CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-15 Medicaid Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12467	**Date: January 18, 2024**
	Change Request 13403

SUBJECT: Updates of Chapter 1, Chapter 3, and Chapter 5 in Publication (Pub.) 100-15, Including Updates to the Definitions and Additional Clarification to the Proactive Project Development and Creation of Overpayment Records Guidance

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update sections within Chapter 1, Chapter 3, and Chapter 5 in Pub. 100-15. The updates in this CR include updating definitions in Chapter 1, adding clarifying language to the Proactive Project Development section in Chapter 3, and adding clarifying language to the Creating Overpayment Records section in Chapter 5.

EFFECTIVE DATE: February 19, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: February 19, 2024
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	1/1.3/Definitions
R	3/3.2/Proactive Project Development
R	5/5.3/Creating Overpayment (OPT) Records

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. 100-15	Transmittal: 12467	Date: January 18, 2024	Change Request: 13403

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EFFECTIVE DATE: February 19, 2024
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I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to update sections in Chapters 1, 3, and 5 in Pub. 100-15. Several definitions will be updated in Chapter 1. Also, clarifying language is being added to a section in Chapter 3 as it relates to proactive project development and Chapter 5 as it relates to the creation of overpayment records.

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	
13403.1	The Unified Program Integrity Contractor shall identify Medicaid leads and investigations dollars-at-risk at two levels.									UPICs
13403.1.1	The UPIC shall be advised that total dollars at risk include only the dollars for the service code/scheme that are outliers on any specific data algorithm, and which will be the focus of the investigation/audit.									UPICs
13403.1.1.1	The UPIC shall be advised that the total dollars at risk amount shall be required when submitting a potential lead to the Centers for Medicare & Medicaid Services (CMS) for review/approval and for pre-vetting with CMS and vetting with the State Medicaid Agency (SMA).									UPICs
13403.1.2	The UPIC shall be advised that sample dollars at risk									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	include dollars associated with the sample to be selected for review.									
13403.1.2.1	The UPIC shall be advised that when extrapolation is not being used, and the focus of the investigation/audit is identifying an overpayment (unlike an opioid project, which may focus more on quality of care or prescribing behavior), the sample dollars at risk must meet the $50,000 threshold for a Medicaid investigation/audit.									UPICs
13403.1.2.1.1	The UPIC shall be advised that the $50,000 threshold for a Medicaid investigation/audit is required in the Investigative Plan of Action for review/approval by CMS and the SMA.									UPICs
13403.2	The UPIC shall include dollars-at-risk for the scheme or service codes in question (not total dollars paid for all services during the time period) in the Investigative Plan, which would include total dollars-at-risk for the scheme or code and sample dollars-at-risk for the actual claims/claim lines to be reviewed.									UPICs
13403.3	The UPIC shall include the size of the sample to be reviewed and whether extrapolation will be used the Investigative Plan.									UPICs
13403.4	The UPIC shall be advised that reliable information of fraud exists if the allegation is made by a credible person or source, the source is knowledgeable and in a position to know, and the source experienced or learned of the alleged act firsthand, i.e., saw it, heard it, read it.									UPICs
13403.5	The UPIC shall identify those “targets” or “potential leads” that meet the criteria of the project and submit those potential leads to the Medicaid Business Function Lead (BFL) for review/approval upon review of the data, clarification of policy interpretation, and agreement by the state on the focus of the investigation.									UPICs
13403.5.1	The UPIC shall submit the total dollars at risk for the									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	allegation to be investigated when submitting a potential lead to CMS.									
13403.5.2	The UPIC shall be advised that the dollars at risk do not include the total amount billed by the provider for all services.									UPICs
13403.5.3	The UPIC shall be advised that the dollars at risk will only include the dollars for the service code(s) that are outliers on any specific data algorithm or analysis, and which will be the focus of the investigation/audit.									UPICs
13403.5.4	The UPIC shall be advised that once approved, those leads will then be screened in accordance with Section 3.3 of Information Only Manual 100-15.									UPICs
13403.6	The UPIC shall spawn an overpayment record in Unified Case Management System from the case record associated with the investigation/audit when a Medicaid investigation/audit results in low/no findings or the identification of an overpayment.									UPICs
13403.6.1	The UPIC shall be aware that the purpose of the overpayment record for low/no findings is to track all investigations and their outcomes.									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

1.3 - Definitions

(Rev.12467; Issued: 01-18-24, Effective: 02-19-24, Implementation: 02-19-24)

The following definitions provide additional context for the UPICs to reference while collaborating with SMAs. However, CMS recognizes that each SMA may use other terms and definitions than those noted below. The UPIC shall consult with each SMA to determine the appropriate terms and definitions to utilize during the collaboration. In addition, the UPICs may refer to Exhibit 1 of the Medicare PIM for further definitions.

