

**EL PASO HEALTH'S
PLAN TO PREVENT AND REDUCE
WASTE, ABUSE, AND FRAUD**

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SECTION 1

SPECIAL INVESTIGATIVE UNIT PLAN TO PREVENT AND REDUCE WASTE, ABUSE, AND FRAUD

1.0 Introduction and Purpose

This Special Investigative Unit Plan to Prevent and Reduce Waste, Abuse, and Fraud (“SIU Plan”) has been instituted in accordance with 42 U.S.C. 1396 et seq. 42 CFR §438.608; Texas Government Code Chapter 531, which includes §531.113 and §531.1131, and the Texas Administrative Code Title 1, Rule §353.501 through §353.505 and §370.501 through §370.505, as amended from time to time. This SIU Plan has been developed to comply with all standards set forth by the regulations and laws of the United States Department of Health & Human Services Centers for Medicare and Medicaid Services (CMS), Texas Health and Human Services Commission (“HHSC”) and the Office of Inspector General (“OIG”) of the State of Texas.

This SIU Plan reflects the principles, values, and priorities of El Paso Health (“MCO”). This SIU Plan focuses on increasing healthcare fraud awareness, maintaining a process of fraud identity, educational programs, deterrents to fraud, and reporting suspected fraud to the HHSC-OIG.

El Paso Health has arranged for a special investigative unit (“SIU”) to detect and investigate potential wasteful, abusive, and fraudulent claims and other types of program abuse by Providers and Recipients. El Paso Health has developed a plan to prevent and reduce waste, abuse, and fraud.

This SIU Plan is reviewed periodically and El Paso Health submits this SIU Plan annually to the HHSC-OIG for approval. This plan is submitted no later than the date as specified by HHSC-OIG, for each year El Paso Health is enrolled with the State of Texas.

The purpose of the SIU Plan is to ensure the fair and correct payment of claims submitted to El Paso Health, as well as the identification, investigation, and possible recrimination and prosecution of parties involved in occurrences of waste, abuse, and/or fraud. This SIU Plan oversees and describes the policies and procedures of the SIU.

1.1 Regulation Compliance Standards

Provider Waste, Abuse and/or Fraud

The procedures for detecting errors, waste, abuse, and fraud are explained in detail and include, but are not limited to:

1. Use of Audits to monitor compliance and assist in detecting and identifying Medicaid/CHIP program violations and possible waste, abuse and fraud overpayments through data matching, analysis, trending and statistical activities
2. Monitoring of service patterns for providers, subcontractors, and recipients
3. Use of a hotline or another mechanism to report potential or suspected violations
4. Use of random payment review of claims submitted by providers for reimbursement to detect potential waste, abuse or fraud
5. Use of edits or other evaluation techniques to prevent payment for fraudulent or abusive claims
6. Use of routine validation of El Paso Health data
7. Verification that El Paso Health recipients actually received services that were billed

Preliminary provider investigations are conducted within 15 working days of the identification and/or reporting of suspected and/or potential waste, abuse or fraud. The preliminary provider investigation requirements described in detail in this SIU Plan consist of, but are not limited to, the following:

1. Determine if El Paso Health has received any previous reports of incidences of suspected waste, abuse or fraud or conducted any previous investigations of the provider in question. If so, the investigation should include a review of all materials related to the previous investigations, the outcome of the previous investigations and a determination of whether the new allegations are the same or relate to the previous investigation.
2. Determine if provider in question has received educational training in regard to the allegation(s).
3. Review provider's billing pattern to determine suspicious indicators.
4. Review provider's payment history for the prior three years, if available, to determine if there are any suspicious indicators.
5. Review policies and procedures for the program type in question to determine if what has been alleged is a violation.

If it is determined that suspicious indicators of possible waste, abuse, and/or fraud exist, within 15 working days of the completion of the preliminary investigation, a sample will be selected to include a minimum of 30 recipients or 15% of the provider's recipients who have claims that may be related to the suspected waste, abuse and fraud. Provided, however that if El Paso Health selects 15% of the claims, El Paso Health must include claims relating to at least 30 recipients. El Paso Health may confirm the suspicious indicators of fraud, waste and abuse with a review of fewer recipients or claims, provided that El Paso Health submits, as part of El Paso Health's referral, a written justification for the decision to substantiate the waste, abuse or fraud with fewer recipients or claims. Once recipients or claims are selected for review, El Paso Health must:

1. Within 15 working days of the selection of the sample, a request for medical or dental records and encounter data for the sample recipients will be requested.
2. Within 45 working days of receipt of the requested medical records and encounter data, the medical records for all recipients chosen in the sample will be reviewed to:
 - Validate the sufficiency of service delivery data and to assess utilization and quality of care.
 - Ensure that the encounter data submitted by the provider is accurate.
 - Evaluate if the review of other pertinent records is necessary to determine if waste, abuse or fraud has occurred. If the review of additional records is necessary, then conduct such review.

After an investigation is complete, El Paso Health will determine if there is sufficient evidence of possible waste, abuse, or fraud, as well as the dollar amounts related to the possible waste, abuse or fraud. If El Paso Health determines that there is sufficient evidence of possible waste, abuse, or fraud, then El Paso Health will refer the party to the OIG Medicaid Provider Integrity (MPI) section within 30 working days of the completion of El Paso Health SIU's investigation for further action by the OIG MPI. If the OIG MPI declines to take further action, the El Paso Health may complete a full-scale investigation of the matter for potential prosecution and refer the party to the OIG Sanctions section for possible administrative enforcement.

Recipient Waste, Abuse and/or Fraud

Detecting possible acts of waste, abuse and fraud by recipients is conducted through review of claims, medical records or the use of edits or other analytics. Specifically, detection of waste, abuse and fraud by recipients includes, but is not limited to:

1. Review of claims when waste, abuse or fraud is suspected or reported to determine:
 - a. Treatment(s) and/or medication(s) prescribed by more than one provider appears to be duplicative, excessive or contraindicated;
 - b. Recipients are using more than one physician to obtain similar treatments and/or medications;
 - c. Providers other than the assigned Primary Care Provider (PCP) are treating the recipient, and there is no evidence that the recipient was treated by the assigned PCP for a similar or related condition; and/or
 - d. The recipient has a high volume of emergency room visits with a non-emergent diagnosis.
2. Review medical records for the recipients in question if claims review does not clearly determine if waste, abuse or fraud has occurred.
3. Use of edits or other evaluation techniques to identify possible overuse and/or abuse of psychotropic and/or controlled medications by recipients who are allegedly treated at least monthly by two or more physicians. A physician includes but is not limited to: psychiatrists, pain management specialists, anesthesiologists, physical medicine and rehabilitation specialists.

Preliminary recipient investigations are conducted within 15 working days of the identification and/or reporting of suspected and/or potential waste, abuse or fraud. The preliminary recipient investigation requirements described in detail in this SIU Plan may include the following:

1. Review of acute care and emergency room claims submitted by providers for the suspected recipient.
2. Analysis of pharmacy claims data submitted by providers for the suspected recipient to determine possible abuse of controlled or non-controlled medications. If El Paso Health does not have the data necessary to conduct the pharmacy claims review, the data is requested within 15 working days of the initial identification and/or reporting of the suspected or potential waste, abuse or fraud.
3. Analysis of claims submitted by providers to determine if the diagnosis is appropriate for the medications prescribed.

If it is determined that a recipient has perpetrated possible waste, abuse, and/or fraud an investigation will be required that will include:

1. A request for medical records and encounter data within 15 working days of case opening.
2. Within 45 working days of receipt of the requested medical records and encounter data, the medical records for the recipient will be reviewed.

Referring Possible Acts of Waste, Abuse or Fraud

Referring possible errors, waste, abuse, and fraud to the Special Investigative Unit (SIU) and the mandatory reporting of potential acts of waste, abuse, and fraud by providers or recipients to the HHSC-OIG will include, but are not limited to:

1. Assigning an officer or director the authority and responsibility to report all investigations resulting in a finding of possible acts of waste, abuse, and/or fraud to the OIG. An officer could be, but is not limited to, a Compliance Officer, a Manager of Government Programs, or a Regulatory Compliance Analyst.
2. Provision of specific detailed internal procedures for officers, directors, managers, and employees to report possible waste, abuse, and/or fraud to the SIU. These procedures include, but are not limited to:
 - a. What information must be reported to the assigned officer or director; and
 - b. A requirement that information must be reported to El Paso Health's SIU within 24 hours of identification or reporting of suspected waste, abuse and fraud.
3. Provision of specific and detailed procedures for the SIU to report investigations resulting in a finding of error, waste, abuse, and/or fraud to the assigned officer or director including, but not limited to:
 - a. Guidance regarding what information must be reported to the assigned officer or director.
 - b. All possible acts of waste, abuse or fraud must be reported to the assigned officer or director within 15 working days of making the determination.

4. Refer all possible acts of waste, abuse, and/or fraud to the HHSC-OIG utilizing the HHSC-OIG fraud referral form within 30 working days of receiving the reports of possible acts of waste, abuse or fraud from the SIU, with the exception of an expedited referral. The report and referral must include:
 - a. The provider's enrollment/credentialing documents
 - b. The complete SIU investigative file of the provider, which must include:
 - i. An investigative report identifying the allegation, statutes/regulations/rules violated or considered, and the results of the investigation;
 - ii. The estimated overpayment identified;
 - iii. A summary of interviews conducted;
 - iv. A list of all claims and associated overpayments identified by the preliminary investigation
 - c. A summary of all past investigations of the provider conducted by El Paso Health or El Paso Health's SIU. Upon request, El Paso Health shall provide the complete investigative files or any other information regarding those past investigations to the HHSC-OIG investigator;
 - d. Copies of HHSC program and El Paso Health policy, contract, and other requirements, as well as statutes/regulations/rules, alleged to be violated for the time period in question;
 - e. All education letters (including education documents) and/or recoupment letters issued to the provider by El Paso Health or El Paso Health's SIU at any time;
 - f. All medical records;
 - g. All clinical review reports/summaries generated by El Paso Health;
 - h. Any and all correspondence and/or communications between El Paso Health, El Paso Health's subcontractors, and any of their employees, contractors, or agents, and the provider related to the investigation. This should include but not be limited to agents, servants and employees of El Paso Health, regardless of whether those agents, servants and employees are part of the SIU who investigated the provider;
 - i. Copies of all settlement agreements between El Paso Health and its contractors and the provider; and
 - j. If the referral contains fewer recipients or claims than the minimum described above, a written justification for the decision to substantiate the waste, abuse or fraud with fewer recipients or claims. The justification will be subject to review and approval by HHSC-OIG, who may require El Paso Health to provide further information.
5. An expedited referral is required when El Paso Health has reason to believe that a delay may result in:
 - a. Harm or death to patients;
 - b. The loss, destruction or alteration of valuable evidence;
 - c. A potential for significant monetary loss that may not be recoverable; and/or
 - d. Hindrance of an investigation or criminal prosecution of the alleged offense.

Education and Training

Educational and training procedures for providers, recipients and training personnel for errors, waste, abuse, and fraud prevention include, but are not limited to:

1. Annually provide waste, abuse and fraud training to each employee who is directly involved in any aspect of Medicaid/CHIP. This includes, but is not limited to, any employees responsible for data collection, provider enrollment or disenrollment, encounter data, claims processing, utilization review, appeals or grievances, quality assurance and marketing.
2. Training must be specific to the area of responsibility or the staff receiving the training and contain examples of waste, abuse or fraud in their particular area of interest.
3. General training must be provided to Medicaid/CHIP managed care staff that is not specified above. General training must include:
 - a. Definition of waste, abuse and fraud
 - b. How to report suspected waste, abuse and fraud and to whom it must be reported
4. Training must be provided to all new staff directly involved in any aspect of Medicaid/CHIP within 90 days of the employee's employment date.
5. Provision of updates to all affected areas when changes to policies and/or procedures may affect their area(s). Updates must be provided within 20 working days of the changes occurring.
6. Educate recipients, providers and employees about their responsibilities, the responsibility of others, the definition of waste, abuse and fraud and how and where to report it. Appropriate methods of educating recipients, providers and employees may include but are not limited to: newsletters, pamphlets, bulletins and provider manuals.
7. Maintenance and updating of training log for all training pertaining to waste, abuse and/or fraud in Medicaid/CHIP. The log must be provided immediately upon request to the HHSC-OIG, Office of the Attorney General's (OAG)-Medicaid Fraud Control Unit (MFCU) and OAG-Civil Medicaid Fraud Division (CMFD), and the United States Department of Health and Human Services - Office of Inspector General (DHHS-OIG). The log must include:
 - a. Name and title of the trainer
 - b. Date
 - c. Names of all staff attending the training
8. Written standards of conduct, and written policies and procedures that include a clear delineated commitment to the detection, prevention and investigation of waste, abuse, and fraud.

Responsible Personnel

This SIU Plan details the procedures and the organizational arrangement of the investigation and reporting processes for errors, waste, abuse, and fraud. Included in the organizational arrangement detail are the name, title, address, telephone number, and fax number of the officer in charge of carrying out this SIU Plan. The person carrying out the

plan for El Paso Health is Rocio Chavez, Chief Compliance Officer. When the person responsible for carrying out the plan changes, the required information is to be reported to HHSC_OIG within 15 working days of the change.

Organizational Arrangement

A description, process flow diagram or chart outlining the organization arrangement of El Paso Health's personnel responsible for investigating and reporting possible acts of waste, abuse or fraud.

Advertising and Marketing Materials

All advertising and marketing materials will be in compliance with regulation standards and will accurately reflect the information about El Paso Health.

Maintenance and Reporting Log of Investigations and Acts/Incidences of Suspected Waste, Abuse and Fraud

El Paso Health maintains a log of suspected waste, abuse, and fraud.

1. On a monthly basis, submit to the HHSC-OIG a report listing all investigations conducted that resulted in no findings of waste, abuse or fraud. The report must include:
 - a. The allegation
 - b. The Medicaid identification number of the investigated recipient(s) or provider(s)
 - c. The source
 - d. The time period in question
 - e. The date of receipt of the identification and/or reporting of suspected and/or potential waste, abuse or fraud.
2. Maintain a log of all incidences of suspected waste, abuse and fraud, received by El Paso Health regardless of the source. The log shall contain:
 - a. Subject of the complaint
 - b. Source
 - c. Allegation
 - d. Date the allegation was received
 - e. Recipient or Providers Medicaid/CHIP number
 - f. Status of investigation
3. The log should be provided at the time of a reasonable request to the HHSC-OIG, OAG-MFCU, OAG-CMFD, and the DHHS-OIG. Reasonable request means a request made during hours that the business or premises is open for business.

Confidentiality

El Paso Health must maintain the confidentiality of any patient information relevant to an investigation of waste, abuse or fraud.

Record Retention

El Paso Health has a strict policy of retaining all records obtained as a result of an investigation for a minimum of five (5) years, or until all audit questions, appealed hearings, investigations or court cases are deemed resolved.

Record Requests

Provider must supply records requested by El Paso Health, failure to do so will result in the provider being reported to the HHSC-OIG as refusing to supply records upon request and the provider may be subject to sanction or immediate payment hold.

Other Considerations

Benefit Verification Procedure (42 CFR § 455.20)

El Paso Health must have a method to verify with beneficiaries whether services billed by providers were received.

Suspension of Payments in Cases of Fraud or Willful Misrepresentation (42 CFR § 455.23)

In the event of credible allegations of fraud, El Paso Health will suspend all Medicaid payments.

