CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11696	**Date: November 9, 2022**
	Change Request 12942

SUBJECT: Updates to Chapter 4 of Publication (Pub.) 100-08, to Include the Addition of a Congressional Inquiries Section, Updates to the Vetting Leads with CMS Process, and Various Other Updates

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update various sections in Chapter 4 of Pub. 100-08. The primary updates in this CR include adding a section regarding the Congressional Inquiry process and updating the Vetting Leads with CMS section. Various other sections of Chapter 4 in Pub. 100-08 are also being revised.

EFFECTIVE DATE: December 12, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: December 12, 2022

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	4/4.2/4.2.3/Durable Medical Equipment Medicare Administrative Contractor Fraud Functions
R	4/4.6/Vetting Leads with CMS
R	4/4.7/4.7.4.1/Production of Medical Records and Documentation for an Appeals Case File
N	4/4.8/4.8.3/Congressional Inquiries
R	4/4.11/4.11.2/Administrative Actions
R	4/4.11/4.11.5.1/Civil Monetary Penalties Delegated to CMS

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: 11696**	**Date: November 9, 2022**	**Change Request: 12942**

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I. GENERAL INFORMATION

A. Background: The CMS is revising various sections in Chapter 4 of Pub. 100-08 Program Integrity Manual (PIM), 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 MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12942.1	The contractor shall be responsible for all program integrity unit activities, including the coordination with outside organizations, as specified in Section 4.2.2.8 in Chapter 4 of Pub. 100-08 (PIM).									UPICs
12942.2	The contractor shall submit leads to CMS via the Unified Case Management System (UCM) within two (2) business days of the contractor determining that the lead should be transitioned into an									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	investigation.									
12942.2.1	The contractor shall submit leads to the UCM queue for vetting, ensuring that each lead includes: National Provider Identification Number, provider/supplier name, and the date the lead is being submitted for vetting.									UPICs
12942.2.2	The contractor shall submit the designated CMS Vetting Form to CMS via CPI-PILeads@cms.hhs.gov only in instances when a case has been previously vetted and a subsequent secondary subject(s) is identified for additional vetting.									UPICs
12942.2.3	The contractor shall submit the designated CMS Vetting Form to CMS via CPI-PILeads@cms.hhs.gov when an initial case is opened under the Medicare-only or Medicaid-only program type, but it is later determined that a separate case needs to be opened in the other program.									UPICs
12942.3	The contractor shall contact the Qualified Independent Contractor									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	immediately upon receipt of a notice of hearing.									
12942.4	The contractor shall immediately submit a Congressional Inquiry for processing to the appropriate CMS Business Function Lead or designated staff person (dependent upon the nature of the Congressional Inquiry; i.e. investigation related, payment suspension related, etc.) if the contractor directly receives a Congressional Inquiry from any external requestor and/or CMS component other than the Center for Program Integrity.									UPICs
12942.4.1	The contractor shall send a copy of the communication to their Contracting Officer's Representative.									UPICs
12942.4.2	The contractor shall prepare all relevant information as requested in the Congressional Inquiry upon receipt of a Congressional Inquiry assignment.									UPICs
12942.4.3	The contractor shall submit the information to the appropriate CMS Business Function Lead or designated staff person, with a									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	copy to their Contracting Officer's Representative, by an agreed upon date and delivery method.									
12942.5	The contractor shall take the appropriate steps to inform and educate providers of the non-compliance and encourage future compliance when violations are noted (either through internal reviews or through a complaint process).	X	X	X	X					SMRC, UPICs
12942.6	The contractor shall issue a final warning notice of plans to propose a corrective action by certified mail (return receipt required), other courier service with a signature required, or provider/Electronic Submission of Medical Documentation portal (with evidence of receipt).	X	X	X	X					

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. 11696; Issued: 11-09-22)

Transmittals for Chapter 4

4.8.3 – Congressional Inquiries

4.2.3 - Durable Medical Equipment Medicare Administrative Contractor Fraud Functions

(Rev.: 11696; Issued: 11-09-22; Effective: 12-12-22; Implementation: 12-12-22)

The UPICs shall process all complaints alleging DMEPOS fraud and abuse that are filed in their regions/zones in accordance with requirements of PIM Chapter 4, §4.6.

The PI unit manager has responsibility for all PI unit activity, including the coordination with outside organizations as specified in the PIM, chapter 4, *§4.2.2.8*.

A. General Requirements

Since the Medicare program has become particularly vulnerable to fraudulent activity in the DMEPOS area, each UPIC shall:

- Routinely communicate with and exchange information with its MR unit and ensure that referrals for prepayment MR review or other actions are made.

- Consult with the UPIC medical directors in cases involving medical policy or coding issues.