Abuse - Abuse means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes beneficiary practices that result in unnecessary cost to the Medicaid program.

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

Closing Summary – The Closing Summary is completed when an investigation/audit reveals that there are low/no findings (LNF) to pursue or the investigation/audit is being closed for other reasons, e.g., discontinued by the SMA and no overpayment was identified that would normally trigger an Initial Findings Report (IFR). The UPICs shall use the "Closing Summary" template found at Appendix B to summarize the investigation/audit.

Dollars-at-Risk *– For Medicaid leads and investigations, dollars at risk will be identified at two levels:*

1. ***Total dollars at risk*** *include only the dollars for the service code/scheme that are outliers on any specific data algorithm, and which will be the focus of the investigation/audit. This amount is required when submitting a potential lead to CMS for review/approval and for pre-vetting with CMS and vetting with the SMA.*
2. ***Sample dollars at risk*** *are those dollars associated with the sample to be selected for review. When extrapolation is not being used, and the focus of the investigation/audit is identifying an overpayment (unlike an opioid project, which may focus more on quality of care or prescribing behavior), the sample dollars at risk must meet the $50,000 threshold for a Medicaid investigation/audit. This amount is required in the Investigative Plan of Action for review/approval by CMS and the SMA.*

Fraud – Fraud means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.

Investigation/Audit – An investigation/audit is the formal review of suspicious aberrancies in a provider's submitted Medicaid claims to establish evidence that potential fraudulent activities or other improper payments have occurred. The UPIC shall focus its investigation/audit in an effort to establish the facts and the magnitude of the alleged fraud, waste, or abuse and take any appropriate action to protect Medicaid dollars.

Generally, the activities associated with an investigation/audit may include, but are not limited to:

- Interviews of recipients or providers,
- Documentation requests to providers in the form of questionnaires, attestations, request for medical records, Managed Care Plan (MCP) contracts and contract deliverables, etc.
- Post-payment reviews of claims,
- Auditing for third party liability as well as usual and customary charges,
- Identifying overpayment determinations,

- Making referrals to the SMA for potential administrative actions, such as payment suspension or termination actions, and
- Making referrals to law enforcement agencies for possible fraudulent activity.

Investigative Plan of Action (IPA) – The Investigation Plan of Action (or Audit Test Plan) outlines the plan of action for conducting the investigation/audit of a provider. The plan shall include the steps and timeframes necessary to meet investigative objectives. Please refer to the TO SOW at 4.4.1.

The Investigative Plan should include, at a minimum, the following elements:

- Provider Name
- Provider NPI
- Provider Medicaid Number, if different from NPI
- Provider Address
- Provider Type
- Service codes and/or scheme being investigated
- Dollars-at-risk for the scheme or service codes in question (not total dollars paid for *all services during* the time period):
    - *Total dollars-at-risk for the scheme or code and*
    - *Sample dollars-at-risk for the actual claims/claim lines to be reviewed*
- Time period being reviewed
- Proposed action steps and estimated time to complete each step (NOTE: Action steps need to include frequency of communication with the SMA)
- *Size of sample (i.e., number of claims/claim lines) to be reviewed and whether extrapolation will be used*

Lead ("Initiation of an Issue") - A lead is some indication that points toward a suspected instance of fraud, waste, or abuse. A lead can come in the form of either proactive or reactive efforts, typically through complaints, data analysis, SMAs, newspaper articles, anonymous tips or some other channel.

Medicaid - The Medicaid program was established under title XIX of the Social Security Act. The program is a joint federal-state funded health insurance program that is the primary source of medical assistance for millions of low-income, disabled, and elderly Americans. The federal government establishes minimum requirements for the program, and states design, implement, administer, and oversee their own Medicaid programs. In general, states pay for the health benefits provided, and the federal government, in turn, matches qualified state expenditures based on the Federal Medical Assistance Percentage (FMAP), which can be no lower than 50 percent.

All states participate in the Medicaid program, and as a requirement for receipt of federal matching, payments must cover individuals who meet certain minimum financial eligibility standards. Additionally, the states must cover certain medical services, such as physician, hospital, and nursing home care, and are provided the flexibility to offer a large number of optional benefits to beneficiaries. States also have the option to expand their Medicaid programs to cover additional beneficiaries who have income above the minimum financial threshold, up to statutory limits on income levels. State governments have a great deal of programmatic flexibility within which to tailor their Medicaid programs to their unique political, budgetary, and economic environments.

