CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11962	**Date: April 21, 2023**
	Change Request 13173

SUBJECT: Updates of Chapters 4 and 8 in Publication (Pub.) 100-08, Including Point of Contact Clarification and Update to Statistical Sampling Terminology

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update sections within Chapters 4 and 8 in Pub. 100-08. The updates in this CR include revising sections in Chapter 4 in Pub. 100-08 that refer to Program Integrity contractor coordination with Business Function Leads (BFL) and Contracting Officer's Representatives (COR). Also, various sections within Chapter 8 in Pub. 100-08 are also being revised to include the term "sampling" for consistency purposes.

EFFECTIVE DATE: May 22, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 22, 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	4/4.1/Introduction
R	4/4.2/4.2.2/4.2.2.3/Organizational Requirements
R	4/4.2/4.2.2/4.2.2.6/Procedural Requirements
R	4/4.2/4.2.2/4.2.2.8/4.2.2.8.1/4.2.2.8.1.1/Coordination with the Office of Inspector General
R	4/4.2/4.2.2/4.2.2.8/4.2.2.8.1/4.2.2.8.1.4/UPIC Coordination with Other Contractors Related to the RAC Data Warehouse
R	4/4.2/4.2.3/Durable Medical Equipment Medicare Administrative Contractor Fraud Functions
R	4/4.5/Screening Leads
R	4/4.6/Vetting Leads with CMS
R	4/4.7/4.7.1/Conducting Investigations
R	4/4.7/4.7.2/Identity Theft Investigations and Victimized Provider Waiver of Liability Process
R	4/4.7/4.7.3/Durable Medical Equipment Medicare Investigative Functions
R	4/4.7/4.7.4/4.7.4.1/Production of Medical Records and Documentation for an Appeals Case File
R	4/4.7/4.7.4/4.7.4.2/Reversed Denials by Administrative Law Judges on Open Cases
R	4/4.7/4.7.5/Administrative Relief from Program Integrity Review in the Presence of a Disaster
R	4/4.8/Requests for Information From Outside Organizations
R	4/4.8/4.8.1/Reversed Denials by Administrative Law Judges on Open Cases
R	4/4.8/4.8.2/Production of Medical Records and Documentation for an Appeals Case File
R	4/4.9/4.9.1/Immediate Advisements to the OIG/OI
R	4/4.9/4.9.2/Referral of Cases to the OIG/OI
R	4/4.9/4.9.2/4.9.2.2/Take Administrative Action on Cases Referred to and Declined/Returned by OIG/OI
R	4/4.9/4.9.3/Referral to Other Law Enforcement Agencies
R	4/4.9/4.9.4/4.9.4.1/Referral to State Agencies or Other Organizations
R	4/4.9/4.9.4/4.9.4.2/UPICs and QIOs
R	4/4.11/4.11.6/4.11.6.1/Referral Process to CMS

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/4.12/4.12.8/Deleting Entries in the UCM
R	4/4.13/Vulnerabilities
R	4/4.14/Fraud Alerts
R	8/Table of Contents
R	8/8.4/8.4.1/8.4.1.3/Steps for Conducting Statistical Sampling
R	8/8.4/8.4.2/Probability Sampling
R	8/8.4/8.4.3/8.4.3.2/Defining the Universe, the Sampling Unit, and the Sampling Frame
R	8/8.4/8.4.3/8.4.3.2/8.4.3.2.1/Composition of the Universe
R	8/8.4/8.4.3/8.4.3.2/8.4.3.2.2/The Sampling Unit
R	8/8.4/8.4.3/8.4.3.2/8.4.3.2.3/The Sampling Frame
R	8/8.4/8.4.4/8.4.4.3/Determining Sample Size
R	8/8.4/8.4.4/8.4.4.4/8.4.4.4.1/Documentation of Universe and Sampling Frame
R	8/8.4/8.4.4/8.4.4.5/Maintenance of Documentation
R	8/8.4/8.4.5/Calculating the Estimated Overpayment
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

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: 11962	Date: April 21, 2023	Change Request: 13173

SUBJECT: Updates of Chapters 4 and 8 in Publication (Pub.) 100-08, Including Point of Contact Clarification and Update to Statistical Sampling Terminology

EFFECTIVE DATE: May 22, 2023
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I. GENERAL INFORMATION

A. Background: This CR will update Chapters 4 and 8 in Pub. 100-08. For purposes of the Chapter 4 updates, the Center for Program Integrity (CPI) is clarifying when the Program Integrity contractors shall coordinate with their BFL, their COR, or a combination of the two. For purposes of the Chapter 8 updates, CPI will be using the term "sampling" rather than the term "sample" throughout the chapter.

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	
13173.1	The Unified Program Integrity Contractors (UPIC), Investigations Medicare Drug Integrity Contractor (I-MEDIC), Supplemental Medical Review Contractors (SMRC) and MACs shall ensure that Medicare pays the right amount for covered and correctly coded services rendered to eligible beneficiaries by	X	X	X	X					SMRC, UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	legitimate providers.									
13173.2	The contractor shall coordinate with their COR and their BFL to fulfill all direction as described in the Program Integrity Manual (Pub. 100-08).									UPICs
13173.3	The contractor shall directly contact the appropriate UPIC BFL, with a copy to the UPIC COR, for any technical issues and/or questions.									UPICs
13173.4	The contractor shall directly contact the UPIC COR, with a copy to the appropriate UPIC BFL, for any business issues and/or questions.									UPICs
13173.5	The contractor shall report to the BFL, with a copy to the COR, all situations that have been identified in which a provider consistently fails to comply with the provisions of the assignment agreement.									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13173.6	The contractor shall notify, via e-mail, the BFL, with a copy to the COR, when asked to accompany the Office of Inspector General (OIG)/Office of Investigations (OI) or any other Law Enforcement (LE) agency onsite to a provider/supplier for the purpose of gathering evidence in a potential fraud case.									UPICs
13173.7	The contractor shall work with the BFL, with a copy to the COR, to develop and organize external programs and perform training.									UPICs
13173.8	The contractor shall submit written outreach material to the BFL, with a copy to the COR, for clearance prior to submission to the requesting party.									UPICs
13173.9	The contractor shall submit fraud-related articles for MAC newsletters/bulletins to the BFL, with a copy to the COR, for									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	clearance prior to submission to the requesting party.									
13173.10	The contactor shall discuss the case with the BFL, with a copy to the COR, if the OIG expresses interest in the case.									UPICs
13173.11	The contractor shall consult with its BFL, with a copy to the COR, and/or the CMS Recovery Audit Contractor liaison to determine the appropriate level of suppression or exclusion.									UPICs
13173.12	The contractor shall keep the Pricing, Data Analysis and Coding (PDAC) contractor, other UPICs, BFL, with a copy to the COR, and subject matter experts informed of its ongoing activities regarding 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.									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13173.13	The contractor shall document in the Unified Case Management Systems (UCM) and monthly reporting the reasons, circumstances, dates, and actions associated with the delay in the 45-calendar day lead screening timeframe.									UPICs
13173.14	The contractor shall contact the BFL, with a copy to the COR, for further guidance if specific concerns are identified while screening a lead that warrants contact with a specific provider/supplier.									UPICs
13173.15	The contractor shall be notified by CMS via technical direction when instances such as the need for expedited vetting are identified.									UPICs
13173.16	The contractor shall notify its BFL, with a copy to the COR, for CMS escalation to the appropriate LE contacts when the contractor does not receive a									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	response after attempting to contact LE on multiple occasions within five business days.									
13173.17	The contractor shall keep the PDAC contractor, other UPICs, BFL, with a copy to the COR, and subject matter experts informed of 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.									UPICs
13173.18	The contractor shall contact the Qualitied Independent Contractor (QIC) and their BFL, with a copy to the COR, immediately should they receive notice that their participation in an Administrative Law Judge (ALJ) hearing is required.									UPICs
13173.19	The UPIC shall consult with its									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	BFL, with a copy to the COR, before initiating a protest of an ALJ's decision.									
13173.20	The contractor shall delay requests for medical records for a period of 60-days beginning on the date designated by the Federal Emergency Management Agency (FEMA)/as advised by the COR and ending as directed by their COR should the contractor confirm that medical record loss resulted from this disaster to the point where administrative relief from medical review requirements is necessary to allow the provider sufficient time to retrieve copies of, or restore damaged, medical documentation.									UPICs
13173.21	The contractors shall consult with their BFL, with a copy to the COR, on any time sensitive issues that must be									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	resolved involving contact with a provider or beneficiary in the areas affected by FEMA declared natural disasters.									
13173.22	The contractor shall consult with its BFL, with a copy to the COR, to determine the appropriateness of a request to reconstruct medical records in the case of complete destruction of medical records in which no backup records exist.									UPICs
13173.23	The contractor shall ask the BFL, with a copy to the COR, for assistance when upon receipt of a duplicate or similar Request for Information (RFI) from the OIG and Department of Justice, the requestors are not willing to share the information.									UPICs
13173.24	The contactor shall contact its BFL, with a copy to the COR, if they receive an RFI from law enforcement that									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	crosses several UPIC zones.									
13173.25	The contractor shall consult with its BFL, with a copy to the COR, before initiating a protest of an ALJ's decision.									UPICs
13173.26	The contractor shall contact the QIC and their BFL, with a copy to the COR, immediately should they receive notice that their participation in an ALJ hearing is required.									UPICs
13173.27	The contractor shall notify its BFL, with a copy to the COR, to request exemption from applicable Immediate Advisement (IA) criteria in a particular jurisdiction should local LE have specific parameters or thresholds in place that do not allow them to accept certain IAs.									UPICs
13173.28	The contractor shall send notification to its appropriate BFL, with a copy to the COR, of potential									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	IAs.									
13173.29	The UPIC shall notify its appropriate BFL, with a copy to the COR, and await further instructions if they do not receive a response from the OIG/OI within two business days.									UPICs
13173.30	The I-MEDIC shall notify its appropriate BFL, with a copy to the COR, and await further instructions if they do not receive a response from the OIG/OI within five business days.									UPICs
13173.31	The contractor shall advise its appropriate BFL, with a copy to the COR, and immediately continue its investigation if the OIG/OI determines that a formal IA is not needed.									UPICs
13173.32	The contractor shall contact its appropriate BFL, with a copy to the COR, for further guidance if they do not receive a response from the OIG/OI within									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	five business days from the date of the IA notification.									
13173.33	The contractor shall coordinate with its appropriate BFL, with a copy to the COR if they have questions following the case coordination meeting.									UPICs
13173.34	The contractor shall notify the appropriate BFL, with a copy to the COR, in the event that written confirmation from LE acknowledging receipt of the referral is not received.									UPICs
13173.35	The contractor shall implement any identified secondary administrative action, advise their BFL, with a copy to the COR, to determine if referral to another LE agency is appropriate, should the OIG/OI decline a case that the UPIC believes has merit.									UPICs
13173.36	The contractor shall notify its									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	BFL, with a copy to the COR, of referrals to state agencies or other organizations.									
13173.37	The contractor shall notify the BFL, with a copy to the COR, within two business days once the potential patient harm issue is discovered.									UPICs
13173.38	The contractor shall forward MAC referrals to the BFL, with a copy to the COR, that are regarding providers failing to take corrective action and continue to remain non-compliant.									UPICs
13173.39	The contractor shall contact its BFL, with a copy to the COR, to discuss the need for deleting an entry in the UCM.									UPICs
13173.40	The contractor shall send an e-mail to its BFL, with a copy to the COR, detailing the need for a UCM entry deletion.									UPICs
13173.41	The contractor shall submit an overview of the potential program									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	vulnerability, program impact, and proposed action to the BFL, with a copy to the COR, via email should the BFL need additional information.									
13173.42	The contractor shall provide the BFL, with a copy to the COR, a summary of the circumstances should they identify the need for a fraud alert.									UPICs
13173.43	The contractor shall be advised that the term "sample" has been revised to "sampling" in sections 8.4.1.3, 8.4.2, 8.4.3.2, 8.4.3.2.1, 8.4.3.2.2, 8.4.3.2.3, 8.4.4.3, 8.4.4.4.1, 8.4.4.5, 8.4.5, 8.4.7.1, and 8.4.9.1 in Chapter 8 of Pub. 100-08.									UPICs
13173.44	The contractor shall be advised that the universe is the target population that contains all claims/claim lines potentially under review and is used to construct the sampling frame.									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13173.45	The contractor shall be advised that the fact that the point estimate or the lower bound of the estimate for the total overpayment in the sampling frame may be greater than the total payment in the sampling frame is expected to occur frequently when the true error rate is high.									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. 11962, Issued: 04-21-23)

