CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10383	**Date: October 9, 2020**
	Change Request 11999

SUBJECT: Updates to Chapters 4, 5, 8, 15, and Exhibits of Publication (Pub.) 100-08

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update various sections within Chapters 4, 5, 8, 15, and Exhibits in Pub. 100-08

EFFECTIVE DATE: November 10, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: November 10, 2020

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/Table of Contents
R	4/4.6/4.6.4/Vetting Leads with CMS
R	4/4.18/4.18.1/4.18.1.2/Immediate Advisements to the OIG/OI
R	4/4.18/4.18.2/Referral to State Agencies or Other Organizations
R	4/4.28/Joint Operating Agreements
R	5/Table of Contents
R	5/5.5/Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)
R	5/5.5/5.5.1/Completing a CMN or DIF
R	5/5.5/5.5.2/Cover Letters for CMNs
R	5/5.6/DME MACs and UPIC's Authority to Initiate an Overpayment and/or Civil Monetary Penalty (CMP) When Invalid CMNs or DIFs Are Identified
R	5/5.9/Documentation in the Patient's Medical Record
R	5/5.10/Supplier Documentation
R	5/5.11/Evidence of Medical Necessity
R	5/5.11/5.11.1/Evidence of Medical Necessity for the Oxygen Claims
R	5/5.12/Period of Medical Necessity - Home Dialysis Equipment
R	5/5.13/Safeguards in Making Monthly Payments
R	5/5.14/Pick-up Slips
R	5/5.18/Advance Determination of Medicare Coverage (ADMC) of Customized DMEPOS
R	8/8.3/8.3.3/8.3.3.1/DME Payment Suspensions (MACs and UPICs)
R	8/8.3/8.3.3/8.3.3.2/Non-DME National Payment Suspensions (MACs and UPICs)
R	15/15.18/Ordering and Certifying Documentation – Maintenance Requirements
R	15/15.27/15.27.2/Revocations
R	Exhibits/Exhibit 27/National Medicare Fraud Alert
R	Exhibits/Exhibit 28/Restricted Medicare Fraud Alert

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: 10383	Date: October 9, 2020	Change Request: 11999

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I. GENERAL INFORMATION

A. Background: The CMS is making revisions to Chapters 4, 5, 8, 15, and Exhibits in Pub. 100-08 based on updates to Unified Program Integrity Contractor (UPIC) and Investigations Medicare Drug Integrity Contractor (I-MEDIC) processes, procedures, and direction.

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

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	
11999.1	Contractors shall be aware that all references to Program Safeguard Contractor and Zone Program Integrity Contractor within Chapters 5, 15, and Exhibits in Pub. 100-08 shall now be referred to as UPIC.	X	X	X	X					UPICs
11999.2	The UPIC shall vet leads in an expedited timeframe as directed by									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	CMS based on high priority fraud schemes identified by CMS and/or Law Enforcement.									
11999.3	The UPIC shall submit an immediate advisement after confirmation of beneficiary recruitment into potentially fraudulent schemes and/or provider participation (e.g., telemarketing or solicitation schemes).									UPICs
11999.4	The UPIC shall submit an immediate advisement after identifying indication of provider/supplier fraud related to a national emergency, pandemic, etc.									UPICs
11999.5	The UPIC shall follow the direction regarding referrals to state agencies or other organizations as outlined in section 4.18.2,									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Chapter 4 of Pub. 100-08.									
11999.6	The UPIC shall have joint operating agreements with the entities as outlined in their Statement of Work.									UPICs
11999.7	The UPIC shall not create a case record type if they are approved to opt out of a Durable Medical Equipment (DME) Payment Suspension.									UPICs
11999.7.1	The Lead UPIC shall document any non-Lead UPICs that are approved to opt out of a DME Payment Suspension.									UPICs
11999.8	The UPIC shall not create a case record type if they are approved to opt out of a Non-DME National Payment Suspension.									UPICs
11999.8.1	The Lead UPIC shall document any non-Lead UPICs that are approved to opt									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	out of a Non-DME National Payment Suspension.									

III. PROVIDER EDUCATION TABLE

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

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

Pre-Implementation Contact(s): Jesse Havens, 410-786-6566 or jesse.havens@cms.hhs.gov

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If

the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Program Integrity Manual

Chapter 4 – Program Integrity

Table of Contents
(Rev. 10383; Issued: 10-09-2020)

Transmittals for Chapter 4

4.6.4 - Vetting Leads with CMS

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

All leads and any new subjects that the UPIC determines warrant further investigation shall be vetted through CMS for approval before transitioning to an investigation. The UPIC shall vet all applicable National Provider Identifiers (NPIs) and Provider Identifiers associated with the provider or supplier's tax-identification number, when initially vetting the lead with CMS. The UPIC shall submit the lead to CMS within two (2) business days of the UPIC determining that the lead should be transitioned into an investigation. *Periodically, based on high priority fraud schemes identified by CMS and/or Law Enforcement, CMS may require the UPIC to vet leads in an expedited timeframe. When instances such as this are identified, the details associated with the expedited vetting will be communicated to the UPIC by their COR and IAG BFL.*

For the submission to CMS, the UPIC shall use the designated CMS Vetting Form, which shall include, at a minimum, NPI, name, and practice location.

The UPIC shall only open investigations on leads that are approved by CMS. Once the lead is approved by CMS, the UPIC shall notate the date the lead was initially vetted and approved by CMS in UCM. If the UPIC is instructed by CMS to close the lead without further action, the UPIC shall do so within two (2) business days. If the screening results in a new investigation or becomes part of an existing investigation, the aforementioned screening information shall become part of the investigation file. If, during the course of a UPIC investigation, it is determined that additional NPIs should be incorporated into the ongoing investigation, the UPIC shall vet each additional NPI with CMS utilizing the approved CMS process described above before implementing any investigative actions (noted in section 4.7 of this chapter) on the additional NPIs. For any new investigations, the UPIC shall complete the appropriate updates in the UCM within seven (7) calendar days.

If multiple contractors become involved with the investigation, the UPIC that initially vetted the lead with CMS shall become the lead contractor, unless otherwise specified by CMS. The lead contractor shall notify all applicable contractors of the date the lead was vetted and approved by CMS for investigation. Therefore, no additional vetting is required by the other participating contractors. The other participating contractors shall also notate the date the lead was initially vetted and approved by CMS in their applicable case tracking system(s).

4.18.1.2 – Immediate Advisements to the OIG/OI

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

The UPIC shall notify the OIG/OI of an immediate advisement as quickly as possible, but not more than four (4) business days after identifying a lead or investigation that meets the following criteria. The UPIC shall maintain internal documentation on these advisements when it receives allegations with one or more of the following characteristics:

- Indications of UPIC or MAC employee fraud
- Allegations of kickbacks or bribes, discounts, rebates, and other reductions in price
- Allegations of a crime committed by a federal or state employee in the execution of their duties
- Indications of fraud by a third-party insurer that is primary to Medicare
- Confirmation of forged documentation during the course of an investigation, include, but is not limited to:

    - identification of forged documents through medical review; and/or
    - attestation from provider confirming forged documentation.
- Allegations and subsequent verification of services not rendered as a result of any of the following:

    - medical review findings;
    - interviews or attestations from a minimum of three (3) beneficiaries indicating that they did not receive services; and/or
    - attestations from referring/ordering providers indicating they did not refer/order a service (e.g., confirmation of no relationship with the beneficiary prior to service, or confirmed impossible day billings).
- Confirmed complaints from current or former employees that indicate the provider in question inappropriately billed Medicare for all or a majority of its services. Confirmation would be required though one of the following:

    - minimum of three (3) beneficiary interviews confirming the inappropriate billing;
    - provider attestation(s) confirming the inappropriate billing; or
    - medical review findings.
- Confirmation of beneficiary recruitment into potentially fraudulent schemes *and/or provider participation* (e.g., telemarketing or solicitation schemes);
- Substantiated identity theft of a provider's Medicare number, a beneficiary's Medicare number, or selling or sharing of beneficiary lists;
- Confirmed indication of patient harm (e.g., through medical review findings or confirmation of issues identified during an onsite visit or interviews with providers or beneficiaries).
- *Indication of provider/supplier fraud related to national emergency, pandemic, etc.*
    - *Should an IA of this nature be identified, the UPIC shall notify their IAG BFL to determine if the IA should be forwarded to a specific OIG/OI point-of-contact.*

IAs should be referred to the OIG/OI only when the above criteria are met, unless prior approval is given by the COR and IAG BFL.