1. Basis for suspension
 - a. Medicaid payments must be suspended after a credible allegation of fraud is determined for which an investigation is pending under the Medicaid program against an individual or entity unless the agency has good cause to not suspend payments or to suspend payment only in part.
 - b. Payments may be suspended without first notifying the provider
 - c. A provider may request, and must be granted, administrative review where State law so requires
2. Notice of suspension
 - a. Notice must be sent of its suspension of program payments within the following timeframes:
 - i. Five (5) days of taking such action unless requested in writing by a law enforcement agency to temporarily withhold such notice.
 - ii. Thirty (30) days if requested by law enforcement in writing to delay sending such notice. The request to delay may be renewed in writing up twice, not to exceed 90 days.
 - b. The notice must include or address:
 - i. Payments are being suspended in accordance with the provision.
 - ii. General allegation as to the nature of the suspension action, but need not disclose any specific information concerning an ongoing investigation.

- iii. State that the suspension is for a temporary period, indicated below, and cite the circumstances under which the suspension will be terminated.
 - iv. Specify, when applicable, to which type or types of Medicaid claims or business units of a provider suspension is effective.
 - v. Inform the provider of the right to submit written evidence for consideration.
 - vi. Set for the applicable State administrative appeals process and corresponding citations to State law.
3. Duration of suspension
- a. Suspension of payment actions will be temporary and will not continue after either of the following:
 - i. El Paso Health or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider.
 - ii. Legal proceedings related to the provider's alleged fraud are completed.
 - b. A State must document in writing the termination of a suspension including, where applicable and appropriate, any appeal rights available to a provider.
4. Referrals to the Medicaid Fraud Control Unit
- a. Whenever an investigation leads to the initiation of a payment suspension in whole or part, a fraud referral must be made to:
 - i. Texas Medicaid fraud control unit established and certified under *42 CFR § 1007*
 - b. Fraud referral must meet all of these requirements:
 - i. Provided to the Texas MFCU in writing no later than the next business day after the suspension is enacted.
 - ii. Conform to fraud referral performance standards issued by the Secretary.
 - c. Acceptance
 - i. If the Texas MFCU accepts the fraud referral for investigation, the payment suspension may be continued until such time as the investigation and any associated enforcement proceedings are completed.
 - ii. On a quarterly basis, the State must request certification from the Texas MFCU that any matter accepted on the basis of referral continues to be under investigation thus warranting continuation of the suspension.
 - d. Rejection
 - i. If the Texas MFCU declines to accept the fraud referral for investigation, the payment suspension must be discontinued unless El Paso Health has alternative Federal or State authority by which it may impose a suspension or makes a fraud referral to another law enforcement agency. If accepted by another authority, the acceptance requirements indicated above must be enforced.

- e. Obligation to refer
 - i. Any credible allegation of fraud must be referred to the MFCU regardless if a partial or total suspension of payments is enforced.
- 5. Good cause not to suspend payments
 - a. If an individual or entity against which there is an investigation of a credible allegation of fraud, good cause may exist to continue payments if any of the following are applicable:
 - i. Law enforcement officials have specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation.
 - ii. Other available remedies implemented by the State more effectively or quickly protect Medicaid funds.
 - iii. Based upon the submission of written evidence by the individual or entity that is the subject of the payment suspension, that the suspension should be removed, as determined by the State.
 - iv. Recipient access to items or services would be jeopardized by a payment suspension because of either:
 - 1. An individual or entity is the sole source of essential specialized services in a community.
 - 2. The individual or entity serves a large number of beneficiaries with a HRSA-designated medically underserved area.
 - v. Law enforcement declines to certify that a matter continues to be under investigation per the requirements above.
 - vi. The State determines that the payment suspension is not in the best interests of the Medicaid program.
- 6. Good cause to suspend payment only in part
 - a. A State may find that good cause exists to suspend payments in part, or to convert a payment suspension previously imposed in whole to one only in part, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:
 - i. beneficiary access to items or services would be jeopardized by a payment suspension in whole or part because of either of the following:
 - 1. An individual or entity is the sole community physician or the sole source of essential specialized services in a community.
 - 2. The individual or entity serves a large number of beneficiaries within a HRSA-designated medically underserved area.
 - ii. The State determines, based upon the submission of written evidence by the individual or entity that is the subject of a whole payment suspension, that such suspension should be imposed only in part.

- iii. Fraud effectively addressed
 - 1. The credible allegation focuses solely and definitively on only a specific type of claim or arises from only a specific business unit of a provider; and
 - 2. The State determines and documents in writing that a payment suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.
 - iv. Law enforcement declines to certify that a matter continues to be under investigation per the requirements above.
 - v. The State determines that payment suspension only in part is in the best interests of the Medicaid program.
- 7. Documentation and record retention
- 8. The following requirements must be met:
 - a. Maintain for a minimum of 5 years from the date of issuance all materials documenting the life cycle of a payment suspension that was imposed in whole or part, including the following:
 - i. All notices of suspension of payment in whole or part.
 - ii. All fraud referrals to the Medicaid fraud control unit or other law enforcement agency.
 - iii. All quarterly certifications of continuing investigation status by law enforcement.
 - iv. All notices documenting the termination of a suspension.
 - b. Type of materials
 - i. Maintain for a minimum of 5 years from the date of issuance all materials documenting each instance where a payment suspension was not imposed, imposed only in part, or discontinued for good cause.
 - ii. This type of documentation must include, at a minimum:
 - 1. Detailed information on the basis for the existence of the good cause not to suspend payments, to suspend payments only in part, or to discontinue a payment suspension
 - 2. Specify how long the State anticipates such good cause will exist.
 - c. Annually report to the Secretary summary information on each of following:
 - i. Suspension of payment, including the nature of the suspected fraud, the basis for suspension, and the outcome of the suspension. Situation in which the State determined good cause existed to not suspend payments, to suspend payments only in part, or to discontinue a payment suspension as described in this section, including describing the nature of the suspected fraud and the nature of the good cause.

Program Integrity Requirements (42 CFR § 438.608)

El Paso Health must have administrative and management arrangements or procedures, including a mandatory compliance plan that are designed to guard against fraud and abuse. The arrangements or procedures must include:

1. Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.
2. The designation of a compliance officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract and who reports directly to the Chief Executive Officer and the Board of Directors.
3. The establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the contract.
4. A system for training and education for the compliance officer, the organization's senior management, and the organization's employees for the Federal and State standards and requirements under the contract.
5. Effective lines of communication between the compliance officer and the organization's employees.
6. Enforcement of standards through well-publicized disciplinary guidelines.
7. Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract.

Fraud and Abuse Recovery by Certain Persons; Retention of Recovered Amounts (Texas Gov. Code § 531.1131 and HB 2379)

El Paso Health must have procedures in place to recover payments after fraud and abuse is discovered.

1. If the Special Investigation Unit (SIU) or contracted SIU discovers fraud or abuse in the Medicaid program or the child health plan program, the unit or entity shall:
 - a. Immediately submit written notice to the commission's Office of Inspector General and the Office of the Attorney General in the form and manner prescribed by the office of the inspector general and containing a detailed description of the fraud or abuse and each payment made to a provider as a result of the fraud or abuse;
 - b. Subject to Subsection (b), Begin payment recovery efforts;

- c. Ensure that any payment recovery efforts in which the organization engages are in accordance with applicable rules adopted by the executive commissioner.
2. (Subsection b) If the amount sought to be recovered under Subsection (a) exceeds \$100,000, the managed care organization's SIU or contracted SIU may not engage in payment recovery efforts if, not later than the 10th business day after the date the unit or entity notified the commission's Office of Inspector General and the Office of the Attorney General, El Paso Health receives a notice from either office indicating that the organization or entity is not authorized to proceed with recovery efforts.
3. El Paso Health may retain one-half of the money recovered under Subsection (a) 2 by El Paso Health or contracted entity.
 - a. El Paso Health shall remit the remaining amount of money recovered, under Subsection (a) (2) to the commission's office of the inspector general for deposit to the credit of the general revenue fund.
 - b. If the commissions office of the inspector general notifies El Paso Health under subsection (b), proceeds with recovery efforts and recovers all or part of the payments the organization identifies as required by Subsection (a) 1, El Paso Health is entitled to one-half of the amount recovered for each payment the organization identified after any applicable federal share is deducted. El Paso Health may not receive more than one-half of the total amount of money recovered after any applicable federal share is deducted.
4. El Paso Health shall submit a quarterly report to the commission's Office of Inspector General detailing the amount of money recovered under Subsection (a) (2).
5. The executive commissioner shall adopt rules necessary to implement this section, including rules establishing due process procedures that must be followed by managed care organizations when engaging in payment recovery efforts as provided by this section.
6. The managed care organization or an entity with which the managed care organization contracts under Section 531.113(a) (2) that engages in payment recovery efforts in accordance with this section and Section 531.1135 provide:
 - a. Written notice to a provider required to use electronic visit verification of the organization's intent to recoup overpayments in accordance with Section 531.1135; and
 - b. A provider described by Subdivision (1) at least 60 days to cure any defect in a claim before the organization may begin any efforts to collect overpayments.

SECTION 2

PROCEDURES FOR DETECTING POSSIBLE ACTS OF WASTE, ABUSE, OR FRAUD BY PROVIDERS

2.0 Detecting Program Violations through Audits to Monitor Compliance

In addition to the various procedures and tasks described below, El Paso Health periodically conducts audits of Providers to monitor compliance with all aspects of the Medicaid program, including claims submissions, licensure, and credentialing.

The scope and structure of El Paso Health credentialing and re-credentialing process is consistent with recognized industry standards such as the National Committee for Quality Assurance (NCQA) and relevant state and federal regulations including 42 C.F.R. §438.214(b) and 28 T.A.C. §11.1902, relating to credentialing of Providers.

2.0.1 Credentialing and Licensure

Initial credentialing is completed before the effective date of the initial contract with a physician or Provider and includes verification of application, a site visit (as applicable), and medical record reviews to ensure conformance with El Paso Health and State standards. The re-credentialing process occurs not less than every three (3) years following initial credentialing to ensure program conformance with State standards and regulations. At minimum, the review includes Provider performance data, as follows:

1. Quality of care
2. Utilization management, including over-utilization and under-utilization
3. Recipient complaints, appeals and satisfaction surveys
4. Provider profiles
5. Medical Records Review for legibility, organization, completion, and program conformance including accessibility, availability and content.

2.0.2 Screening and Terminating Providers

During the initial credentialing process, re-credentialing process, and periodically throughout any contract with a physician or Provider, El Paso Health screens physicians and providers for the certain possible program integrity violations. Any such violation will subject the physician or Provider to termination. These program integrity violations include, but are not limited to, the following:

1. Failure to repay overpayments to Medicaid;
2. Affiliation with a provider who has been prohibited from participating in Medicaid;
3. Not billing for twelve (12) consecutive months;

4. Being terminated from Medicaid, Medicare, or CHIP in another state;
5. Being convicted of a Medicaid, Medicare, or CHIP related offense within the past ten (10) years;
6. Failing to submit timely and accurate disclosures; and
7. Refusing access for a site visit during enrollment screening.

2.0.3 Periodic Provider Audits

El Paso Health categorizes providers based upon risk for fraud, waste and abuse. El Paso Health periodically audits and monitors providers that have been categorized as high risk providers.

El Paso Health also conducts retrospective audits on randomly selected Providers on a periodic basis. Other providers or specific claims are subject to retrospective audit based on known risks or potential for waste, abuse or fraud. All claim audits are intended to verify delivery of items or services claimed and billed; proper documentation, accurate coding and appropriate payment.

2.1 Monitoring Service Patterns

2.1.1 Data Analysis

Data analysis is used to identify aberrant billing patterns, potential areas of over-utilization or under-utilization, changes in Provider billing behavior, and possible improper billing schemes. The goal of the data analysis process is to identify practices that pose the greatest financial risk to El Paso Health.

The data analysis process provides a comparative data review on a Provider, Recipient, and global basis. The SIU analyzes comparative data on how the Provider varies from other Providers rendering the same or similar services in the same geographic area. The SIU maintains data for a minimum of thirty-six (36) months in the SIU system for data analysis. The data analysis:

1. Establishes a baseline to enable the SIU to recognize unusual trends, changes in utilization, and/or schemes to inappropriately maximize reimbursement.
2. Identifies specific Provider and common billing patterns.
3. Identifies high volume or high cost services.
4. Identifies Provider and patient utilization patterns.
5. Identifies Provider referral patterns.

Data analysis is a tool for identifying potential errors, waste, abuse, and fraud through analytical methodologies. The data analysis process uses claim information and other related data to identify potential errors, waste, abuse, and fraud for individual Providers or Recipients or the aggregate. Data analysis is an integrated component of

the SIU and varies based on the specific incident being investigated. The data analysis process involves using the analytics and reporting capabilities inherent in the SIU system.

When a Provider or Recipient's billing pattern has been identified as a statistical outlier or a subject within a scheme based analytics model, the SIU conducts a preliminary investigation to ascertain if the services and detected outcomes are reasonable for the Provider's recipients or with a Recipient's history. If the preliminary investigation results in confirmation of questionable billing, an extensive review may be indicated.

2.1.2 Data Matching, Trending, and Statistical Analysis

Data matching, trending, and statistical analysis are conducted on a continual basis for each area defined:

1. High cost provider peer comparisons
2. Paid provider analysis (year over year trend and metrics)
3. Provider Diagnosis billing and peer comparison
4. High cost Recipient analysis
5. Comparison analysis of procedures which are commonly abused or inappropriately billed.

2.1.3 Claims Data Analysis

In addition to the prospective claim payment review and the retrospective claim payment review, other focused claims analyses are conducted. The SIU analyzes specific selection criteria when a prior analysis indicates a potential waste, abuse, and/or fraud pattern and when the claim payment reviews or analysis patterns indicate possible waste, abuse, and/or fraud. Analyses may include:

1. Emergency transportation utilization analysis – high frequency use
2. Transportation without medical services
3. Laboratory tests without medical services
4. Multi-unit drug screens
5. Deceased patient
6. Readmissions or surgeries within thirty days of original procedure for case management review
7. Claims submitted for Sundays and holidays (non-urgent or non-emergent)
8. Recipients with receiving services from an unusual number of providers
9. Patients seeing an unusually high number of specialty providers
10. Speech Therapy utilization
11. Hospice Service analysis – abuse of services
12. Provider's changing billing patterns and amounts for CPT codes that may indicate that the Provider may be fishing for maximum payment amount (improper billing)

13. High incidence of shared Recipients between providers
14. Medical bills show questionable services on days immediately prior to Recipient termination date
15. Infrequently used codes analysis by Provider
16. Psychological testing procedures and diagnosis
17. Referring doctor and medical Provider belong to the same professional corporation (TIN) or share same address
18. Services with extended lengths of time
19. Profile therapy visits to identify Providers billing consistently and whether the average number visits per Recipient has increased
20. Profile frequency of specific tests, pharmacy, and additional dialysis sessions by Recipient for End State Renal Dialysis (ESRD) Claims
21. Identify patterns for Home Health Agencies with similar demographics, such as frequency of visits, types of visits, visits per Recipient, and lengths of stay
22. Diagnosis upcoding and multiple codes inconsistent to CPTs billed
23. Inconsistent findings between Providers, such as anesthesia bill show one (1) hour and hospital shows 1.5 hours
24. Provider changes codes for on-going care
25. Delivery inductions and cesarean sections before 39 weeks' gestation

2.2 Reporting a Possible Waste, Abuse, and Fraud by Hotline

Allegations of possible waste, abuse, and/or fraud are identified and reported from many sources such as a Recipient, Provider, El Paso Health employee, or a third party (reporting party).

2.2.1 Reporting an Allegation (One of the Following):

1. Call the "Hotline" toll free number at 1-866-356-8395.
Write a letter addressed to the <<health plan>> Compliance Officer or Responsible Entity marked "confidential" at
El Paso Health
Attn: Rocio Chavez, Chief Compliance Officer
1145 Westmoreland Drive
El Paso, TX 79925
2. Contact or call the compliance department by voice at 915-298-7198 ext. 1032 or by fax at 915-532-2877

2.2.2 Hotline Procedures

El Paso Health maintains a toll free phone number for employees, providers, recipients, and third parties to report possible waste, abuse, and/or fraud. El Paso Health staff must treat all calls as a legitimate complaint until proven otherwise. El

Paso Health must report all incoming Hotline complaints to the SIU within one working day (24 hours) of the complaint for follow-up according to policies and procedures.

