

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12127	Date: July 21, 2023
	Change Request 13281

SUBJECT: Updates of Chapters 4, Chapter 8, and Exhibits in Publication (Pub.) 100-08, Including Adding Additional Clarification to Ongoing Direction

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update sections within Chapter 4, Chapter 8, and Exhibits in Pub. 100-08. The updates in this CR include removing the directive that the UPICs shall not employ temporary employees (such as those from temporary agencies, or students (nonpaid or interns)), adding additional clarification for the handling of potential assignment violations, congressional inquiries, and Health Plan Management System (HPMS) memos, and revising sections in Chapter 8 in Pub. 100-08 that refer to Program Integrity contractor coordination with Business Function Leads (BFL) and Contracting Officer's Representatives (COR). Additionally, the "case" definition has been updated in the Exhibits chapter.

EFFECTIVE DATE: August 21, 2023

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: August 21, 2023

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	4/4.2/4.2.2/4.2.2.7/Program Integrity Security Requirements
R	4/4.5/Screening Leads
R	4/4.8/4.8.3/Congressional Inquiries
R	4/4.14/Fraud Alerts & HPMS Memos
R	8/8.3/Suspension of Payment
R	8/8.3/8.3.2/8.3.2.1/CMS Approval
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	8/8.4/8.4.1/8.4.1.4/Determining When Statistical Sampling May Be Used
R	8/8.4/8.4.7/8.4.7.1/Recovery From Provider or Supplier
R	8/8.4/8.4.9/8.4.9.1/Sampling Methodology Overturned
R	Exhibits/Exhibit 1 - Definitions

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**

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CFW	
	shall be closed when no further action will be required of the UPIC, or Medicare contractor benefit integrity unit by the law enforcement agency(ies) working the case and when the law enforcement agency(ies) has ended all its activity on the case.									

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

V. CONTACTS

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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

ATTACHMENTS: 0

Medicare Program Integrity Manual

Chapter 4 - Program Integrity

Table of Contents
(Rev. 12127; Issued: 07-21-23)

Transmittals for Chapter 4

4.14 - Fraud Alerts *& HPMS Memos*

4.2.2.7 – Program Integrity Security Requirements

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

This section applies to UPICs.

To ensure a high level of security for the UPIC functions, the UPIC shall develop, implement, operate, and maintain security policies and procedures that meet and conform to the requirements of the Business Partners System Security Manual (BPSSM) and the CMS Informational Security Acceptable Risk Safeguards (ISARS). Further, the UPIC shall adequately inform and train all UPIC employees to follow UPIC security policies and procedures so that the information the UPIC obtain is confidential.

Note: The data UPICs collect in administering UPIC contracts belong to CMS. Thus, the UPICs collect and use individually identifiable information on behalf of the Medicare program to routinely perform the business functions necessary for administering the Medicare program, such as MR and program integrity activities to prevent fraud, waste, and abuse. Consequently, any disclosure of individually identifiable information without prior consent from the individual to whom the information pertains, or without statutory or contract authority, requires CMS' prior approval.

This section discusses broad security requirements that UPICs shall follow. The requirements listed below are in the BPSSM or ARS. There are several exceptions. The first is requirement A (concerning UPIC operations), which addresses several broad requirements; CMS has included requirement A here for emphasis and clarification. Two others are in requirement B (concerning sensitive information) and requirement G (concerning telephone security). Requirements B and G relate to security issues that are not systems related and are not in the BPSSM.

A. Unified Program Integrity Contractor Operations

- The UPIC shall conduct their activities in areas not accessible to the general public.
- The UPIC shall completely segregate itself from all other operations. Segregation shall include floor-to-ceiling walls and/or other measures described in ARS Appendix B PE-3 and CMS-2 that prevent unauthorized persons access to or inadvertent observation of sensitive and investigative information.
- Other requirements regarding UPIC operations shall include sections 3.1, 3.1.2, 4.2, 4.2.5, and 4.2.6 of the BPSSM.

B. Handling and Physical Security of Sensitive and Investigative Material

Refer to ARS Appendix B PE-3 and CMS-1 for definitions of sensitive and investigative material.