Should local LE have specific parameters or thresholds in place that do not allow them to accept certain IAs, the UPIC shall notify its COR/BFL and request exemption from the applicable IA criteria in that particular jurisdiction.

When IA criteria are met, the UPICs shall perform an initial assessment to identify and document dollars currently pending payment to the provider, and/or if RAP claim payment is pending, if applicable. Should high dollar amounts be identified with either scenario, the UPIC shall notify CMS immediately, but not to exceed two (2) business days from date of identification.

Once the criteria for an IA are met, the UPIC shall notify the OIG/OI via phone or email to determine if a formal IA referral should be sent to the OIG/OI. If the IA is related to a provider/supplier that spans multiple jurisdictions, the UPIC shall notify any impacted UPIC and/or I-MEDIC Program Directors of the potential IA, allegation, and IA criteria. The UPIC shall document this communication in UCM. The UPIC shall also send notification to its COR and IAG BFL of the potential IA. If the UPIC does not receive a response from the OIG/OI within two (2) business days (5 business days for the I- MEDIC), it shall notify its

COR and BFL team and await further instructions. If the OIG/OI confirms that a formal IA should be sent, the UPIC shall provide all available documentation to the OIG/OI within four (4) business days of receiving the response from OIG/OI. Upon submission of the IA to the OIG/OI, the UPIC shall request written and/or email confirmation from the OIG/OI acknowledging receipt of the IA. Simultaneously, the UPICI-MEDIC shall notify the CMS identified Strike Force points of contacts, if the notification includes providers/suppliers located within a Strike Force jurisdiction. Additionally, the UPIC shall notify and send a copy of the IA to its COR/BFL and the case coordination team, at CPIMCCNotifications@cms.hhs.gov, the same day the advisement is made to OIG/OI. If the OIG/OI determines that a formal IA is not needed, the UPIC shall advise its COR/BFL and immediately continue its investigation. In instances where an IA is related to a Plan employee whistleblower, the I- MEDIC does not have to notify the case coordination team of the IA nor does the IA have to be discussed at a case coordination meeting. Rather, the I-MEDIC shall close the complaint upon acceptance and/or declination of the IA due to these complaint types being outside of the I-MEDIC's SOW.

In this notification to CMS, the UPIC shall advise if it has any other potential administrative actions it may want to pursue related to the provider(s)/supplier(s). The provider(s)/supplier(s) identified in an accepted IA shall be added to the UPIC's next scheduled case coordination meeting.

If the IA is related to a provider/supplier that spans multiple jurisdictions, the UPIC shall send a notification to the other UPIC and/or I-MEDIC Program Directors on the same date the formal IA is sent to OIG/OI. The UPIC shall copy its COR/BFL on such communication. Upon receipt of the notification from the primary UPIC, the other UPICs and/or I-MEDIC shall provide confirmation to the primary UPIC and its COR/BFL that the notification has been received, and it is ceasing activity as instructed below. Upon receipt of acceptance or declination of the IA from the OIG/OI, the primary UPIC shall notify the other UPIC and/or I-MEDIC Program Directors of the outcome.

Upon identification and submission of an IA to the OIG/OI, unless otherwise directed, all impacted UPICs and/or I-MEDIC shall cease all investigative and administrative activities, with the exception of screening activities, data analysis, etc., until the OIG/OI responds with its acceptance or declination of the IA. If the UPIC does not receive an immediate response from the OIG/OI, the UPIC shall contact OIG/OI after two (2) business days from the date of the IA notification and document the communication in the UCM system. If the UPIC does not receive a response from the OIG/OI within five (5) business days from the date of the IA notification, the UPIC shall contact its COR/BFL for further guidance.

If the OIG/OI declines or accepts the IA, the UPIC shall document the decision in UCM and follow the processes described in Chapter 4, § 4.6.3, 4.6.4, and § 4.7 of the PIM, unless otherwise directed by CMS.

Additionally, until the necessary updates are made in the UCM, if the UPIC submits an IA based on the updated criteria, it shall select all six (6) IA options on the "External Stakeholders" page of the UCM, and notate the justification of the IA in the Record Summary section of the UCM.

During the case coordination meeting, the UPIC may receive additional guidance from CMS related to subsequent actions related to the IA. If the UPIC has questions following the case coordination meeting, the UPIC shall coordinate with its COR and IAG BFL.

4.18.2 - *Referral to State Agencies or Other Organizations*

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

The UPIC shall refer instances of apparent unethical or improper practices or unprofessional conduct to state licensing authorities, medical boards, the QIO, or professional societies for review and possible disciplinary action.

Additionally, referrals should be made to the Medicare survey and certification agency which exist in each state, typically within the state's Department of Health. The survey agency has a contract with CMS to survey and certify institutional providers, indicating whether they meet or do not meet applicable Medicare health and safety requirements, called "conditions of participation." Providers not meeting these requirements are subject to a variety of adverse actions, including bans on new admissions to termination of their provider agreements. These administrative sanctions are imposed by the Regional Office, typically after an onsite survey by the survey agency.

The UPIC's and the MAC's MR staffs shall confer before such referrals, to avoid duplicate referrals. The UPIC shall gather available information and leave any further investigation, review, and disciplinary action to the appropriate professional society or State board. Consultation and agreement between the UPIC's and the MAC's MR staffs shall precede any referral to these agencies.

The UPIC shall notify its CORs and IAG BFL of these referrals.

4.28 – Joint Operating Agreement

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

This section applies to UPICs, SMRCs, MACs, RACs, and QICs, as indicated.

A JOA is a document developed between two entities (CMS contractors) that delineates the roles and responsibilities of each entity regarding their interactions with each other on CMS contracts.

The UPICs shall have JOAs with the *entities as outlined in their Statement of Work.*

As it applies to the UPIC's task orders, the JOA with the MACs shall, at a minimum, provide information on assigned responsibilities, timeframes, processes and procedures, and coordination. Additional detail related to this information is referenced in the UPIC *Statement of Work.*

Periodically, there are instances in which the UPIC is in need of the requested information in a shorter timeframe than 30 calendar days. To account for these instances, the UPICs and MACs may add language to their JOA that allows for a shorter timeframe for the MAC to furnish the requested information (i.e. 48 hours, 72, hours, etc.).

Medicare Program Integrity Manual

Chapter 5 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items and Services Having Special DME Review Considerations

Table of Contents
(Rev. 10383; Issued: 10-09-2020)

Transmittals for Chapter 5

5.5 – Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

A Certificate of Medical Necessity (CMN) or a DME Information Form (DIF) is a form required to help document the medical necessity and other coverage criteria for selected DMEPOS items. CMNs contain Sections A through D. Sections A and C are completed by the supplier and Sections B and D are completed by the physician. A DIF is completed and signed by the supplier. It does not require a narrative description of equipment and cost or a physician signature.

The following forms below have been approved by the Office of Management and Budget (OMB). For the CMS. For the CMS forms 484, 846, 847, 848, 849, 854, 10125 and 10126, the OMB# is 0938-0679.

- CMN CMS-484 – Oxygen
- CMN CMS-846 – Pneumatic Compression Devices
- CMN CMS-847 -- Osteogenesis Stimulators
- CMN CMS-848 – Transcutaneous Electrical Nerve Stimulators
- CMN CMS-849 – Seat Lift Mechanisms
- CMN CMS-854 – Section C Continuation Form
- DME Information Form CMS-10125 – External Infusion Pumps
- DME Information Form CMS-10126 – Enteral & Parenteral Nutrition

The TENS CMN is for purchases only. A TENS CMN will no longer be necessary for rentals.

For certain items or services billed to a DME MAC, the supplier must receive a signed CMN from the treating physician or a signed DIF from the supplier. For these items, a supplier must have a signed original, faxed, photocopied, or electronic CMN or DIF in their records when submitting a claim for payment to Medicare.