El Paso Health's Hotline staff discusses all allegations with the reporting party and enters the information into the SIU system.

2.3 Claim Payment Review

The purpose of the claim payment review is to identify any claims errors, inconsistencies, waste, abuse, or fraud contained in claims submitted by Providers. El Paso Health performs prepayment editing and reviews on all claims submitted by providers rather than performing random post-payment reviews.

At the beginning of each month and multiple times during the month, El Paso Health sends to the SIU the following data files of additions, deletions, and changes that have occurred since the last data download (as applicable):

1. Recipient data.
2. Provider profile data.

The claims review process includes, but is not limited to the following:

1. El Paso Health sends all claims prior to payment (or post-payment if applicable) to the SIU.
2. Upon the SIU's receipt of the prepayment claim file, the SIU processes all claims through the SIU system and identifies claims as suspicious based on the SIU system claims edits and rules. Findings include:
 - a. All transactions flagged for "denial" based on correct coding from CMS and Texas State Medicaid and other applicable programs.
 - b. All transactions flagged as an "adjustment" based on a previously paid claim.
 - c. All transactions flagged for "review" prior to payment.
 - d. All transactions flagged as "informational" for possible investigation.
3. The SIU provides El Paso Health with electronic access to the transactions flagged by the SIU system.
4. El Paso Health is responsible for the necessary adjustments to El Paso Health's claims processing system prior to claim payment.

2.4 SIU Use of System Claim Edits and Rules

2.4.1 Use of Edits

Each claim transaction is processed through the SIU system edits and rules to isolate potential waste, abuse, and fraud. Claim transaction edits and rules determine and report incorrect or abusive billing codes and include, but are not limited to:

1. Surgical services unrelated to or inconsistent with diagnosis
2. Unbundling - separate services that should be combined into one CPT code
3. Double coding - charging separately for various steps in a procedure (“exploded coding”)
4. Incidental billing - charging for services that are considered to be a component of a more comprehensive procedure or mutually exclusive to another service
5. Surgical “payment split” percentage rules
6. Evaluation and management code churning – multiple E&M visits on same day
7. Global fee screening - verifies services that are part of a global surgical procedure (ex. post-operative procedures)
8. Duplicate billing on same or separate claims with same date of service
9. Multiple like services provided on same day
10. Primary care services performed by specialty care physician
11. Service inconsistent to gender or age of Recipient
12. Primary and assistant surgeon services billed by same Provider
13. New vs. established patient
14. Pathology bundling/unbundling
15. Validate modifiers by procedure
16. Anesthesia billed where not indicated during Med/Surgical procedure
17. Multiple procedure reduction rules
18. Surgical team, co-surgeon, and assistant rules/reductions
19. Professional and technical procedures - double billing
20. Claims paid for an amount greater than the billed amount
21. Service date versus received date exceeds Client’s submission days

2.4.2 History Retention

The SIU system maintains a minimum of a thirty-six (36) month claims history for analysis and comparative processing. The claims information is utilized for claim-by-claim payment comparisons through the SIU system as well as for Data Analysis.

2.5 Routine Validation of Data

2.5.1. Validation of Data through Retrospective Claims Payment Review

El Paso Health routinely validates its data through the use of retrospective claims payment review. In addition to validating the data, the retrospective claims payment review also identifies any claim errors, inconsistencies, waste, abuse, or fraud for claims that have been paid without a prospective review; verifies that adjustments have been made correctly to claims identified in a prior prospective review, and edits carve-out vendor claims for accuracy.

The validation of data through the retrospective claims review process is as follows:

1. **El Paso Health** sends the SIU all claims that were paid since the last paid claim file transmission. The paid claim file must be sent to the SIU not less than once per calendar month for each of the following:
 - a. Claims paid, denied, or closed by El Paso Health
 - b. Claims paid, denied, or closed by all carve-out entities
2. The SIU then loads all paid claims in the SIU system updating information as needed. The pre-pay version of the claim is also retained in the database for reporting purposes.
3. All analytic models are updated with the new claims. All Provider and Recipient Profiles are updated with the new claim information. System Reports may also access the updated claims.
4. Optional post-payment edits may be used. Claims that were paid without a prepayment review are processed to identify claims that contain potential errors based on the SIU system claims edits and rules. The edits may include the following:
 - a. All transactions flagged for “denial” based on correct coding from CMS and Texas State Medicaid as well as other applicable programs;
 - b. All transactions flagged as an “adjustment” based on a previously paid claim;
 - c. All transactions flagged for “review”; and/or
 - d. All transactions flagged as “information only” for possible investigation.
5. The SIU then provides **El Paso Health** with electronic access to the transactions flagged by the SIU system.
6. If the claim review shows an overpayment, **El Paso Health** may flag the claim for possible recovery.

2.5.2 Retrospective Analysis of Prescription Drug Claims

All prescription drug claims (RX claims) paid through the Texas State Prescription Drug Vendor program or other El Paso Health prescription vendor’s programs analyzed by the SIU system.

1. Monthly, **El Paso Health** forwards the paid RX claims to the SIU.
2. All RX claims are loaded to the SIU system and displayed in the analytic model results. Updated claim data is also available for the RX focused reports. All Provider and Recipient Profiles are also updated with new RX claim information.
3. RX models include:
 - a. Patient Rx Abuse
 - b. Prescriber Rx Utilization
 - c. Pharmacy Rx Utilization
 - d. Patient Rx Utilization
 - e. Opioid Utilization by Zip Code and Year
4. RX focused reports may also be run and include:

- a. Quantity of prescriptions for a Recipient is excessive
 - b. Multiple pharmacies are filling the same or a like prescription within 30-day period for a Recipient
 - c. Multiple Providers prescribing or administering the drug concurrently and the drug is being duplicated during the month
 - d. Duplicate prescription or prescription refills within 30-day period
 - e. Prescriptions for scheduled controlled substances for more than six (6) weeks
 - f. Psychotropic and commonly sold drugs
5. Recipients or Prescribers identified as possible perpetrators of waste, abuse or fraud during the RX claims review are flagged for a preliminary investigation.

2.6 Verification of Billed Services Actually Received by Recipients

El Paso Health has implemented procedures to verify that services billed by providers were actually received by recipients. These procedures include surveys of recipients by mail, telephone or personal interviews and may be incorporated with sending recipients an explanation of benefits or with eligibility confirmations. El Paso Health also verifies receipt of services during any extensive investigation performed when applicable.

SECTION 3

PROCEDURES FOR INVESTIGATING POSSIBLE ACTS OF WASTE, ABUSE AND FRAUD BY PROVIDERS

3.0 Investigation Guidelines

The SIU conducts preliminary investigations related to instances of suspected waste, abuse, and/or fraud by Providers, Recipients, El Paso Health employees and other persons. The purpose of an investigation is to gather facts relating to an allegation, not to prove or disprove an allegation of fraud or abuse. Impartiality is extremely important in the collection of facts and is the only way an investigator can properly compile all aspects of an investigation.

The way an SIU investigator compiles an investigation file (all case notes and documents gathered during investigation) determines whether the evidence can be admissible in court. An investigator must always keep in mind that the information and work they compile in an investigation may be used as evidence in a criminal proceeding, a civil action, a regulatory hearing, or other court proceeding. All case notes made by an investigator must be strictly factual, containing material that is relevant only to the case. In the compiled investigation file there can never be any personal reflections, opinions, comments, or other materials that are not strict factual information.

3.0.1 Required Target Days

The SIU tracks the investigation process and enters the appropriate dates.

	Within Working Days
Identified / allegation received	
Allegation reported to SIU within one working day	
Preliminary investigation complete	
Preliminary investigation report sent to Health Plan	
SIU notified of Health Pan decision	15
Health Plan decision of medical review	
Initiate extensive investigation	
Record selection complete	15
Medical record(s) requests sent to all applicable parties	
Request hardcopy or EDI claims from Health Plan	15

Medical records received	
Medical records sent for medical review	
Medical records sent for medical coding review	
Medical review completed	
Medical coding review completed	
Investigative history report sent to Health Plan	45
Investigation records to Health Plan	
Investigation completed /closed	
Final Investigative report to OIG	30

3.1 Documentation Guidelines

Special care must be taken in documenting an investigation. The investigative file is legally admissible as evidence in court cases and incomplete and sloppy documentation can ruin an investigation. Guidelines to document an investigation are:

1. Include the investigation number and date received on the face of all physical documents.
2. All entries to the SIU system include the date of the entry and the party entering the information.
3. All entries are reviewed prior to final reporting.
4. Present the entry logically and clearly.
5. Enter all interviews for the investigation immediately.
6. Investigators can only make entries in regards to work that the particular investigator has performed.
7. If an incorrect entry is made to the investigation file, enter the corrected information in a separate adjusting entry.
8. Never delete an entry.
9. Never change the record to cover mistakes or insert fresh material after the fact as this can destroy the credibility of an investigation.
10. All paper notes created by the investigator are shredded immediately upon the entering of the factual information into the SIU system.

3.2 Preliminary Investigation

The purpose of a preliminary investigation is to determine if a reported Hotline allegation or a Provider or Recipient identified as suspicious during the claims payment review (retrospective and prospective), claims analysis, or data analysis process has a basis for further investigation. A preliminary investigation is conducted for all Hotline allegations and those Providers identified as suspicious or as an outlier.

The SIU completes all preliminary investigations of a Provider or Recipient within 15 working days of identification or reporting of suspected or potential waste, abuse, and/or fraud.

3.2.1 Preliminary Investigation: Incident Reports

When a preliminary investigation is initiated, the SIU immediately notifies the Compliance Officer or Responsible Entity of the incident and enters the following information into the SIU system:

1. The investigation number and the reference number to the allegation (if applicable).
2. If the complainant has requested that his/her identification remain confidential.
3. Source of the investigation (Hotline or SIU)
4. Type of reporting party (Provider, Recipients, El Paso Health, third party).
5. The suspect's ID number, business name, Provider name, address, and phone number (as applicable).
6. The complainant's ID number, business name, Provider name, address, and phone number (as applicable).
7. The allegation description.

3.2.2 Preliminary Investigation: SIU Procedures

Upon determination that a preliminary investigation is to be performed, the SIU:

1. Determines if the Provider or Recipient is currently under investigation or has had a prior investigation.
 - a. If the Provider or Recipient has had a prior investigation, the SIU initiates a new investigation and reviews the prior investigation(s) to determine if the new investigation is related to the prior investigation, the actions taken, and the reported outcome.
 - b. If the Provider or Recipient is currently under investigation for the same cause, the SIU updates the SIU system and enters the current issue into the SIU system for inclusion.
 - c. If the Provider or Recipient is currently under investigation for a separate cause, the SIU initiates a new investigation for the new cause.
 - d. If the Provider or Recipient is not under investigation and does not have a prior investigation, the SIU initiates a new investigation.
2. If the case is initiated by a Hotline allegation, the SIU initiates a new investigation.
3. Verify the Provider's licensure status and disciplinary actions available through public resources.
4. The SIU reviews the Provider or Recipient history to determine if the Provider or Recipient has received educational training regarding the investigative issue.
5. The SIU extracts a minimum of thirty-six (36) months claims history data from the SIU system for the Provider or Recipient under investigation.
6. The SIU reviews the claims history and run the necessary claim analysis reports to make a determination if the incident is an isolated situation or part of a pattern. The preliminary investigation encompasses all of the Provider or Recipient

claims, including claims that are unrelated to the cause of the investigation. When additional data is necessary, such as when a preliminary investigation involving possible abuse of controlled or non-controlled medications and El Paso Health does not have the data necessary to conduct a pharmacy claims review, El Paso Health will requests the data within 15 working days of the initial identification and/or reporting of the suspected or potential waste, abuse or fraud.

7. The SIU determines if there are any Provider overpayments associated with the preliminary investigation.
8. The SIU sends a Preliminary Investigation Report of all findings to the Compliance Officer or Responsible Entity and makes a recommendation as to possible actions to be taken. The Preliminary Investigation report includes:
 - a. The allegation information shown on the incident report.
 - b. The suspect's ID number, business name, Provider name, address, and phone number (as applicable).
 - c. The complainant's ID number, business name, Provider name, address, and phone number (as applicable).
 - d. The allegation description.
 - e. Claims analysis or the preliminary investigation.
 - f. Investigative notes.
 - g. SIU findings.
 - h. Interviews with all parties to the action.
9. El Paso Health reviews all internal policies and procedures to determine if the incident/allegation is in violation.
10. The Compliance Officer or Responsible Entity makes a determination as to what actions are to be taken based on the SIU findings. Actions may include:
 - a. Refer the Provider or Recipient to El Paso Health's education program.
 - b. Refer the Provider or Recipient to the monitoring program for the period of time designated by the Compliance Officer or Responsible Entity.
 - c. If El Paso Health determines that suspicious indicators of possible waste, abuse, or fraud exist then El Paso Health instructs the SIU to conduct a further review of medical records. (Please See "Extensive Investigations / Further Review" below for procedural details).
 - d. Close the case and instruct the SIU to take no additional action.

3.2.3 Preliminary Investigation: Unsubstantiated

If during the preliminary investigation, it is determined that the allegation is not substantiated or may have been a misunderstanding by the complainant or if the alleged fraud is found to be claims processing or clerical error, the SIU:

1. Reports to El Paso Health the findings.
2. Enters the finding into the investigation file and closes the investigation.

3.3 Extensive Investigations / Further Review

If El Paso Health determines that, based on the preliminary investigation and the SIU findings, there are indicators of possible waste, abuse, and/or fraud, El Paso Health shall direct the SIU to conduct a further review of the Provider beyond a preliminary investigation, called an “extensive investigation”.

3.3.1 Extensive Investigation: Medical Record Request - Provider

If El Paso Health determines that a more extensive investigation is to be conducted for a specific Provider:

1. Within 15 working days of the completion of the preliminary investigation the SIU utilizes appropriate sampling methodology selecting a minimum of 30 Recipients or 15% of the Provider’s claims from the data files in accordance to El Paso Health Policy Directive #2 – dated October 1, 2011 from the Office of Inspector General relating to SIU Overpayment Recovery Process, to detect patterns related to the suspected waste, abuse, and/or fraud through extrapolation, which is a statistically valid, reliable measure of total errors and overpayments.
2. The SIU may select other Provider(s) medical records required either as a party to the action or as a third party for information verification only.
3. Within 15 working days of the selection of the records to be audited, the SIU sends a request for medical records.
4. If Provider requires payment for copying the medical records, the SIU forwards all Provider correspondence to El Paso Health for payment determination.
5. If the Provider cannot make copies for any reason, the SIU notifies El Paso Health for resolution.

3.3.2 Extensive Investigation: Additional Record Request (as Appropriate)

The SIU may request records from supporting Providers to verify consistency in information for service procedures and for further evaluation of quality of care. If necessary for a complete and accurate audit, other records may be requested and reviewed. These include, but are not limited to:

1. Lab results from the pathologist
2. Imaging and x-ray results from the radiologist
3. Superbills used to input into the physicians accounting system that was completed by the physician
4. Accounting records/printout from the physician’s billing system
5. Supplier’s invoices
6. DME equipment delivery records
7. Recipient’s inpatient charts

8. Detailed supply listings
9. Documents and agreements between parties being investigated
10. Hospital discharge summaries and transfer forms
11. Physician orders and progress notes that describe the Recipient's response to treatments and his physical/mental status
12. Patient care plans
13. Nursing and rehabilitation therapy notes
14. Treatment and flow charts and vital sign records, weight charts and medication records

3.3.3 Extensive Investigation: Provider's Refusal to Make Copies

If a provider fails to respond to the initial request for records, a second request letter is sent. If again no response is received, a third and final request is sent. The SIU notifies El Paso Health if the Provider fails or refuses to supply the medical records requested. 1 TAC §353.502(g) states that:

“Failure of the Provider to supply the records requested by El Paso Health will result in the Provider being reported to the HHSC-OIG as refusing to supply records upon request and the Provider may be subject to sanction or immediate payment hold.”