4.1 – Introduction

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The CMS Pub. 100-08, Program Integrity Manual (PIM), reflects the principles, values, and priorities of the Medicare Integrity Program (MIP). The primary principle of program integrity (PI) is to pay claims correctly. To meet this goal, Unified Program Integrity Contractors (UPICs), *Investigations Medicare Drug Integrity Contractor (I-MEDIC),* Supplemental Medical Review Contractors (SMRC) and Medicare Administrative Contractors (MACs) must ensure that Medicare pays the right amount for covered and correctly coded services rendered to eligible beneficiaries by legitimate providers. The focus of the UPICs, SMRCs and MACs shall be to ensure compliance with Medicare regulations, refer suspected fraud and abuse to our Law Enforcement (LE) partners, and/or recommend revocation of providers that are non-compliant with Medicare regulation and policies. The Centers for Medicare & Medicaid Services (CMS) follows four parallel strategies in meeting this goal:

1. Prevent fraud through effective enrollment and education of providers/suppliers and beneficiaries;

2. Encourage early detection (through, for example, the Fraud Prevention System (FPS), medical review (MR) and data analysis);

3. Coordinate closely with partners, including other UPICs, SMRCs, MACs, LE agencies, and State PI units; and

4. Enact fair and firm enforcement policies.

The UPICs shall coordinate with their Contracting Officer's Representative(s) (COR) and their Business Function Lead(s) (BFL) to fulfill all direction as described in the PIM. For all guidance and instruction described in this chapter, the UPIC shall directly contact the appropriate UPIC BFL, with a copy to the UPIC COR, for any Technical issues and/or questions (i.e. process related issues/inquiries, workload prioritization, etc.). Additionally, the UPIC shall directly contact the UPIC COR, with a copy to the appropriate UPIC BFL, for any Business issues and/or questions (i.e., level of effort concerns, funding issues, etc.).

The UPICs shall follow the PIM to the extent outlined in their respective task orders' Statement of Work (SOW). The UPICs shall only perform the functions outlined in the PIM as they pertain to their own operation. The UPICs, in partnership with CMS, shall be proactive and innovative in finding ways to enhance the performance of PIM guidelines.

For this entire chapter, any reference to UPICs shall also apply to the I-MEDIC, unless otherwise noted or identified in the Contractors' SOW. MACs shall follow the PIM in accordance with their SOW.

To facilitate understanding, the terms used in the PIM are defined in PIM Exhibit 1. The acronyms used in the PIM are listed in PIM Exhibit 23.

4.2.2.3 – Organizational Requirements

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

This section applies to UPICs and MACs, as indicated.

UPIC program integrity (PI) managers shall have sufficient authority to guide PI activities and establish, control, evaluate, and revise fraud-detection procedures to ensure their compliance with Medicare requirements.

The UPIC shall follow the requirements in its UPIC SOW for prioritizing leads. UPIC PI managers shall prioritize work coming into the UPIC to ensure that investigations with the greatest program impact and/or urgency are given the highest priority. The UPIC shall prioritize all work on an ongoing basis as new work is received.

Allegations having the greatest program impact and priority would include investigations cases involving, but not limited to:

- Patient abuse or harm
- Multi-state fraud
- High dollar amounts of potential overpayment or potential for other admin actions, e.g. payment suspensions and revocations
- Likelihood of an increase in the amount of fraud or enlargement of a pattern
- LE requests for assistance that involve responding to court-imposed deadlines
- LE requests for assistance in ongoing investigations that involve national interagency (HHS-DOJ) initiatives or projects.
- **Note:** The UPIC and MAC shall give high priority to fraud, waste, or abuse complaints made by Medicare supplemental insurers. If a referral by a Medigap insurer includes investigatory findings indicating fraud stemming from site reviews, beneficiary interviews, and/or medical record reviews, the UPIC shall 1) conduct an immediate data run to determine possible Medicare losses, and 2) refer the case to the OIG.

4.2.2.6 – Procedural Requirements

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

This section applies to UPICs and MACs, as indicated.

The MAC personnel conducting each segment of claims adjudication, MR, and professional relations functions shall be aware of their responsibility for identifying potential fraud, waste, or abuse and be familiar with internal procedures for forwarding potential fraud, waste, or abuse instances to the UPIC. Any area within the MAC (e.g., MR, enrollment, screening staff) that refers potential fraud, waste, and abuse to the UPIC shall maintain a log of all these referrals. At a minimum, the log shall include the following information: provider/physician/supplier name, beneficiary name, Health Insurance Claim Number (HICN), nature of the referral, date the referral is forwarded to the UPIC, name and contact information of the individual who made the referral, and the name of the UPIC to which the referral was made.

The MAC shall provide written procedures for personnel in various contractor functions (claims processing, MR, beneficiary services, POE, cost report audit, etc.) to help identify potential fraud situations. The MAC shall include provisions to ensure that personnel shall:

- Refer potential fraud, waste, or abuse situations promptly to the UPIC;
- Forward complaints alleging fraud through the screening staff to the UPIC;
- Maintain confidentiality of referrals to the UPIC;
- Forward to the UPIC detailed documentation of telephone or personal contacts involving fraud issues discussed with providers/suppliers or provider/supplier staff, and retain such information in individual provider/supplier files; and

The UPIC shall ensure the performance of the functions below and have written procedures for implementing these functions:

Investigations:

- Keep educational/warning correspondence with providers/suppliers and other fraud documentation concerning specific issues in individual provider/supplier files so that the UPICs are able to easily retrieve such documentation;

- Maintain documentation on the number of investigations alleging fraud, waste or abuse, the number of cases referred to the OIG/OI (and the disposition of those cases), processing time of investigations, and types of violations referred to the OIG (e.g., item or service not received, unbundling, waiver of co-payment) and;

- Conduct investigations (following a plan of action) and make the appropriate beneficiary and provider contacts.

Communications/Coordination:

- Maintain communication and information flowing between the UPIC and the MAC MR staff, and as appropriate, MAC audit staff;

- Communicate with the MAC MR staff on all findings of overutilization and coordinate with the MAC POE staff to determine what, if any, education has been provided before any PI investigation is pursued;

- Obtain and share information on health care fraud issues/fraud investigations among MACs, UPICs, CMS, and LE;

- Coordinate, attend, and actively participate in fraud-related meetings/conferences and inform, as well as, include all appropriate parties in these meetings/conferences. These meetings/conferences include, but are not limited to, health care fraud task force meetings, conference calls, and industry- specific events;

- Distribute Fraud Alerts released by CMS to their staff;

- Serve as a resource to CMS, as necessary; for example, serve as a resource to CMS on the UCM, provide ideas and feedback on Fraud Alerts and/or vulnerabilities within the Medicare or Medicaid programs;

- Report to the *BFL, with a copy to the* COR all situations that have been identified in which a provider consistently fails to comply with the provisions of the assignment agreement; and

- Coordinate and communicate with the MR units within the MACs to avoid duplication of work.

Coordination with Law Enforcement:

- Serve as a reference point for LE and other organizations and agencies to contact when they need help or information on Medicare fraud issues and do not know whom to contact;

- Hire and retain employees who are qualified to testify in a criminal and civil trial when requested by LE;

- Provide support to LE agencies for investigation of potential fraud, including those for which an initial referral to LE did not originate from the UPIC;

- Meet (in person or via telephone call) with OIG agents to discuss pending or potential cases, as necessary;

- Meet (in person or via telephone) when needed with the DOJ to enhance coordination on current or pending cases;

- Furnish all available information upon request to the OIG/OI with respect to excluded providers/suppliers requesting reinstatement;

- Notify, via e-mail, *the BFL, with a copy to the COR,* who will obtain approval or disapproval when the UPIC is asked to accompany the OIG/OI or any other LE agency onsite to a provider/supplier for the purpose of gathering evidence in a potential fraud case (e.g., executing a search warrant). However, LE must make clear the role of UPIC personnel in the proposed onsite visit. The potential harm to the case and the safety of UPIC personnel shall be thoroughly evaluated. The UPIC personnel shall properly identify themselves as UPIC employees and under no circumstances shall they represent themselves as LE personnel or special agents. Lastly, under no circumstances shall UPIC personnel accompany LE in situations in which their personal safety is in question; and

- Maintain independence from LE and do not collect evidence, i.e., request medical records or conduct interviews, at LE's request. The UPIC is expected to follow the current vetting process and the requirements of PIM Section 4.6.

Training:

- Work with the *BFL, with a copy to the COR,* to develop and organize external programs and perform training, as appropriate, for LE, ombudsmen, grantees (e.g., Senior Medicare Patrols), and other CMS health care partners (e.g., Administration on Aging, state MFCUs);

- Help to develop fraud-related outreach materials (e.g., pamphlets, brochures, videos) in cooperation with beneficiary services and/or provider relations department of the MACs for use in their training. *Prior to submission to the requesting party, the UPIC shall* submit *the* written outreach material to the *BFL, with a copy to the COR,* for clearance;

- Assist in preparing and developing fraud-related articles for MAC newsletters/bulletins. Once completed *but prior to submission to the requesting party*, the UPIC shall submit such materials to the *BFL, with a copy to the COR, for clearance*; and

- Provide resources and training for the development of existing employees and new hires.

The MACs shall ensure the performance of the functions below and have written procedures for these functions:

- Ensure no payments are made for items or services ordered, referred, or furnished by an individual or entity following the effective date of exclusion (refer to § 4.10, for exceptions);

- Ensure all instances in which an excluded individual or entity that submits claims for which payment may not be made after the effective date of the exclusion are reported to the OIG (refer to PIM, Chapter 8); and

- Ensure no payments are made to a Medicare provider/supplier that employs an excluded individual or entity.

4.2.2.8.1.1 - Coordination with the Office of Inspector General

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The UPICs shall establish regular (i.e., monthly or quarterly) teleconference meetings with Regional LE from OIG and CMS for the purpose of discussing:

- the status of referrals and immediate advisements;
- any relevant updates to previously discussed cases (i.e., contractor identified spikes in billing, change to the operational status of a provider, patient harm situations, etc.);
- data analysis projects (i.e., planned data projects, results of recently completed data projects, etc.); and
- areas of interest to CMS, OIG, or other regional partners.

