CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10749	**Date: May 11, 2021**
	Change Request 12257

SUBJECT: Updates to Chapter 4 and Chapter 5 of Publication (Pub.) 100-08

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

EFFECTIVE DATE: June 11, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: June 11, 2021

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
D	4/4.2/4.2.2/4.2.2.5.1/Reserved for Future Use
D	4/4.2/4.2.2/4.2.2.5.2/Reserved for Future Use
D	4/4.10/4.10.1/Reserved for Future Use
D	4/4.10/4.10.2/Reserved for Future Use
D	4/4.10/4.10.3/Reserved for Future Use
D	4/4.10/4.10.4/Reserved for Future Use
D	4/4.10/4.10.5/Reserved for Future Use
R	4/4.23/Identity Theft Investigations and Victimized Provider Waiver of Liability
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 UPICs 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	5/5.11/5.11.1/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

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: 10749	Date: May 11, 2021	Change Request: 12257

SUBJECT: Updates to Chapter 4 and Chapter 5 of Publication (Pub.) 100-08

EFFECTIVE DATE: June 11, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: June 11, 2021

I. GENERAL INFORMATION

A. Background: The CMS will make revisions to Chapters 4 and 5 in Pub. 100-08 based on updates to the Unified Program Integrity Contractor (UPIC) and Investigations Medicare Drug Integrity Contractor processes.

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	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
12257.1	Contractors shall be aware that all references to Program Safeguard Contractor and Zone Program Integrity Contractor within Chapter 5 in Pub. 100-08 shall now be referred to as UPIC.				X					CERT, RAC, SMRC, UPICs
12257.2	Contractors shall be aware that various sections within Chapter 4 in Pub. 100-08 titled "Reserved for Future Use" have been removed.	X	X	X	X					CERT, RAC, SMRC, UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12257.3	The UPICs shall report validated compromised numbers into the Unified Case Management System Compromised Number Records module, in accordance with the applicable instruction and guidance documents.									UPICs

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. 10749; Issued: 05-11-21)

Transmittals for Chapter 4

4.23 Identity Theft Investigations and Victimized Provider Waiver of Liability

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

This section applies to UPICs.

For purposes of this chapter, a "compromised number" is a beneficiary or provider/supplier number that has been stolen and used by unauthorized entities or individuals to submit claims to, i.e., bill, the Medicare program.

The UPICs shall investigate the alleged theft of provider identities*, and report validated compromised numbers into the UCM Compromised Number Records module, in accordance with the applicable instruction and guidance documents (Of note, the instruction and guidance documents are located in the "Job Aids" and "Release Notes" section of the UCM Documentation Storage site. These documents are updated each time updates/enhancements occur.)*. An example of provider identity theft may include a provider's identity having been stolen and used to establish a new Medicare enrollment or a new billing number (reassignment) under an existing Medicare enrollment, or updating a current Medicare provider identification number with a different electronic funds transfer (EFT) payment account causing inappropriate Medicare payments to unknown person(s) and potential Medicare overpayment and eventually, U.S. Department of Treasury (UST) debt issued to the victimized provider.

The UPICs shall discuss the identity theft case with the COR and BFL. If claims are still being submitted and Medicare payments are being made, the UPIC should pursue strategies to prevent likely overpayments from being disbursed, such as prepayment reviews, auto-denial edits, Do Not Forward (DNF) requests, or immediate payment suspensions. The purpose of these administrative actions is to stop the payments. The UPICs are not authorized to request the MAC to write-off any overpayments related to the ID theft. Prior to any enrollment actions, the UPIC should be aware of the suspected victim's reassignments and consider the effect of Medicare enrollment enforcement actions on the alleged ID theft victim's current employments.