A signed original, faxed, photocopied, or electronic CMN or DIF must be maintained by the supplier and be available to the DME MACs, UPICs, SMRC, and DME RACs on request. When hardcopy CMNs or DIFs are submitted to the DME MACs, UPICs, SMRC and DME RACs, the supplier must include a copy of only the front side. When CMNs are submitted electronically to the DME MAC, information from sections A and B are required.

It is in the supplier's interest to maintain a copy of what they faxed to the physician. Suppliers must maintain a copy of the completed CMN or DIF in their records. However, if the physician only faxes the front of the completed CMN then the supplier is only required to maintain the front portion of the CMN.

However, when the CMN or DIF is submitted electronically and the supplier chooses to maintain a hard copy CMN or DIF, the font may be modified as follows:

- Pitch may vary from 10 characters per inch (cpi) to 17.7 cpi;
- Line spacing must be 6 lines per inch
- Each form must have a minimum 1/4 inch margin on all four sides.

Without exception, these modified hard copy forms must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions printed on the back; and CMN question sets may not be combined.

The CMN can serve as the physician's detailed written order if the narrative description in section C is sufficiently detailed. This would include quantities needed and frequency of replacement for accessories and supplies. For items requiring both a CMN and a written order prior to delivery (e.g., seat lift mechanisms) suppliers may utilize a completed and physician-signed CMN for this purpose. Otherwise, a separate order in addition to a subsequently completed and signed CMN is necessary.

The supplier may not complete the information in section B of the CMN. A supplier who knowingly and willfully completes section B of the form is subject to a civil monetary penalty up to $1,000 for each form or document so distributed. Any supplier who remains in non-compliance after repeated attempts by the contractor to get the supplier into compliance, refer to your RO (for UPICs refer the supplier to the primary GTL or associate GTL and SME) as a potential civil monetary penalty case.

The fee schedule amount, narrative description of the items furnished and the supplier's charge for the medical equipment or supplies being furnished must be completed on a CMN by the supplier prior to it being furnished to the physician. A supplier who knowingly and willfully fails to include this information may be subject to a civil monetary penalty up to $1,000 for each form or document so distributed. Any supplier who remains in non-compliance, after repeated attempts by the contractor to get the supplier into compliance, refer to your RO (for UPICs, refer the supplier to the primary GTL or associate GTL and SME) as a potential civil monetary penalty case.

CMS will not accept any other certifications of medical necessity by other insurers or government agencies.

Suppliers and physician may choose to utilize electronic CMNs (e-CMNs) or electronic DIFs (e-DIFs). E-CMNs or e-DIFS must adhere to all privacy, security, and electronic signature rules and regulations promulgated by CMS and DHHS. Additionally, e-CMNs or e-DIFs must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions as printed on the back of the hardcopy form.

If an item requires a CMN or a DIF and the supplier does not have a faxed, photocopied, original hardcopy, or an electronic signed CMN or DIF in their records when they submit a claim to Medicare, the claim will be denied.

In cases where two or more suppliers merge, the resultant supplier should make all reasonable attempts to secure copies of all active CMNs or DIFs from the supplier(s) purchased. This document should be kept on file by the resultant supplier for future presentation to the DME MACs, and UPICs.

When reviewing claims where the medical record contains a copied, faxed or electronically maintained CMN or DIF (any CMN or DIF created, modified, and stored via electronic means such as commercially available software packages and servers), the DME MACs, or UPICs must accept the copied, faxed or electronic document as fulfilling the requirements for these documents.

When a UPIC is investigating potentially fraudulent behavior by a supplier, it will be the supplier's responsibility to prove the authenticity/validity of the claim(s) under investigation. UPICs may require the supplier to prove the authenticity/validity of the signature on the CMN, DIF, order, or any other questionable portion of the claim(s) under investigation.

Upon request by the DME MACs, UPICs, SMRC or DME RACs, suppliers must provide the CMN or DIF, in a format that the DME MACs, UPICs, SMRC, and DME RACs can accept, in a timely manner. Upon medical review, the DME MACs, UPICs, SMRC, and DME RACs should not deny claims solely because the CMN or DIF is faxed, copied, or electronic. The DME MACs, UPICs, SMRC, and DME RACs may request the supplier to download and print a hard copy of an electronic order, CMN or DIF if the DME MACs, UPICs, SMRC, and DME RACs cannot access it electronically.

For items that require a CMN, and for accessories, supplies, and drugs related to an item requiring a CMN, the CMN may serve as the written order if the narrative description in Section C is sufficiently detailed (as described above). This applies to both hard copy and electronic orders or CMNs. A DIF does not contain a section for a narrative description and is not applicable.

A supplier must have a hard copied, faxed or electronic order, CMN or DIF in their records when they can submit a claim for payment to Medicare. Suppliers must ensure the security and integrity of electronically maintained CMNs or DIFs are in accordance with any regulations published by CMS.

The DME MACs or UPICs need not make any shared system changes to electronically accept e-CMNs or e-DIFS as CMS views e-CMNs or e-DIFs as a transaction between the physician and suppliers. Suppliers must continue to use current systems for transmitting claim information to the DME MAC or UPICs.

5.5.1 – Completing a CMN or DIF

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

The "Initial Date" found in Section A of the CMN, should be either the specific date that the physician gives as the start of the medical necessity or, if the physician does not give a specific start date, the "Initial Date" would be the date of the order.

The "Signature Date" is the date the physician signed and dated Section D of the CMN. This date might not be the same as the "Initial Date", since the "Signature Date" must indicate when the physician signed Section D of the CMN. Medicare requires a legible identifier for services provided/ordered. The method used shall be handwritten or an electronic signature in accordance with chapter 3, section 3.4.1.1 to sign an order or other medical record documentation for medical review purposes. Signature and date stamps are not acceptable for use on CMNs and DIFs.

The "Delivery Date/Date of Service" on the claim must not precede the "Initial Date" on the CMN or DIF or the start date on the written order. To ensure that an item is still medically necessary, the delivery date/date of service must be within 3 months from the "Initial Date" of the CMN or DIF or 3 months from the date of the physician's signature.

The DME MACs and *UPICs* have the authority to request to verify the information on a CMN or DIF at any time. If the information contained either in the supplier’s records or in the patient’s medical record maintained by the ordering physician fails to substantiate the CMN or DIF, or if it appears that the CMN or DIF has been altered, the DME MACs and

UPICs should deny the service and initiate the appropriate administrative or corrective actions.

In the event of a post pay audit, the supplier must be able to produce the CMN or DIF and, if requested by the DME MACs or *UPICs* produce information to substantiate the information on the CMN or DIF. If the supplier cannot produce this information, the DME MACs and *UPICs* should deny the service and initiate the appropriate administrative or corrective actions.

If there is a change made to any section of the CMN after the physician has signed the CMN, the physician must line through the error, initial and date the correction; or the supplier may choose to have the physician complete a new CMN.

5.5.2 – Cover Letters for CMNs

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

Cover letters can be used by a supplier as a method of communication between the supplier and the physician. It is not CMS's intent to restrict necessary communication between the supplier and the physician. CMS does not require nor regulate the cover letter. The DME MACs and *UPICs* should not take adverse action against suppliers that solely involve cover letters.

The DME MACs should regularly publish an article in their bulletins asking suppliers to remind physicians and suppliers of their responsibility in completing and signing the CMN or DIF. It is the physician's and supplier's responsibility to determine both the medical need for, and the utilization of, all health care services. The physician and supplier should ensure that information relating to the beneficiary's condition is correct. The DME MAC and *UPICs* should encourage suppliers to include language in their cover letters to remind physicians of their responsibilities.