In addition, the UPIC shall follow the requirements provided below:

- Establish a policy that employees shall discuss specific allegations of fraud only within the context of their professional duties and only with those who have a valid need to know, which includes (this is not an exhaustive list):
 - Appropriate CMS personnel
 - UPIC staff

 - MAC MR staff

- UPIC or MAC audit staff
 - UPIC or MAC data analysis staff
 - UPIC or MAC senior management
 - UPIC or MAC corporate counsel
- The ARSs require that:
 - The following workstation security requirements are specified and implemented: (1) what workstation functions can be performed, (2) the manner in which those functions are to be performed, and (3) the physical attributes of the surroundings of a specific workstation or class of workstation that can access sensitive CMS information. CMS requires that for UPICs all local workstations as well as workstations used at home by UPICs comply with these requirements.
 - If UPIC employees are authorized to work at home on sensitive data, they shall observe the same security practices that they observe at the office. These shall address such items as viruses, virtual private networks, and protection of sensitive data, including printed documents.
 - Users are prohibited from installing desktop modems.
 - The connection of portable computing or portable network devices on the CMS claims processing network is restricted to approved devices only. Removable hard drives and/or a Federal Information Processing Standards (FIPS)-approved method of cryptography shall be employed to protect information residing on portable and mobile information systems.
 - Alternate work sites are those areas where employees, subcontractors, consultants, auditors, etc. perform work associated duties. The most common alternate work site is an employee's home. However, there may be other alternate work sites such as training centers, specialized work areas, processing centers, etc. For alternate work site equipment controls, (1) only CMS Business Partner-owned computers and software are used to process, access, and store sensitive information; (2) a specific room or area that has the appropriate space and facilities is used; (3) means are available to facilitate communication with the managers or other members of the Business Partner Security staff in case of security problems; (4) locking file cabinets or desk drawers; (5) "locking hardware" to secure IT equipment to larger objects such as desks or tables; and (6) smaller Business Partner-owned equipment is locked in a storage cabinet or desk when not in use. If wireless networks are used at alternate work sites, wireless base stations are placed away from outside walls to minimize transmission of data outside of the building.

The UPIC shall also adhere to the following:

- Ensure the mailroom, general correspondence, and telephone inquiries procedures maintain confidentiality whenever the UPIC receives correspondence, telephone calls, or other communication alleging fraud. Further, all internal written operating procedures shall clearly state security procedures.
- Direct mailroom staff not to open UPIC mail in the mailroom unless the UPIC has

requested the mailroom do so for safety and health precautions. Alternately, if mailroom staff opens UPIC mail, mailroom staff shall not read the contents.

- For mail processing sites separate from the UPIC, the UPIC shall minimize the handling of UPIC mail by multiple parties before delivery to the UPIC.
- The UPIC shall mark mail to CMS Central Office or to another UPIC “personal and confidential” and address it to a specific person.
- Where more specialized instructions do not prohibit UPIC employees, they may retain sensitive and investigative materials at their desks, in office work baskets, and at other points in the office during the course of the normal work day. Regardless of other requirements, the employees shall restrict access to sensitive and investigative materials, and UPIC staff shall not leave such material unattended.
- The UPIC staff shall safeguard all sensitive or investigative material when the materials are being transported or sent by UPIC staff.
- The UPIC shall maintain a controlled filing system (refer to section 4.2.2.6.1).

C. Designation of a Security Officer

The security officer shall take such action as is necessary to correct breaches of the security standards and to prevent recurrence of the breaches. In addition, the security officer shall document the action taken and maintain that documentation for at least seven (7) years.

Actions shall include:

- Within one (1) hour of discovering a security incident, clearly and accurately report the incident following BPSSM requirements for reporting of security incidents. For purposes of this requirement, a security incident is the same as the definition in section 3.6 of the BPSSM, Incident Reporting and Response.
- Specifically, the report shall address the following where appropriate:
 - Types of information about beneficiaries shall at a minimum address whether the compromised information includes name, address, HICNs, and date of birth;
 - Types of information about providers/suppliers shall at a minimum address if the compromised information includes name, address, and provider/supplier ID;
 - Whether LE is investigating any of the providers/suppliers with compromised information; and
 - Police reports.
- Provide additional information that CMS requests within 72 hours of the request.
- If CMS requests, issue a Fraud Alert to all CMS Medicare contractors within 72 hours of the discovery that the data was compromised, listing the HICNs and provider/supplier IDs that were compromised.
- Within 72 hours of discovery of a security incident, when feasible, review all

security measures and revise them if necessary so they are adequate to protect data against physical or electronic theft.

Refer to section 3.1 of the BPSSM and Attachment 1 of this manual section (letter from Director, Office of Financial Management, concerning security and confidentiality of UPIC data) for additional requirements.

D. Staffing of the Unified Program Integrity Contractor and Security Training

The UPIC shall perform thorough background and character reference checks, including at a minimum credit checks, for potential employees to verify their suitability for employment. Specifically, background checks shall at least be at level 2- moderate risk. (People with access to sensitive data at CMS have a level 5 risk). The UPIC may require investigations above a level 2 if the UPIC believes the higher level is required to protect sensitive information.