Other agenda topics may include a discussion regarding areas of concern in the UPIC and/or Regional LE respective region, case/project developments (including planned provider onsite reviews to ensure the proposed activities do not negatively affect any ongoing LE efforts), and other topics. In preparation for the meeting, the UPIC shall set the agenda and prepare any additional documents or reports for the participants at least three (3) business days prior to the meeting.

However, at no time shall a referral be made as a result of discussions during these regular meetings. If OIG expresses interest, the contractor shall discuss the case with *the BFL, with a copy to the COR,* to determine if it should be added to the next case coordination meeting with CMS.

4.2.2.8.1.4 – UPIC Coordination with Other Contractors Related to the RAC Data Warehouse

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

This section applies to UPICs, RACs, MACs, CERT, and SMRC as indicated.

The CMS established the RAC Data Warehouse (RACDW) to track RAC activity and prevent conflicts between RAC reviews and other program integrity activities. The success of this mission depends on timely and accurate information reporting by the UPICs, as well as by claims processing contractors and by the RACs themselves. CMS has expanded the functionality of the RACDW to allow all contractors that perform medical review to collaborate so there is no duplication of effort.

To prevent other contractors from interference with active investigations or cases, UPICs shall enter suppressions in the RAC Data Warehouse to temporarily mark entire providers/suppliers or subsets of a provider's/supplier's claims as "off-limits" to the RACs, MACs, CERT, and SMRC. The suppression must be entered in the RACDW when the investigation is opened, but no later than 2 business days after the investigation is opened.

Individual claims that have been previously reviewed (or that are part of an extrapolated settlement universe) shall be excluded to permanently block them from repeat reviews by a RAC, MAC, CERT, or SMRC.

The RAC Data Warehouse allows users to enter suppressions on any combination of provider ID, Diagnostic Related Group (DRG), International Classification of Diseases-9/10 (ICD- 9/10) procedure code, Healthcare Common Procedure Coding System (HCPCS) code,

State, or ZIP code although CMS requires that suppressions be tailored as narrowly as possible.

UPICs shall suppress targeted procedure codes from specific providers/suppliers associated with open investigations/cases. Suppressions of one or more procedure codes across an entire geographic area may be considered in egregious situations of widespread fraud, waste and/or abuse of specific codes or types of services (e.g., infusion therapy in South Florida).

The Data Warehouse can accept suppressions on a rendering provider, supplier, or institution ID. Suppressions on referring, ordering, billing (for professional DME claims) and attending providers (institutional claims) are not currently supported.

Whether suppressing an entire provider or only a portion of a provider's claims, the UPIC shall indicate the nature of the provider being suppressed (i.e., hospital, individual physician, physician group, home health agency, etc.) in the provider type field, using the codes specified in the Data Warehouse. The UPIC shall also indicate the name of the provider being suppressed in the comment field, which can accommodate up to 256 characters.

When entering a suppression on a six-digit provider/supplier ID, the UPIC shall also enter the provider's/supplier's practice State. States are not required for NPIs, National Provider Enrollment (NPE) numbers, alphanumeric or PTANs that are other than six digits long; but six-digit PTANs potentially overlap with six-digit CMS institutional provider numbers. Having the provider/supplier state will help CMS suppression reviewers to differentiate among multiple providers/suppliers with the same ID.

Specific suppression start and end dates are also mandatory. Suppressions can extend up to three (3) years into the past and one (1) year forward from date of entry (the start date is initially fixed at 10/1/2007, which is the earliest start date that RACs can select for their reviews). Users will be notified as their suppressions approach the expiration dates and can renew them if necessary. CMS expects users to release them sooner if the underlying investigations/cases are closed.

Once a suppression is lifted or expires, UPICs are also responsible for entering any necessary exclusions. Any claims for which the UPIC has requested medical records shall be excluded to prevent re-review by a RAC.

In addition, the UPICs shall review the RACDW to determine if other contractors currently have a particular provider under review. If the provider is under review by another contractor (RAC, MAC, CERT, SMRC) the UPIC shall contact that respective contractor to determine which entity should continue to review that provider and how to handle the current medical review,
i.e. close it out or complete the medical review and then refer to the UPIC.

Below are examples of suppressions and exclusions in various circumstances: this list is not all-inclusive. The UPIC staff may need to consult with its *BFL, with a copy to the COR,* and/or CMS RAC liaison to determine the appropriate level of suppression or exclusion.

4.2.3 - Durable Medical Equipment Medicare Administrative Contractor Fraud Functions

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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

4.5 - Screening Leads

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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.

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).

4.6 - Vetting Leads with CMS

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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 *CMS via technical direction*.

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).

4.7.1 – Conducting Investigations

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The UPIC shall, unless otherwise advised by CMS, use one or more of the following investigative methods (this is not an exhaustive list):

- Screening activities as referenced in Section 4.5;
- Contact with the subject provider or ordering/referring providers via telephone or on-site visit;
- Medical record requests and reviews (as defined in PIM, chapter 3);
- Prepayment medical reviews associated with a limited claim count (i.e., 25- 50

claims) or targeted review (i.e., specific CPT codes) (as defined in PIM, chapter 3);
- Implementation of auto-denial edits; and
- Recommendation of other administrative actions (as defined in PIM chapters 3, 8, and 10) to CMS. These items will include any administrative actions identified below to be discussed during the case coordination meetings.

Additionally, the UPICs shall coordinate with LE partners prior to making contact with any provider/supplier, when it knows there is or was a LE case on the provider/supplier.

The UPIC shall review the Unified Case Management (UCM) system prior to contacting any provider/supplier to verify the following:

- There are no current or prior requests for information from LE;
- There are no other current or prior coordination activities with LE concerning the provider; and
- The CMS vetting response indicates there is no current LE activity associated with the provider/supplier.

If the UPIC identifies prior LE activity within the past 24 months, the UPIC shall communicate with the LE contact person identified in the UCM to determine if making contact with a provider/supplier will impact its case. If the UPIC is not able to identify the LE contact person in UCM, the UPIC shall consult with its BFL for further guidance. Once the UPIC contacts LE, it shall document the results of the conversation, including the date, time, name of the individual, and the specific LE agency in UCM prior to contacting the provider/supplier. If the UPIC has attempted to contact LE on multiple occasions within five (5) business days, but does not receive a response, the UPIC shall notify its *BFL, with a copy to the COR,* for CMS escalation to the appropriate LE contacts.

For any investigative activities that require approval by CMS (i.e., Payment Suspension or revocation/deactivation requests), the UPIC shall submit those requests through its current processes (i.e., via UCM) and coordinate subsequent actions with the appropriate points of contact within CMS.

After reviewing the provider's/supplier's background, specialty, and profile, the UPIC decides whether the situation involves potential fraud, waste, or abuse, or may be more accurately categorized as a billing error. For example, records might indicate that a physician has billed, in some instances, both Medicare and the beneficiary for the same service. Upon review, the UPIC may determine that, rather than attempting to be paid twice for the same service, the physician made an error in his/her billing methodology. Therefore, this error would be considered a determination of incorrect billing, rather than potential fraud, waste, or abuse involving intentional duplicate billing. If the UPIC determines that an overpayment exists solely on data analysis, the UPIC shall obtain BFL approval prior to initiating the overpayment.

4.7.2 – Identity Theft Investigations and Victimized Provider Waiver of Liability Process

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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 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.

4.7.3 - Durable Medical Equipment Medicare Investigative Functions

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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

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

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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). If the 5th business day falls on an observed holiday where either the UPIC or MAC is closed for business, documentation shall be sent on the next 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 *BFL, with a copy to the COR,* immediately.

4.7.4.2 – Reversed Denials by Administrative Law Judges on Open Cases

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

If a case is still pending at the OIG, FBI, or AUSA, and denials are reversed by an Administrative Law Judge (ALJ), the UPIC should recommend to CMS that it consider protesting the ALJ's decision to the DHHS Appeals Council, which has the authority to remand or reverse the ALJ's decision. UPICs should be aware, however, that ALJs are bound only by statutory and administrative law (federal regulations), CMS rulings, and National Coverage Determinations.

The UPIC shall consult with its *BFL, with a copy to the COR,* before initiating a protest of an ALJ's decision. They should be aware that the Appeals Council has only 60 days in which to decide whether to review an ALJ's decisions. Thus, CMS needs to protest the ALJ decision within 30 days of the decision, to allow the Appeals Council to review within the 60-day limit. The UPIC shall notify all involved parties immediately if it learns that claims/claim denials have been reversed by an ALJ in a case pending prosecution.

4.7.5 - Administrative Relief from Program Integrity Review in the Presence of a Disaster

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

This applies to the UPICs.

The UPICs shall be aware of Federal Emergency Management Agency (FEMA) declared natural disasters that occur in their jurisdiction(s). In the immediate aftermath of these occurrences, the UPICs shall assess the circumstances with each provider in declared disaster areas before pursuing investigative activities.

Due to the nature of fraud, waste and abuse that exists in the Medicare program and the potential for emerging trends specific to FEMA declared natural disasters, contractors should remain vigilant in their oversight, monitoring, and proactive/reactive analysis but follow the guidance identified below:

1) Should the contractor confirm that medical record loss resulted from this disaster to the point where administrative relief from medical review requirements is necessary to allow the provider sufficient time to retrieve copies of, or restore damaged, medical documentation, the contractors shall delay the request for medical records for a period of 60-days beginning on the date designated by FEMA/as advised by *the* COR and ending as directed by their COR. The contractors are permitted to respond to inquiries, requests, or complaints that are submitted by a provider or beneficiary during this 60-day period;

2) The contractors shall consult with their *BFL, with a copy to the COR,* on any time sensitive issues that must be resolved involving contact with a provider or beneficiary in the areas affected by FEMA declared natural disasters;

3) The contractors shall closely monitor Technical Direction Letters (TDLs) and Change Requests (CRs) issued to the MACs related to FEMA designated disaster relief efforts; and

4) The contractors are reminded to contact their COR and BFL prior to granting specific relief based on any TDL guidance or PIM requirement. Each contractor shall maintain a list of cases/investigations/complaints to which any exception is granted or applied and must include the basis (TDL or PIM reference) and the actual exception applied.

During a governmentally declared disaster, whether manmade or otherwise, the UPIC shall continue every effort to identify cases of potential fraud, waste, and abuse. If the UPIC suspects fraud of a provider/supplier who cannot furnish medical records in a timely manner

due to a disaster, the UPIC shall ensure that the provider/supplier is not attempting to harm the Medicare Trust Fund by taking an unreasonable amount of time to furnish records. The UPIC shall request and review verification documentation in all instances where fraud is suspected.

In the case of complete destruction of medical records/documentation in which backup records exist, the UPIC shall accept reproduced medical records from microfiche, microfilm, or optical disk systems that may be available in larger facilities, in lieu of the original document. In the case of complete destruction of medical records in which no backup records exist, the UPICs shall consult with its *BFL, with a copy to the COR,* to determine the appropriateness of the request to reconstruct the medical records. If the BFL determines that MR is appropriate, the UPIC shall instruct providers/suppliers to reconstruct the records as completely as possible with whatever original records can be salvaged. Providers/suppliers should note on the face sheet of the completely or partially reconstructed medical record: "This record was reconstructed because of disaster."