El Paso Health notifies the OIG of Provider's refusal to provide copies (if applicable) or take other corrective actions.

3.3.4 Extensive Investigation: Receipt of Medical Records

Upon receipt of all the medical records requested pertaining to the investigation from all Provider(s) the SIU:

1. Organizes the documents by chart note within date of service, patient information, superbills and financial information within date of service for each Recipient.
2. Logs the documents into the SIU system.
3. Compares the documents types to the claims history data to verify that the documents needed are received.
4. Date stamps the documents.
5. Scans the documents and each scanned page is compared to the hardcopy received to assure accuracy and clarity.
6. Sends a copy of the medical records to El Paso Health's designated physician/provider for medical review, if applicable.
7. Sends a copy of the medical records to the SIU's investigative staff for coding or investigator review.

8. Makes available to medical and coding reviewers:
 - a. Detail list of all claims paid to the investigated Provider for each specific Recipient record subject to the investigation.
 - b. Detail list of all claims paid to Providers other than the investigated Provider for each specific Recipient record subject to the investigation (if applicable).
 - c. List of prescription drugs dispensed to Recipient(s) subject to the investigation, when applicable.

3.3.5 Extensive Investigation: Records Review – Medical (Medical Director, Physician, or Professional)

The purpose for reviewing the medical records is to verify if the Provider has provided the appropriate level of services, tests, and procedures for the health and well-being of the Recipient. The reviewing physician or professional shall review the records for correctness of diagnosis coding, medical care, proper utilization of services, quality of care, and adherence to billing standards.

El Paso Health informs the SIU as to who will be providing the medical records review for the investigation on a case-by-case basis. Areas reviewed in the medical records by the physician or professional include (as appropriate):

1. All services provided are necessary and appropriate for the Recipient's health and well-being.
2. Medical treatments are related to and consistent with diagnosis.
3. Procedures, tests, and treatments are necessary and related to injury or illness.
4. There is or is not an indication of over-utilization or under-utilization.
5. Pathology reports are correct with diagnosis, services, and medication.
6. Provider is not referring out for services that should have been done in-office.
7. All services were done in an appropriate setting.
8. Consultation or evaluation was done prior to the services being rendered.
9. The exam and service intervals were appropriate.
10. Prescriptions dispensed appear to be appropriate for Recipient's health conditions.
11. Prescription drugs prescribed are directly related to the wellness, injury, or illness of Recipient.
12. If brand name drugs were prescribed instead of generic, justification is documented.
13. Prescribing patterns appear to be appropriate. Volumes of medications are appropriate and not over prescribed.
14. Quantity, dosage, and frequency per prescription are correct.
15. Drugs do not appear to be contraindicated.
16. There does not appear to be multiple prescriptions prescribed by multiple Providers for like drug.
17. Off-label drugs are indicated appropriately.

18. If Recipient is prescribed controlled substances, psychotropic drugs, or commonly “street sold” drugs, are they limited to correct quantity and no other Provider is prescribing a similar drug?
19. Drugs in claims list equal the prescriptions in the Recipient’s file. If not, note all suspicious prescriptions.

Upon the completion of the medical review, the reviewer or designee:

1. Enters all findings for each medical record file into the SIU system.
2. Notifies the SIU of the completion of medical record review.

3.3.6 Extensive Investigation: Record Review - Medical Coding

The purpose of the medical coding review of the medical records and financial account records is to verify if the claims submitted for payment by the Provider are supported by the documentation in the patient’s medical file. The SIU reviews the records as follows (as applicable to investigation):

1. Verify that the services billed on the claims in the SIU system are supported by the information contained in the medical records.
2. Review other Provider data to determine if there is a conflicting medical report; i.e. medical examinations, emergency room reports, subsequent office visits, operative reports, anesthesia reports, pathology reports, and consent forms.
3. For electronic medical records, compare records across dates to determine if there is variability and to identify potential cloned or falsified records.
4. Verify that the actual number of units requested equals the units dispensed from other Providers. Verify that all DME and supplies requested (type and quantity) match the claims received from the dispensing Provider.
5. Dental services rendered for an injury where supported by medical records or evidence.
6. Check for alteration of dates, charges, and diagnosis.
7. Verify that there was no balance billing or additional fees paid by Recipient for covered services.
8. Verify if there were two carriers billed for the same services. If there were two carriers, notify El Paso Health of the findings so that El Paso Health can verify that Recipient qualifies for the program. If the Recipient does qualify, then verify that the payments were coordinated according to plan requirements.
9. Verify that the diagnosis submitted for payments equal the diagnosis in the Recipient’s file. Verify that the diagnosis has not been up-coded.
10. Verify that copies of referrals are in the Recipient's records.
11. Verify that all dates of service are listed in chronological order and all types of services provided are indicated on the correct date.
12. Verify that there are no missing dates of service.
13. Verify that there are sequential notes.

14. Verify that all dates of service in notes match dates of service on the claim.
15. Review type styles used in different areas of medical records listing services, treatments, diagnoses, procedures, and charges.
16. Verify that Provider signatures in the medical files are the same as the claims submitted.
17. Review handwriting is the same for each date of service (if records are handwritten).
18. Review that the records are not in the same handwriting covering a lengthy period of time (if records are handwritten).
19. Verify that records or claims do not contain whiteout (if records are handwritten).
20. Verify Recipient's address in record is the same as El Paso Health's mailing address for Recipient.
21. Verify that there is a copy of Recipient's identification card/number in the records and that the numbers match the claims submitted.
22. Verify prescription data received from PBM matches the medical records.
23. Recalculate each evaluation and management code (E&M) to verify that the CPT code was correctly billed according to accepted industry and program standards.

3.3.7 Extensive Investigation: Pharmacy Record Review (Physician, Pharmacist, or Pharmaceutical Professional)

If a Recipient has been flagged for a pharmaceutical review, El Paso Health's Physician, Pharmacist, and/or Pharmaceutical Professional determines if the prescriptions are appropriate and medically necessary for the Recipient and that no abuse is taking place.

If drug abuse is suspected or there is a documented diagnosis of a morbid addictive state (rather than abuse), the Physician, Pharmacist, and/or Pharmaceutical Professional reviewing the files discuss the case with the attending physician(s). If abuse is confirmed, the investigation is referred to El Paso Health's Compliance Officer or Responsible Entity for appropriate action.

The Pharmacy review includes (as appropriate):

1. Prescribing patterns appear to be appropriate. Volumes of medications are appropriate and not over prescribed.
2. Quantity, dosage, and frequency per prescription are correct.
3. High number of units per prescription that is inconsistent to FDA standards.
4. Duplicate prescriptions dispensed within a 30-day period (or 90 days if mail order).
5. Multiple physicians prescribing the same or similar prescription to a Recipient.
6. Drugs do not appear to be contraindicated.
7. Drugs dispensed are inconsistent to the Recipient's overall medical condition and listed diagnoses.

8. Off-label drugs are indicated appropriately.
9. If Recipient is prescribed scheduled controlled substances, psychotropic drugs, or commonly sold “street drugs”, are they limited to correct quantity and no other Providers are prescribing a similar drug.
10. The actual prescription copies are requested from the dispensing drug store to determine if the script has been altered (subject to authorization to audit the pharmacy).
11. Quantity per prescription is unusually large.
12. Brand name drugs when a generic alternative is available and the RX record does not indicate “DNS” or “DAW”.

3.3.8 Extensive Investigation: Completion of Record Review(s)

Within 45 working days of the SIU’s receipt of the medical records, all records reviews, including medical reviews and medical coding reviews are completed; all findings and recommendations are entered into the SIU system, and an investigative report is sent to El Paso Health’s Compliance Officer or Responsible Entity.

Reviewers inform the SIU that the medical records are complete. The SIU notifies El Paso Health that all documentation is ready for El Paso Health’s review.

El Paso Health makes a determination as to the appropriate actions to be taken and notify the SIU of those actions. The actions may include one or more of the following:

1. Referral of Provider or Recipient to El Paso Health’s education program.
2. Referral of Provider or Recipient to the SIU monitoring program.
3. Determine that no additional action is to be taken and the case is closed.
4. Determine if a review of other pertinent records is necessary, and if yes then conduct such review.
5. Report the Provider or Recipient to the Texas Office of Inspector General.

3.3.9 Extensive Investigation: Medical Records Are Not Available

In the case where a Provider’s medical records were partially or totally destroyed by accident or nature, the Provider must complete an attestation that no medical records exist.

If a Provider has sold his/her practice and another Provider is in possession of the original Provider’s medical records, the request for records is sent to the new Provider.

SECTION 4

PROCEDURES FOR DETECTING POSSIBLE ACTS OF WASTE, ABUSE OR FRAUD BY RECIPIENTS

4.1 Claims Review

The procedures for detecting possible acts of waste, abuse, or fraud by Recipients is substantially similar to the procedures reviewing payment of claims to detect possible errors, waste, abuse or fraud by Providers as described above.

At the beginning of each month and multiple times during the month, El Paso Health sends to the SIU the Recipient data files for additions, deletions, and changes that have occurred since the last data download (as applicable):

The claims review process includes, but is not limited to the following:

1. **El Paso Health** sends all prospective claims received for processing to the SIU.
2. Upon the SIU's receipt of the prospective claim download, the SIU processes all prospective claims through the SIU system and identifies claims as suspicious based on the SIU system claims edits and rules. Findings may include:
 - a. Duplicative, excessive or contraindicated claims;
 - b. The use of more than one Provider to obtain similar treatments and/or medications by a Recipient;
 - c. The treatment of a Recipient by Provider(s) other than the assigned Primary Care Provider with no evidence that the Recipient was treated by the assigned Primary Care Provider for a condition related to or similar to services rendered by other Provider(s);
 - d. High volumes of services including urgent care and emergency room visits by a Recipient with non-urgent or non-emergent diagnoses
3. The SIU provides **El Paso Health** with electronic access to the transactions flagged by the SIU system.
4. **El Paso Health** then reviews the SIU findings and determines if further action is to be taken. If the claims review does not clearly determine if errors, waste, abuse or fraud has occurred, then medical records for the Recipient(s) in question are reviewed as more fully described below in Section 5.

4.2 SIU Use of System Claim Edits and Rules

4.2.1 Use of Edits

Each claim transaction is processed through the SIU system edits and rules to isolate potential waste, abuse, and fraud. The SIU system described above also determine and report possible overuse and/or abuse of psychotropic and/or

controlled medications by Recipients who are allegedly treated at least monthly by two or more physician Providers such as psychiatrists, pain management specialists, anesthesiologists, and physical medicine and rehabilitation specialists.

SECTION 5

PROCEDURES FOR INVESTIGATING POSSIBLE ACTS OF WASTE, ABUSE OR FRAUD BY RECIPIENTS

5.0 Investigations of Recipients

The procedures for investigating possible acts of waste, abuse, and/or fraud perpetrated by Recipients is the same as the procedures and guidelines described above for investigating possible acts of waste, abuse, and/or fraud by Providers. This includes, but is not limited to, all procedures for Preliminary Investigations, Extensive Investigations, Records Review – Medical, Records Review –Medical Coding, and Pharmacy Reviews. However, the following variations to the above procedures apply:

5.0.1 Extensive Investigation: Medical Record Request – Recipient

If El Paso Health determines that an extensive investigation is to be conducted for a Recipient:

1. Within 15 working days of the completion of the preliminary investigation, the SIU identifies all Providers and claims that are subject to the Recipient's investigation.
2. Within 15 working days of the selection of the Providers and claims, the SIU sends a request for medical records to Provider(s).
3. If Providers requires payment for copying the medical records, the SIU forwards all Provider correspondence to El Paso Health for payment determination.
4. If the Providers cannot make copies for any reason, the SIU notifies El Paso Health for resolution.

SECTION 6

PROCEDURES FOR REPORTING POSSIBLE ACTS OF WASTE, ABUSE OR FRAUD TO THE SIU AND TO HHSC-OIG

6.1 Internal Reporting to SIU

The claims edit and rule processing of the SIU system is programmed to identify inconsistencies and billing errors. The SIU system identifies appropriate coding and documents the discrepancies. The SIU system recognizes if a Provider has coded services incorrectly and evaluates the codes submitted by the Provider based on the relationships between thousands of surgical, medicine, radiology, laboratory, and pathology procedures and diagnosis codes.

The SIU reports data matching, trending, statistical abnormalities and other suspicious indicators of possible waste, abuse, fraud or program violations to the Compliance Officer or Responsible Entity. The Compliance Officer or Responsible Entity causes the findings to be recorded in the log of all incidents of suspected waste, abuse and fraud. The SIU and the Compliance Officer or Responsible Entity consult with each other and take further action as deemed appropriate.

In addition to detecting possible errors, waste, abuse or fraud through the SIU system, El Paso Health has established a hotline described above for employees, Providers, Recipients, and third parties to report possible waste, abuse, and/or fraud. El Paso Health staff must treat all calls as a legitimate complaint until proven otherwise. El Paso Health must report all incoming Hotline complaints to the SIU within one working day (24 hours) of the complaint for follow-up according to policies and procedures.

The following information should be included in reports to the SIU:

Complainant's Identity

(Note: if the reporting party prefers to remain anonymous, the employee receiving the information must adhere to the wish of the reporting party and indicate "confidential".) This should include the complainant's name including any alias or alternative names, address, phone numbers (work, home and cell), e-mail addresses, complainant's Recipient or Provider ID number, if applicable.

Complainant's Relationship to Suspect

What is the relationship between the complainant and the reported suspect?

Date Received

Date the reporting party reports the allegation.

Suspect's Identity

This should include the suspect's name including any alias or alternative names, address, phone numbers (work, home and cell), e-mail addresses, suspect's Recipient or Provider ID number, if applicable.

Witnesses

This should include the identity of all witnesses including names, any alias or alternative names, addresses, phone numbers (work, home and cell), e-mail addresses, Recipient or Provider ID number, if applicable, and relationship to the suspect and/or the complainant.

Date(s) of Occurrence

Dates (from and to) that the allegation took place.

Allegation

A complete description of the allegation, including the type of error, waste abuse or fraud, such as balance billing, Recipient falsification of information, claims for services not rendered, or services not provided, should be included. It is important to include all of the information, with a presentation of the applicable facts only. No additional commentary or explanations should be included. An accurate account of the discussion should be the only thing reported.

Reports may be sent to the SIU as follows:

Email: SIU@HMS.COM

6.2 Internal Reporting from SIU to El Paso Health

All allegations are reported to the SIU within 24 hours of identification or reporting of suspected error, waste, abuse or fraud. Upon receipt of the allegation, the SIU immediately reviews the suspected waste, abuse, and/or fraud to determine if there is a basis to continue. If it is determined that a basis to continue exists, a preliminary investigation is commenced and a report from the SIU to El Paso Health will be made within fifteen (15) working days of that determination.

The SIU contacts El Paso Health's Chief Compliance Officer or Responsible Entity for questionable allegations. The SIU contacts the complainant if there is any further information or documentation needed to continue the investigation.

When reporting suspected error, waste, abuse or fraud, El Paso Health employees and the SIU shall adhere to the following requirements when drafting notes and comments contained in all reports:

1. Avoid an emotional writing style such as frequent exclamation points, underlining, and bold type. State the issue in as matter-of-fact way as possible.
2. Focus on the billing practice or issue. Avoid generalizing the problem to groups, specialties, or types of Providers.
3. Do not state that performance of the activity is fraudulent, even though the practice violates requirements. Always use the words "alleged," "suspected," "potential," "possible," or "maybe".
4. Avoid unnecessary terms and use plain English while remaining technically accurate. If technical terms are necessary, define the term.