At the point the UPIC makes a hiring decision for a UPIC position, and prior to the selected person's starting work, the UPIC shall require the proposed candidate to fill out a conflict of interest declaration, as well as a confidentiality statement.

Annually, the UPICs shall require existing employees to complete a conflict of interest declaration, as well as a confidentiality statement.

At least once a year, the UPICs shall thoroughly explain to and discuss with employees the special security considerations under which the UPIC operates. Further, this training shall emphasize that in no instance shall employees disclose sensitive or investigative information, even in casual conversation. The UPIC shall ensure that employees understand the training provided.

Refer to section 2.0 of the BPSSM and ARS Appendix B AT-2, AT-3, AT-4, SA-6, MA-5.0, PE-5.CMS.1, IR2-2.2, CP 3.1, CP 3.2, CP 3.3, and SA 3.CMS.1 for additional training requirements.

E. Access to Unified Program Integrity Contractor Information

Refer to section 2.3.4 of the BPSSM for requirements regarding access to UPIC information. The UPIC shall notify the OIG if parties without a need to know are asking inappropriate questions regarding any investigations. The UPICs shall refer all requests from the press related to the Medicare Integrity Program to the CMS contracting officer with a copy to the CORs and BFLs for approval prior to release. This includes, but is not limited to, contractor initiated press releases, media questions, media interviews, and Internet postings.

F. Computer Security

Refer to section 4.1.1 of the BPSSM for the computer security requirements.

G. Telephone and Fax Security

The UPICs shall implement phone security practices. The UPICs shall discuss investigations only with those individuals who need to know the information and shall not divulge information to individuals not known to the UPIC involved in the investigation of the related issue.

Additionally, the UPICs shall only use CMS, the OIG, the DOJ, and the FBI phone numbers that they can verify. To assist with this requirement, UPIC management shall provide UPIC

staff with a list of the names and telephone numbers of the individuals of the authorized agencies that the UPICs deal with and shall ensure that this list is properly maintained and periodically updated.

Employees shall be polite and brief in responding to phone calls but shall not volunteer any information or confirm or deny that an investigation is in process. However, UPICs shall not respond to questions concerning any case the OIG, the FBI, or any other LE agency is investigating. The UPICs shall refer such questions to the OIG, the FBI, etc., as appropriate.

Finally, the UPICs shall transmit sensitive and investigative information via facsimile (fax) lines only after the UPIC has verified that the receiving fax machine is secure. Unless the fax machine is secure, UPICs shall make arrangements with the addressee to have someone waiting at the receiving machine while the fax is transmitting. The UPICs shall not transmit sensitive and investigative information via fax if the sender must delay a feature, such as entering the information into the machine's memory.

4.5 - Screening Leads

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

This section applies to UPICs.

Screening is the initial step in the review of a lead (described in section 4.2.2.1 of this chapter) to determine the need to perform further investigation based on the potential for fraud, waste, or abuse. Screening shall be completed within 45 calendar days after receipt of the lead.

The receipt date of the lead is generally determined by the date the UPIC receives a complaint. If the lead resulted from data analysis conducted by the UPIC, the receipt of the lead shall be the date the lead was referred from the UPIC data analysis department to its investigation or screening unit. For a new lead that is identified from an active or current UPIC investigation, the receipt of the lead shall be the date the new lead was identified by the UPIC investigator.

Note: If criteria for an IA are met during evaluation of the lead, the UPIC shall forward the IA to LE and continue to screen the lead, if deemed appropriate.

Activities that the UPIC may perform in relation to the screening process include, but are not limited to:

- Verification of provider's enrollment status;
- Coordination with the MAC on prior activities (i.e., prior medical reviews, education, appeals information, etc.);
- Data analysis;
- Policy / regulation analysis;
- Contact with the complainant, when the lead source is a complaint;
- Beneficiary interviews; and
- Site verification to validate the provider's/supplier's practice location. Note: While there is no requirement to check locked doors during a site verification, UPICs are authorized to check the doors. As such, the UPIC shall assess the environment and use sound judgement to determine when it is appropriate to check locked doors.

Any screening activities shall not involve contact with the subject provider/supplier or implementation of any administrative actions (i.e., post-payment reviews, prepayment reviews/edits, payment suspension, and revocation). However, if the lead is based solely on a potential assignment violation issue, the UPIC may contact the provider directly to resolve

only the assignment violation issue. If the lead involves potential patient harm, the UPIC shall immediately notify CMS within two (2) business days.