4.8 - Requests for Information From Outside Organizations

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

This section applies to UPICs.

Federal, state, and local LE agencies may seek beneficiary and provider/supplier information to further their investigations or prosecutions of individuals or businesses alleged to have committed health care fraud and other crimes for which medical records may be sought as evidence. When these agencies request that a UPIC disclose beneficiary records or provider/supplier information, the responsive disclosure shall comply with applicable federal law as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Business Associate provision of the UPIC's contract. Federal law will dictate whether, and how much, requested information can be disclosed. The determination regarding disclosure will be contingent on the purpose for which it is sought and whether information is sought about beneficiaries or providers/suppliers. For example, certain general information that does not include specific beneficiary identifiers may be shared with a broader community, including private insurers. The information may include that of a general nature of how fraudulent practices were detected, the actions being taken, and aggregated data showing trends and/or patterns.

The UPIC may release information, in accordance with the requirements specified in Sections A – G below, to the following organizations:

- Other UPICs;
- Qualified Independent Contractors (QICs);
- QIOs;
- State Attorneys General and State Agencies;
- MFCUs;
- OIG;
- DOJ; and
- FBI.

Requests for information from entities not listed above shall be submitted to the COR for approval, with a copy to the BFL.

In deciding to share information voluntarily or in response to outside requests, the UPIC shall carefully review each request to ensure that disclosure would not violate the requirements of the Privacy Act of 1974 (5 U.S.C. §552a) and/or the Privacy Rule (45 CFR, Parts 160 and 164) implemented under the HIPAA. Both the Privacy Act and the Privacy

Rule seek to strike a balance that allows the flow of health information needed to provide and promote high-quality health care while protecting the privacy of people who seek this care. In addition, both statutes provide individuals with the right to know with whom their personal information has been shared, necessitating the tracking of any disclosures of information by the UPIC. The UPIC shall direct questions concerning what information may be disclosed under the Privacy Act or Privacy Rule to the CMS Regional Office Freedom of Information Act /privacy coordinator. Ultimately, the authority to release information from a Privacy Act System of Records to a third-party rests with the system manager/business owner of the system of records.

The HIPAA Privacy Rule establishes national standards for the use and disclosure of individuals' health information (also called protected health information [PHI]) by organizations subject to the Privacy Rule (which are called "covered entities"). As "business associates" of CMS, UPICs are contractually required to comply with the HIPAA Privacy Rule. The Privacy Rule restricts the disclosure of any information, in any form, that can identify the recipient of medical services; unless that disclosure is expressly permitted under the Privacy Rule. Two of the circumstances in which the Privacy Rule allows disclosure are for "health oversight activities" (45 CFR §164.512(d)) and for "law enforcement purposes" (45 CFR §164.512 (f)), provided the disclosure meets all the relevant prerequisite procedural requirements in those subsections.

Generally, PHI may be disclosed to a health oversight agency (as defined in 45 CFR §164.501) for purposes of health oversight activities authorized by law, including administrative, civil, and criminal investigations necessary for appropriate oversight of the health care system (45 CFR §164.512(d)). The DOJ, through its U.S. Attorneys' Offices and its headquarters-level litigating divisions; the FBI; the HHS OIG; and other federal, state, or local enforcement agencies, are acting in the capacity of health oversight agencies when they investigate fraud against Medicare, Medicaid, or other health care insurers or programs.

The Privacy Rule also permits disclosures for other LE purposes that are not health oversight activities but involve other specified LE activities for which disclosures are permitted under HIPAA, which include a response to grand jury or administrative subpoenas and court orders, and for assistance in locating and identifying material witnesses, suspects, or fugitives. The complete list of circumstances that permit disclosures to a LE agency is detailed in 45 CFR §164.512(f). Furthermore, the Privacy Rule permits covered entities and business associates acting on their behalf to rely on the representation of public officials seeking disclosures of PHI for health oversight or LE purposes, provided that the identities of the public officials requesting the disclosure have been verified by the methods specified in the Privacy Rule (45 CFR §164.514(h)).

The Privacy Act of 1974 protects information about an individual that is collected and maintained by a federal agency in a system of records. A "record" is any item, collection, or grouping of information about an individual that is maintained by an agency. This includes, but is not limited to, information about educational background, financial transactions, medical history, criminal history, or employment history that contains a name or an identifying number, symbol, or other identifying particulars assigned to the individual. The identifying particulars can be a finger or voiceprint or a photograph. A "system of records" is any group of records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identification assigned to the individual. For example, Medicare beneficiary data used by UPICs are maintained in a CMS "system of records" covered by the Privacy Act.

Information from some systems of records may be released only if the disclosure would be consistent with "routine uses" that CMS has issued and published. Routine uses specify who may be given the information and the basis or reason for access that must exist.

Routine uses vary by the specified systems of record, and a decision concerning the applicability of a routine use lies solely in the purview of the system's manager for each system of record. In instances where information is released as a routine use, the Privacy Act and Privacy Rule remain applicable. For example, the HHS has published a routine use that permits the disclosure of personal information concerning individuals to the DOJ, as needed for the evaluation of potential violations of civil or criminal law and for detecting, discovering, investigating, litigating, addressing, or prosecuting a violation or potential violation of law, in health benefits programs administered by CMS. Refer to 63 Fed. Reg. 38414 (July 16, 1998).

The 1994 Agreement and the 2003 form letter (refer to PIM Exhibits 35 and 25 respectively) are consistent with the Privacy Act. Therefore, requests that appear on the 2003 form letter do not violate the Privacy Act. The Privacy Act of 1974 requires federal agencies that collect information on individuals that will be retrieved by the name or another unique characteristic of the individual to maintain this information in a system of records.

The Privacy Act permits disclosure of a record without the prior written consent of an individual if at least one (1) of 12 disclosure provisions apply. Two of these provisions, the "routine use" provision and/or another "law enforcement" provision, may apply to requests from the DOJ and/or the FBI.

Disclosure is permitted under the Privacy Act if a routine use exists in a system of records.

Both the Fiscal Intermediary Shared System (FISS) #8 and #10, the Multi-Carrier System (MCS), and the VIPS Medicare System (VMS) contain a routine use that permits disclosure to:

> "The Department of Justice for investigating and prosecuting violations of the Social Security Act to which criminal penalties attach, or other criminal statutes as they pertain to Social Security Act programs, for representing the Secretary, and for investigating issues of fraud by agency officers or employees, or violation of civil rights."
>
> The CMS Utilization Review Investigatory File, System No. 09-70-0527, contains a routine use that permits disclosure to "The Department of Justice for consideration of criminal prosecution or civil action."
>
> The latter routine use is more limited than the former, in that it is only for "consideration of criminal or civil action." It is important to evaluate each request based on its applicability to the specifications of the routine use.
>
> In most cases, such routine uses will permit disclosure from these systems of records; however, each request should be evaluated on an individual basis.
>
> Disclosure from other CMS systems of records is not permitted (i.e., use of such records compatible with the purpose for which the record was collected) unless a routine use exists or one (1) of the 11 other exceptions to the Privacy Act applies.
>
> The LE provision may apply to requests from the DOJ and/or the FBI. This provision permits disclosures "to another agency or to an instrumentality of any jurisdiction within or under the control of the U.S. for a civil or criminal LE activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency that maintains the record

specifying the particular portion desired and the LE activity for which the record is sought."

The LE provision may permit disclosure from any system of records if all of the criteria established in the provision are satisfied. Again, requests should be evaluated on an individual basis.

To be in full compliance with the Privacy Act, all requests must be in writing and must satisfy the requirements of the disclosure provision. However, subsequent requests for the same provider/supplier that are within the scope of the initial request do not have to be in writing. The UPICs shall refer requests that raise Privacy Act concerns and/or issues to the CORs for further consideration.

A. Requests from Private, Non-LE Agencies

Generally, UPICs may furnish information on a scheme (e.g., where it is operating or specialties involved). Neither the name of a beneficiary or suspect can be disclosed. If it is not possible to determine whether or not information may be released to an outside entity, the UPIC shall contact its COR and BFL for further guidance.

B. Requests from Other UPICs

The UPICs may furnish requested specific information concerning ongoing fraud investigations and individually identifiable PHI to any UPIC, SMRC or MAC. The UPICs, SMRCs and MACs are "business associates" of CMS under the Privacy Rule and thus are permitted to exchange information necessary to conduct health care operations. If the request concerns investigations already referred to the OIG/OI, the UPIC shall notify the OIG/OI of the RFI received from another UPIC and notify the requesting UPIC that the case has been referred to the OIG/OI.

C. RFI from QICs

When a QIC receives a request for reconsideration on a claim arising from a UPIC review determination, it shall coordinate with the MAC to obtain all records and supporting documentation that the UPIC provided to the MAC in support of the MAC's first level appeals activities (redeterminations). As necessary, the QIC may also contact the UPIC to discuss materials obtained from the MAC and/or obtain additional information to support the QIC's reconsideration activities. The QIC shall send any requests to the UPIC for additional information via electronic mail, facsimile, and/or telephone.

These requests should be minimal. The QIC shall include in its request a name, phone number, and address to which the requested information shall be sent and/or follow-up questions shall be directed. The UPIC shall document the date of the QIC's request and send the requested information within seven (7) calendar days of the date of the QIC's request. The date of the QIC's request is defined as the date the phone call was made (if a message was left, it is defined as the date the message was left), the date the facsimile was received, or the date of the e-mail request.

Note: Individually identifiable beneficiary information shall not be included in an e- mail. If a QIC identifies a situation of potential fraud, waste, and abuse, it shall immediately refer all related information to the appropriate UPIC for further investigation. Refer to PIM Exhibit 38 for QIC task orders and jurisdictions.

D. Requests from QIOs and State Survey and Certification Agencies

The UPIC may furnish requested specific information concerning ongoing fraud investigations containing personally identifiable information to the QIOs and state survey and certification agencies. The functions QIOs perform for CMS are required by law; thus the Privacy Rule permits disclosures to them. State survey and certification agencies are required by law to perform inspections, licensures, and other activities necessary for appropriate oversight of entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; thus the Privacy Rule permits disclosures to them. If the request concerns cases already referred to the OIG/OI, UPICs shall refer the requestor to the OIG/OI.

E. Requests from State Attorneys General and State Agencies

The UPIC may furnish requested specific information on ongoing fraud investigations to state Attorneys General and to state agencies. Releases of information to these entities in connection with their responsibility to investigate, prosecute, enforce, or implement a state statute, rule, or regulation may be made as a routine use under the Privacy Act of 1974, as amended; 5 USC §552a(b)(3) and 45 CFR Part 5b Appendix B (5). If individually identifiable PHI is requested, the disclosure shall comply with the Privacy Rule. (Refer to subsection H below and PIM Exhibit 25 for guidance on how requests should be structured to comply with the Privacy Rule.)

The UPIC may, at its discretion, share PIM Exhibit 25 with the requestor as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, the UPIC shall refer the requestor to the OIG/OI.