6.3 Reporting Possible Acts of Waste, Abuse, and Fraud to the HHSC-OIG and OAG

If El Paso Health determines at any time after an allegation of waste, abuse or fraud is received that the allegation is sufficient for further action, El Paso Health shall send notice of the violation via email to the Office of Attorney General – Medicaid Fraud Control Unit (OAG-MFCU) at: MFCU@oag.texas.gov with the following in the subject line of the email: "MCO Notice." The notice shall include the following:

1. The allegation;
2. The provider name;
3. The provider's NPI, TPI and TIN;
4. And all of the information accumulated during the preliminary investigation, including copies of the relevant policies and procedures.

If it is determined, upon completion of the preliminary investigation and extensive investigation and medical records review, that a Provider or Recipient has committed possible acts of waste, abuse and/or fraud, El Paso Health shall report the Provider or Recipient to the HHSC-OIG and the OAG-MFCU for further action electronically. Notices sent to the HHSC-OIG are done electronically at the following website:

OIG Fraud, waste and abuse reporting
https://oig.hhsc.state.tx.us/Fraud_Report_Home.aspx

Notices are sent to the OAG-MFCU via e-mail. All notices must include "MCO Referral" in the subject line of the email and are sent to the below address:

MFCU@oag.texas.gov

All referrals to the OIG and the OAG-MFCU must be reported utilizing the HHSC-OIG fraud referral form within thirty (30) working days of receiving possible reports of waste, abuse or fraud. El Paso Health's Compliance Officer or Responsible Entity accesses the HHSC-OIG website and completes the HHSC-OIG fraud referral form referenced above unless it is an expedited referral to the HHSC-OIG.

El Paso Health prepares the referral in an approved format for filing with the HHSC-OIG and the OAG-MFCU. The referral and documentation include:

1. The final investigative report identifying the allegation, statutes/regulations violated or considered.
2. Copies of program rules, statutes, and regulations violated or considered for the time period in question.
3. The results of the investigation.
4. The estimated overpayment identified.
5. A summary of interviews conducted.
6. The encounter data submitted by the Provider for the time period in question.
7. All supporting documentation obtained as the result of the investigation.

6.3.1 Monthly Report of Open Cases

In addition to any referrals, on a monthly basis, El Paso Health will submit to the OIG and OAG-MFCU a report listing all open cases. This Monthly Open Case List Report shall be submitted on the first Monday after the 14th of each following month. (i.e., report for January would be due on the first Monday after February 14.) El Paso Health shall not initiate any enforcement action on cases reported to the monthly report of open cases until El Paso Health receives notification from the OIG and OAG-MFCU that neither will accept the case or ten business days have elapsed from the filing of the monthly report, whichever occurs first.

This monthly report shall be in a format specified by the OIG and will include cases that:

1. Are completed within the month (“Up to \$100,000” and “Over \$100,000”);
2. Are not completed (“Cases Pending”);
3. Did not result in a finding (“No Findings”);
4. Resulted in a recoupment of any overpayments;
5. Resulted in the suspension of payments to the provider based upon a credible allegation of fraud;
6. Not accepted by OIG (“All MCO Cases Not Accepted by OIG”); or
7. Were referred directly to OIG Sanctions within the month (note in “Comments” column whether the case is “Up to \$100,000” or “Over \$100,000”);

6.3.2 Investigation Log

All investigations are entered into the SIU system and available for reporting anytime to El Paso Health. The SIU system maintains a continual log of all investigations conducted for all suspected waste, abuse, and/or fraud received, regardless of the source. The log shall contain:

1. The investigation number.

2. The allegation.
3. The subject of the complaint.
4. The suspected Recipient's or Provider's Medicaid number.
5. The source where the allegation was determined (Hotline, SIU, Claims Department, Compliance officer, Responsible Entity).
6. Date of occurrence (The time period in question).
7. Date received/identified. (The date the incident was reported).
8. SIU findings (Reporting of suspected and/or potential waste, abuse, and/or fraud).
9. The status of the investigation.
10. If the status is open or closed; and if closed, what action taken.

The log is provided at the time of a reasonable request to the HHSC-OIG, OAG-MFCU, OAG-CMFD, and the HHS-OIG. A reasonable request means a request made during hours that the business or premises is open for business.

6.4 Confidentiality

El Paso Health and the SIU must maintain the confidentiality of any Provider and/or patient information relevant to an investigation of waste, abuse, or fraud before, during, and after the investigation process for any reason whatsoever.

Upon completion of the investigation by the SIU, all documentation, records, and reports obtained and completed during the investigation and audit are forwarded to the Compliance Officer or Responsible Entity for secure storage and/or routing to the OIG as necessary.

6.5 Expedited Referrals

An expedited referral may be filed with the OIG if El Paso Health has reason to believe that a delay may result in:

1. Harm or death to patients.
2. The loss, destruction, or alteration of valuable evidence.
3. A potential for significant monetary loss that may not be recoverable.
4. Hindrance of an investigation or criminal prosecution of the alleged offense.

If El Paso Health has reason to believe that a delay may result or has resulted in bodily harm, exploitation or death El Paso Health shall send an expedited referral to both the OIG and OAG-MFCU. Any expedited referral should be marked "EXPEDITED" on the cover sheet and first page at the top of the page.

6.6 Additional Reporting to Texas Department of Insurance

In addition to other reporting duties and obligations, the Compliance Officer or Responsible Entity shall comply with Texas Insurance Code § 701.051. Specifically, whenever the Compliance Officer or Responsible Entity makes a determination or reasonably suspects that a Fraudulent Insurance Act, as described below, has been or is about to be committed in Texas, he/she, within thirty days of making such determination or having such reasonable suspicion, report the information in writing to the insurance fraud unit of the Texas Department of Insurance in the format prescribed by the fraud unit or by the National Association of Insurance Commissioners

A "Fraudulent Insurance Act", as defined by Texas Insurance Code § 701.001 (2), means an act that is a violation of a penal law and is:

- (A) Committed or attempted while engaging in the business of insurance;
- (B) Committed or attempted as part of or in support of an insurance transaction; or
- (C) Part of an attempt to defraud an insurer.

SECTION 7

PROCEDURES FOR EDUCATING RECIPIENTS AND PROVIDERS TO PREVENT WASTE, ABUSE, AND FRAUD

7.0 Provider Education Program

Education is the key to ensure proper Provider billing. The Provider waste, abuse, and fraud education program encompasses proactive material and communication as well as retrospective, which includes Provider communications and reports of Provider compliance actions. Inherent to that success is a comprehensive effort to educate the Provider coverage and coding principles to ensure correct billing practices.

El Paso Health may determine that the resolution of a case does not warrant a referral to the OIG and that a meeting with the Provider is more appropriate. El Paso Health informs the Provider of questionable or improper practices and the correct procedure to be followed. El Paso Health documents all contacts and/or warnings by entering the actions into the SIU system. If the improper practices continue, El Paso Health may take action.

Management for the Provider Education Program is the responsibility of the Compliance Officer or Responsible Entity.

The aspects of these education programs are as follows:

1. Proactive education may include:
 - a. Publishing of periodic information articles regarding the waste, abuse and fraud program in the Provider newsletters, pamphlets, brochures, bulletins, articles for newsletters, alerts, and e-mail and/or fax blasts.
 - b. Updating the Provider manuals as changes occur to policies and procedures that effect the Provider's participation in the waste, abuse and fraud program.
 - c. A description of the violations for a specific Provider claim on the explanation of benefits at the time of payment.
 - d. Web-site information including a question and answer section.
 - e. Solicitation of assistance from local medical and specialty societies.
 - f. Proactive local educational meetings including seminars, workshops, and classes.
2. Retrospective education includes on-site education, as a violation occurs, to explain the specific claim incident. The educational training sessions include on-site meetings, telephone conferences, and/or educational letters. While Provider specific education may correct most issues in the first educational meeting, some Providers may require additional education contacts to provide further instruction.
3. Provider education materials may include:

- a. The consequences of fraud, waste and abuse, including enforcement of standards through disciplinary guidelines.
- b. Understanding Healthcare Waste, Abuse, and Fraud.
- c. Definition of Possible Waste, Abuse, and Fraud.
- d. A Description of How Waste, Abuse, and Fraud are being identified within El Paso Health.
- e. The Provider's Responsibility within the Program.
- f. How and Who to Report Suspected Waste, Abuse, and Fraud.

7.1 Provider On-Site Education Program

If El Paso Health determines that the investigative issue found during the preliminary investigation and/or medical records review can be corrected by education, El Paso Health and the SIU initiate the proper actions of the education process.

Education Process

The education process responsibilities involve both the SIU and El Paso Health. The steps to the Education program are as follows:

El Paso Health Duties

1. Determine if Provider will participate in the education program.
2. Conduct Provider education based on the SIU findings. El Paso Health's Provider Relations staff will be sent to the Provider to perform on-site training that may include:
 - a. Explain the SIU program and the governmental regulations requiring the SIU functions.
 - b. Explain Provider's potential liability and risks associated with the lack of adhering to the laws and regulations.
 - c. Present Provider irregular and suspicious billing findings.
 - d. Present Provider comparative data as to how the Provider varies significantly from other Providers in the same specialty and geographic area through the SIU data analysis process.
 - e. Explain the claims processing standards, policies, and procedures utilizing prepared training materials.
 - f. Provide education materials.
3. Once the education process is completed and entered into the SIU system, the SIU will track the progress of the Provider or Recipient through the monitoring program.

SIU Duties

1. Provide detailed reports to Compliance Officer or Responsible Entity of specific issues found during preliminary investigation and monitoring program so that they can be discussed with Provider's staff for educational process.

7.2 Recipient Education Program

The waste, abuse, and fraud education program encompasses proactive material and communication as well as retrospective, which include Provider communications and reports of Recipient compliance actions.

1. Proactive education includes:
 - a. The consequences of fraud, waste and abuse, including enforcement of standards through disciplinary guidelines.
 - b. Publishing of periodic information articles regarding the waste, abuse and fraud program in the Recipient's newsletters, pamphlets, brochures, and bulletins.
 - c. Updating the Recipient handbooks and sending supplemental information pages as changes occur to policies and procedures that effect the Recipient's participation in the waste, abuse and fraud program.
 - d. Website information.
2. Retrospective education includes letters and phone calls explaining the possible violation.
3. Recipient education materials may include:
 - a. Understanding Healthcare Waste, Abuse, and Fraud.
 - b. Definition of Possible Waste, Abuse, and Fraud.
 - c. The Recipient's Responsibility within the Program.
 - d. How and Who to Report Suspected Waste, Abuse, and Fraud.

7.3 Monitoring Program

The purpose of the monitoring program is to track the Provider or Recipient's progress over a period of time to determine if there are any changes in behavioral patterns or if actions have been taken by the Provider or Recipient to correct a prior investigation.

Based on El Paso Health directives derived in response to the preliminary investigations, education program, and/or medical records review, the SIU monitors the Providers or Recipients determined to require placement in the monitoring program for an amount of time designated by MCO or until the case is closed. The SIU enters all findings into the SIU system for management, tracking, and reporting purposes.

7.3.1 Monitoring Process

Based on El Paso Health's directives, a Provider or Recipient may be placed under the monitoring program for a designated period of time or until the case is closed.

El Paso Health *Duties*

El Paso Health takes the following steps in the monitoring program process:

1. Determine if Provider or Recipient will participate in the monitoring program.
2. Determine the length of time a Provider or Recipient will participate in monitoring program.
3. Once the SIU has reported its monitoring findings to El Paso Health, determine if any additional actions are to be taken regarding matter and notify the SIU of decision.

SIU Duties

The SIU takes the following steps in the monitoring process:

1. Monitor Provider or Recipient claims as to the investigative issues and enter the findings into the SIU system.
2. Report to El Paso Health the results of the Provider or Recipient monitoring program based on the data analysis upon completion of the monitoring period.
3. Once El Paso Health has determined if any additional actions are to be taken regarding the matter and has notified the SIU of the determination, the SIU updates the SIU system accordingly for continued monitoring or, if Provider/Recipient is found to be in compliance, the halting of any further monitoring of the Provider/Recipient.

7.3.2 Post-Monitoring Surveillance

The SIU follows the monitoring program for future claims and related actions of the Provider or Recipient for El Paso Health's designated time period, to assure the propriety of future claims transactions. If, at the end of El Paso Health's designated time period, there is no indication of a continuing deviant pattern, the SIU reports the analysis to El Paso Health and discontinues the monitoring at the direction of El Paso Health.

7.3.3 Case Education Resolution

El Paso Health may determine that the resolution of a case does not warrant a referral to the OIG and that a meeting with the Provider is more appropriate. El Paso Health must inform the Provider of questionable or improper practices, the correct procedure to be followed, and that continuation of the improper practice will result in being reported to the OIG. El Paso Health documents all contacts and/or warnings with written reports and correspondence and places them in an Investigative file. If the improper practices continue, El Paso Health takes action.

7.4 Provider Education for DEFRA Compliance

El Paso Health informs all Providers who receive five (5) million dollars or more from El Paso Health in any given year, of the Deficit Reduction Act of 2005. El Paso Health disseminates information that makes all of these Providers aware of the Federal False

Claims Act, appropriate state false claims acts, and the Program Fraud Civil Remedies Act of 1986.

El Paso Health complies with all standards and requirements of the Deficit Reduction Act of 2005.

The following is a description of Federal and State False Claims Act laws that describe the rights and duties of El Paso Health's employees, specifically "Whistle Blower" rights of employees. Under Section 6032 of the Deficit Reduction Act of 2005, Congress has required that any entity that makes or receives annual payments of \$5 million or more under a state Medicaid program must include a description of both the Federal False Claims Act and the relevant State False Claims Act in which the entity resides in the entity's compliance plan and employee handbook.

The purpose of this section is to ensure compliance with the Deficit Reduction Act by ensuring that all employees, including management, and any contractors or agents are educated regarding the federal and state false claims statutes and the role of these laws in preventing and detecting fraud, waste and abuse in federal health care programs. All employees, contractors and agents of El Paso Health are educated and informed regarding the following information:

7.4.1 Federal False Claims Act

The Federal False Claims Act ("Act") permits any person who knows of fraud against the United States Government to file a lawsuit on behalf of the Government against the person or business that committed the fraud. The person who files the lawsuit is known as a "qui tam plaintiff". If the action is successful, the qui tam plaintiff is rewarded with a percentage of the recovery.

The qui tam plaintiff must notify the U.S Department of Justice (DOJ) of their lawsuit and provide the DOJ with all information about the fraud. The DOJ then has the option of intervening and taking over prosecution of the lawsuit from the qui tam plaintiff. If the Justice Department decides not to intervene, the qui tam plaintiff may pursue the lawsuit on behalf of the Government.

If the DOJ takes over, the qui tam plaintiff is entitled to between 15% and 25% of the recovery. If the DOJ does not intervene, and the qui tam plaintiff pursues the action individually, the qui tam plaintiff is entitled to between 25% and 30% of the recovery.

If the fraud is proven, the defendant is generally liable for three times the damages sustained by the Government because of the fraud. In addition, the defendant is liable for an additional \$5,000 to \$10,000 for each false claim it made to the Government.

7.4.2 Whistleblower "Qui Tam" Plaintiff

Any person may bring a qui tam action regardless of whether he or she has "direct" or first-hand knowledge of the fraud, conditioned that the fraud has not already been publicly disclosed. Thus an employee that learns from a colleague of fraud by his or her employer at work may bring a qui tam action, even if the qui tam plaintiff personally has no first-hand knowledge.

If the fraud has already been publicly disclosed, a person may still bring a qui tam action if he or she has direct knowledge of the fraud, independent of the publicly disclosed information. Thus, if an employee personally observes or uncovers fraud by his or her employer, or another person or company, the employee may bring a qui tam action even if the information has already been publicly disclosed.