5.6 – DME MACs and *UPIC's* Authority to Initiate an Overpayment and/or Civil Monetary Penalty (CMP) When Invalid CMNs or DIFs Are Identified

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

Section 1862(a)(1)(A) of the Act prohibits Medicare payment for services that are not reasonable and necessary. Section 1833(e) of the Act requires that Medicare be furnished by providers and suppliers "such information as may be necessary in order to determine the amount due.…" These sections provide support that a failure to have a valid CMN or DIF on file or to submit a valid CMN or DIF to the DME MACs or *UPICs* makes the underlying claim improper because Medicare does not have sufficient information to determine whether the claim is reasonable and necessary. A valid CMN is one in which the treating physician has attested to and signed supporting the medical need for the item, and the appropriate individuals have completed the medical portion of the CMN. A valid DIF is one in which the supplier has attested to and signed supporting the medical need for the item. When the DME MACs and *UPICs* identify a claim for which a CMN or DIF is not valid, they may deny the claim and/or initiate overpayment action.

If a DME MAC or *UPIC* identifies a supplier that has a pattern of improperly completing the CMN or DIF, the DME MAC *UPIC* may choose to initiate a potential Civil Monetary Penalty (CMP) case against the supplier. The authority for such action is found in §1834(j)(2)(A)(iii) of the Act which states that "any supplier of medical equipment and

supplies who knowingly and willfully distributes a CMN in violation of clause (I) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed." The provisions of §1128A of the Act (other than subsections (a) and (b) shall apply to CMPs penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under §1128(A)(a)) of the Act.

5.9 – Documentation in the Patient's Medical Record

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. If an item requires a CMN or DIF, it is recommended that a copy of the completed CMN or DIF be kept in the patient's record. However, neither a physician's order nor a CMN nor a DIF nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier prepared statement or physician attestation (if applicable). When a CMN or DIF and a medical record contain conflicting information due to a minor error or omission within the CMN or DIF, but all coverage, coding and payment criteria are substantiated through the medical record, the reviewer shall rely upon the content of the medical record (absent suspicion of abuse or gaming) and shall not issue a denial.

See PIM, chapter 3, section 3.4.1.1, for additional instructions regarding review of documentation during pre- and post-payment review.

The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals.

The documentation in the patient's medical record does not have to be routinely sent to the supplier or to the DME MACs or *UPICs*. However, the DME MACs or *UPICs* may request this information in selected cases. If the DME or *UPICs* do not receive the information when requested or if the information in the patient's medical record does not adequately support the medical necessity for the item, then on assigned claims the supplier is liable for the dollar amount involved unless a properly executed advance beneficiary notice (ABN) of possible denial has been obtained.

5.10 - Supplier Documentation

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

A. General

Before submitting a claim to the DME MAC (or before dispensing the item – see section 5.2.4), the supplier must have on file a standard written order, the CMN (if applicable), the DIF (if applicable), information from the treating practitioner concerning the patient's diagnosis, and any information required for the use of specific modifiers or attestation statements as defined in certain DME MAC policies. The supplier should also obtain as much

documentation from the patient's medical record as they determine they need to assure themselves that coverage criteria for an item have been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed ABN of possible denial has been obtained.

Documentation must be maintained in the supplier's files for seven (7) years from date of service. If the provider responds, in writing, that the Medicare qualifying supplier documentation is older than 7 years, and provides proof of continued medical necessity of the item or necessity of the repair, the contractors shall not deny the claim based solely on missing the supporting Medicare qualifying documentation that is over 7 years old.

B. Proof of Delivery

Section 424.57(c)(12) requires suppliers, as part of their standards to be met for enrollment and participation, to maintain proof of delivery documentation in their files.
In certain instances, compliance with proof of delivery may be required as a condition of payment, and must be available to the DME MAC, RAC, SMRC, CERT, and UPIC on request. For such items, if the supplier does not have appropriate proof of delivery documentation within the prescribed timeframes, associated claims will be denied and overpayments recouped. We note that non-compliance with supplier standards may also result in revocation from the Medicare program. Suppliers who consistently do not provide documentation to support their services may be referred to the OIG or NSC for investigation and/or imposition of sanctions. If the beneficiary is newly eligible to the Medicare program, the proof of delivery standards require the supplier to obtain a statement, signed and dated by the beneficiary (or beneficiary's designee), that the supplier has examined the item.

Please refer to IOM 100-08. Ch. 4, Section 4.26 for additional information regarding all proof of delivery requirements.

5.11 - Evidence of Medical Necessity

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

If replacement supplies are needed for the therapeutic use of purchased DMEPOS, the treating practitioner must specify on the standard written order, or on the CMN, the type of supplies needed. Suppliers are also encouraged to include the frequency with which they must be replaced, used, or consumed. DME MACs and *UPICs* evaluate supply utilization information as part of the medical necessity determination for DMEPOS. They do not accept "PRN" or "as needed" utilization estimates for supply replacement, use, or consumption.

Absent a State law to the contrary or a supply utilization problem, the standard written order or CMN submitted for the DMEPOS may also serve as medical evidence for supply replacement claims. However, when a standard written order for DMEPOS is renewed or revised, supply utilization information must be specified or updated by the treating practitioner on the CMN. DME MACs and *UPICs* assess the continuing medical necessity.

The DME MACs and *UPICs* must establish procedures for monitoring the utilization of replacement supplies. Suppliers must have documentation to support the medical necessity of changes in the equipment, device, or supply utilization requirements. Absent such notification, DME MACs and *UPICs* do not allow claims for unexplained increases in supply utilization above the usage level they previously determined as medically necessary. Suppliers shall make this information available to the DME MACs or *UPICs* on request.

If necessary or appropriate for a medical necessity determination, the DME MAC or *UPIC* must ask the supplier to obtain documentation from the treating practitioner, establishing the severity of the patient's condition and the immediate and long term need for the equipment and the therapeutic benefits the patient is expected to realize from its use. A claim of therapeutic effectiveness or benefit based on speculation or theory alone cannot be accepted. When restoration of function is cited as a reason for use of DMEPOS, the exact nature of the deformity or medical problem should be clear from the medical evidence submitted. Also, the manner in which the equipment or device will restore or improve the bodily function should be explained by the treating practitioner.

If the DME MAC or *UPIC* is unsuccessful in obtaining medical information from the supplier for non-assigned claims, it gives the beneficiary the opportunity to obtain the desired information from the supplier. If, after obtaining the requested information, a question of medical necessity remains, the DME MAC or *UPICs* must resolve the issue.

5.11.1 – Evidence of Medical Necessity for the Oxygen Claims

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

If DME MACs, CERT, *UPICs*, Recovery Auditors or the SMRC learn that the physician of record is no longer the treating physician, the supplier shall obtain from the physician currently responsible for the patient's pulmonary condition a current fully-completed oxygen CMN. After review of this oxygen CMN, DME MACs continue monthly payments if the evidence establishes medical necessity. Their records must be updated to identify the new treating physician.

For an initial claim, the physician must submit a signed certification of medical necessity that includes an oxygen/blood gas lab result. This certification must be corroborated with information in the medical record. A physician signature on the oxygen lab test result is not necessary to corroborate the certification. Instead, the reviewer should consider all submitted records from all of the beneficiary’s healthcare professionals.

Therefore, contractors shall not deny an oxygen or oxygen equipment claim solely because the claim lacks a physician signature on the oxygen lab test result.

5.12 – Period of Medical Necessity - Home Dialysis Equipment

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

Situations may occur causing temporary non-use of equipment:

- Beneficiary requires in-facility treatment for re-stabilization or as a result of some acute condition. The beneficiary is expected to return to home dialysis;
- Beneficiary is temporarily without a suitable home dialysis assistant;
- Beneficiary is away from home but expects to return; or
- Beneficiary is a transplant candidate and is taken off home dialysis preparatory to transplant. (If the transplant cannot occur, or if the transplant is not successful, the patient will very likely resume home dialysis and an evaluation can be made whether it will be within the immediate or foreseeable future.)

Under such circumstances, DME MACs or *UPICs* determine that medical necessity exists and pay for a period of up to 3 months after the month home dialysis equipment was last used. This does not eliminate the necessity for periodic reevaluation of medical necessity. It provides a tolerance to avoid frequent reevaluation in renal dialysis situations and provides for continuity of payments where economically advantageous.