- Fully utilize data available from the MAC with the pricing, data analysis and coding function (PDAC) to identify items susceptible to fraud.

- Keep the PDAC contractor, other UPICs, CORs, BFLs, and SMEs informed of its ongoing activities and share information concerning aberrancies identified using data analysis, ongoing and emerging fraud schemes identified, and any other information that may be used to prevent similar activity from spreading to other jurisdictions.

4.6 - Vetting Leads with CMS

(Rev.: 11696; Issued: 11-09-22; Effective: 12-12-22; Implementation: 12-12-22)

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 *via UCM* 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 BFL.

For the submission to CMS, the UPIC shall:

- *Submit leads to the UCM queue for CMS vetting, ensuring that each lead includes: NPI, provider/supplier name, and the date the lead is being submitted for vetting;*
- *Submit the designated CMS Vetting Form to CMS via CPI-PILeads@cms.hhs.gov only in instances when a case (CSE) has been previously vetted and a subsequent secondary subject(s) is identified for additional vetting; and/or*
- *Submit the designated CMS Vetting Form to CMS via CPI-PILeads@cms.hhs.gov when an initial CSE is opened under the Medicare-*

only or Medicaid-only program type, but it is later determined that a separate CSE needs to be opened in the other program.

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).

4.7.4.1 - Production of Medical Records and Documentation for an Appeals Case File

(Rev.: 11696; Issued: 11-09-22; Effective: 12-12-22; Implementation: 12-12-22)

When the UPIC denies a claim and the provider, supplier, physician or beneficiary appeals the denial, the MAC shall request the medical records and documentation that the UPIC used in making its determination. The UPIC shall assemble the case file and send it to the MAC within five (5) business days. If the MAC request is received outside of normal business hours or on an observed holiday that the UPIC is closed for business, the first business day will not be counted until the first business day after receipt of the request (i.e., if received on Saturday, the following Monday will be counted as the first business day).

The UPIC shall include any position papers or rationale and support for its decision so that the appeals adjudicator can consider it during the appeals process. However, UPICs shall be aware that an appeals case file is discoverable by the appellant. This means that the appellant can receive a complete copy of the case file. Since the provider may receive the case file, the UPIC shall consult with law enforcement before including any sensitive information relative to a case.

If the UPIC would like to be notified of an Administrative Law Judge (ALJ) hearing on a particular case, the UPIC shall put a cover sheet in the case file before sending it to the MAC. The cover sheet shall state that the UPIC would like to be notified of an ALJ hearing and list a contact name with a phone and fax number where the contact can be reached. The cover sheet shall also include language stating, “PLEASE DO NOT REMOVE” to ensure it stays on the case file should the file be sent to the Quality Improvement Contractor. If the UPIC receives a notice of hearing, the UPIC shall contact the *Qualified Independent Contractor* (QIC) immediately.

The QICs are tasked with participating in ALJ hearings; therefore, they are the primary Medicare contractor responsible for this function. UPICs may participate in an ALJ hearing, but they shall work with the QIC to ensure that duplicative work is not being performed by both the UPIC and the QIC in preparation for the hearing. UPICs shall never invoke party status. If the UPIC participates in a hearing, it shall be as a non-party. An ALJ cannot require

participation in a hearing, whether it is party or non-party. If a UPIC receives a notice that appears contrary to this instruction, the UPIC shall contact the QIC and their primary COR and BFL immediately.

4.8.3 – Congressional Inquiries

(Rev.: 11696; Issued: 11-09-22; Effective: 12-12-22; Implementation: 12-12-22)

If a UPIC directly receives a Congressional Inquiry from any external requestor and/or CMS components other than CPI, they shall immediately submit the Congressional Inquiry for processing to the appropriate CMS BFL or designated staff person (dependent upon the nature of the Congressional Inquiry; i.e. investigation related, payment suspension related, etc.). The UPIC shall also send a copy of the communication to their COR.

Once the Congressional Inquiry is received by CMS, it will be logged, reviewed, and assigned to the appropriate UPIC(s), as needed. Upon UPIC receipt of a Congressional Inquiry assignment, the UPIC shall prepare all relevant information as requested in the Congressional Inquiry, and submit the information to the appropriate CMS BFL or designated staff person, with a copy to their COR, by an agreed upon date and delivery method.

4.11.2 - Administrative Actions

(Rev.: 11696; Issued: 11-09-22; Effective: 12-12-22; Implementation: 12-12-22)

The UPICs, SMRCs and MACs shall ensure that the program rules and regulations are being appropriately followed. If violations are noted (either through internal reviews or through a complaint process), *the contractor* shall take the appropriate steps to inform and educate the provider of the non-compliance and encourage future compliance.