As it relates to the UPIC's handling of potential assignment violations, if the UPIC is unable to make contact with the provider at least five (5) attempts, the UPIC shall refer the assignment violation issue to the appropriate CMS Regional Office for resolution.

After completing its screening, the UPIC shall close the lead if it does not appear to be related to fraud, waste, or abuse. Prior to closing the lead, the UPIC shall take any appropriate actions (i.e., referrals to the MAC, RA, state, or QIO). For example, if a lead does not appear to be related to potential fraud, waste, or abuse but the lead needs to be referred to the MAC, the date that the UPIC refers the information to the MAC is the last day of the screening.

At a minimum, the UPIC shall document the following information in its case file:

- The date the lead was received and closed;
- Lead source (e.g., beneficiary, MAC, provider/supplier);
- Record the name and telephone number of the individual (or organization), if applicable, that provided the information concerning the alleged fraud or abuse;
- Indicate the provider's/supplier's name, address, and ID number;
- Start and end date of the screening;
- Description of the actions/activities performed;
- Start and end date of each action/activity;
- A brief description of the action taken to close the lead (e.g., reviewed records and substantiated amounts billed). Ensure that sufficient information is provided to understand the reason for the closeout;
- The number of leads received to date regarding this provider/supplier, including the present lead. This information is useful in identifying providers/suppliers that are involved in an undue number of complaints; and
- Any documentation associated with the UPIC's activities (i.e., referrals to other entities).

Additionally, if the screening process exceeds 45 calendar days, the UPIC shall document the reasons, circumstances, dates, and actions associated with the delay in the UCM and its monthly reporting in CMS ARTS.

If the UPIC identifies specific concerns while screening a lead that warrants contact with a specific provider/supplier, the UPIC shall contact the BFL, with a copy to the COR, for further guidance (e.g., UPIC determines that provider/supplier contact is needed in order to determine if the case warrants further investigation).

4.8.3 – Congressional Inquiries

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

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. *The UPIC shall not respond directly to the Congressional Office. Upon CMS receipt of the UPIC's relevant information, CMS will coordinate internally and respond to the inquiry as needed.*

4.14 - Fraud Alerts & HPMS Memos

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

This section applies to UPICs.

Fraud Alerts are issued when circumstances arise that indicate a need to advise the UPICs, SMRCs, MACs, LE, state Medicaid agencies, and other appropriate stakeholders about an activity that resulted in the filing of inappropriate and potentially false Medicare claims. If the UPIC identifies the need for a Fraud Alert, it shall provide the BFL, with a copy to the COR, a summary of the circumstances. The CMS will evaluate the need to issue a Fraud Alert. All Fraud Alerts will be disseminated by CMS to the appropriate stakeholders.

The following direction applies to the I-MEDIC:

HPMS Memos are issued when circumstances arise that indicate a need to advise the Part C plans and Part D Plan Sponsors, and other appropriate stakeholders about an activity that resulted in the filing of inappropriate and potentially false Medicare claims. If the I-MEDIC identifies the need for an HPMS Memo, it shall provide the BFL, with a copy to the COR, a summary of the circumstances. CMS will evaluate the need to issue an HPMS Memo. All HPMS Memos will be disseminated by CMS to the appropriate stakeholders through the HPMS Portal.

Medicare Program Integrity Manual

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

Table of Contents
(Rev. 12127, Issued: 07-21-23)

Transmittals for Chapter 8

8.3 – Suspension of Payment

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

This section applies to Medicare Administrative Contractors (MACs) and Unified Program Integrity Contractors (UPICs).

Hereinafter, suspension of payment may be referenced as “payment suspension.”

Requests for Suspension of Payment (“Payment Suspension”) may be approved when there is reliable information that an overpayment exists, when payments to be made may not be correct, or when there is a credible allegation of fraud existing against a provider. The process by which the UPIC notifies and coordinates with the MAC to implement a CMS-approved suspension of payment shall be documented in the Joint Operating Agreement (JOA) between the MAC and the UPIC. The UPICs shall advise and coordinate the imposition of a payment suspension with the appropriate MAC when a payment suspension has been approved by CMS. The UPIC shall perform the necessary medical review and development of overpayments for payment suspensions that have received CMS approval, when appropriate.

Medicare authority to withhold payment in whole or in part for claims otherwise determined to be payable is found in federal regulations at 42 CFR §405.370-375, which provide for the suspension of payments.

All payment suspensions shall be referred to the CMS/Center for Program Integrity (CPI) via the Unified Case Management System (UCM) for approval. UPICs shall notify their appropriate CPI *Business Function Lead (BFL)*, with a copy to the *Contracting Officer’s Representative (COR)*, of the submission by providing the UCM number via email.