F. Requests from MFCUs

Under current Privacy Act requirements applicable to PI investigations, the UPIC may respond to requests from MFCUs for information on current investigations. Releases of information to MFCUs in connection with their responsibility to investigate, prosecute, enforce, or implement a state statute, rule or regulation may be made as a routine use under the Privacy Act of 1974, as amended; 5 USC §552a(b)(3) and 45 CFR Part 5b Appendix B (5). Refer to Subsection H below for further information regarding the Privacy Act requirements. If individually identifiable PHI is requested, the disclosure shall comply with the Privacy Rule. Refer to subsection H below and PIM Exhibit 25 for guidance on how requests should be structured to comply with the Privacy Rule.

The UPIC may, at its discretion, share PIM Exhibit 25 with the requestors as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, the UPIC shall refer the requestor to the OIG/OI.

G. Requests from the OIG/OI for Data and Other Records

The UPIC shall provide the OIG/OI with requested information and shall maintain cost information related to fulfilling these requests. An RFI shall consist of requests to run data for the OIG (including OnePI national data for suppliers and entities whose billed claims span across multiple jurisdictions), extract of records, or a request to furnish any documentation or reports (see below for requests for assistance). Such requested information may include LE requests for voluntary refund data (see section 4.2.2.8.1.3of this chapter). The UPIC shall not fulfill a request if there is a substantial impact (i.e., 40 hours or more) on the budget without prior COR approval. The UPIC shall copy the BFL on these requests for approval from the COR. These requests generally fall into one of the following categories:

Priority I – This type of request is a top priority request requiring a quick turnaround. The information is essential to the prosecution of a provider/supplier. The request shall be completed with the utmost urgency. Priority I requests shall be fulfilled within thirty (30) calendar days when the information or material is contained in the UPIC's files unless an exception exists as described below.

The UPIC shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested within 30 calendar days or sooner, when possible. The MAC shall furnish requested information to the UPIC within 20 calendar days of receipt of the request from the UPIC unless there are extenuating circumstances. The MAC shall communicate any extenuating circumstances to the UPIC and the MAC COR as soon as they become known. The UPIC shall communicate these extenuating circumstances to its COR.

Periodically, there are instances in which the OIG/OI is in need of the requested information in a shorter timeframe than (30) calendar days. To account for these instances, the UPIC and MAC may add language to their Joint Operating Agreement (JOA) that allows for a shorter timeframe for the MAC to furnish the requested information (i.e. 48 hours, 72, hours, etc.). In these instances, the OIG/OI must provide justification as to why the requested information is needed in a shorter timeframe than the standard Priority I request.

Otherwise, the UPIC shall follow-up with other contractors, and document all communication with contractors to ensure the request is not delayed unnecessarily. If extenuating circumstances exist that prevent the UPIC from meeting the thirty (30) day timeframe, the UPIC shall inform the requestor what, if any, portion of the request can be provided within thirty (30) days. The UPIC shall notify the requesting office as soon as possible (but not later than thirty (30) days) after receiving the request. The UPIC shall also document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

Priority II – This type of request is less critical than a Priority I request. An RFI shall consist of requests to run data for the OIG, extract of records, or a request to furnish any documentation or reports (see below for requests for assistance). Based on the review of its available resources, the UPIC shall inform the requestor what, if any, portion of the request can be provided. The UPIC shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The UPICs shall respond to such requests within 45 calendar days or sooner, when possible. The MAC shall furnish requested information to the UPIC within 30 calendar days of receipt of the request from the UPIC unless there are extenuating circumstances. The MAC shall communicate any extenuating circumstances to the UPIC and the MAC COR as soon as they become known. The UPIC shall communicate these extenuating circumstances to its COR. The UPIC shall follow-up with other contractors, and document all communication with contractors to ensure the request is not delayed unnecessarily. If extenuating circumstances exist that prevent the UPIC from meeting the 45-day timeframe, the UPIC shall inform the requestor what, if any, portion of the request can be provided within 45 calendar days. The UPIC shall notify the requesting office as soon as possible (but not later than 45 calendar days) after receiving the request. The UPIC shall also document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

Request for Assistance (RFA) – An LE RFA is a type of RFI and shall consist of any LE requests that do not include running data and reports but include requests such as the review and interpretation of medical records/medical documentation, interpretation of policies, and reviewing cost reports. The timeframes for RFIs specified in Priority I and II do not apply to RFAs. Due dates shall be negotiated with the requesting entity and documented

appropriately along with the reasons for not meeting the agreed upon timeframes. The UPIC shall contact the COR if an agreement cannot be reached on the timeframe for completion. Disclosures of information to the OIG shall comply with the Privacy Rule and Privacy Act. When the OIG makes a data request, the UPIC shall track these requests and document the following: (1) nature/purpose of the disclosure (cite a specific investigation and have a general description); (2) what information was disclosed; and (3) the name of the individual and the agency. The aforementioned information shall be maintained in a secure file and made available to CMS upon request through a secure means.

The CMS has established a level of effort limit of 40 hours for any individual request for support RFIs and RFAs. If the estimated level of effort to fulfill any one request is likely to meet or exceed this figure, the UPIC shall contact its COR for approval to proceed. A CMS representative will contact the OIG to explore the feasibility of other data search and/or production options.

The UPIC shall obtain approval from the COR regarding requests started by the UPIC that it subsequently anticipates will exceed that 40-hour level of effort. The UPIC shall not exceed the 40-hour level of effort until it receives COR approval.

H. Procedures for Sharing CMS Data with the DOJ

In April 1994, CMS entered into an interagency agreement with the OIG and the DOJ that permitted UPICs to furnish information that previously had to be routed through OIG (refer to PIM Exhibit 16) including data related to the investigation of health care fraud matters directly to the DOJ that previously had to be routed through OIG (refer to PIM Exhibit 35). This agreement was supplemented on April 11, 2003, when in order to comply with the HIPAA Privacy Rule, the DOJ issued procedures, guidance, and a form letter for obtaining information (refer to PIM Exhibit 25). CMS and the DOJ have agreed that the DOJ's requests for individually identifiable health information will follow the procedures that appear on the form letter (refer to PIM Exhibit 25). The 2003 form letter must be customized to each request. The form letter mechanism is not applicable to requests regarding Medicare Secondary Payer (MSP) information, unless the DOJ requestor indicates he or she is pursuing an MSP fraud matter.

The PIM Exhibit 25 contains the entire document issued by the DOJ on April 11, 2003. The UPIC shall familiarize itself with the instructions contained in this document. Data requests for individually identifiable PHI related to the investigation of health care fraud matters will come directly from those individuals at the FBI or the DOJ who are involved in the work of the health care oversight agency (including, for example, FBI agents, Assistant U.S. Attorneys, or designees such as analysts, auditors, investigators, or paralegals). For example, data may be sought to assess allegations of fraud; examine billing patterns; ascertain dollar losses to the Medicare program for a procedure, service, or time period; determine the nature and extent of a provider's/supplier's voluntary refund(s); or conduct a random sample of claims for MR. The LE agency should begin by consulting with the appropriate Medicare contractor (usually the UPIC, but possibly also the MAC) or CMS to discuss the purpose or goal of the data request. Requests for cost report audits and/or associated documents shall be referred directly to the appropriate MAC.

The UPIC shall discuss the information needed by the DOJ and determine the most efficient and timely way to provide the information. When feasible, the UPIC shall use statistical systems to inform the DOJ of the amount of dollars associated with its investigation, and the probable number of claims to expect from a claims-level data run. The UPIC shall obtain and transmit relevant statistical information to the DOJ (as soon as possible but no later than five (5) calendar days). The UPIC shall advise the DOJ of the anticipated volume, format, and media to be used (or alternative options, if any) for fulfilling a request for claims data.

The UPIC shall provide the DOJ with the requested information and shall maintain cost information related to fulfilling these requests. An RFI shall consist of requests to run data for the DOJ (including national data for suppliers and entities whose claims billings span across multiple jurisdictions), extract of records, or a request to furnish any documentation or reports.

The DOJ will confirm whether a request for claims data remains necessary based on the results of statistical analysis. If so, the DOJ and CMS will discuss issues involving the infrastructure and data expertise necessary to analyze and further process the data that CMS will provide to the DOJ.

If the DOJ confirms that claims data are necessary, the DOJ will prepare a formal request letter to the UPIC with existing DOJ guidance (Exhibit 25).

The UPIC shall provide data to the DOJ, when feasible, in a format to be agreed upon by the UPIC and the DOJ. Expected time frames for fulfilling the DOJ claims-level data requests will depend on the respective source(s) and duration of time for which data are sought, with the exception of emergency requests, which require coordination with Headquarters, the DOJ, and CMS staff. These are as follows:

Emergency Requests - Require coordination with Headquarters DOJ and CMS staff.

Priority I – This type of request is a top priority request requiring a quick turnaround. The information is essential to the prosecution of a provider/supplier. A RFI shall consist of requests to run data for the DOJ, extract of records, or a request to furnish any documentation or reports (see below for requests for assistance). The request shall be completed with the utmost urgency. Priority I requests shall be fulfilled within thirty (30) calendar days when the information or material is contained in the UPIC's files unless an exception exists as described below.

The UPIC shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested within 30 calendar days or sooner, when possible. The MAC shall furnish requested information to the UPIC within 20 calendar days of receipt of the request from the UPIC unless there are extenuating circumstances. The MAC shall communicate any extenuating circumstances to the UPIC and the MAC COR as soon as they become known. The UPIC shall communicate these extenuating circumstances to its COR.

Periodically, there are instances in which the DOJ is in need of the requested information in a shorter timeframe than (30) calendar days. To account for these instances, the UPIC and MAC may add language to their JOA that allows for a shorter timeframe for the MAC to furnish the requested information (i.e. 48 hours, 72, hours, etc.). In these instances, the DOJ must provide justification as to why the requested information is needed in a shorter timeframe than the standard Priority I request.

Otherwise, the UPIC shall follow-up with other contractors, and document all communication with contractors to ensure the request is not delayed unnecessarily. If extenuating circumstances exist that prevent the UPIC from meeting the thirty (30) day timeframe, the UPIC shall inform the requestor what, if any, portion of the request can be provided within thirty (30) days. The UPIC shall notify the requesting office as soon as possible (but not later than thirty (30) days) after receiving the request. The UPIC shall also document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

Priority II Requests – This type of request is less critical than a Priority I request. An RFI shall consist of requests to run data for the DOJ, extract of records, or a request to furnish any documentation or reports (see below for requests for assistance). Based on the review of its available resources, the UPIC shall inform the requestor what, if any, portion of the request can be provided. The UPIC shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The UPIC shall respond to such requests within 45 calendar days or sooner, when possible. The MAC shall furnish requested information to the UPIC within 30 calendar days of receipt of the request from the UPIC unless there are extenuating circumstances. The MAC shall communicate any extenuating circumstances to the UPIC and the MAC COR as soon as they become known. The UPIC shall communicate these extenuating circumstances to its COR. The UPIC shall follow-up with other contractors, and document all communication with contractors to ensure the request is not delayed unnecessarily. If extenuating circumstances exist that prevent the UPIC from meeting the 45-day timeframe, the UPIC shall inform the requestor what, if any, portion of the request can be provided within 45 calendar days. The UPIC shall notify the requesting office as soon as possible (but not later than 45 calendar days) after receiving the request. The UPIC shall also document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

RFA – A LE RFA is a type of RFI and shall consist of any LE requests that do not include running data and reports, but include requests such as the review and interpretation of medical records/medical documentation, interpretation of policies, and reviewing cost reports. The timeframes for RFIs specified in Priority I and II do not apply to RFAs. Due dates shall be negotiated with the requesting entity and documented appropriately along with the reasons for not meeting the agreed upon timeframes. The UPIC shall contact the COR if an agreement cannot be reached on the timeframe for completion.