For MACs, if, after a period of time, there is no significant change by the provider (the non-compliance continues), then a final warning notice of plans to propose a corrective action (such as a CMP) shall be issued. This notice shall be sent by certified mail (return receipt required)*, other courier service with a signature required, or provider/ Electronic Submission of Medical Documentation (esMD) portal (with evidence of receipt)*. The notice shall indicate that previous notifications sent to the provider failed to correct the problem, and that this is a final warning. Additionally, it shall indicate that any further continuation of the non- compliance will result in the matter being forwarded to CMS or the OIG for administrative enforcement. While not specifically assessing a monetary penalty amount, the notice shall indicate that this is one type of sanction that may be applied.

4.11.5.1 - Civil Monetary Penalties Delegated to CMS

(Rev.: 11696; Issued: 11-09-22; Effective: 12-12-22; Implementation: 12-12-22)

The following is a brief description of authorities from the Social Security Act:

- Section 1806(b)(2)(B) - Any person or entity that fails to provide an itemized statement describing each item or service requested by a Medicare beneficiary.

- Section 1833(h)(5)(D) - Any person billing for a clinical diagnostic laboratory test, other than on an assignment-related basis. This provision includes tests performed in a physician's office but excludes tests performed in a rural health clinic. (This violation may also cause an assessment and an exclusion.)

- Section 1833(i)(6) - Any person billing for an intraocular lens inserted during or after cataract surgery for which payment may be made for services in an ambulatory surgical center.

- Section 1833(q)(2)(B) - When seeking payment on an unassigned basis, any entity failing to provide information about a referring physician, including the referring physician's name and unique physician identification number. (This violation may also cause an exclusion.)

- Sections 1834(a)(11)(A) and 1842(j)(2) - Any supplier of durable medical equipment charging for covered items (furnished on a rental basis) after the rental payments may no longer be made (except for maintenance and servicing) as provided in §1834(a)(7)(A) of the Act. (This violation may also cause an assessment and an exclusion.)

- Section 1834(a)(17)(C) - Unsolicited telephone contacts by any supplier of durable medical equipment to Medicare beneficiaries regarding the furnishing of covered services. (This violation may only cause an exclusion.)

- Sections 1834(a)(18)(B) and 1842(j)(2) - Any durable medical equipment supplier that fails to make a refund to Medicare beneficiaries for a covered item for which payment is precluded due to an unsolicited telephone contact from the supplier. (This violation may also cause an assessment and an exclusion.)

- Sections 1834(b)(5)(C) and 1842(j)(2) - Any non-participating physician or supplier that charges a Medicare beneficiary more than the limiting charge as specified in §1834(b)(5)(B) of the Act for radiologist services. (This violation may also cause an assessment and an exclusion.)

- Sections 1834(c)(4)(C) and 1842(j)(2) - Any non-participating physician or supplier charging a Medicare beneficiary more than the limiting charge for mammography screening, as specified in §1834(c)(3) of the Act. (This violation may also cause an assessment and an exclusion.)

- Sections 1834(h)(3) and 1842(j)(2) - Any supplier of durable medical equipment, prosthetics, orthotics, and supplies charging for a covered prosthetic device, orthotic, or prosthetic (furnished on a rental basis) after the rental payment may no longer be made (except for maintenance and servicing). (This violation may also cause an assessment and an exclusion.)

- Section 1834(h)(3) - Unsolicited telephone contacts by any supplier of durable medical equipment, prosthetics, orthotics to Medicare beneficiaries regarding the furnishing of prosthetic devices, orthotics, or prosthetics. (This violation may only cause an exclusion.)

- Sections 1834(j)(4) and 1842(j)(2) - Any supplier of durable medical equipment, prosthetics, orthotics, and supplies that fails to make refunds in a timely manner to Medicare beneficiaries (for items or services billed on a non-assigned basis) if the supplier does not possess a Medicare supplier number, if the item or service is denied in advance, or if the item or service is determined not to be medically necessary or reasonable. (This violation may also cause an assessment and an exclusion.)

- Sections 1834(k)(6) and 1842(j)(2) - Any practitioner or other person that bills or collects for outpatient therapy services or comprehensive outpatient rehabilitation services on a non-assigned basis. (This violation may also cause an assessment and an exclusion.)

- Section 1842(b)(18)(B) - For practitioners specified in §1842(b)(18)(C) of the Act (physician assistants, nurse practitioners, clinical nurse specialists, certified

registered nurse anesthetists, certified nurse-midwives, clinical social workers, and clinical psychologists), any practitioner billing (or collecting) for any services on a non-assigned basis. (This violation may also cause an assessment and an exclusion.)

- Section 1842(k) - Any physician presenting a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987. (This violation may also cause an assessment and an exclusion.)