5.13 - Safeguards in Making Monthly Payments

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

The DME MACs and *UPICs* shall establish appropriate safeguards to assure that payments are not made beyond the last month of medical necessity. They must develop appropriate safeguards to identify and investigate the following:

- Multiple claims for rental of the same or similar equipment from the same supplier within the same rental month (e.g., rental claims with different start dates but within the same rental period); Pub. 100-04, chapter 20, §30.5 specifically forbids payments for multiple claims for rental of the same or similar equipment from either the same or a different supplier during the same rental month.

- Contraindicated items of rented or purchased equipment;

- Incompatible claims information (e.g., liquid oxygen contents billed for a purchased gas delivery system);

- Medical equipment rentals or purchases after a beneficiary's death;

- Rental start dates on or after the purchase of the same or comparable equipment (absent evidence that the beneficiary has disposed of purchased equipment);

- Rental claims for the same or similar equipment from different suppliers for the same or overlapping rental months; and

- Equipment rental start dates within periods of confinement in an institution that cannot be considered a patient's home.

The DME MACs and *UPICs* shall resolve these situations on a prepayment basis. Development, if necessary, may be via written or telephone contact per Pub. 100-08 subject to any other documentation or development guidelines specified in Pub. 100-02, chapter 15, §100-01, Pub. 100-04, chapter 20, §10.1.1 and Pub. 100-04, chapter 20, §100.2.3.

To the extent possible, DME MACs and *UPICs* give beneficiaries and supplier-assignees advance notice of the date and reason that payments are scheduled to stop. (See Pub. 100-04, chapter 21 for EOMB language.)

5.14 – Pick-up Slips

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

For purposes of this section, a pick-up slip is written confirmation, provided by a supplier, that the supplier has removed an item of DME from the beneficiary’s home.

When making determinations, DME MACs and *UPICs* must ascertain not only whether equipment is present in the home, but must determine which equipment is actually being used

by the patient. Therefore, it is inappropriate to determine, solely based on lack of a pick up slip that a piece of equipment may still be in use. Likewise, it is inappropriate for DME MACs and *UPICs* to deny claims solely based on lack of a pick-up slip. DME MACs and *UPICs* should develop these claims to determine which piece of equipment is medically necessary.

5.18 – Advance Determination of Medicare Coverage (ADMC) of Customized DMEPOS

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

Section 1834(a)(15)(C) of the Act provides that carriers shall, at the request of a supplier or beneficiary, determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered if:

- The item is a customized item,
- The patient to whom the item is to be furnished, or the supplier, requests that such advance determination be made, and
- The item is not an inexpensive item as specified by the Secretary.

This section provides for direction in implementing §1834 (a)(15)(C) of the Act.
It is important to note that ADMCs are not initial determinations as defined at 42 CFR 405.801(a), because no request for payment is being made. As such, an ADMC cannot be appealed.

This is a voluntary program. Beneficiaries and suppliers are not required to submit ADMC requests in order to submit claims for items. Additionally, *UPICs* may not require an ADMC request as a prerequisite for submitting a claim.

Medicare Program Integrity Manual

Chapter 8 – Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation

Table of Contents

(Rev. 10383; Issued: 10-09-2020)

8.3.3.1 – DME Payment Suspensions (MACs and UPICs)

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

For national payment suspensions involving durable medical equipment (DME) suppliers that are enrolled in multiple jurisdictions, the following is applicable for DME MACs and UPICs:

- When CMS suspends payments to a DME supplier, all payments to the supplier are suspended in all DME jurisdictions if the same Tax Identification Number is used. The information (whether based on fraud or non-fraud) that payments should be suspended in one DME jurisdiction is sufficient reason for payment suspension decisions to apply to the other locations.

- The UPIC that requests the national payment suspension to CPI shall become the "Lead" UPIC for the payment suspension if the payment suspension is approved. The Lead UPIC is responsible for informing the other UPICs (non-lead UPICs) of the payment suspension being initiated and for the coordination of the payment suspension activities. CMS suggests that monthly contractor calls be held to communicate the current activities of the national suspension by each of the contractors.

- The Lead UPIC is responsible for coordinating and reporting to its CORs and BFLs whether the non-lead UPICs are compliant with the payment suspension timeframe and activities.

- All non-lead UPICs are responsible for determining an overpayment(s) for its jurisdiction. Non-lead UPICs shall take into account the findings of the Lead UPIC and take appropriate measures (prepayment review, etc.) to protect and safeguard Medicare Trust Fund dollars from being inappropriately paid.

For UPIC-initiated DME payment suspensions:

- Each UPIC shall be responsible for ensuring that the payment suspension edit has been initiated in its respective DME MAC jurisdiction and has communicated this to the lead UPIC. If non-lead UPIC determines that medical review would not be appropriate in their jurisdiction for subject provider, non-lead UPIC shall notify and request permission from their BFL to opt out of the medical review.

- The Lead UPIC shall create both a CSE record, if not already created, to track the investigative activities and a PSP record to track the activities specific to the payment suspension in UCM. The lead UPIC shall check the "lead" checkbox. Non-lead UPICs shall not create a separate PSP and is responsible for timely updating the lead UPIC's PSP with monthly escrow amounts within their jurisdictions, as well as adding any pertinent comments and/or documentation.

  Non-lead UPICs shall create a CSE and the appropriate administrative action records to track their activities. *However, if the UPIC is approved to opt out, meaning they are not assisting the payment suspension in any way, they shall not create a CSE. The Lead UPIC shall document in the UCM of any non-Lead UPICs that are approved to opt out.*

8.3.3.2 – Non-DME National Payment Suspensions (MACs and UPICs)

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

For national payment suspensions involving national providers (such as chain hospitals, chain Skilled Nursing Facilities, franchised clinics, laboratories, etc.) that are enrolled in multiple jurisdictions, the following may be applicable for MACs and UPICs:

- When CMS suspends payments to a national provider, all payments to the national provider are suspended in all jurisdictions if they share the same Tax Identification Number. The information (whether based on fraud or non-fraud) that payments should be suspended in one jurisdiction is sufficient reason for payment suspension decisions to apply to the other locations.

- The UPIC that requests the national payment suspension to CPI shall become the "Lead" UPIC for the payment suspension. The Lead UPIC is responsible for informing the other UPICs (non-lead UPICs) of the payment suspension being initiated and for the coordination regarding the payment suspension activities. CMS suggests that monthly contractor calls be held to communicate the current activities by each of the contractors.

- The Lead UPIC is responsible for coordinating and reporting to its CORs and BFLs whether the non-lead UPICs are compliant with the payment suspension timeframe and activities.

- All non-lead UPICs are responsible for determining an overpayment(s) for its jurisdiction. Non-lead UPICs shall take into account the findings of the Lead UPIC and take appropriate measures (prepayment review, etc.) to protect and safeguard Medicare Trust Fund dollars from being inappropriately paid.

For UPIC-initiated non-DME national payment suspensions:

- Each UPIC shall be responsible for ensuring that the payment suspension edit has been initiated in its respective MAC jurisdiction and has communicated this to the Lead UPIC. If non-lead UPIC determines that medical review would not be appropriate in their jurisdiction for subject provider, non-lead UPIC shall notify and request permission from their BFL to opt out of the medical review.

- The Lead UPIC shall create both a CSE record to track the investigative activities and a PSP record to track the activities specific to the payment suspension in UCM. The lead UPIC shall check the "lead" checkbox. Non-lead UPICs shall not create a separate PSP and is responsible for timely updating the lead UPIC's PSP with monthly escrow amounts within their jurisdictions, as well as adding any pertinent comments and/or documentation.

  Non-lead UPICs shall create a CSE and the appropriate administrative action records to track their activities. *However, if the UPIC is approved to opt out, meaning they are not assisting the payment suspension in any way, they shall not create a CSE. The Lead UPIC shall document in the UCM of any non-Lead UPICs that are approved to opt out.*

Medicare Program Integrity Manual

Chapter 15 – Medicare Enrollment

Table of Contents

(Rev. 10383; Issued: 10-09-2020)

15.18 – Ordering and Certifying Documentation – Maintenance Requirements

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

A. Background

Under 42 CFR §424.516(f)(1), a provider or supplier that furnishes covered ordered items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), clinical laboratory, imaging services, or covered ordered/certified home health services is required to:

- Maintain documentation (see next paragraph) for 7 years from the date of service, and

- Upon the request of CMS or a Medicare contractor, provide access to that documentation.

