enrollment record with us, or your revalidation application has been rejected because you did not timely respond to our requests for more information. We will not pay any claims after this date.

Every five years [three for DMEPOS suppliers], CMS requires you to revalidate your Medicare enrollment record.

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>

CMS lists the records that need revalidating at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Revalidations.html.

Rebuttal Rights:

If you believe that this determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.546. 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 deactivation 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 rebuttal should be sent to the following:

[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

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].

How to recover your billing privileges

Revalidate your Medicare enrollment record, through PECOS.cms.hhs.gov, 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 deserve a hardship waiver, mail us a request on practice letterhead with financial statements, application form, and certification.

If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN, however will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

If you need help Visit https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Revalidations.html.

Call [contractor telephone number] or visit [contractorsite.com] for more options.

Sincerely,

[Name]
[Title]
[Company]

G. Revalidation Past-Due Group Member Letter

REVALIDATION | Past-Due Group Member

[month] [day], [year]

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

Dear [Provider/Supplier Name],

Every five years, CMS requires providers to revalidate their Medicare enrollment records. You have not revalidated by the requested due date of [revalidation due date].

You need to update or confirm all the information in your record, including your practice locations and reassignments. If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN, however will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

If multiple records below need to be revalidated, please coordinate with the appropriate parties to provide only one response.

What record needs revalidating

[Name] | **NPI** [NPI] | **PTAN** [PTAN]
Reassignments: <Only include this title if the record has any reassignments>
[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]
<Repeat for other reassignments>

CMS lists the records that need revalidating at **go.cms.gov/MedicareRevalidation**.

What your group member needs to do

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

If your group member needs help

Visit **go.cms.gov/MedicareRevalidation**
Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]

H. Model Return Revalidation Letter

RETURN REVALIDATION

[month] [day], [year]

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

NPI: [xxxxxxxxxx]

Dear [Provider/Supplier Name],

Your Medicare enrollment application(s) was received on [date]. We are closing this request and returning your application(s) for the following reason(s):

- The [Form CMS-855 or Form CMS-20134] application received by [PROVIDER/SUPPLIER NAME] was unsolicited.
    - An unsolicited revalidation is one that is received more than seven months prior to the provider/supplier's due date. Due dates are established around 5 years from the provider/suppliers last successful revalidation or their initial enrollment.
    - To find the provider/suppliers revalidation due date, please go to http://go.cms.gov/MedicareRevalidation.
    - If you are not due for revalidation in the current seven-month period, you will find that your due date is listed as "TBD" (or To Be Determined). This means that you do not yet have a due date for revalidation within the current seven-month period. This list with be updated monthly.

- If your intention is to change information on your Medicare enrollment file, you must complete a new Medicare enrollment application(s) and mark ‘change’ in section 1 of the [form CMS-855 or Form CMS-20134].

- Please address the above issues as well as sign and date the new certification statement page on your resubmitted application(s).

Providers and suppliers can apply to enroll in the Medicare program using one of the following two methods:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). Go to: https://pecos.cms.hhs.gov/pecos/login.do.

2. Paper application process: Download and complete the Medicare enrollment application(s) at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html.

If you need help

Visit http://go.cms.gov/MedicareRevalidation, or
Call2 [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]