Disclosures of information to the DOJ shall comply with the Privacy Rule and Privacy Act. When DOJ makes a data request, the UPIC shall track these requests and document the following: (1) nature/purpose of the disclosure (cite a specific investigation and have a general description); (2) what information was disclosed; and (3) name of the individual and the agency. The aforementioned information shall be maintained in a secure file and made available to CMS upon request through a secure means.

The CMS has established a level of effort limit of 40 hours for any individual request for support (RFIs and RFAs). If the estimated level of effort to fulfill any one request is likely to meet or exceed this figure, the PI contractor shall contact its COR for approval to proceed. A CMS representative will contact the OIG to explore the feasibility of other data search and/or production options.

The UPIC shall obtain approval from the COR regarding requests started by the UPIC that it subsequently anticipates will exceed that 40-hour level of effort. The UPIC shall not exceed the 40-hour level of effort until it receives COR approval.

I. Duplicate/Similar RFIs

If the UPIC receives duplicate or similar RFIs from OIG and DOJ, the UPIC shall notify the requestors. If the requestors are not willing to share the information, the UPIC shall ask *the BFL, with a copy to the COR,* for assistance.

J. Reporting Requirements for the DOJ and OIG

For each data request received from the DOJ and the OIG, the UPIC shall maintain a record that includes:

- The name and organization of the requestor;
- The date of the written request (all requests must be in writing);
- The nature of the request;
- Any subsequent modifications to the request;
- The cost of furnishing a response to each request; and
- The date completed.

K. LE Requests for MR

The UPIC shall not send document request letters or go onsite to providers/suppliers to obtain medical records solely at the direction of LE. However, if LE furnishes the medical records and requests the UPIC to review and interpret medical records for them, the UPIC shall require LE to put this request in writing. At a minimum, this request shall include the following information:

- The nature of the request (e.g., what type of service is in question, what is the allegation, and what should the reviewer be looking for in the medical record);
- The volume of records furnished;
- The due date; and
- The format required for response.

The UPIC shall present the written request to the COR, and copy its BFL prior to fulfilling the request. Each written request will be considered on a case-by-case basis to determine whether the UPIC has resources to fulfill the request. If so, the request may be approved.

If LE requests the UPIC to perform MR on all investigations the UPIC initiates, the UPIC shall perform MR if it deems it necessary, on a case-by-case basis. The UPIC shall inform the COR and copy its BFL of such requests by LE.

It is recommended that the MR Manager be included in the evaluation of the Request for MR to provide input as to:

- The resources required;
- The resources available; and
- Recommended revisions to the volume of records to be reviewed that will still provide a statistically and clinically significant sample to support the purpose or allegation in the request and provide for the best use of MR resources.

L. LE Requests for UPIC Audits of Medicare Provider Cost Reports Relating to Fraud

If LE requests the UPIC to perform an audit of a Medicare provider's cost report for fraud, the UPIC shall consult with the MAC to inquire if an audit of the cost report has already been performed. The UPIC shall also consult with the COR and BFL. The UPIC shall provide its COR and copy its BFL with the basis for the LE request and a detailed cost estimate to complete the audit. If the COR approves the audit, the UPIC shall perform the audit within the timeframe and cost agreed upon with LE.

M. Requests from LE for Information Crossing Several UPIC Jurisdictions

If a UPIC receives a RFI from LE that crosses several UPIC zones, the UPIC shall contact its *BFL, with a copy to the COR*. In the event that multiple zones are providing information

in connection with the request, each UPIC shall enter a separate entry into the UCM as described in Section 4.12 of this chapter. The BFL may assign a lead UPIC to process these requests that will coordinate with the other UPICs to obtain the necessary data and consolidate the information into one comprehensive response for the requestor. The lead UPIC may be the UPIC that initially received the request; however, the nature of the RFI should be considered when assigning a lead UPIC.

4.8.1 – Reversed Denials by Administrative Law Judges on Open Cases

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

If a case is still pending at the OIG, FBI, or AUSA, and denials are reversed by an Administrative Law Judge (ALJ), the UPIC should recommend to CMS that it consider protesting the ALJ's decision to the DHHS Appeals Council, which has the authority to remand or reverse the ALJ's decision. UPICs should be aware, however, that ALJs are bound only by statutory and administrative law (federal regulations), CMS rulings, and National Coverage Determinations.

The UPIC shall consult with its *BFL, with a copy to the COR,* before initiating a protest of an ALJ's decision. They should be aware that the Appeals Council has only 60 days in which to decide whether to review an ALJ's decisions. Thus, CMS needs to protest the ALJ decision within 30 days of the decision, to allow the Appeals Council to review within the 60-day limit. The UPIC shall notify all involved parties immediately if it learns that claims/claim denials have been reversed by an ALJ in a case pending prosecution.

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

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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) calendar 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 calendar 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 calendar 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 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 QIC. If the UPIC receives a notice of hearing, the UPIC shall contact the 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 *BFL, with a copy to the COR,* immediately.

4.9.1 - Immediate Advisements to the OIG/OI

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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

- Indications of UPIC or MAC employee fraud
- Allegations of kickbacks or bribes, discounts, rebates, and other reductions in price
- Allegations of a crime committed by a federal or state employee in the execution of their duties
- Indications of fraud by a third-party insurer that is primary to Medicare
- Confirmation of forged documentation during the course of an investigation, include, but is not limited to:
    - o identification of forged documents through medical review; and/or
    - o attestation from provider confirming forged documentation.
- Allegations and subsequent verification of services not rendered as a result of any of the following:
    - o medical review findings;
    - o interviews or attestations from a minimum of three (3) beneficiaries indicating that they did not receive services; and/or
    - o attestations from referring/ordering providers indicating they did not refer/order a service (e.g., confirmation of no relationship with the beneficiary prior to service, or confirmed impossible day billings).
- Confirmed complaints from current or former employees that indicate the provider in question inappropriately billed Medicare for all or a majority of its services. Confirmation would be required though one of the following:
    - o minimum of three (3) beneficiary interviews confirming the inappropriate billing;
    - o provider attestation(s) confirming the inappropriate billing; or
    - o medical review findings.
- Confirmation of beneficiary recruitment into potentially fraudulent schemes and/or provider participation (e.g., telemarketing or solicitation schemes);
- Substantiated identity theft of a provider's Medicare number, a beneficiary's Medicare number, or selling or sharing of beneficiary lists;
- Confirmed indication of patient harm (e.g., through medical review findings or confirmation of issues identified during an onsite visit or interviews with providers or beneficiaries).
- Indication of provider/supplier fraud related to national emergency, pandemic, etc.
    - o Should an IA of this nature be identified, the UPIC shall notify their BFL to determine if the IA should be forwarded to a specific OIG/OI point-of-contact.

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

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

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

Once the criteria for an IA are met, the UPIC shall notify the OIG/OI via phone or email to determine if a formal IA referral should be sent to the OIG/OI. If the IA is related to a provider/supplier that spans multiple jurisdictions, the UPIC shall notify any impacted UPIC and/or I-MEDIC Program Directors of the potential IA, allegation, and IA criteria.

The UPIC shall document this communication in UCM. The UPIC shall also send notification to its *appropriate BFL, with a copy to the COR,* of the potential IA. If the UPIC does not receive a response from the OIG/OI within two (2) business days (5 business days for the I- MEDIC), it shall notify its *appropriate BFL, with a copy to the COR,* and await further instructions. If the OIG/OI confirms that a formal IA should be sent, the UPIC shall provide all available documentation, including billed/paid amounts for the YTD and the previous year, to the OIG/OI within four (4) business days of receiving the response from OIG/OI. Upon submission of the IA to the OIG/OI, the UPIC shall request written and/or email confirmation from the OIG/OI acknowledging receipt of the IA. Simultaneously, the UPIC shall notify the CMS identified Strike Force points of contacts, if the notification includes providers/suppliers located within a Strike Force jurisdiction. Additionally, the UPIC shall notify and send a copy of the IA to its COR/BFL and the case coordination team, at CPIMCCNotifications@cms.hhs.gov, the same day the advisement is made to OIG/OI. In this notification to CMS, the UPIC shall advise if it has any other potential administrative actions it may want to pursue related to the provider(s)/supplier(s). The provider(s)/supplier(s) identified in an accepted IA shall be added to the UPIC's next scheduled case coordination meeting.

If the OIG/OI determines that a formal IA is not needed, the UPIC shall advise its *appropriate BFL, with a copy to the COR,* and immediately continue its investigation. In instances where an IA is related to a Plan employee whistleblower, the I-MEDIC does not have to notify the case coordination team of the IA nor does the IA have to be discussed at a case coordination meeting. Rather, the I-MEDIC shall close the complaint upon acceptance and/or declination of the IA due to these complaint types being outside of the I-MEDIC's SOW.

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

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

If the OIG/OI declines or accepts the IA, the UPIC shall document the decision in UCM and follow the processes described in Chapter 4, § 4.5, 4.6, and 4.7 of the PIM, unless otherwise directed by CMS.

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

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

4.9.2 - Referral of Cases to the OIG/OI

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The UPIC shall identify cases of potential fraud and shall make referrals of such cases, as appropriate, to the OIG/OI, regardless of dollar thresholds or subject matter. Matters shall be referred when the UPIC has documented allegations including, but not limited to, a provider, beneficiary, supplier, or other subject, a) engaged in a pattern of improper billing, b) submitted improper claims with suspected knowledge of their falsity or c) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity.

If the UPIC believes a case should be referred to LE, the UPIC shall discuss the matter with its BFL. If the BFL agrees that referral to LE is appropriate, the UPIC shall update the UCM appropriately to ensure the provider/supplier is included in the next case coordination meeting discussion for final approval. If it is determined an investigation should be referred to LE, the UPIC shall refer the matter to the designated OIG/OI Special Agents-in-Charge (SAC), Department of Justice Assistant United States Trial Attorneys, or other parties identified during the case coordination discussion. In such instances, the UPIC shall make immediate referrals to the designated parties within seven (7) calendar days, unless otherwise specified by its BFL.

Referrals to LE shall include all applicable information that the UPIC has obtained through its investigation at the time of the referral. The UPIC shall utilize the "LE Referral Template" available in PIM Exhibit 16.1 Additionally, if the referral is related to a multi-jurisdiction or national provider/supplier, the UPIC shall coordinate and collect all applicable investigative information from the other UPICs that have an open investigation on that same provider/supplier. The UPIC shall then send one comprehensive referral with all the UPICs' investigative findings to LE. Once the referral package is complete, the UPIC shall submit the referral to LE and copy its COR and BFL. Upon submission of the referral to LE, the UPIC shall request written and/or email confirmation from LE acknowledging receipt of the referral. UCM shall be updated with the date the referral was sent, the name of the agent acknowledging receipt of the referral, and the date of receipt. In the event that written confirmation is not received, the UPIC shall notify the *appropriate BFL, with a copy to the COR*.

As previously instructed, the UPIC shall continue to refrain from implementing any additional administrative actions against the provider/supplier without CMS approval during the 60-day window OIG/OI and/or DOJ has to respond to the referral.