The documentation to be maintained includes written and electronic documents (including the National Provider Identifier (NPI) of the physician who ordered/certified the home health services and the NPI of the physician - or, when permitted, other eligible professional - who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

In addition, under §424.516(f)(2), a physician who orders/certifies home health services and the physician - or, when permitted, other eligible professional - who orders items of DMEPOS or clinical laboratory or imaging services is required to maintain the documentation described in the previous paragraph for 7 years from the date of service and to provide access to that documentation pursuant to a CMS or Medicare contractor request.

If the provider, supplier, physician or eligible professional (as applicable) fails to maintain this documentation or to furnish this documentation upon request, the contractor may revoke enrollment under §424.535(a)(10).

A. Justification for Request for Documentation

Absent a CMS directive to the contrary, the contractor shall request the documentation described in subsection (A) if it has reason to believe that the provider, supplier, physician or eligible professional (hereinafter collectively referred to as “provider”) is not maintaining the documentation in accordance with §424.516(f)(1) or (2). Examples of when a request might be appropriate include, but are not limited to:

- The contractor has detected an unusually high number of denied claims involving the provider, or the Fraud Prevention System has generated an alert with respect to the provider.

- The provider has been the subject of a recent *Unified* Program Integrity Contractor referral.

- The provider maintains an elevated surety bond amount.

These are, of course, only examples of when a request could perhaps be warranted. Ultimately, the contractor would have to consider the surrounding circumstances of each

case, including those involving situations not addressed in the aforementioned examples. The contractor may always contact its CMS Provider Enrollment Business Function Lead (PEBFL) if it is uncertain as to whether a particular documentation request should be made.

NOTE: Documentation cannot be requested for written orders and certifications dated prior to July 6, 2010.

C. Maintaining and Providing Access to Documentation

Under §424.516(f), CMS or a Medicare contractor may request access to documentation described in §424.516(f). The term "access to documentation" means that the documentation is actually provided or made available in the manner requested by CMS or a Medicare contractor. All providers and suppliers who either furnish, order, or certify the items described in section A above are subject to this requirement and are individually responsible for maintaining these records and providing them upon request.

For example, if a Medicare contractor requests copies of all orders for wheelchairs from an ordering physician for all beneficiaries with dates of service from November 1, 2014 through November 10, 2014, the ordering physician must provide the copies, in full, according to the specific request. If copies cannot be provided because the physician or eligible professional did not personally maintain the records or can only be partially provided, then the requirement to maintain this documentation and provide access to it will not have been met and the provider, supplier, physician, or eligible professional may be subject to the revocation basis set forth in §424.535(a)(10).

Examples of Sufficient and Deficient Access may include, but are not limited to:

Sufficient Access	Deficient Access
• All documentation requested	• Providing none of the requested documentation
• Documentation specific to the order(s) or certification(s), as requested	• Providing only a portion of the requested documentation
• Documentation for the dates of service or billing periods requested	• Providing similar documentation that does not contain the order or certification requested
	• Providing other documents NOT requested by CMS or a Medicare contractor and/or not specifically directing attention to the requested documentation

The CMS recognizes that providers and suppliers often rely upon an employer or another entity to maintain these records on their behalf. However, it remains the responsibility of the individual or entity upon whom/which the request has been made to provide documentation. All individuals and entities subject to this documentation requirement are responsible for ensuring that documents are provided upon request and may ultimately be subject to the revocation basis associated with not complying with the documentation request.

D. Process

If the contractor believes that a request for documentation is warranted, it shall prepare and send a request letter to the provider via mail. If the provider:

- Fails to respond within 30 calendar days of the contractor's request (i.e., a complete non-response), the contractor shall revoke enrollment using §424.535(a)(10) as the basis. Prior approval from the contractor's PEOG BFL is not necessary. A 1-year re-enrollment bar shall be imposed.

- Timely furnishes documentation that the contractor nevertheless deems inadequate, the contractor shall send a developmental letter via mail, e-mail or fax to the provider that requests more sufficient documentation. If the provider fails to submit such documentation (either via a complete nonresponse or by submitting additional inadequate documentation), the contractor shall refer the matter (including the documentation submitted to date) to its CMS PEBFL. CMS will determine whether a revocation is warranted and will notify the contractor via e-mail of its decision.

- Furnishes documentation that the contractor deems adequate, the contractor need not take further action other than to place the documentation and the documentation request letter(s) in the provider file.

E. Additional Guidance

The contractor shall also abide by the following:

1. When preparing the letter referred to in (C)(1) above, the contractor shall use the appropriate model language in (E) or (F) below. Note, however, that while the letters request copies of orders, the contractor has the discretion to ask for different or additional documentation (e.g., documentation that supports the legitimacy of a particular service or the payment of a particular claim). Copies of orders need not be requested in every situation. As alluded to in (B) above, the contractor would have to examine the facts of each case in determining the type(s) of documentation to be requested.

2. There may be situations in which CMS directs the contractor to request documentation in a particular case. The contractor shall follow the instructions in this section 15.18 with respect to doing so.

3. The contractor shall contact its CMS PEBFL if it has questions as to whether particular submitted documentation is adequate or legitimate – specifically, whether it falls within the category of documentation described in section (A) above.

F. Model Language for § 424.516(f)(1) Situations

The contractor shall use the model language below if it is requesting documentation from a provider or supplier furnishing the items or services addressed in §424.516(f)(1).

"Dear Provider/Supplier:

Under 42 CFR §424.516(f)(1), a provider or supplier that furnishes covered ordered items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), clinical laboratory, imaging services, or covered ordered/certified home health services is required to:

- Maintain documentation for 7 years from the date of service, and

- Upon the request of CMS or a Medicare contractor, provide access to that

documentation.

The documentation to be maintained includes written and electronic documents (including the National Provider Identifier (NPI) of the physician who ordered/certified the home health services and the NPI of the physician - or, when permitted, other eligible professional - who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

Consistent with §424.516(f)(1), please mail to us copies of the orders for the items or services that were furnished to the following beneficiaries on the dates specified:

(Contractors shall insert the beneficiaries' names (up to 5 may be listed, unless CMS specifies otherwise), appropriate identification information, and the dates on which the provider or supplier furnished the items/services in question. The contractor has the discretion to determine the cases/services that are included in this documentation request as well as the type(s) of documentation to be requested.)

The documentation must be received at the following address no later than 30 calendar days after the date of this letter:

(Cite appropriate address)

Failure to timely submit this documentation may result in the revocation of your enrollment pursuant to 42 CFR §424.535(a)(10)."

G. Model Language for §424.516(f)(2) Situations

The contractor shall use the model language below if it is requesting documentation from a provider or supplier furnishing the items or services addressed in § 424.516(f)(2).

"Dear Physician/Professional:

Under 42 CFR §424.516(f)(2), a physician who orders/certifies home health services and the physician - or, when permitted, other eligible professional - who orders items of DMEPOS or clinical laboratory or imaging services is required to maintain documentation for 7 years from the date of service and to provide access to that documentation pursuant to a CMS or Medicare contractor request. The documentation to be maintained includes written and electronic documents relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

Consistent with §424.516(f)(2), please mail to us copies of the orders for items or services that you issued for the following beneficiaries on the dates specified:

(Contractors shall insert the beneficiaries' names (up to 5 may be listed, unless CMS specifies otherwise), appropriate identification information, and the dates on which the orders were made. The contractor has the discretion to determine the cases/services that are included in this documentation request as well as the type(s) of documentation to be requested.)

The documentation must be received at the following address no later than 30 calendar days after the date of this letter:

(Cite appropriate address)

Failure to timely submit this documentation may result in the revocation of your enrollment pursuant to 42 CFR §424.535(a)(10).” (For individuals enrolled via the Form CMS-855O, the contractor shall instead use the following language: “Failure to timely submit this documentation may result in the revocation of your Form CMS-855O enrollment.”)

15.27.2 – Revocations

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

A. Revocation Reasons

(Except as described in section 15.27.2(B)(2) below, the contractor shall not issue any revocation or revocation letter without prior approval from CMS’ Provider Enrollment & Oversight Group (PEOG).)