8.3.2.1 – CMS Approval

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

If the UPIC believes that a UPIC-initiated Payment Suspension is a viable option for an investigation, they shall update UCM appropriately to ensure the case is included on the next case coordination meeting agenda for discussion. For national or multi-regional suspensions, only the lead UPIC shall discuss the suspension at the case coordination meeting.

During the case coordination meeting, if CMS agrees that the criteria for Payment Suspension is met, CMS will instruct the UPIC to submit the Payment Suspension request(s) with the completed Administrative Action Review (AAR) form to *CPI* through the UCM. The Payment Suspension team member will review the submissions and make a formal determination as to whether a Payment Suspension is a viable option.

During the case coordination meeting, the UPIC may receive additional guidance from CMS related to subsequent actions related to these investigations. If the UPIC has questions following the case coordination meeting, the UPIC shall coordinate with its COR, BFL, and/or suspension team member, *as needed*.

When a payment suspension is approved by CPI, the UPIC shall inform the respective MAC of this action and the MAC shall effectuate the suspension of payments to the provider unless prior notice of the payment suspension is necessary. When prior notice is necessary, the MAC shall effectuate the suspension of payment in concert with the established date from the payment suspension notice. The MACs shall ensure that all money on the payment floor is not released to the provider after the effective date of the suspension and the money is withheld in accordance with the payment suspension rules and regulations. MACs shall

provide an accounting of the money withheld on day one of the payment suspension to the UPIC. The UPIC shall enter this amount in the UCM as the first monetary entry.

Unless otherwise specified, when a payment suspension is imposed, no payments are to be released to the provider as of the effective date of the payment suspension. This includes payments for new claims processed, payments for adjustments to claims previously paid, interim PIPs. If it is discovered that money is released to the provider after the effective date of the payment suspension, the MAC or UPIC shall contact CPI for guidance.

8.3.3.1 – DME Payment Suspensions (MACs and UPICs)

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

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 *BFL, with a copy to the COR*, 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. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)*

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 *BFL, with a copy to the COR*, 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.

8.4.1.4 - Determining When Statistical Sampling May Be Used

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

The contractor shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. The use of statistical sampling may be used after documented educational intervention has failed to correct the payment error. For purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to:

- high error rate determinations by the contractor or by other medical reviews compared to similar service providers;
- provider/supplier history (i.e., prior history of non-compliance for the same or similar billing issues, or historical pattern of non-compliant billing practices);
- CMS approval provided in connection to a payment suspension;
- information from law enforcement investigations;
- allegations of wrongdoing by current or former employees of a provider/supplier; and/or
- audits or evaluations conducted by the OIG.

If the contractor believes that statistical sampling and/or extrapolation should be used for purposes of estimation, and it does not meet any of the criteria listed above, it shall consult with its *BFL, with a copy to the COR*, as defined in PIM Chapter 4, §4.7 – Investigations, prior to creating a statistical sample and issuing a request for medical records from the provider/supplier. Examples of this may include, but are not limited to: billing for non-covered services, billing for services not rendered, etc. Extrapolation should not be used when the above criteria is not met unless prior approval is given by the COR and BFL.

When an overpayment is identified by data analysis alone, the contractor shall consult with its *BFL, with a copy to the COR*. In addition, if CMS approves the data driven overpayment, the contractor shall also consult with its *BFL, with a copy to the COR*, on whether statistical sampling and extrapolation are necessary to identify the overpayment.

Additionally, a UPIC shall consult with the appropriate MAC on whether an extrapolated overpayment is more efficient in processing a data-driven overpayment before requesting recoupment from the MAC.

Once a decision has been made that statistical sampling may be used, factors also to be considered for determining when to undertake statistical sampling for overpayment estimation instead of a claim-by-claim review, include, but are not limited to: the number of claims in the universe and the dollar values associated with those claims; available resources; and the cost effectiveness of the expected sampling results.

8.4.7.1 - Recovery From Provider or Supplier

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

Once an overpayment has been determined to exist, the UPIC shall provide its *BFL, with a copy to the COR*, a summary of the investigation, any prior history (if applicable), the medical review results (including denial reasons), and the extrapolated overpayment amount in a format agreed upon by *CPI for all extrapolation requests* not associated with a Payment Suspension.

If the *CPI* agree that an extrapolated overpayment is appropriate, the UPIC shall include the case on the next case coordination meeting agenda for discussion and final approval. During the case coordination meeting, the UPIC may receive additional guidance from CMS related to subsequent actions associated with the investigations. If the UPIC has subsequent

questions following the case coordination meeting, the UPIC shall coordinate with its COR *and/or* BFL, *as needed*.