If OIG/OI and/or DOJ declines the case, the UPIC shall notify its COR and respective CPI points of contact within two (2) business days in order to move forward with the secondary administrative actions identified during the case coordination meeting.

Following this notice, the UPIC shall work with its respective BFL or suspension team member on developing the appropriate documentation for the designated secondary actions.

Regarding LE Referrals that are declined and/or returned to the I-MEDIC to take appropriate administrative action to the extent possible, should there be an outstanding overpayment that the Medicare Part C Plan Sponsor(s) could develop, upon receipt of LE's Referral declination/return, the I-MEDIC shall notify the appropriate Medicare Part C Plan Sponsor(s) of the status of the LE Referral and the outstanding overpayment, and advise the Medicare Part C Plan Sponsor(s) to move forward with the overpayment recovery efforts.

This notification shall take place within five (5) business days upon receipt of the declination/return of the LE Referral. In addition, the I-MEDIC shall document this communication in the UCM REF record, indicating the date of the LE Referral declination/return, outstanding overpayment amount, if appropriate. The I-MEDIC shall also document the Medicare Part C Plan Sponsors impacted, the date the notification was issued to the Medicare Part C Plan Sponsors, as well as the point-of-contact at the Medicare Part C Plan Sponsor(s) who received the notification. Upon submission of this notification to the Medicare Part C Plan Sponsor(s), the I-MEDIC shall close the REF record as required.

4.9.2.2 - Take Administrative Action on Cases Referred to and Declined/Returned by OIG/OI

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The UPICs take immediate action to implement appropriate administrative remedies, including the suspension or denial of payments, and the recovery of overpayments (see PIM, chapter 3). Because the case has been rejected by LE, UPICs shall consult with the BFL or Suspension SME concerning the imposition of suspension. They pursue administrative and/or civil sanctions by OIG where LE has declined a case.

4.9.3 - Referral to Other Law Enforcement Agencies

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

If the OIG/OI declines a case that the UPIC believes has merit, the UPIC shall first implement any identified secondary administrative action, and then advise their *BFL, with a copy to the COR,* to determine if referral to another law enforcement agency, such as the FBI, DEA, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), RRB/OIG, and/or MFCU, is appropriate. The UPIC must receive BFL approval prior to submitting a referral to another law enforcement agency, of which the UPIC shall document in the UCM.

4.9.4.1 - Referral to State Agencies or Other Organizations

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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

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

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

The UPIC shall notify its *BFL, with a copy to the COR,* of these referrals.

4.9.4.2 - UPICs and QIOs

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

Communication with the QIO is essential to discuss the potential impact of efforts to prevent abuse, as well as ensure efforts are made to improve quality of care and access to such care.

If potential patient harm is discovered during the course of screening a lead or through the investigation process, the UPIC shall refer those instances to the QIO, state medical board, or state licensing agency. In addition to making the appropriate referrals, the UPIC shall notify the *BFL, with a copy to the COR,* within two (2) business days once the potential patient harm issue is discovered.

If the UPIC refers a provider to the State licensing agency or medical society (i.e., those referrals that need immediate response from the State licensing agency), the UPIC shall also send a copy of the referral to the QIO.

If a claim has been reviewed by the QIO, the decision made is final and binding on CMS, and the specific decision rendered by the QIO shall not be overturned by the UPIC.

4.11.6.1 - Referral Process to CMS

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

Compliance is promoted through both administrative and formal legal actions. Administrative compliance action shall first be attempted by MACs through education and warning letters that request the provider to comply with Medicare's rules and regulations. If the provider fails to take corrective action and continues to remain non- compliant, the MAC shall make a referral to the UPIC who shall forward it to the *BFL, with a copy to the COR*.

It is important for MACs to promote program compliance in their respective jurisdictions. The MACs shall ensure that all materials presented to providers through education, published bulletins, or written communication are clear and concise and accurately represent the facts of compliance versus non-compliance. Providers shall also be allowed the opportunity to present additional facts that may represent mitigating circumstances.

UPICs shall consider this information in an objective manner before proceeding with a CMP referral to CMS.

When a UPIC elects to make a CMP referral to CMS, the initial referral package shall consist of a brief overview of the case; supportive documentation is not required at such time. The initial referral package shall consist of:

1. Identification of the provider, including the provider's name, address, date of birth, Social Security number, Medicare identification number(s), and medical specialty. If the provider is an entity, include the names of its applicable owners, officers, and directors.

2. Identification of the CMP authorities to be considered (use the authorities identified in PIM Chapter 4, §4.11.5).

3. Identification of any applicable Medicare manual provisions.

4. A brief description of how the violations identified above were discovered, and the volume of violations identified.

5. Total overpayments due the program or the beneficiary(ies), respectively.

6. A brief chronological listing of events depicting communication (oral and written) between the MAC and the provider.

7. A brief chronological listing of bulletins addressing the non-compliant area (starting with the bulletin released immediately prior to the first incident of non-compliance by the provider).

8. Any additional information that may be of value to support the referral.

9. The name and phone number of contacts at the UPIC.

Upon receipt of the above information, CMS staff will review the materials and may conduct follow-up discussions with the UPIC regarding the referral. Typically, within 90 days of receipt of the referral, CMS will notify the UPIC of its decision to accept or decline the referral.

If CMS declines the referral, the UPIC shall communicate this to the MAC to continue in their efforts to educate and promote compliance by the provider. The UPIC shall also consider other (less severe) administrative remedies, which, at a minimum, may include revocation of assignment privileges, establishing prepayment or postpayment medical reviews, and referral of situations to state licensing boards or medical/professional societies, where applicable. In all situations where inappropriate Medicare payments have been identified, MACs shall initiate the appropriate steps for recovery.

If CMS accepts the referral, the UPIC shall provide any supportive documentation that may be requested, and be able to clarify any issues regarding the data in the case file or UPIC and MAC processes.

4.12.8 - Deleting Entries in the UCM

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

Entries can be deleted from the UCM only by users with the system administrator designation. The UPIC shall contact its *BFL, with a copy to the COR,* to discuss the need for deleting an entry. If the BFLs agree that the entry should be deleted, the UCM system administrator has the ability to delete any entries. To initiate any deletions, the UPIC shall send an e-mail to its *BFL, with a copy to the COR,* detailing the need for the entry deletion. The BFL will then forward the issue to the UCM SME, who will be responsible for coordinating the deletion of the entry.

4.13 - Vulnerabilities

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

This section applies to UPICs and SMRCs.

Program vulnerabilities are identified flaws or weaknesses in policy and/or regulatory authority that increases the likelihood of significant inappropriate payments being made to a

broad provider/supplier population. Program vulnerabilities can be identified through a variety of sources such as the Chief Financial Officer's audit, Fraud Alerts, the GAO, the OIG, data driven studies, and UPIC and Medicare contractor operations.

Program Integrity concerns are issues CPI and/or the UPICs/SMRCs have identified through their own analysis and have the ability to mitigate through existing operations. Examples of PI concerns include, but are not limited to: routine changes and implementation of new billing codes (i.e. ICD-10, HCPCs, CPT codes, etc.) that may lead to questionable billing practices, reports/complaints of a potential fraud schemes that can be addressed in CMS regulations or policy guidance, or identified concerns and significant mitigating changes to enrollment processes.

The UPICs and SMRC shall discuss potential program vulnerabilities with the BFL(s) during the established recurring workload meetings. Program vulnerabilities should be submitted sooner if the UPIC/SMRC believes it requires immediate consideration. The BFL will validate the lead to determine whether the potential issue is a program vulnerability, a PI Concern, or another type of issue that may need to be addressed. Should the BFL need additional information, the UPIC shall submit an overview of the potential program vulnerability, program impact, and proposed action to the *BFL, with a copy to the COR,* via email.

Should the BFL(s) agree that the identified issue is a program vulnerability, the UPIC/SMRC shall submit the proposed program vulnerability to the vulnerability mailbox at CPIVulnerabilityIntake@cms.hhs.gov, using the Vulnerability Template.

Additionally, all program vulnerabilities that are submitted to the mailbox shall be documented in the UPIC/SMRC program vulnerability report. If the UPIC/SMRC believes the proposed program vulnerability has potential Medicaid impact, the UPIC/SMRC shall document this in the submission to the vulnerability mailbox.

Should the BFL(s) determine that the identified issue is a PI concern, the BFL(s) shall advise the UPIC/SMRC to mitigate the concern through its existing operations. Issues not considered to be program vulnerabilities or PI concerns will be addressed on a case by case basis.

Vulnerability Template Date Submitted:

Submitted by:

Name:
Organization:
Phone:
Email:

Vulnerability

Vulnerability Title:

Provider Type (if applicable):

Vulnerability Description:

Risk Factors (specific conditions, drivers, and/or actions that likely cause the vulnerability or increase the chances of it occurring):

* Be as specific as possible about what the root cause(s) of the vulnerability may be. This field provides detail that may be used to ultimately help “solve the problem” and mitigate the vulnerability.

For the below, provide risk assessment point valuation and provide a written justification for each (This is not required but will greatly assist in the vulnerability process).

Likelihood (Likelihood for the identified vulnerability. Provide 1-2 sentences behind the reasoning for selecting this level of likelihood for the vulnerability):

4 -- Almost Certain (>=75% likelihood to occur) 3 -- Likely (>=50% - <75% likelihood to occur)
2 -- Possible (>=25% - <50% likelihood to occur) 1 -- Unlikely (<25% likelihood to occur)

Patient Harm (Provide 1-2 sentences behind the reasoning for selecting this level of likelihood for the vulnerability):

4 -- Life Threatening 3 -- Significant
2 -- Minimal 1 -- No harm

Financial Impact (Provide 1-2 sentences behind the reasoning for selecting this level of financial impact for the vulnerability):

4 -- Greater than $200m (>=$200 million)
3 -- $100m - $200m (>=$100 million <$200 million) 2 -- $10m - $100m (>=$10 million <=$100 million) 1 -- Less than $10m (<$10 million)

Breadth (Provide 1-2 sentences behind the reasoning for selecting this level of breadth for the vulnerability):

4 -- National
3 -- Regional
2 -- Pocketed
1 -- Isolated

Existing Controls (Provide current projects or activities that are underway to address the risk factor):

Suggested Mitigation Activities (Suggestions for action items (i.e. key results) that may help to mitigate the risk factor(s):

Source (i.e. person/organization that first identified it):

FPS Model-Related (Y/N):

* If yes, simultaneously report the information consistent with requirements of the FPS.

Attachments (If applicable, upload document(s), such as Office of Inspector General reports or relevant data that can provide additional information or context on the vulnerability being reported):

4.14 - Fraud Alerts

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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 and supplied to the UPICs in the UCM.