Anyone who has knowledge of fraud against the Government should seek legal advice to determine whether he or she qualifies to bring a qui tam action.

7.4.3 How the Act Applies to Waste, Abuse, and Fraud

Under the False Claims Act, fraud has a very wide and inclusive meaning. Under the Act, the defendant does need to have known that the information it provided to the Government was false. It is sufficient that the defendant supplied the information to the Government either: (i) in "deliberate ignorance" of the truth or falsity of the information; or (ii) in "reckless disregard" of the truth or falsity of the information.

Thus, the Act is not limited solely to those who intentionally misrepresent facts, it also covers reckless conduct.

Whether the reported act is intentional fraud, waste, or abuse, the same penalties may be assessed against the wrongdoer and the same reward is payable to the qui tam plaintiff.

The Act permits recovery from those who "cause" misrepresentations to be made to the federal Government by others. In other words, a person may violate the law even if he or she does not actually submit the false information to the Government, but instead creates or provides false information that is then submitted to the Government by another.

7.4.3.1 Whistle Blower Protection

The Act provides protection to employees who are retaliated against by an employer because of the employee's participation in a qui tam action. The protection is available to any employee who is fired, demoted, threatened, harassed or otherwise discriminated against by his or her employer because the employee investigates, files, or participates in a qui tam action.

This "whistleblower" protection includes reinstatement and damages of double the amount of lost wages if the employee is fired, and any other damages sustained if the employee is otherwise discriminated against.

7.4.4 Texas False Claims Act

The Texas False Claims Act is substantially similar to the Federal False Claims Act. However, under the Texas False Claims Act, a person may also be liable if he presents a claim for payment under the Medicaid program for a product or service that was rendered by an unlicensed Provider or that has not been approved by a healthcare practitioner. The civil penalty under the Texas False Claims Act is greater than the Federal False Claims Act for unlawful acts that result in injury to an elderly person, a disabled person, or someone under the age of eighteen.

7.4.4.1 Whistleblower Protection

The Texas False Claims Act has a whistleblower provision. Similar to the Federal False Claims Act, the Texas False Claims Act includes provisions to prevent employers from retaliating against employees who report their employer's false claims.

7.4.5 Program Fraud Civil Remedies Act of 1986

The Program Fraud Civil Remedies Act of 1986 (the "PFCRA") provides administrative remedies against any person who makes a false claim or written statement to any of certain federal agencies. A false claim or statement includes submitting a claim or making a written statement that is for services that were not provided, or that asserts a material fact that is false, or that omits a material fact. A violation of the PFCRA results in a maximum civil penalty of \$5,000 per claim plus an assessment of up to twice the amount of each false or fraudulent claim.

7.4.6 Dissemination of policies to Employees, Contractors and Agents

El Paso Health has adopted written policies for the prevention and detection of fraud, waste and abuse. All current employees, contractors and agents have been informed of such policies, and all future employees, contractors and agents are made aware of these policies upon commencement of employment, contract or agency. These policies are readily available to all employees, contractors and agents for dissemination upon request and are contained in all employee handbooks, if any.

7.5 Waste, Abuse, and Fraud Definitions

The following definitions are included in all Provider and Recipient education:

Waste

Practices that spend carelessly and/or allow inefficient use of resources, items or services(1 TAC §371.1601 (57))

Abuse

Practices that are inconsistent with sound fiscal, business, or medical practices and that result in unnecessary program cost or in reimbursement for services that are not medically necessary; do not meet professionally recognized standards for health care; or do not meet standards required by contract, statute, regulation, previously sent interpretations of any of the items listed, or authorized governmental explanations of any of the foregoing.
(1 TAC §371.1601 (1))

Fraud

Any act that constitutes fraud under applicable Federal or State law, including any intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to that person or some other person. Fraud may include any acts prohibited by the Texas Human Resources Code Chapter 36 or Texas Penal Code Chapter 35A.
(1 TAC §371.1601 (16))

The applicable Federal law definition is:

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.
(42 CFR 455.2)

Program Violations

A failure to comply with Medicaid or other HHS Provider contractor agreements, the Texas Medicaid Provider Procedures Manual, or other official program publications or any state or federal statute or regulation applicable to the Texas Medicaid or other HHS program including any official written explanation or interpretation of the above. Waste, abuse, and fraud are program violations, but not all program violations are included in waste, abuse, and fraud. Program violations are defined in 1 TAC §371.1617

SECTION 8

PROCEDURES FOR EDUCATING AND TRAINING EL PASO HEALTHPERSONNEL TO PREVENT WASTE, ABUSE, AND FRAUD

8.0 Education Training Program Overview

While the SIU review process assures appropriate claims payment and allegation investigation, the Employee Education and Training Program assures appropriate claims payment and identification of possible waste, abuse, and fraud through proactive and reactive employee education.

8.1 Education Training Program Management

Management for the Education Training Program is the responsibility of the Compliance Officer or Responsible Entity. The Compliance Officer or Responsible Entity:

1. Oversees the education training programs.
2. Manages and tracks all employee annual and new hire fraud training.
3. Manages and tracks all subcontractor fraud training.
4. Is responsible for ensuring the Compliance Officer or Responsible Entity's education and training is current and at the appropriate level to educate and train El Paso Health's employees, providers and recipients. This includes attending and participating in any annual training offered by HHSC-OIG in compliance with Texas Government Code §531.105.

8.2 Analysis to Identify Educational Needs

El Paso Health identifies areas requiring education from a wide variety of sources. Some of the areas that are used for identification are the SIU data analysis, claims review, and hotline allegations.

8.3 Education Materials and Programs

The Education Training Program includes:

1. PowerPoint presentations for general and department specific education programs.
2. Employee access to Provider and Recipient education materials.
3. Updates to the employee handbooks.

8.4 Employee Education Programs

Employee awareness and monitoring of waste, abuse, and fraud is an essential key to the effectiveness and success of the Compliance Plan. When used in this section, the term “employee” means all El Paso Healthstaff, vendor staff, and contractor staff that are directly or indirectly involved in the Medicaid or CHIP programs.

8.5 General Education Training Classes

A general education class is held on a periodic basis but at a minimum annually for all employees. The general training class includes the following:

1. Understanding Healthcare Fraud and Abuse - Definition of possible waste, abuse, and fraud.
2. Detection and Identification of Potential Fraud - A description of how waste, abuse, and fraud are being identified within the organization.
3. Understanding the Financial Impact.
4. The Employee’s Responsibility within the Program.
5. A Description of Departmental Responsibilities within El Paso Health in Identifying Waste, Abuse, and Fraud.
6. How to Report Suspected Waste, Abuse, and Fraud.
7. To Whom to Report Suspected Waste, Abuse, and Fraud.
8. The consequences of fraud, waste and abuse, including enforcement of standards through disciplinary guidelines.

8.6 Specific Education Training Classes

On an annual basis each employee who is directly involved in the Medicaid or CHIP programs is required to attend a waste, abuse, and/or fraud education class to reinforce the employees’ awareness of the program and be cognizant of the actions of potential abusers. In addition to all of the topics included in the “General Education Training Class”, the specific education training class includes employee’s specific responsibility areas for awareness and examples of waste, abuse, and fraud. The employees required to attend the class include:

1. All management staff.
2. All employees involved in all aspects of the handling of an electronic or hardcopy claim. This includes, but is not limited to, logging, entering, processing, adjudication, adjusting, verification of the claims for payment, post-review, and check printing.
3. Information systems personnel who have any access to the claims adjudication system or any data download received or sent to a third party.
4. Accounting department employees who manage the Recipient enrollment downloads from the state and the reconciliation data.
5. Utilization management and review departments who have direct access or authority for authorization of a medical service or procedure.

6. Quality assurance employees.
7. Appeals or grievances processing employees.
8. Provider management employees who have direct contact with the Providers either by phone or on-site.
9. All indirect staff that have direct or indirect access to the Provider contracts and managing Provider data in the claims processing system.
10. Marketing staff that has direct or indirect contact with Recipients or Providers. This includes the managing of all Provider and Recipient brochures, marketing materials, handbooks, website content, and Provider manuals.
11. Customer service staff that have direct contact with the Providers and Recipients either by phone or on-site.
12. Credentialing staff that processes the Provider's credentialing and application information. All staff that performs on-site inspections required for the credentialing process.

8.7 New Employee Training Classes

Within 90 days of an employee's employment date, the employee is required to attend a waste, abuse, and fraud training class. The specific class for the employee, be it the general class or a job specific class, will depend on the employees' specific job requirements.

8.8 Employee Training Class Log

El Paso Health maintains a training log identifying all employees attending the training classes pertaining to waste, abuse, and fraud in Medicaid and CHIP. The log includes:

1. Name and title of the trainer.
2. Names of all employees attending the training.
3. Date of the training.
4. Length of time (number of hours) of the class.

The log is made immediately available upon request to the HHSC-OIG, Office of the Attorney General's (OAG) - Medicaid Fraud Control Unit (MFCU) and OAG – Civil Medicaid Fraud Division (CMFD), and the United States Department of Health and Human Services- Office of Inspector General (DHHS-OIG).

8.9 Changes to Policies and Procedure within the Plan

If a policy or procedure changes within any department and such change directly or indirectly affects the waste, abuse and fraud program, the policies and procedures of the employee-training program are updated within twenty (20) working days of the change. A notice of the change is sent to all departmental managers. If the change has a great effect on the Waste, Abuse and Fraud Program, a special training class is given to all direct employees.

8.10 Personnel Education for DEFRA Compliance

El Paso Health educates and disseminates information to all employees regarding the Deficit Reduction Act of 2005. El Paso Health makes all employees aware of the Federal False Claims Act; appropriate state false claims acts, and the Program Fraud Civil Remedies Act of 1986.

Please see “Provider Education for DEFRA Compliance” above for details regarding specific DEFRA educational topics and information.

8.11 Subcontractor Education and Training

El Paso Health requires all subcontractors to provide fraud, waste, and abuse training as described above in “General Education Training Classes.” El Paso Health informs all subcontractors who receive five (5) million dollars or more from El Paso Health in any given year, of the Deficit Reduction Act of 2005. El Paso Health disseminates information that makes all of these Subcontractors aware of the Federal False Claims Act, appropriate state false claims acts, and the Program Fraud Civil Remedies Act of 1986. The specific DEFRA educational topics and information are the same as described above for “Provider Education for DEFRA Compliance.”

8.12 Waste, Abuse, and Fraud Definitions

The following definitions are included in all personnel training and education:

Waste

Practices that spend carelessly and/ or allow inefficient use of resources, items or services.

((1 TAC §371.1601 (57))

Abuse

Practices that are inconsistent with sound fiscal, business, or medical practices and that result in unnecessary program cost or in reimbursement for services that are not medically necessary; do not meet professionally recognized standards for health care; or do not meet standards required by contract, statute, regulation, previously sent interpretations of any of the items listed, or authorized governmental explanations of any of the foregoing.

((1 TAC §371.1607 (1))

Fraud

Any act that constitutes fraud under applicable Federal or State law, including any intentional deception or misrepresentation made by a person with the knowledge that the

deception could result in some unauthorized benefit to that person or some other person. Fraud may include any acts prohibited by the Texas Human Resources Code Chapter 36 or Texas Penal Code Chapter 35A.
(1 TAC §371.1607 (16))

The applicable Federal law definition is:

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.
(42 CFR 455.2)

Program Violations

A failure to comply with Medicaid or other HHS Provider contractor agreements, the Texas Medicaid Provider Procedures Manual, or other official program publications or any state or federal statute or regulation applicable to the Texas Medicaid or other HHS program including any official written explanation or interpretation of the above. Waste, abuse, and fraud are program violations, but not all program violations are included in waste, abuse, and fraud. Program violations are defined in 1 TAC §371.1617.

SECTION 9

ASSIGNED PERSON RESPONSIBLE FOR CARRYING OUT SIU PLAN

9.0 Responsible Entity

El Paso Health is responsible for the oversight and management of the FWA Compliance Plan and should be, but is not limited to a Compliance Officer, a Manager of Government Programs, Regulatory Compliance Analyst, Director of Quality Integrity or person in senior management. The responsible entity shall also be the chairperson of El Paso Health's FWA Compliance Committee who collectively is accountable to senior management of El Paso Health. El Paso Health has designated the responsible entity as the individual responsible for and has the authority to:

1. Review all documents and compliance activities.
2. Report all investigations resulting in a finding of possible waste, abuse, and/or fraud to the OIG within thirty (30) days of receiving the reports of possible waste, abuse, and/or fraud.
3. Oversee and direct the activities for the SIU.
4. Report to El Paso Health's governing body, CEO, and all senior staff.
5. Review, update, and maintain standards and manuals.
6. Promptly take the appropriate steps when receiving hotline tips of possible cases of waste, abuse, and/or fraud.
7. Ensure that employees are receiving adequate education and training and that all education is documented.
8. Implement proper audit and oversight procedures.
9. Maintain the incidence log.
10. Oversee and direct the activities of El Paso Health's FWA Compliance Committee.

9.0.1 Compliance Officer or Responsible Entity's Contact Information

Address:

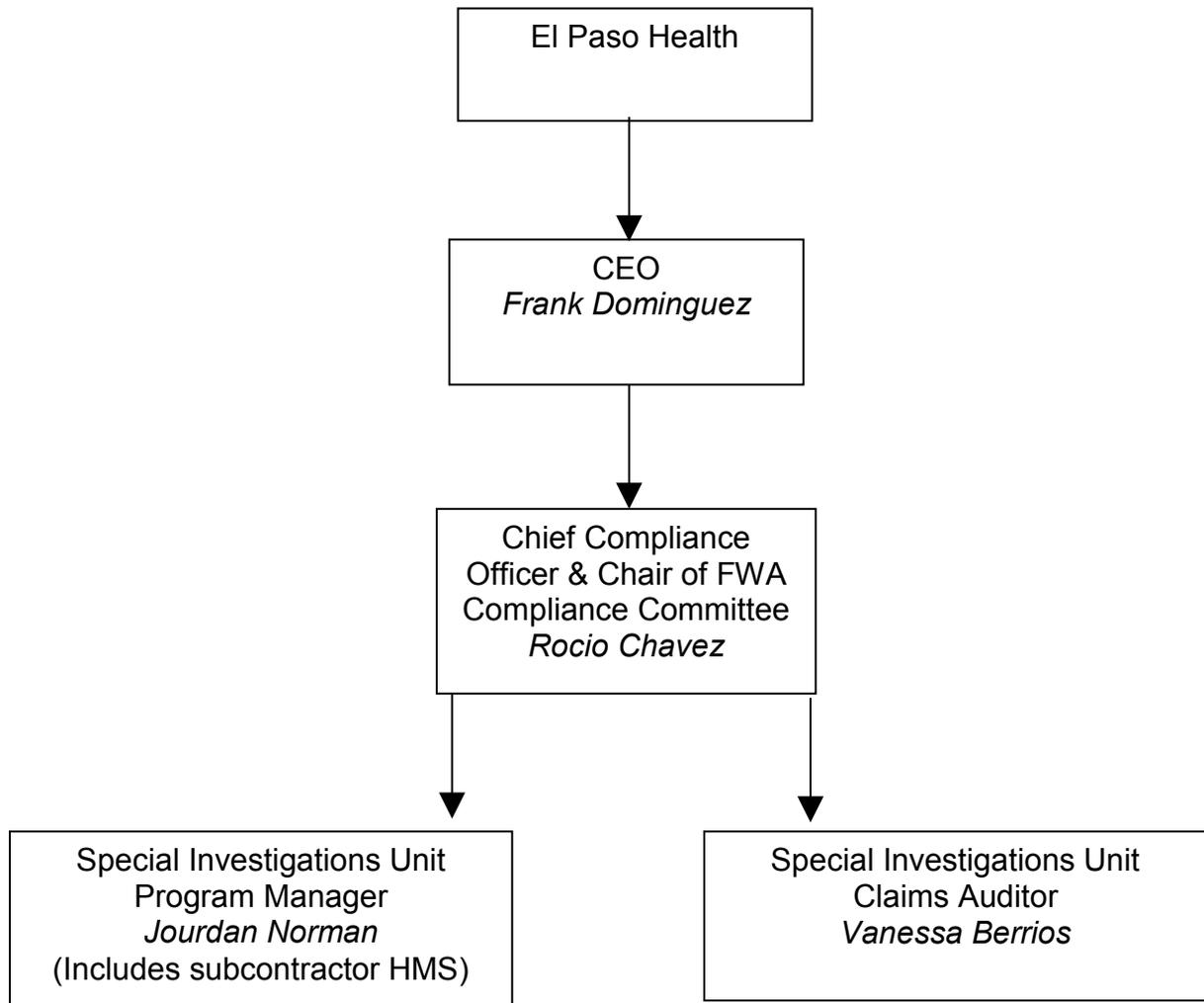
El Paso Health
Attn: Rocio Chavez, Chief Compliance Officer
1145 Westmoreland
El Paso, TX 79925

Contact or call the compliance department by voice at 915-298-7198 ext. 1032 or by fax at 915-532-2877.