Medicaid Initial Findings Report – The Medicaid Initial Findings Report (IFR), is a summary of findings resulting from a UPIC investigation/audit of a Medicaid provider. The IFR will detail the timeframe and summary of the initial findings from the claims review, along with any other findings discovered during the investigation.

Medicaid Final Findings Report – The Medicaid Final Findings Report (FFR) is a final summary of the findings resulting from a UPIC investigation/audit of a Medicaid provider when an overpayment has been identified and is being referred to the SMA for recovery. In addition, the FFR may include areas where provider education is recommended. The FFR is developed after CMS, the SMA, and the provider have fully reviewed the IFR, and the provider has had an opportunity to provide any rebuttal records to the initial findings, when applicable to the type of investigation/audit being conducted. Although the FFR is created by the UPIC, CMS is responsible for sending the FFR to the SMA. The FFR provides details on the time period of the review, findings discovered during the investigation, summary of the claims review findings, total computable overpayment, and the total federal financial participation overpayment. As part of the FFR, there is a transmittal letter attached to the report which contains details associated with the federal requirement for the state to remit the federal share of the overpayment to CMS within one year from the date of the letter.

Medicaid Major Case Coordination – The Medicaid Major Case Coordination (Medicaid MCC) is a collaborative meeting held with SMA staff, law enforcement (LE), the respective UPIC, and CMS whenever the UPIC has identified a potential case warranting a fraud referral to LE. It provides the opportunity for all entities to jointly discuss details of the investigation, determine whether LE will accept the referral, discuss any necessary administrative actions to be taken, and determine next steps following the MCC.

Medical Review - A medical review is a formal review of medical records by qualified UPIC personnel to determine if the documentation in the medical record supports what was billed by the provider and paid for by the Medicaid and/or Medicare programs. The process is used as part of an investigation/audit to determine potential fraud, waste, or abuse.

Overpayment – Overpayment means the amount paid by a Medicaid agency to a provider which is in excess of the amount that is allowable for services furnished under section 1902 of the Act and which is required to be refunded under section 1903 of the Act.

Referral - A referral is the formal presentation of an issue to the SMA or law enforcement, or the receipt of a potential fraud lead from an SMA or another source.

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

Reliable information of fraud exists if the following elements are found:

- **The allegation is made by a credible person or source.** The source is knowledgeable and, in a position, to know. The source experienced or learned of the alleged act *firsthand*, i.e., saw it, heard it, read it. The source is more credible if the source has nothing to gain by not being truthful. The source is competent, e.g., a beneficiary may not always be a credible source in stating that services received were not medically necessary. An employee of a provider who holds a key management position and who continues to work for the provider is often a highly credible source. The friend of a beneficiary who heard that the provider is defrauding Medicare may not be a particularly credible source.

- **The information is material.** The information supports the allegation that fraud has been committed by making it more plausible, reasonable, and probable (e.g., instructions handwritten by the provider delineating how to falsify claim forms).

- **The act alleged is not likely the result of an accident or honest mistake**. For example, the provider was already educated on the proper way to complete the form, or the provider should know that billing for a

service not performed is inappropriate, or claims are submitted the same way over a period of time by different employees.

Reliable evidence includes, but is not limited to, the following:

- Documented allegations from credible sources that items or services were not furnished or received as billed.
- Billing patterns so aberrant from the norm that they bring into question the correctness of the payments made or about to be made.
- Data analysis that shows the provider's utilization to be well above that of its peers without any apparent legitimate rationale for this.
- Statements by beneficiaries and/or their families attesting to the provider's fraudulent behavior.
- Corroboration from provider employees (official and unofficial whistle blowers).
- Other sources, such as prepayment and postpayment review of medical records.
- Recommendations for suspension by OIG/OI, FBI, Assistant U.S. Attorneys (AUSAs), or CMS, based on their finding that the provider has already received overpayments and continued payments should be made only after a determination that continued payment is appropriate.

Screening - Screening is the initial step in the review of a lead to determine whether further investigation/audit is warranted based on the potential for fraud, waste, or abuse. Screening shall be completed within 45 calendar days after receipt of the lead.

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

- Verification of provider's enrollment status
- Data analysis
- Contact with the complainant, when the lead source is a complaint
- Beneficiary interviews
- Site verification to validate the provider's/supplier's practice location
- Review of state policy and regulations

State Medicaid Agency (SMA) — This is the single state agency administering or supervising the administration of a state Medicaid plan. Each SMA establishes and administers their own Medicaid programs; they determine the type, amount, duration, and scope of benefits within broad federal guidelines.