When drafting a revocation letter (which, except as described in section 15.27.2(B)(2) below, must be sent to PEOG via the enrollmentescalations@cms.hhs.gov mailbox for approval), the contractor shall insert the appropriate regulatory basis (e.g., 42 CFR §424.535(a)(1)) into the letter. The contractor shall not use provisions from this chapter as the basis for revocation.

1. Revocation Reason 1(42 CFR §424.535(a)(1)) – Not in Compliance with Medicare Requirements

The provider or supplier is determined not to be in compliance with the enrollment requirements in subpart P (of Part 424) 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.

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

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

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

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

c. The provider or supplier is not appropriately licensed.

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

e. The provider or supplier does not meet CMS regulatory requirements for the specialty that it is enrolled as.

f. 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.

g. The provider or supplier fails to furnish complete and accurate information and all supporting documentation within 60 calendar days of the provider or 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 be used in these cases if CMS has explicitly instructed the contractor to use deactivation reason §424.540(a)(3) in lieu thereof.)

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

i. The provider or supplier has its provider or supplier agreement involuntarily terminated by the CMS regional office (RO) (as evidenced by a tie-in/tie-out notice, CMS-2007, or other notice from the RO/state).

With respect to (e) above – and, as applicable, (c) and (d) -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 or supplier type. For a listing of some of these statutes and regulations, refer to section 15.4 et seq. of this chapter.

NOTE: The contractor must identify in its revocation letter the exact provision within said statute(s)/regulation(s) that the provider/supplier is not in compliance with.

2. Revocation Reason 2 (42 CFR §424.535(a)(2)) – Excluded/Debarred from Federal Program

The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel 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 nonprocurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

If an excluded party is found, the contractor shall notify its CMS PEOG Business Function Lead (PEOG BFL) immediately. PEOG will notify the Contracting Officer's Representative (COR) for the appropriate *Unified* Program Integrity Contractor. The COR will, in turn, contact the Office of Inspector General's office with the findings for further investigation.

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

The provider, supplier, or any owner or managing employee 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:

(A) 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.

(B) 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.

(C) 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.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(ii) 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.

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

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

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.)

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

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.

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

(i) (A) 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

(B) 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.

(ii) (A) Either of the following occurs:

(1) CMS is not able to deposit the full application amount into a government-owned

account; or

(2) The funds are not able to be credited to the United States Treasury;

(B) 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

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

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

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.

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

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:

(A) Where the beneficiary is deceased.

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

(C) 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:

(A) The percentage of submitted claims that were denied.

(B) The reason(s) for the claim denials.

(C) 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.

(D) The length of time over which the pattern has continued.

(E) How long the provider or supplier has been enrolled in Medicare.

(F) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination as to whether the provider or supplier has or has not engaged in the pattern or practice described in this paragraph.

(**NOTE:** With respect to (a)(8), PEOG --rather than the contractor --will (1) make all determinations regarding whether a provider or supplier has a pattern or practice of submitting non-compliant claims; (2) consider the relevant factors; (3) accumulate all information needed to make such determinations; and (4) prepare and send all revocation letters.)

9. Revocation Reason 9 (42 CFR §424.535(a)(9)) – Failure to Report Changes The physician, non-physician practitioner, physician organization or non-physician organization failed to comply with the reporting requirements specified in 42 CFR §424.516(d)(1)(ii) or (iii), which pertain to the reporting of changes in adverse actions and practice locations, respectively, within 30 days of the reportable event.

With respect to Revocation Reason 9:

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

- If the individual or organization 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 individual's or organization's address has changed and the supplier has not notified the contractor of this within the aforementioned 30-day timeframe, the contractor may pursue a revocation (e.g., seeking PEOG's approval to revoke).

10. Revocation Reason 10 (42 CFR §424.535(a)(10)) – Non-Compliance with Documentation Requirements

The provider or supplier did not comply with the documentation requirements specified in 42 CFR §424.516(f).

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

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

12. Revocation Reason 12 (42 CFR §424.535(a)(12)) – Medicaid Billing Privileges Revoked

The provider or supplier's Medicaid billing privileges are terminated or revoked by a State Medicaid Agency.

(Medicare may not terminate a provider or supplier's Medicare billing privileges unless and until the provider or supplier has exhausted all applicable Medicaid appeal rights).

13. Revocation Reason 13 (42 CFR §424.535(a)(13)) -DEA Certificate/State Prescribing Authority Suspension or Revocation

(i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or

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

14. Revocation Reason 14 (42 CFR §424.535(a)(14)) -CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part 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.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements.

15. Refer to 15.27.3.c for an additional revocation reason specific to MDPP suppliers alone.

B. Prior PEOG Approval

1. Prior PEOG Approval Necessary

Except as described in section 15.27.2(B)(2) below, the contractor shall obtain approval of both the revocation and the revocation letter from PEOG via the MACRevocationRequests@cms.hhs.gov mailbox prior to sending the revocation letter. During its review, PEOG will also determine (1) the extent to which the revoked provider's or supplier's other locations are affected by the revocation, (2) the geographic application of the reenrollment bar, and (3) the effective date of the revocation. PEOG will notify the contractor of its determinations and instruct the contractor as to how to proceed.

2. Prior PEOG Approval Unnecessary

The contractor need not obtain prior PEOG approval of the revocation and the revocation letter if the revocation involves any of the following situations:

- Situation (a), (c), (d), (e), (g), (h), or (i) under Revocation Reason 1 above §424.535(a)(6) or (a)(11)

C. Effective Date of Revocations

Per 42 CFR §424.535(g), a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier. However, a revocation based on a: (1) Federal exclusion or debarment; (2) felony conviction as described in 42 CFR §424.535(a)(3); (3) license suspension or revocation; or (4) determination that the provider or supplier is no longer operational, is effective with the date of the exclusion, debarment, felony conviction, license suspension or revocation, or the date that CMS or the contractor determined that the provider or supplier is no longer operational. As stated in 42 CFR §424.535(d), if the revocation was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare services and/or supplies, the revocation may be reversed (with prior 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 revocation notification. The contractor, however:

- Need not solicit or ask for such proof in its revocation letter. It is up to the provider/supplier to furnish this data on its own volition.

- Has the discretion to determine whether sufficient "proof" exists.

D. Re-enrollment Bar

1. Background

As stated in 42 CFR §424.535(c), if a provider, supplier, owner, or managing employee 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 re-enrollment bar. The re-enrollment 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 3 years, depending on the severity of the basis for revocation. (Felony convictions, however, always entail a 3-year bar.) Per §424.535(c), the reenrollment bar does not apply if the revocation (1) is based on §424.535(a)(1), and (2) stems from a provider or 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 the Provider Enrollment, Chain and Ownership System (PECOS) to reflect that the individual is prohibited from participating in Medicare for the applicable 1, 2, or 3-year period.

(NOTE: Reenrollment bars apply only to revocations, not to denials. The contractor shall not impose a reenrollment bar following a denial of an application.)

2. 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, and 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 3 years):

- §424.535(a)(1) (Noncompliance) -- For licensure issues, 1 year if no billing after loss of license; 3 years if billing after loss of license; 3 years for violation of a Medicare policy (using certification statement)

- §424.535(a)(2) (Provider or Supplier Conduct) – 3 years

- §424.535(a)(3) (Felonies) – 3 years

- §424.535(a)(4) (False or Misleading Information) – 3 years

- §424.535(a)(5) (Onsite Review) – 2 years

- §424.535(a)(6) (Grounds Related to Screening) – 1 year

- §424.535(a)(7) (Misuse of Billing Number) – 3 years
- §424.535(a)(8) (Abuse of Billing) – 3 years
- §424.535(a)(9) (Failure to Report) -1 year if licensure, practice location, revocation; 3 years if felony or exclusion
- §424.535(a)(10) (Failure to Provide CMS Access) – 1 year
- §424.535(a)(11) (Initial Reserve Operating Funds) – 1 year
- §424.535(a)(12) (Medicaid Termination) – 2 years
- §424.535(a)(13) (Prescribing Authority) – 2 years
- § 424.535(a)(14) (Improper Prescribing Practices) – 3 years

3. Applicability of Bar

In general, and unless stated otherwise above, any re-enrollment barat a minimum applies to (1) all practice locations under the provider's PECOS or legacy enrollment record, (2) any effort to re-establish 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 as to whether a revoked provider is attempting to re-establish 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:

- 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.
- 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.
- 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, and John Smith is listed as a 75 percent owner.