The contractor shall include in the overpayment demand letter information about the review and statistical sampling methodology that was followed. Only MACs shall issue demand letters and recoup the overpayment. In the Final Review Results sent to the provider/supplier, the contractor shall include information about the review and statistical sampling methodology that was utilized for estimation.

The explanation of the sampling methodology that was followed shall include all of the following:

- A description of the universe, the sampling frame, and the sampling methodology,
- A definition of the sampling unit,
- The sample selection procedure followed, and the numbers and definitions of the strata and size of the sample, including allocations, if stratified,
- The time period under review,
- The overpayment estimation, the overpayment estimation methodology, and the calculated sampling error; and
- The amount of the actual overpayment/underpayment from each of the claims reviewed.

The contractor shall also include a list of any problems/issues identified during the review and any recommended corrective actions.

8.4.9.1 - Sampling Methodology Overturned

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

If the decision issued on appeal contains a finding that the sampling methodology was invalid, there are several options for revising the estimated overpayment based upon the appellate decision:

- A. If the decision issued on appeal permits correction of errors in the sampling methodology, the contractor shall revise the overpayment determination after making the corrections. The contractor shall consult with its BFL, *with a copy to the COR*, to confirm that this course of action is consistent with the decision of the MAC, Qualified Independent Contractor (QIC), Administrative Law Judge (ALJ), Medicare Appeals Council (the Council) within the Departmental Appeals Board (DAB), or Federal District Court.
- B. The contractor may elect to recover the actual overpayments related to the sampled claims and then initiate a new review of the provider or supplier. If the actual overpayments related to the sampling units in the original review have been recovered, these individual sampling units shall be eliminated from the sampling frame used for any new review. The contractor shall consult with its BFL, *with a copy to the COR*, to confirm that this course of action is consistent with the decision of the MAC, QIC, ALJ, the Council or Federal District Court.
- C. The contractor may conduct a new review (using a new, valid methodology) for the same time period covered by the previous review. If this option is chosen, the

contractor shall not recover the actual overpayments on any of the sample claims found to be in error in the original sample. Before employing this option, the contractor shall consult with its BFL, *with a copy to the COR*, to verify that this course of action is consistent with the decision of the MAC, QIC, ALJ, Council, or the Federal District Court.

Medicare Program Integrity Manual Exhibits

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(Rev. 12127; Issued: 07-21-23)

Transmittals for Exhibits

Exhibit 1 - Definitions

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

A

Abuse

Billing Medicare for services that are not covered or are not correctly coded.

Affiliated Contractor (AC)

A Medicare carrier, Fiscal Intermediary (FI), or other contractor such as a Durable Medical Equipment Medicare Administrative Contractor (DME MAC), which shares some or all of the Unified Program Integrity Contractor's (UPIC's) jurisdiction; Affiliated Contractors perform non-UPIC Medicare functions such as claims processing.

B-C

Carrier

The Carrier is an entity that has entered into a contract with CMS to process Medicare claims under Part B for non-facility providers (e.g., physicians, suppliers, laboratories). DME MACs are those carriers that CMS has designated to process DME, prosthetic, orthotic and supply claims.

Case

A case is a work product that the UPIC opens as an investigation after screening and vetting of a potential lead.

Contractor

Contractor includes all intermediaries, carriers, DME MAC, RHHIs, MACs, and UPICs.

Centers for Medicare & Medicaid Services (CMS)

CMS administers the Medicare program. CMS' responsibilities include management of AC and Medicare contractor claims payment, managing UPIC, AC, and Medicare contractor fiscal audit and/or overpayment prevention and recovery, and the development and the monitoring of payment safeguards necessary to detect and respond to payment errors or abusive patterns of service delivery. CMS was formerly known as the Health Care Financing Administration (HCFA).

Closed Case

A *UCM* case shall be closed when no further action will be required of the UPIC, or Medicare contractor BI unit by the law enforcement agency(ies) working the case and when the law enforcement agency(ies) has ended all its activity on the case. Note that even after the case is closed, there may still be administrative actions that the UPIC, or Medicare contractor BI unit will take.

D-E

Department of Justice (DOJ)

Attorneys from DOJ and United States Attorney's Offices have criminal and civil authority to prosecute those providers who de-fraud the Medicare program.