Vetting - Vetting is the process of determining whether a provider, who has been selected for an investigation/audit, is clear to pursue. All leads and any new subjects that the UPIC determines warrants further investigation/audit are vetted through CMS and the SMA for approval before transitioning to an investigation/audit. Determinations are based on any ongoing law enforcement activity and/or current SMA activity with the provider.

3.2 – Proactive Project Development

(Rev.12467; Issued: 01-18-24, Effective: 02-19-24, Implementation: 02-19-24)

Through ongoing collaboration with each state, the UPIC shall discuss areas of interest and convey CMS' priorities related to Medicaid fraud, waste, and abuse for purposes of potential investigations. As outlined in the UPIC statement of work, the UPIC shall be flexible and shall have the capability to adapt to the changing landscape of fraud, waste, and abuse in their jurisdiction. The UPIC shall keep CMS and the state informed as to the highest investigative priorities in such a way as to assure that CMS and the state always has a full understanding of the UPIC's highest priorities and supports State PI efforts.

Once an investigative area of interest is identified, the UPIC shall access the applicable Medicaid claims data for analysis through the CMS/CPI Integrated Data Repository (IDR).

Concurrently, the UPIC shall conduct state policy research and communicate with the appropriate state policy experts. Once the policies have been researched and clarified, the UPIC will conduct an analysis of the applicable data. The UPICs shall develop proactive, innovative and robust analytic tools for investigations that commence with an exposure (i.e. Medicaid dollars-at-risk associated with the specific scheme/allegation) greater than $50,000 total computable. If a state is interested in pursuing an audit where exposure does not reach the $50,000 threshold, UPICs shall ensure that the exposure is greater than the total cost of the audit. In these instances, the UPICs should consult with their Medicaid BFLs/CORs prior to lead screening to discuss the value of proceeding and document the reason for proceeding in the UCM case record. The threshold would not apply to cases where fraud is suspected.

Upon review of the data, clarification of policy interpretation, and agreement by the state on the focus of the investigation, the UPIC will identify those "targets" or "*potential* leads" that meet the criteria of the project *and submit those potential leads to the Medicaid BFL for review/approval. When submitting a potential lead to CMS, the UPIC will submit the total dollars at risk for the allegation to be investigated. The dollars at risk do not include the total amount billed by the provider for all services. The dollars at risk will only include the dollars for the service code(s) that are outliers on any specific data algorithm or analysis, and which will be the focus of the investigation/audit. Once approved,* those leads will then be screened in accordance with Section 3.3 of this manual.

5.3 - Creating Overpayment (OPT) Records

(Rev.12467; Issued: 01-18-24, Effective: 02-19-24, Implementation: 02-19-24)

When a Medicaid investigation/audit results in low/no findings or the identification of an overpayment, the UPIC shall spawn an overpayment (OPT) record in UCM from the CSE associated with the investigation/audit. The UPIC shall refer to the UCM User Manual for opening OPT records. *The purpose of the OPT record for low/no findings is to track all investigations and their outcomes. [NOTE: As UCM evolves, these procedures may change.]*

For investigations/audits of managed care network providers, where the provider is enrolled in multiple managed care organizations (MCOs), an OPT record will be opened for each MCO where the provider is enrolled, unless directed otherwise by the SMA.

In circumstances where the provider is being investigated/audited for both fee-for-service (FFS) claims and is enrolled in managed care, a separate OPT record will be opened for the FFS portion of the investigation/audit, along with the OPTs for each MCO, unless directed otherwise by the SMA.

For the "Overpayment Financials" section of the OPT record, the 'Original Overpayment Amount' will be the amount in the IFR that goes to the SMA and may include any revisions in the overpayment amount based on the CMS review. Whenever the overpayment is revised—either due to the state's review or the provider's review—the UPIC shall update the financial section of the OPT record with the revised amounts in the 'Revised Overpayment Amount' column and include the date of the revision in the 'Determination Date' column.

For the 'Federal Share Amount' of the "Overpayment Financials" section, the federal share will only be calculated for the FFR and will be entered prior to submitting the FFR to CMS. The amount will be the calculated federal share of the final revised amount (if revised) from the IFR that is listed in the FFR. If the FFR is later revised and the overpayment changes, the 'Revised Overpayment Amount' will be revised using the procedures above, and the federal share will be recalculated, and the amount will be entered in the 'Revised Federal Share' column.

For an FFR Addendum that has occurred after the FFR is issued to the SMA, the UPIC will update the financial amount by editing the original OPT record.