If any change to the above identified, Rocio Chavez, Chief Compliance Officer, is made, then any changes to the above contact information must be reported to the HHSC-OIG within 15 working days of the change.

9.1 Program Organizational Chart

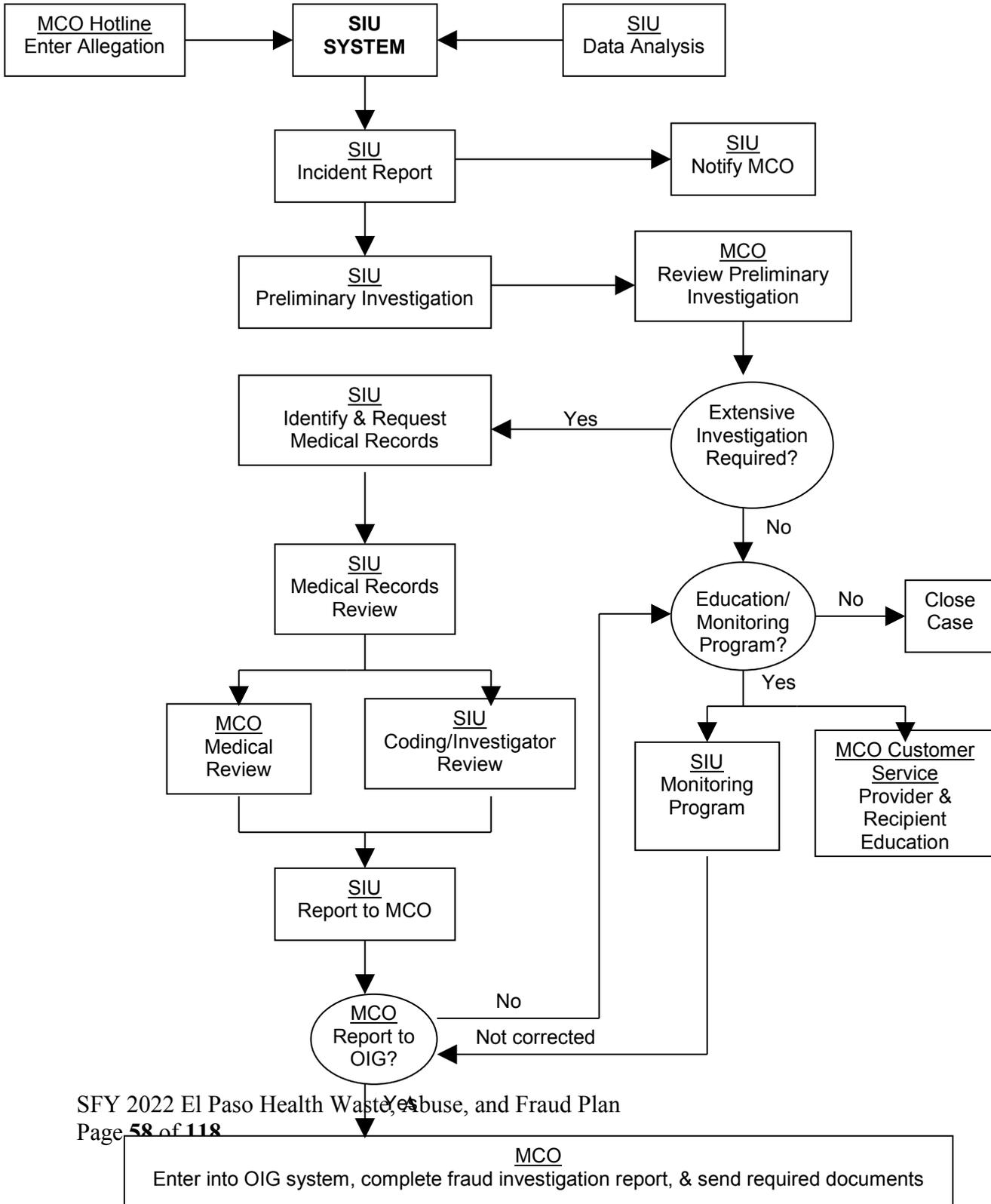
The Program Organizational Chart shows the reporting structure of El Paso Health to the SIU.



SECTION 10

SIU PROCESS FLOW DIAGRAM

10.0 SIU Program Flowchart



SECTION 11

ADVERTISING

11.0 Advertising

The advertising and marketing materials used by El Paso Health must accurately reflect the information about El Paso Health. This includes, but is not limited to, all Provider and Recipient brochures, marketing materials, employee handbooks, web-site content, and Provider manuals.

All documents include information regarding the waste, abuse, and fraud program and the Recipient's responsibility of compliance and reporting.

11.1 Recipient Materials

All material sent to Recipients accurately reflect the information and benefits offered by El Paso Health. All enrollment materials and Recipient handbooks include information regarding the waste, abuse, and fraud program and the Recipient's responsibility of compliance and reporting.

SECTION 12

RECOVERY PROGRAM

12.0 Recovery Program Overview

Many claim errors, waste, abuse, and fraud issues are determined prospectively at the time of claim payment and are deducted from the claim amount paid to the Provider. However, there are some areas that require a medical record review to determine if a deduction can be made. These areas include the retrospective review of claims paid (such as claim history, prospective claim not adjusted prior to payment, or an expedited claim payment outside the normal claims procedures) and Provider and Recipient claims identified through data analysis.

When an investigation leads to a suspected fraudulent or abusive Provider or Recipient, El Paso Health may report the case to the OIG's office for investigation. Upon the discovery of actual fraud or abuse, El Paso Health immediately and contemporaneously notifies the OIG as well as the AG.

If a case with clear evidence of fraud, waste or abuse is referred to OIG/AG, and the recovery amount sought exceeds \$100,000.00, El Paso Health abates any recovery efforts until ten business days' elapses after the OIG/AG was notified. Within this ten business day period, the OIG/AG may notify El Paso Health that it is not authorized to proceed with any recovery efforts. If no such notification is received by El Paso Health within the ten business day period, then El Paso Health shall recommence recovery efforts in accordance to applicable rules and regulations propounded by HHSC and/or the OIG.

If the recovery amount is less than the dollar threshold, and neither the OIG nor the AG accepts the case for recovery, El Paso Health shall pursue recovery efforts in accordance to applicable rules and regulations propounded by HHSC and/or the OIG.

If a case does not have clear evidence of fraud, waste or abuse or cannot be "clearly defined" as suspect for fraud or abuse El Paso Health may elect to collect the funds through El Paso Health's recovery program.

12.1 Recovery Methods

When a claim has been overpaid and a recovery is necessary the methods of recovery are determined on a case-by-case basis and include:

Claim Deduction

El Paso Health must withhold the Provider's future claim payments for a recovery of a prior overpayment, unless there are no potential claims from the Provider in a reasonably

foreseeable amount of time. This requirement is defined in the OIG MCO Policy Directive #1 dated 8-7-06 entitled, "SIU Overpayment Recovery Process". Also, if less than \$100,000.00 is involved, there is no evidence of intentional deception, waste or abuse, and an error rate does not exceed 15%, El Paso Health will educate the provider, document the educational efforts, and recover any overpayment via claims adjustments. This requirement is defined in the OIG MCO Policy Directive #2 dated 4-1-11 entitled, "SIU Overpayment Recovery Process".

Collection Program

If recovery is not possible or improbable through a future claim deduction, El Paso Health may elect to send the Provider or Recipient to collections (internal or external) for recovery of a prior overpayment.

Small Claim Action

If recovery is not possible or improbable through a future claim deduction, El Paso Health may elect to send the recovery to small claims court.

Referral to MCO Attorney for Legal Action

If recovery is not possible or improbable through a future claim deduction, El Paso Health may elect to send the recovery to an attorney for legal action.

OIG Recovery of Funds under 1 TAC §353.505, §531.1131 and as amended per Section 6 of HB2379 effective September 1, 2017.

If an investigation is referred to the OIG, El Paso Health abides by the following: Upon completion of the investigation and final disposition of any administrative, civil, or criminal action taken by the state or federal government, the Health and Human Service Commission-Office of Inspector General (HHSC-OIG) will determine and direct the collection of any overpayment.

1. El Paso Health shall remit the remaining amount of money recovered, under Subsection (a) (2) to the commission's office of the inspector general for deposit to the credit of the general revenue fund.
2. If the commission's office of the inspector general notifies El Paso Health under subsection (b), proceeds with recovery efforts and recovers all or part of the payments the organization identifies as required by Subsection (a) (1), El Paso Health is entitled to one-half of the amount recovered for each payment the organization identified after any applicable federal share is deducted. El Paso Health may not receive more than one-half of the total amount of money recovered after any applicable federal share is deducted.

Suspension of Payments 42 CFR 455.23

If the OIG implements a suspension or hold on payments due to a credible allegation of fraud under 42 CFR 455.23, El Paso Health shall suspend payments upon notification from the OIG. If El Paso Health discovers a verified, credible allegation of fraud, El Paso Health may either suspend payments and notify the OIG of the suspension in its monthly report

or, alternatively, El Paso Health may send a referral as described in Section 6.3 above to OIG-MPI for evaluation and possible imposition of the payment hold. Any such referrals shall be clearly marked to include a suspension of payments. Furthermore, if El Paso Health determines that placing a particular network provider on payment suspension due to a credible allegation of fraud will create provider network and access to care issues, El Paso Health shall include such information to OIG with any notice of suspension or referral.

All withholding of payment actions under 42 CFR 455.23 will be temporary and will not continue after:

1. The HHSC, OIG or the prosecuting authorities determine that there is insufficient evidence of fraud or willful misrepresentation by the provider; or
2. Legal proceedings related to the provider's alleged fraud or willful misrepresentation are completed.

12.2 Recovery Reporting

On a quarterly basis, El Paso Health will submit to the OIG a report on all monies recovered. Said report shall contain details of the amount of money recovered pursuant to guidelines provided by HHS and the OIG.

SECTION 13 STATE MANDATED REQUIREMENTS

13.0 Delivery Induction Audits Overview

This new requirement was implemented effective December 2012 to ensure medical necessity for all delivery inductions and Cesarean Sections before 39 weeks' gestation.

13.1 Process

Responsibility: The El Paso Health's Special Investigations Unit

1. On a monthly basis, the El Paso Health's -SIU generates a random selection of 15 claims with modifiers U1, U2 and U3.
2. SIU sends a letter to the provider requesting medical records with a 15-day turnaround.
3. Upon receipt of medical records, the SIU transfers them to the Medical Director for medical necessity review.
4. Once the review is completed, the SIU will notify the provider of the findings which may include recoupment if necessary.

13.2 Recipient Medical Services Verifications Overview

This new requirement was implemented effective December 2012 to ensure Recipient services were rendered as billed by providers.

13.3 Process

Responsibility: El Paso Health's Special Investigations Unit Claims Auditor

1. At the beginning of the calendar month, the SIU Claims Auditor runs a report that has a sample of claims billed for services rendered in the previous month.
2. The SIU Claims Auditor scrubs the report for member phone numbers and formats the report to run through Go Mobile, an automated text messaging service.
3. SIU Claims Auditor will send out an automated text message to members with a link to a survey asking them to verify if they received services that El Paso Health was billed for.
4. When the number of members having responded to the survey reaches 60, the SIU Claims Auditor will document the outcome of the results of the survey. The SIU Claims Auditor will document on the outcome of the results of the survey by choosing the most appropriate attribute below:
 - a. Verified- services rendered
 - b. Not verified- services not rendered
 - c. Phone number disconnected

If services are verified as not rendered the SIU will request medical records from the provider. If the provider fails to provide medical records for the date of service in question or if it is determined that no services were rendered, a provider preliminary investigation will be initiated and the service is subject to recoupment.

NAVITUS HEALTH SOLUTIONS, LLC

FRAUD, WASTE AND ABUSE PROGRAM

January 2021

For more information about Navitus Health Solutions visit www.navitus.com, or for specific information regarding the Fraud, Waste and Abuse Program, contact the Chief Compliance Officer at 608-298-5763

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I. INTRODUCTION

Fraud, waste and abuse (FWA) in healthcare is an ongoing concern for government entities as well as other organizations that administer benefits. The Department of Health and Human Services (HHS) requires organizations that participate in the Medicaid, Medicare Part-D prescription drug benefit, and Exchange programs to implement an effective plan to prevent, detect, and correct FWA as part of its comprehensive compliance plan.

The Navitus FWA Program follows our guiding principles of transparency, stewardship and performance and is an integral part of the Navitus Compliance Program. Navitus recognizes the impact that FWA has on government payers, our clients, their members and the general healthcare industry. As a result, we are diligent in partnering with health plans, employers, regulators, pharmacies, vendors, and others to identify trends and prevent, detect, and correct instances of FWA. We ensure oversight is comprehensive and timely and we implement policies and procedures that are tailored to requirements, including assigning qualified and dedicated personnel for the Special Investigation Unit (SIU) and Pharmacy Audit functions.

Throughout this document there may be references made that are specific to Medicaid or Medicare Part D where program specifications vary slightly in the monitoring or reporting requirements.

II. PURPOSE

The purpose of Navitus' FWA Program is to reduce FWA, comply with state and federal regulations, and ensure that Navitus is proactively investigating and protecting the financial and reputational interests of our organization and our clients. The FWA Program is used to effectively prevent, detect, correct and refer and report potential FWA. Through its policies and objectives, Navitus is also dedicated to coordinating with law enforcement.

The policies, systems, and processes used to achieve the Program's purpose are intended to complement and support our clients' overarching compliance and FWA programs as we administer and manage the prescription drug benefits. In that effort, Navitus reports suspected FWA to the Special Investigation Units (SIU) of our clients and to pharmacies when appropriate. We also work collaboratively with our clients to develop and implement effective ways to mitigate and remediate instances of identified FWA. In

addition, we will cooperate with external entities regarding FWA inquiries and requests for information, where reasonable, permitted and/or required from clients, law enforcement and other regulatory entities.

III. PROGRAM SCOPE

The elements of the FWA Program applies across all lines of business including Managed Medicaid, Medicare Part D, Health Exchanges, health plans, and employer plans.

As part of the program scope, the FWA Program also considers internal and external risks beyond what is required contractually and by the various state and federal requirements. Such internal risks may be caused intentionally by an employee or contractor or inadvertently if process and system controls are inadequate. External FWA risks include activities by or transactions with our vendors and downstream or related entities.