Demand Bill or Demand Claim

A demand bill or demand claim is a complete, processable claim that must be submitted promptly to Medicare by the physician, supplier or provider at the timely request of the beneficiary, the beneficiary's representative, or, in the case of a beneficiary dually entitled to Medicare and Medicaid, a state as the beneficiary's subrogee. A demand bill or demand claim is requested usually, but not necessarily, pursuant to notification of the beneficiary (or representative or subrogee) of the fact that the physician, supplier or provider expects Medicare to deny payment of the claim. When the beneficiary (or representative or subrogee) selects an option on an advance beneficiary notice that includes a request that a claim be submitted to Medicare, no further demand is necessary; a demand bill or claim must be submitted.

F

Federal Bureau of Investigation (FBI)

Along with OIG, the FBI investigates potential health care fraud. Under a special memorandum of understanding, the FBI has direct access to contractor data and other records to the same extent as OIG.

Fraud

Fraud is the intentional deception or misrepresentation that the individual knows to be false or does not believe to be true, and the individual makes knowing that the deception could result in some unauthorized benefit to himself/herself or some other person.

G-H

I

Intermediary

The intermediary is a public or private agency or organization that has entered into an agreement with CMS to process Medicare claims under both Part A and Part B for institutional providers (e.g., hospitals, SNFs, HHAs, hospices, CORFs, OPT, occupational therapy, speech pathology providers, and ESRD facilities). Regional home health intermediaries (RHHIs) are those FIs that CMS has designated to process Medicare claims received from home health and hospice providers.

J-K-L

Local Coverage Determinations (LCDs)

The LCDs are those policies used to make coverage and coding decisions in the absence of specific statute, regulations, national coverage policy, national coding policy, or as an adjunct to a national coverage policy.

M

Medicare Contractor (Benefit Integrity)

Medicare contractors include all intermediaries and carriers that have not transitioned their benefit integrity work to a UPIC.

Medicare Contractor (Medical Review)

Medicare contractors include intermediaries, carriers and MACs.

Misrepresented

A deliberate false statement made, or caused to be made, that is material to entitlement or payment under the Medicare program.

N

Noncovered (Not Covered)

Noncovered services are those for which there is no benefit category, services that are statutorily excluded (other than §1862 (A)(1)(a)), or services that are not reasonable and necessary under §1862 (A)(1)(a).

O

Office of Audit Services (OAS)

The OAS conducts comprehensive audits to promote economy and efficiency and to prevent and detect fraud, abuse, and waste in operations and programs. OAS may request data for use in auditing aspects of Medicare and other Health and Human Service (HHS) programs and is often involved in assisting OIG/OI in its role in investigations and prosecutions.

Office of Counsel to the Inspector General (OCIG)

The OCIG is responsible for coordinating activities that result in the negotiation and imposition of Civil Monetary Penalties (CMPs), assessments, and other program exclusions. It works with the Office of Investigations (OIG), Office of Audit Services (OAS), CMS, and other organizations in the development of health care fraud and exclusions cases.

Office of Inspector General (OIG)

The OIG investigates suspected fraud or abuse and performs audits and inspections of CMS programs. In carrying out its responsibilities, OIG may request information or assistance from CMS, its Unified Program Integrity Contractor (UPIC), Medicare contractors, and QIOs. OIG has access to CMS's files, records, and data as well as those of CMS's contractors. OIG investigates fraud, develops cases, and has the authority to take action against individual health care providers in the form of CMPs and program exclusion, and to refer cases to the DOJ for criminal or civil action. OIG concentrates its efforts in the following areas:

- Conducting investigations of specific providers suspected of fraud, waste, or abuse for purposes of determining whether criminal, civil, or administrative remedies are warranted;
- Conducting audits, special analyses and reviews for purposes of discovering and documenting Medicare and Medicaid policy and procedural weaknesses contributing to fraud, waste, or abuse, and making recommendations for corrections;
- Conducting reviews and special projects to determine the level of effort and performance in health provider fraud and abuse control;

- Participating in a program of external communications to inform the health care community, the Congress, other interested organizations, and the public of OIG's concerns and activities related to health care financing integrity;
- Collecting and analyzing Medicare contractor, AC, Medicare contractor, and State Medicaid agency-produced information on resources and results; and,
- Participating with other government agencies and private health insurers in special programs to share techniques and knowledge on preventing health care provider fraud and abuse.

Office of Investigations (OI)

The Office of Investigations (OI), within OIG, is staffed with professional criminal investigators and is responsible for all HHS criminal investigations, including Medicare fraud. OIG/OI investigates allegations of fraud or abuse whether committed by UPICs, ACs, Medicare contractors, grantees, beneficiaries, or providers of service (e.g., fraud allegations involving physicians and other providers, contract fraud, and cost report fraud claimed by hospitals).