Medicare Program Integrity Manual

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

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(Rev. 11962, Issued: 04-21-23)

Transmittals for Chapter 8

8.4.1.3 - Steps for Conducting Statistical Sampling

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The major steps in conducting statistical sampling are --

(1) Identifying the provider/supplier;
(2) Identifying the period to be reviewed;
(3) Defining the universe (target population) and the sampling unit, and constructing the sampling frame;
(4) Assessing the distribution of the paid amounts in the *sampling* frame to determine the *sampling* design; it is very likely that the distribution of the overpayments will not be normal. However, there are many sampling methodologies (for example, use of the Central Limit Theorem) that may be used to accommodate non-normal distributions. The statistician should state the assumptions being made about the distribution and explain the sampling methodology selected as a result of that distribution.
(5) Performing the appropriate assessment(s) to determine whether the sample size is appropriate for the statistical analyses used, and identifying, relative to the sample size used, the corresponding confidence interval;
(6) Designing the sampling plan and selecting the sample from the sampling frame;
(7) Examining each of the sampling units and determining if there was an overpayment or an underpayment; and
(8) Estimating the overpayment. When an overpayment has been determined to exist, the contractor shall follow applicable instructions for notification and collection of the overpayment, unless otherwise directed by CMS.

For each step, the contractor shall provide complete and clear documentation sufficient to explain the action(s) taken in the step and to replicate, if needed, the statistical sampling.

8.4.2 - Probability Sampling

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

Regardless of the method of sample selection used, the contractor shall follow a procedure that results in a probability sample. For a procedure to be classified as probability sampling, the following two features must apply:

- It must be possible, in principle, to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe. Although only one sample will be selected, each distinct sample of the set has a known probability of selection. It is not necessary to actually carry out the enumeration or calculate the probabilities. All that is required is that one could, in principle, write down the samples, the sampling units contained therein, and the relevant probabilities; and

- Each sampling unit in each distinct possible sample must have a known probability of selection. In the case of statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.

Once a procedure and design that satisfies these above properties has been selected, execution of the probability sampling may occur. If a particular probability *sampling* design is properly executed, i.e., defining the universe, the *sampling* frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample or that the resulting estimates are “not

statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always "valid." However, because of differences in the choice of a design, the level of available resources, and the method of estimation, some procedures lead to higher precision (smaller confidence intervals) than other methods. A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment as is discussed below.

8.4.3.2 - Defining the Universe, the Sampling Unit, and the Sampling Frame

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The universe is the target population that *contains* all claims/claim lines potentially under review and is used to construct the sampling frame.

The sampling frame lists all sampling units which may be selected by the statistical sampling software, and further refines the review criteria from the claims/claim lines listed in the universe. The sampling unit may be the claim line, or may be a higher-level unit such as:

1. The claim/claim number, or
2. A cluster of claims/claim lines associated with a patient, or
3. A cluster of claims/claim lines associated with a treatment "day," or
4. Any other sampling unit appropriate for the issue under review.

The auditor may refine the selection criteria during the construction of the sampling frame, for example:

1. Excluding claims/claim lines that have been subject to a prior review, or
2. Excluding claims/claim lines for which there was no payment, or
3. Excluding claims/claim lines which cannot be assigned to a *sampling* unit due to missing information.

The extrapolation estimate of total overpayments is an estimate of total overpayment for sampling units in the sampling frame.

All information needed to recreate the *sampling* frame and sample shall be included in the case documentation.

Other approaches to constructing the universe and *sampling* frame are possible depending on the specific circumstances. One possibility is that the *sampling* frame may be created first (for example, a list of beneficiaries) and then the universe corresponding to the *sampling* frame may be constructed by querying claims history for the matching claims. Regardless of the process that is followed, the documentation in the case file must include a list of all *sampling* units in the *sampling* frame, all the universe elements that are incorporated into those *sampling* units, and the elements in the universe. It must be possible to assemble the *sampling* units from the universe during the replication process.

8.4.3.2.1 - Composition of the Universe

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

A. Part A Claims: For providers/suppliers reimbursed through cost report, the universe of claims from which the sample is selected shall consist of fully and partially adjudicated claims obtained from the shared systems that meet the criteria in the definition of the universe. For such claims, use the service date to match findings to the cost report.

For providers/suppliers reimbursed under PPS, the universe of claims from which the sample is selected will consist of all fully and partially paid claims submitted by the provider/supplier for the period under review. *Sampling* units with no final payment

made at the time of sample selection should not be included in the *sampling* frame. Claims with no payment may be included in the universe from which the *sampling* frame is constructed and should be excluded when establishing the *sampling* frame.

B. Part B Claims: The universe shall consist of all fully and partially paid claims submitted by the provider/supplier for the period selected for review and for the sampling units to be reviewed. For example, if the review is of Physician X for the period January 1, 2002 through March 31, 2002, and laboratory and other diagnostic tests have been selected for review, the universe would include all fully and partially paid claims for laboratory and diagnostic tests billed by that physician for the selected time period. For some reviews, the period of review may best be defined in terms of the date(s) of service because changes in coverage policy may have occurred. *Sampling* units with no final payment made at the time of sample selection should not be included in the *sampling* frame. Claims with no payment may be included in the universe from which the same frame is constructed.

8.4.3.2.2 - The Sampling Unit

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

Sampling units are the elements that are selected based on the chosen method of statistical sampling. They may be an individual line(s) within claims, individual claims, or clusters of claims (e.g., a beneficiary). For example, possible sampling units may include specific beneficiaries seen by a physician during the time period under review, or claims for a specific item or service. In certain circumstances (e.g., multi-stage *sampling* designs), other types of clusters of payments may be used.

Certain sampling theorems require an assumption that sampled items are "identically and independently distributed" (iid). In sampling from a finite universe without replacement, there is always a certain amount of dependence because the probability of selection changes with each unit that is selected. However, correlations of characteristics in the target population do not imply dependence in sampling. Sampling units may be correlated because they come from the same location, the same provider/supplier, the same time period, or any number of other reasons. In this context, independence means the selection of one sampling unit does not influence, or gives no information about, the outcome of another selection. Overpayments are not random variables. They are fixed values, though unknown prior to sampling. Therefore, regardless of any correlation that may exist between *sampling* units, the outcome, or overpayment, of any particular unit does not change based on the outcomes of other units.

Unlike procedures for suppliers, overpayment estimation and recovery procedures for providers/suppliers and non-physician practitioners who bill Part A MACs, in a non-PPS environment, must be designed so that overpayment amounts can be accurately reflected on the provider's cost report. Therefore, sampling units must coincide with an estimation methodology designed specifically for that type of provider/supplier to ensure that the results can be placed at the appropriate points on the cost report. The sample may be either claim-based or composed of specific line items. For example, home health cost reports are determined in units of "visits" for disciplines 1 through 6 and "lower of costs or charges" for drugs, supplies, etc. If claims are paid under cost report, the services reviewed and how those units link to the provider/supplier's cost report must be known. The contractor shall follow the instructions contained in section 8.4 et seq., but use the projection methodologies provided in Pub. 100-08, Exhibits 9 through 12, for the appropriate provider type. Pub. 100-08, Exhibits 9 through 12, are to be used only for claims not paid under PPS.

8.4.3.2.3 - The *Sampling* Frame

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The *sampling* frame is the set of all the possible sampling units from which the sample is selected. As examples, the frame may be a list of all beneficiaries receiving items from a selected supplier, a list of all claims for which fully or partially favorable determinations have been issued, or a list of all the line items for specific items or services for which fully or partially favorable determinations have been issued.

8.4.4.3 - Determining Sample Size

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The size of the sample (i.e., the number of sampling units constituting the sample) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. It is neither possible nor desirable to specify a minimum sample size that applies to all situations.

In addition to the above considerations, real-world economic constraints shall be taken into account. As stated earlier, sampling is used when it is not administratively feasible to review the entire target population. In determining the sample size to be used, the contractor shall also consider its available resources. That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling and overpayment estimation have been followed. Some challenges to the validity of the sample that are sometimes made include whether -- (1) The probability sample was chosen and drawn in a statistically appropriate way from the target population or (2) The particular sample size is too small to yield meaningful results. Such challenges are without merit when presented in isolation from any reference to the actual *sampling* methodology used, and when presented without a complete account of the actual *sampling* methodology used.

8.4.4.4.1 - Documentation of Universe and *Sampling* Frame

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

An explicit statement of how the universe is defined and elements included shall be made and maintained in writing. Further, the *sampling* frame and specific details as to the period covered, definition of the sampling unit(s), identifiers for the sampling units (e.g., claim numbers, carrier control numbers), and dates of service and source shall be specified and recorded in the contractor's record of how the sampling was done. If the *sampling* frame does not contain the elements used to define the universe because the sampling unit does not permit it, then an electronic copy of the universe will be kept by the contractor.

A record shall be kept of the random numbers used (if used) in the sample and how they were selected. Documentation shall be kept in sufficient detail so that the *sampling* frame can be re-created should the methodology be challenged. The contractor shall keep an electronic copy of the *sampling* frame.

8.4.4.5 - Maintenance of Documentation

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The contractor shall maintain all documentation pertinent to the calculation of an estimated overpayment including but not limited to the statistician-approved sampling methodology, universe, *sampling* frame and formal worksheets. The documentation must be sufficient to allow for any future replication and/or validation by an administrative or judicial body.

8.4.5 - Calculating the Estimated Overpayment

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The results of the sampling unit reviews are used to calculate an estimate of the overpayment amount. In most situations, the lower limit of a one-sided 90 percent confidence interval should be used as the amount of overpayment to be demanded for recovery from the provider/supplier. This conservative procedure incorporates the uncertainty inherent in the *sampling* design and works to the financial advantage of the provider/supplier. That is, it yields a demand amount for recovery that is very likely less than the true amount of overpayment, and it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate. However, the contractor is not precluded from demanding the point estimate where high precision has been achieved, and when there are statistically sound reasons for the demand.

Standard methods for calculating a one-sided 90 percent confidence interval, such as those based on the central limit theorem or others found in standard statistics texts and journals, are generally acceptable. It may not be feasible to guarantee 90 percent coverage in all circumstances (i.e., that the lower bound of the 90 percent confidence interval is below the true overpayment in 90 percent of audits) due to the use of theoretical assumptions underlying standard statistical methods. Nonetheless, application of these methods is generally appropriate.

In some cases, the point estimate or the lower bound of the estimate for the total overpayment in the sampling frame may be greater than the total payment in the sampling frame. This is expected to occur frequently when the true *error rate* is high. Nonetheless, the use of the lower bound to calculate the demand amount continues to operate in accounting for uncertainty in the estimate and providing a methodology that is generally favorable toward the provider. If the point estimate of overpayment is greater than the total payment in the sampling frame, but the lower bound is less than total payment, then the lower bound may be demanded. If the lower bound of the estimated overpayment is greater than total payment, the demand amount shall be reduced from the lower bound to the total payment amount in the sampling frame to avoid demanding more than originally paid.

The result of each sampling unit review shall be recorded, except that a sampling unit's overpayment shall be set to zero if there is a limitation on liability determination made to waive provider/supplier liability for that sampling unit (per provisions found in section 1879 of the Social Security Act (the Act)) or there is a determination that the provider/supplier is without fault as to that sampling unit overpayment (per provisions found in section 1870 of the Act). Sampling units for which the requested records were not provided are to be treated as improper payments (i.e., as overpayments). Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall be used in calculating the estimated overpayment.

8.4.7.1 - Recovery From Provider or Supplier

(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

Once an overpayment has been determined to exist, the UPIC shall provide its COR and IAG BFL 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 the COR and IAG BFL for all extrapolation requests not associated with a Payment Suspension.

If the COR and IAG BFL 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 IAG BFL.

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. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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/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/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/COR to verify that this course of action is consistent with the decision of the MAC, QIC, ALJ, Council, or the Federal District Court.