If an actual financial harm exists as a result of the ID theft (i.e., existence of Medicare debt or overpayment determination), the UPIC will follow the Victimized Provider Project (VPP) procedures, which include the following:

- At the point in which a UPIC begins to investigate provider ID theft complaints and incurred debt, it sends a letter acknowledging receipt of the complaint, informing the provider that CMS is investigating the complaint and reviewing materials submitted, and designating a VPP point of contact at the UPIC (IOM Pub. #100-08; Exhibit 8 – Letter 1);

- The next steps in this process include, but may not be limited to, the following:

    - Check if the case in question is in the UCM system. Vet the provider(s) with the DHHS - OIG or other appropriate LE agency to ensure that the contractor's investigative process will not interfere with prosecution;
    - A VPP case package must then be completed by the UPIC using the templates provided in the VPP information packet;
    - Describe the case and how the provider's ID was stolen or compromised. List all overpayment(s) for which the provider is being held liable. Clearly indicate those paid amounts that are in DNF and/or on payment suspension status, and the amounts that were paid with an actual check or electronic transfer to the fraudulent bank account;

- Provide legitimate and compromised/stolen 855 forms with provider enrollment and reassignment of benefits information in order to verify legitimate PTAN(s)/NPI(s) and identify the fraudulent ones;
- Get signed provider victim attestation statement(s) about the ID theft from the provider(s)/supplier(s).
- Provide a police report from the alleged victim provider or any law enforcement documentation;
- Provide financial background information, such as
  - IRS Form 1099 or W-2; and
  - Overpayment requests/debt collection notices.
- Include any trial, DOJ and OIG documents like OIG proffers, indictment, judgments and sentencing documents; and
- Based on the information gathered and the investigation conducted, the UPICs will state their recommendation as part of the package and provide the reason for the recommendation. Two recommendations are possible:

  - Hold provider harmless and rescind provider of federal ID theft case-related debt; OR
  - Hold provider liable for debt.

The UPIC will submit the complete VPP packet to the CMS CPI VPP team. In ID theft cases in which the victimized providers are located in multiple states and served by different UPICs, the UPIC jurisdiction in which the perpetrator's trial was located will be the lead UPIC that will coordinate with the other UPICs and submit a completed VPP packet to the CMS CPI VPP team.

The VPP team will validate and remediate all facts and information submitted by the UPIC. Part of the VPP team review may involve consultation with the HHS Office of General Counsel. This consultation may include, but may not be limited to, consideration of supporting documentation or lack thereof to support a decision that the provider is an actual victim of ID theft as well as compliance with federal statutes and regulations related to ID theft policies, debt collection and recall of overpayments.

The VPP team will make a final determination if the alleged ID theft victim is a true victim and approve a rescindment of Medicare overpayments reported in the name of the confirmed ID theft victim.

When calculating the actual overpayments related to the fraudulent claims under each provider victim, there may be situations in which discrepancies exist between LE and contractor loss calculation data. In these situations, the final figures used in making overpayment determinations should come from MAC data on amounts paid out in the name of the victimized providers using the cleared payments transmitted to the fraudulent bank accounts established in the DOJ case.

Once a final decision is made by the VPP team, the UPIC or Lead UPIC, as appropriate, will be informed.

If the provider victim is determined to be a true victim of ID theft, the UPIC will send out a letter using the template in the IOM Pub. #100-08 Exhibits chapter informing the provider of the favorable decision and that the assessed overpayment against the victim will be rescinded ((IOM Pub. #100-08; Exhibit 8 – Letter 2). This decision shall then flow through the UPIC to the MAC for a recall of the associated debt. (NOTE: The MAC's instructions for processing providers' debts that have been confirmed as identity theft are found in the Medicare Financial Management Manual Chapter 4, Section 110 – Confirmed Identity Theft). The MAC shall follow the process

for making adjustments to the claims system and recall the debt registered under the victimized provider from the US Department of Treasury.

If the decision is not positive (i.e. ID theft is not confirmed), the UPIC shall correspond directly with the provider to inform him/her that CMS did not have sufficient information to confirm that identity theft has occurred. The UPIC shall send Letter 3 from the IOM Pub. #100-08 Exhibits chapter to the provider with a copy to the MAC.

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. 10749; Issued: 05-11-21)

Transmittals for Chapter 5

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

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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 DME 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. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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 *UPICs* Authority to Initiate an Overpayment *and/*or *Civil Monetary Penalty (*CMP*)* When Invalid CMNs *or DIFs* Are Identified

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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 or 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. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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 MACs 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. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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.

5.11.1 – Evidence of Medical Necessity for the Oxygen Claims

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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.