The OIG/OI presents cases to the United States Attorney's Office within the Department of Justice (DOJ) for civil or criminal prosecution. When a practitioner or other person is determined to have failed to comply with its obligations in a substantial number of cases or to have grossly and flagrantly violated any obligation in one or more instances, OIG/OI may refer the case to OCIG for consideration of one or both of the following sanctions:

- An exclusion from participation in the Medicare program or any State health care programs as defined under §1128(h) of the Social Security Act (the Act); or
- The imposition of a monetary penalty as a condition to continued participation in the Medicare program and State health care programs.

Offset

The recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

P

Providers

Any Medicare provider (e.g., hospital, skilled nursing facility, home health agency, outpatient physical therapy, comprehensive outpatient rehabilitation facility, renal dialysis facility, hospice, physician, non-physician practitioner, laboratory, supplier, etc.). For purposes of this manual, the term provider is generally used to refer to individuals or organizations that bill carriers, intermediaries, DME MACs, and RHHIs. If references apply to only specific providers (e.g., physicians), the specific provider will be identified.

Q- R

Quality Improvement Organization (QIO)

The Peer Review Improvement Act of 1982 established the utilization and quality control peer review organization (PRO) program. The PRO name has changed to quality

improvement organization. CMS contracts with independent physician organizations in each state to administer the QIO program. Their purpose is to ensure that the provisions of the Peer Review Improvement Act of 1982 are met. Under their contracts with CMS, QIOs are required to perform quality of care reviews of the medical services provided to Medicare beneficiaries in settings including, but not limited to: physician offices, acute care hospitals, specialty hospitals (for example psychiatric and rehabilitation hospitals), and ambulatory surgical centers. In the inpatient setting, QIOs also perform provider-requested higher-weighted DRG reviews for acute inpatient prospective payment system (IPPS) hospitals and long-term care hospital (LTCH) claims.

Recoupment

The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Reliable Information

Reliable information includes credible allegations, oral or written, and/or other material facts that would likely cause a non-interested third party to think that there is a reasonable basis for believing that a certain set of facts exists, for example, that claims are or were false or were submitted for non-covered or miscoded services. Reliable information of fraud exists if the following elements are found:

- The allegation is made by a credible person or source. The source is knowledgeable and in a position to know. The source experienced or learned of the alleged act first hand, i.e., saw it, heard it, read it. The source is more credible if the source has nothing to gain by not being truthful. The source is competent; e.g., a beneficiary may not always be a credible source in stating that services received were not medically necessary. An employee of a provider who holds a key management position and who continues to work for the provider is often a highly credible source. The friend of a beneficiary who heard that the provider is defrauding Medicare may not be a particularly credible source;
- The information is material. The information supports the allegation that fraud has been committed by making it more plausible, reasonable, and probable (e.g., instructions handwritten by the provider delineating how to falsify claim forms).
- The act alleged is not likely the result of an accident or honest mistake. For example, the provider was already educated on the proper way to complete the form, or the provider should know that billing for a service not performed is inappropriate, or claims are submitted the same way over a period of time by different employees.

Reliable evidence includes but is not limited to the following:

- Documented allegations from credible sources that items or services were not furnished or received as billed;
- Billing patterns so aberrant from the norm that they bring into question the correctness of the payments made or about to be made;
- Data analysis that shows the provider's utilization to be well above that of its peers without any apparent legitimate rationale for this;

- Statements by beneficiaries and/or their families attesting to the provider's fraudulent behavior;
- Corroboration from provider employees (official and unofficial whistle blowers);
- Other sources, such as prepayment and postpayment review of medical records; or
- Recommendations for suspension by OIG/OI, FBI, Assistant U.S. Attorneys (AUSAs), or CMS, based on their finding that the provider has already received overpayments and continued payments should be made only after a determination that continued payment is appropriate.

S

Services

Medical care, items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital RPH or SNF facilities. (42CFR 400.202). In other sections of Medicare manuals and remittance advice records, the term item/service is used. However, throughout this manual we will use the term service to be inclusive of item/service. See §1861 of Title 18 for a complete description of services by each provider type.

Suspension of Payment

Suspension of payment is defined in the regulation 42CFR 405.370 as "the withholding of payment by the carrier or intermediary from a provider or supplier of an approved Medicare payment amount before a determination of the amount of overpayment exists." In other words, ACs or Medicare contractors have received processed and approved claims for a provider's items or services; however, the provider has not been paid and the amount of the overpayment has not been established.

T-U-V-W-X

Unified Program Integrity Contractor (UPIC)

The UPIC is a contractor dedicated to program integrity that handles such functions as audit, medical review and potential fraud and abuse investigations consolidated into a single contract.