E. 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 42 CFR §424.535(h) impacts the requirements of § 424.44 regarding the timely filing of claims.

F. Timeframe for Processing of Revocation Actions

If the contractor receives approval from PEOG (or receives an unrelated request from PEOG) to revoke a provider or supplier's billing privileges, the contractor shall complete all steps associated with the revocation no later than 5 business days from the date it received PEOG's approval/request. The contractor shall notify PEOG that it has completed all of the revocation steps no later than 3 business days after these steps have been completed.

G. Provider Enrollment Appeals Process

For more information regarding the provider enrollment appeals process, see section 15.25 of this chapter.

H. Summary

If the contractor determines that a provider's billing privileges should be revoked, it shall undertake the activities described in this section, which include, but are not limited to:

- Preparing a draft revocation letter;
- E-mailing the letter to PEOG via the ProviderEnrollmentRevocations@cms.hhs.gov mailbox with additional pertinent information regarding the basis for revocation;
- Receiving PEOG's determinations and abiding by PEOG's instructions regarding the case;
- If PEOG authorizes the revocation:
    - Revoking the provider's billing privileges back to the appropriate date;
    - Establishing the applicable reenrollment bar;
    - Updating PECOS to show the length of the reenrollment bar;
    - Assessing an overpayment, as applicable; and
    - Affording appeal rights.

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

Section 6401(b)(2) of the Patient Protection and Affordable Health Care Act (i.e., the Affordable Care Act), enacted on March 23, 2010, requires that the Administrator of CMS establish a process for making available to each State Medicaid Plan or Child Health Plan the name, National Provider Identifier, and other identifying information for any provider of medical or other items or services or supplier who have their Medicare billing privileges revoked or denied.

To accomplish this task, CMS will provide 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 through the Share Point Ensemble site. The contractor shall review the monthly revoked and denied provider list for the names of Medicare providers revoked and denied in PECOS. The contractor shall document any appeals actions a provider/supplier may have submitted subsequent to the provider or supplier's revocation or denial.

The contractor shall update the last three columns on the tab named "Filtered Revocations" of the spreadsheet for every provider/supplier revocation or denial action taken. The contractor shall not make any other modifications to the format of this form or its contents. The following terms 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 or suppliers, contractors shall access the PEOG appeals log via the Share Point Ensemble site to determine the appeal status to include on the spreadsheet.

Contractors shall submit their completed reports by the 20th of each month to its designated PEBFL.

J. Special Instructions Regarding Revocations of Certified Providers and Certified Suppliers

The contractor need not obtain prior approval from the state/RO prior to revoking a certified provider or certified supplier's billing privileges. When revoking the provider/supplier, however, the contractor shall:

- E-mail a copy of the revocation letter to the applicable RO's Division of Survey &

Certification corporate mailbox. (The RO will notify the state of the revocation.)

- After determining the effective date of the revocation, end-date the entity's enrollment record in the Provider Enrollment, Chain and Ownership System (PECOS) in the same manner as it would upon receipt of a tie-out notice from the RO.

Afford the appropriate appeal rights per section 25 of this chapter.

K. Overpayments Based Upon Revocations

In situations where a revocation is made with a prospective (i.e., 30 days from the date of CMS or the contractor's mailing of the revocation notification letter to the provider) effective date, the contractor's shall assess an overpayment back to a date when Medicare claims are determined to be ineligible for payment. This date may, but will not always, match the inactive date of the enrollment that is reflected in PECOS and MCS or FISS. The starting date upon which claims are not eligible for reimbursement is what the contractors shall use to assess an overpayment, not the date the enrollment is inactive according to PECOS and MCS or FISS.

The contractor shall initiate procedures to collect overpayment after the appeal filing timeframe has expired or within 10 days of the final appeal determination by the contractor.

- 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 the date of the final adverse action, though said date shall be no earlier than January 1, 2009.

Medicare Program Integrity Manual

Exhibits

Table of Contents

(Rev. 10383; Issued: 10-09-2020)

Exhibit 27 – National Medicare Fraud Alert

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

NATIONAL MEDICARE FRAUD ALERT TEMPLATE

Distribution of this Fraud Alert is Limited to the Following Audience: CMS regional offices, *Unified Program Integrity Contractors*, quality improvement organizations, Medicaid Fraud Control units, the Office of Inspector General, the Defense Criminal Investigation Service, the Department of Justice, the Federal Bureau of Investigation, U.S. Attorney offices, U.S. Postal Inspectors, Internal Revenue Service, State Surveyors, State Attorneys General, and the State Medicaid Program Directors

SUBJECT:

ACTIVITY:

SOURCE:

DISCOVERY:

DETECTION METHODOLOGY:

UCM CASE (S):

STATUS:

CONTACT:

THIS ALERT IS PROVIDED FOR EDUCATIONAL AND INFORMATIONAL PURPOSES ONLY. IT IS INTENDED TO ASSIST PARTIES IN OBTAINING ADDITIONAL INFORMATION CONCERNING POTENTIAL FRAUD AND ABUSE AND TO ALERT AFFECTED PARTIES TO THE NATURE OF THE SUSPECTED FRAUD. IT IS NOT INTENDED TO BE USED AS A BASIS FOR DENIAL OF CLAIMS OR ANY ADVERSE ACTION AGAINST ANY PROVIDER OR SUPPLIER. SUCH DECISIONS MUST BE BASED ON FACTS DEVELOPED INDEPENDENT OF THIS ALERT.

CMS NMFA DATE

Exhibit 28 – Restricted Medicare Fraud Alert

(Rev. 10383; Issued: 10-09-2020; Effective: 11-10-2020; Implementation: 11-10-2020)

RESTRICTED MEDICARE FRAUD ALERT TEMPLATE

THIS ALERT IS CONFIDENTIAL. It is not intended to be used as

a basis for the denial of any claim or adverse action against any provider. Such decisions must be based on facts independent of this alert. Distribution is Limited to the Following Audience: CMS regional offices, *Unified Program Integrity Contractors*, quality improvement organizations, Medicaid Fraud Control units, the Office of Inspector General, the Defense Criminal Investigation Service, the Department of Justice, the Federal Bureau of Investigation, U.S. Attorney offices, U.S. Postal Inspector offices, and the Internal Revenue Service, and the State Medicaid Program Integrity Directors

SUBJECT:

ACTIVITY:

SOURCE:

DISCOVERY:

DETECTION METHODOLOGY:

UCM CASE (S):

STATUS:

CONTACT:

NOTICE: THIS FRAUD ALERT CONTAINS CONFIDENTIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT PURSUANT TO EXEMPTION (b) (2), (b)(5) AND (b)(7)(E) OF THE FOIA. ITS CONTENTS SHOULD NOT BE REPRODUCED OR RELEASED TO ANY OTHER PARTY WITHOUT WRITTEN APPROVAL OF THE BENEFITS INTEGRITY STAFF. DISCLOSURE TO UNAUTHORIZED PERSONS IS PROHIBITED AND MAY BE IN VIOLATION OF THE CRIMINAL PROVISIONS OF THE PRIVACY ACT.
THIS ALERT IS PROVIDED FOR EDUCATIONAL AND INFORMATIONAL PURPOSES ONLY. IT IS INTENDED TO ASSIST PARTIES IN OBTAINING ADDITIONAL INFORMATION CONCERNING POTENTIAL FRAUD AND ABUSE AND TO ALERT AFFECTED PARTIES TO THE NATURE OF THE SUSPECTED FRAUD. IT IS NOT INTENDED TO BE USED AS A BASIS FOR DENIAL OF CLAIMS OR ANY ADVERSE ACTION AGAINST ANY PROVIDER OR SUPPLIER. SUCH DECISIONS MUST BE BASED ON FACTS DEVELOPED INDEPENDENT OF THIS ALERT.