- Section 1842(l)(3) - Any non-participating physician who does not accept payment on an assigned basis and who fails to refund beneficiaries for services that are not reasonable or medically necessary or are of poor quality. (This violation may also cause an assessment and an exclusion.)

- Section 1842(m)(3) - Any non-participating physician billing for an elective surgical procedure on a non-assigned basis, who charges at least $500, fails to disclose charge and coinsurance amounts to the Medicare beneficiary prior to rendering the service, and fails to refund any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (This violation may cause an assessment and an exclusion.)

- Section 1842(n)(3) - Any physician billing diagnostic tests in excess of the scheduled fee amount. (This violation may cause an assessment and an exclusion.)

- Section 1842(p)(3)(A) - Any physician that fails to promptly provide the appropriate diagnosis code or codes upon request by CMS or a carrier on any request for payment or bill submitted on a non-assigned basis.

- Section 1842(p)(3)(B) - Any physician failing to provide the diagnosis code or codes after repeatedly being notified by CMS of the obligations on any request for payment or bill submitted on a non-assigned basis. (This violation is only subject to an exclusion.)

- Section 1848(g)(1)(B) - Any non-participating physician, supplier, or other person who furnishes physicians' services and bills on a non-assigned basis, or collects in excess of the limiting charge, or fails to make an adjustment or refund to the Medicare beneficiary. (This violation may cause an assessment and an exclusion.)

- Section 1848(g)(3) - Any person billing for physicians' services on a non-assigned basis for a Medicare beneficiary who is also eligible for Medicaid (these individuals include qualified Medicare beneficiaries). This provision applies to services furnished on or after April 1, 1990. (This violation may cause an assessment and an exclusion.)

- Section 1848(g)(4) - Any physician, supplier, or other person (except one excluded from the Medicare program) that fails to submit a claim for a beneficiary within one year of providing the service; or imposes a charge for completing and submitting the standard claims form. (This violation may cause an exclusion.)

- Section 1862(b)(5)(C) - Any employer who (before October 1, 1998) fails to provide an employee's group health insurance coverage information to the Medicare contractor.

- Section 1862(b)(6)(B) - Any entity that fails to complete a claim form relating to the availability of other health benefit plans, or provides inaccurate information relating to the availability of other health plans on the claim form.

- Section 1877(g)(5) - Any person failing to report information concerning ownership,

investment, and compensation arrangements. (This violation may cause an assessment and an exclusion.)

- Section 1879(h) - Any durable medical equipment supplier (including a supplier of durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies) failing to make refunds to Medicare beneficiaries for items or services billed on an assigned basis if the supplier did not possess a Medicare supplier number, if the item or service is denied in advance, or if the item or service is determined to be not medically necessary or reasonable. (This violation may cause an assessment and an exclusion.)

- Section 1882(a)(2) - Any person who issues a Medicare supplemental policy that has not been approved by the state regulatory program or does not meet federal standards. (This violation may cause an assessment and an exclusion.)

- Section 1882(p)(8) - Any person who sells or issues non-standard Medicare supplemental policies. (This violation may cause an assessment and an exclusion.)

- Section 1882(p)(9)(C) - Any person who sells a Medicare supplemental policy and fails to make available the core group of basic benefits as part of its product line; or fails to provide the individual (before the sale of the policy) an outline of coverage describing the benefits provided by the policy. (This violation may cause an assessment and an exclusion.)

- Section 1882(q)(5)(C) - Any person who fails to suspend a Medicare supplemental policy at the policyholder's request (if the policyholder applies for and is determined eligible for Medicaid); or to automatically reinstate the policy as of the date the policyholder loses medical assistance eligibility (and the policyholder provides timely notice of losing his or her Medicaid eligibility). (This violation may cause an assessment and an exclusion.)

- Section 1882(r)(6)(A) - Any person that fails to refund or credit as required by the supplemental insurance policy loss ratio requirements. (This violation may cause an assessment and an exclusion.)

- Section 1882(s)(4) - Any issuer of a Medicare supplemental policy that does not waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods if the time periods were already satisfied under a preceding Medicare policy; or denies a policy, conditions the issuance or effectiveness of the policy, or discriminates in the pricing of the policy based on health status or other criteria. (This violation may cause an assessment and an exclusion.)

- Section 1882(t)(2) - Any issuer of a Medicare supplemental policy who fails to provide medically necessary services to enrollees through the issuer's network of entities; imposes premiums on enrollees in excess of the premiums approved by the state; acts to expel an enrollee for reasons other than non-payment of premiums; does not provide each enrollee at the time of enrollment with specific information regarding policy restrictions; or fails to obtain a written acknowledgment from the enrollee of receipt of the information. (This violation may cause an assessment and an exclusion.)