IV. PROGRAM GOALS

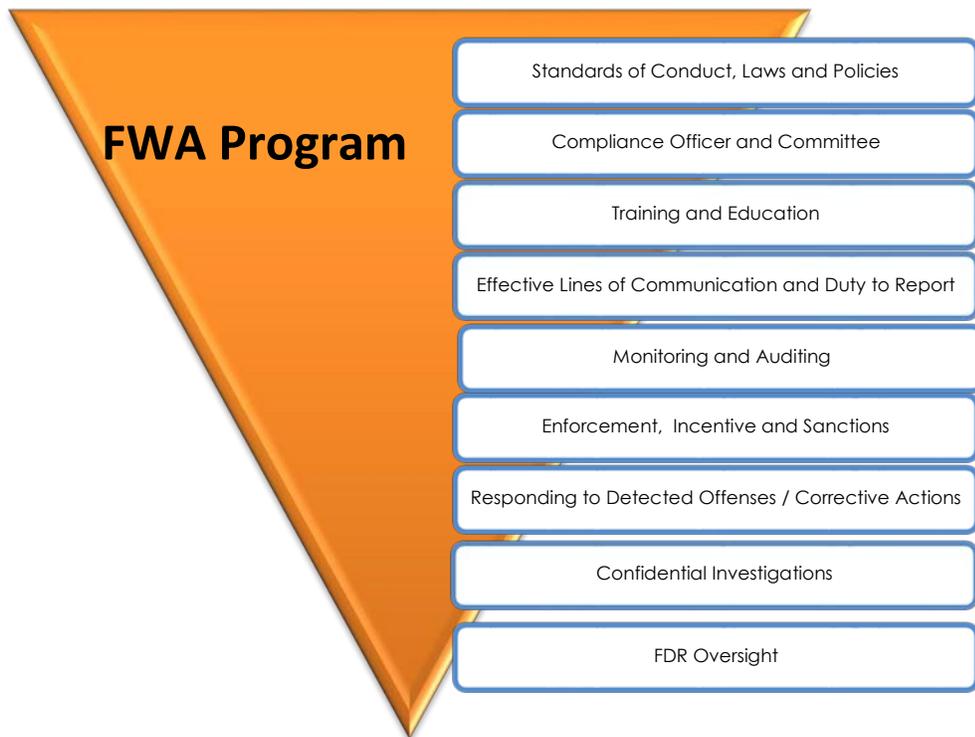
Key goals are developed annually and incorporated into an FWA Work Plan. At Navitus, we review our FWA Program and Work Plan annually. This review assesses and prioritizes risks of FWA throughout the organization, it considers the controls to prevent and detect those risks, changes in regulatory requirements and evaluates Navitus' readiness to adopt and implement those changes.

Both the FWA Program and Work Plan are approved annually by the Navitus FWA Oversight Committee and support the following objectives:

- Ensuring the program addresses FWA delegated functions from clients and Plan Sponsors including timely reporting;
- Reviewing FWA activities, including internal and external referrals, investigations and reporting;
- Identifying FWA vulnerabilities through risk assessment and review of industry best practices and trends;
- Promote awareness efforts that includes information on how to identify and report potential FWA;
- Extend member lock-in program to include all lines of business where approved by the Client;
- Continue to identify medications frequently associated with FWA schemes and explore formulary changes and/or potential system edits

- Identify and monitor pharmacy relationships and shared ownership of pharmacies identified as having potential FWA;
- Identify and analyze potential instances of FWA related to members, pharmacies and prescribers that may arise in the pharmacy claims;
- Enhance process for timely recovery of improper payments or overpayments in accordance with program, state and federal regulations;
- Achieving program objectives based on continuous improvement, defined results, and proactive methods
- Enhancing reports developed by Navitus on reporting, auditing and investigation of potential FWA; and
- Providing FDR oversight and audit that includes a review of requirements such as training and exclusion reviews.
- Evaluating effectiveness of the program overall through monitoring and/or measurement of the program’s return on investment (ROI), client audits including Compliance Program Effectiveness (CPE), data mining criteria, corporate compliance effectiveness measurement, reporting metrics to the FWA Oversight Committee, and other methods.

v. PROGRAM FRAMEWORK



As the above graphic shows, the FWA Program is incorporated into and is considered to be an important element of the Navitus Compliance Plan. As such, its framework includes many of the base elements that are identified as part of an effective compliance program.

The following table shows how some of the FWA Program activities assist with the goals of prevention, detection, and correction:

FWA Program Component	FWA Prevention, Detection, and/or Correction Activity
Code of Conduct / Policies & Procedures	Annual Code of Conduct and Policy & Procedure review and revision to confirm day-to-day FWA risks are appropriately addressed
Compliance Officer and Committee	Periodic FWA reporting to the Compliance Committee and annually to the Board of Directors
Training and Education	Annual FWA training for employees including temporary, agents, and Contractors
Effective Communication	Periodic communications to employees and clients on fraud activities, such as newsletters, ongoing communications and alerts
Duty to Report and Non-Retaliation	Review of FWA referrals and compliance contacts for potential corrective action, process improvement, or reporting.
Auditing and Monitoring	Internal reviews and downstream and related entity auditing and monitoring
Confidential Investigations	SIU investigates referrals, fraud alerts, and through data and trend analysis
Disciplinary Guidelines	FWA related disciplinary actions addressed internally through HR or externally through contractual provisions and Navitus Pharmacy Manual
Corrective Actions	Formal corrective action plan on contractors, vendors and downstream entities for potential FWA
FDR Oversight	Ensure downstream and related entities are complying with contractual obligations and Federal and/or State laws and regulations

In developing the FWA Program, Navitus ensures that the program framework and elements also comply with applicable state and federal regulations and guidance that

governs the healthcare industry, including Managed Medicaid, Medicare Part D, and the Affordable Care Act (Healthcare Exchanges) programs. Some of those regulations are as follows:

- Medicare Advantage Programs, 42 C.F.R. §422.503 and 42 C.F.R. §423.504
- Medicare Prescription Drug Benefit Manual, Chapter 9, Chapter 21
- False Claims Act: 31 U.S.C. §3729-33
- Anti-Kickback: 42 U.S.C.A. §1320a-7b
- Scope and Effect of Exclusion, 42 C.F.R. §1001.1901
- Prohibition on Inducements to Beneficiaries: 42 U.S.C. §1320a-7a (A) (5)
- Privacy and Security of Protected Health Information, Health Insurance Portability and Accountability Act of 1996, 45 CFR §160, 162, 164
- Patient Protection and Affordable Care Act, 75 FR 37187
- Social Security Act section 1902(a)(68)
- Medicaid Laws, 42 U.S.C. §1396 et seq.
- Managed Care: 42 CFR §438.608
- Provider Termination: 42 C.F.R. § 455.101

VI. PROGRAM DESCRIPTION, STRUCTURE AND RESOURCES

A. Description

The FWA Program is an enterprise-wide initiative that utilizes a variety of methods and systems that are both administrative and management oriented to accomplish its goals. It is best described as interwoven connections and mechanisms that allow the compliance team, SIU and others to identify, prioritize, and focus on risks for prevention of FWA and implement best practices for detection and correction. This includes outreach efforts by Certified Fraud Examiners, continuing education, employee training, network credentialing processes, OIG/GSA exclusion reviews, client partnerships, participating pharmacy audits, clinical programs, clinical claims system edits, and government fraud alerts. The FWA Program receives continuous input from many areas of the organization.

B. Policies and Procedures

Navitus' policies and procedures that support FWA activities are tracked within the Compliance department. Policies are reviewed and updated regularly or if material changes need to occur. Oversight of policies occurs through the Navitus Chief

Compliance Officer who may submit a policy to the Compliance or FWA Oversight Committee, for review when appropriate.

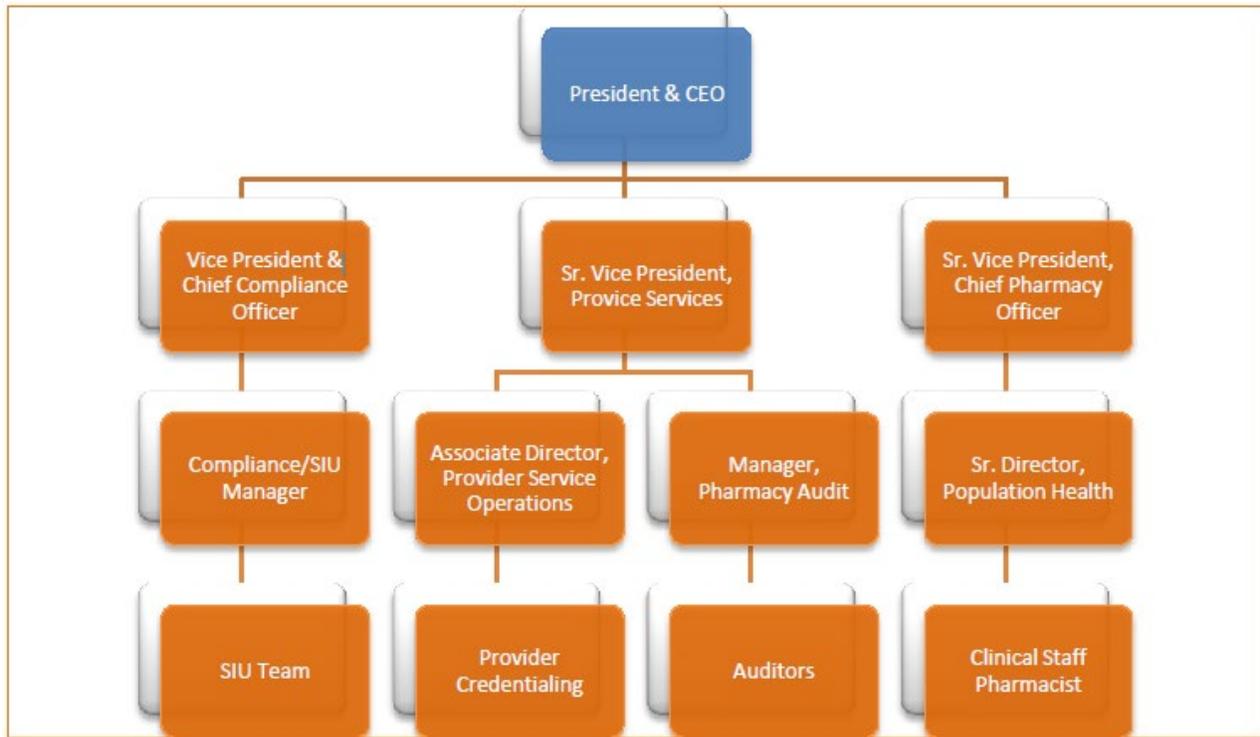
C. Resources & Accountability

As part of the overall Compliance Program, Navitus' FWA Program is accountable to the President and CEO and the Navitus Board of Directors. The Vice President /Chief Compliance Officer is responsible for Program oversight and the adequacy of resources to implement and monitor FWA program activities. The Program is managed by the Compliance and SIU Managerwho

collaborates with Navitus' leadership to support FWA prevention, detection, and correction efforts throughout the organization.

Navitus has dedicated compliance, audit, clinical, and operational staff that are knowledgeable in FWA to carry out program activities. The high-level organizational chart that follows illustrates an organizational structure that supports the FWA Program. The FWA Program is monitored through the FWA Oversight Committee.

Fraud, Waste and Abuse Program



- **Vice President /Chief Compliance Officer:** Oversees the Medicare Part D, Medicaid, and Health Exchange programs for Navitus, including the Medicare Part D and Medicaid Oversight Teams. Responsible for Compliance, FWA/SIU, and Accreditation Quality departments. Chairs the Compliance Committee, FWA Oversight Committee, and Quality Management Committee. Responsible for development and execution of the Navitus Compliance Program, the FWA Program and the Work Plans. Responsible for review and maintenance of organization policies and procedures and HIPAA Privacy compliance Reports to the President and CEO.
- **Compliance/SIU Manager:** Responsible for day-to-day oversight of SIU activities, client communication and policy adherence. Facilitates FWA Oversight Committee and leads metrics, client, and trend reporting for SIU. Maintains FWA Plan and Risk Assessment. Participates in Credentialing, Compliance, and FDR Oversight Committees. Reports to Sr. Director, Corporate Compliance
- **SIU Investigator/Analyst:** Responsible for SIU investigations of potential FWA, conducting FWA analysis, and reporting, and assisting Corporate Compliance in the development, maintenance, and execution of the Navitus FWA Program, controls, associated policies and procedures and training. Investigators will coordinate with law

enforcement, assist with implementing this Plan, and collaborate with Medicare/Medicaid programs and other federal or state authorities. Investigators are proficient in understanding pharmacy claims, coding, payment, and drugs with experience working with investigations of FWA and program integrity authorities. Investigators are members of FWA Oversight Committee Reports to Compliance/SIU Manager.

- **SIU Associate:** Responsible for assisting with the execution and maintenance of the Navitus FWA program, controls, and associated policies and procedures. Responsible for initiating case files, gathering necessary preliminary data to provide to SIU team and making recommendations for next steps on a case referral. Performing exclusion reviews, reviewing fraud alerts, maintaining FWA monitoring and watch lists, preparing and submitting required FWA-related reports, and assisting in FWA training. Reports to Compliance/SIU Manager.
- **Auditors:** Responsible for performing regularly scheduled and ad hoc internal and external audits, including pharmacy desktop and onsite audits, pre-payment audits, focused/targeted audits when a potential issue is identified or suspected, and contractually required audits. Participates in Credentialing and FWA Oversight Committee. Reports to Provider Network Management.

Clinical Staff/RPh: Responsible for providing clinical support to Navitus business units including Member Services, Client Services, and Grievance in responding to and resolving clinical-related inquiries from members, providers and pharmacies. Participates in the appeal process. Serves on Pharmacy & Therapeutics Committee, Formulary Advisory Committee, Clinical Quality Team, PBM Services Team and FWA Oversight Committee. Reports to Health Strategies Leadership.

In addition, the FWA Program also relies on the input, analyses, and referrals from Member Services, Government Programs, Provider Services, Health Strategies, Grievance & Appeals, Population Health, along with other departments. Navitus employees are required to contribute to the success of the Navitus FWA Program, whether formally or informally.

Navitus committees that provide support for FWA activities include:

COMMITTEE	RESPONSIBILITIES
Board of Directors	<ul style="list-style-type: none"> • Oversight of Compliance Program, including FWA •

Compliance Committee	<ul style="list-style-type: none"> • Provides leadership for the execution of the Compliance Program • Annual approval of Compliance and FWA Program descriptions • Review of Code of Conduct, and Compliance and FWA Work Plan ☐ Facilitates annual updates to policies and procedures
Medicare Part D Oversight Team	<ul style="list-style-type: none"> • Monitors Medicare Part D Program compliance, including FWA related activities
FWA Oversight Committee	<ul style="list-style-type: none"> • Oversight of FWA program, policies and procedures review • Program trends and analyses • Annual approval of the FWA Work Plan • SIU investigations and pharmacy audit updates • OIG/GSA sanction/exclusion review trend monitoring • FWA hotline and contact trend monitoring • <u>Review of program effectiveness</u>
Medicaid Oversight Team	<ul style="list-style-type: none"> • Monitors Medicaid Program compliance, including FWA related activities
P&T Committee	<ul style="list-style-type: none"> • Develops and maintains formularies and utilization criteria
Pharmacy Credentialing Committee	<ul style="list-style-type: none"> • Reviews and approves credentialing and re-credentialing applications • Reviews pharmacy audit results that meet termination criteria and approves recommendations for subsequent actions
Compliance Department	<ul style="list-style-type: none"> • FWA program management and Work Plan • FWA Training Content • Conflict of interest attestations • OIG/GSA and other sanction/exclusion reviews • FWA hotline and contact reviews • SIU investigations • Industry anti-fraud monitoring and participation
COMMITTEE	RESPONSIBILITIES
Pharmacy Audit Department	<ul style="list-style-type: none"> • Pharmacy desktop and onsite audits • FWA Pharmacy Watch List • Pre-payment audits
Pharmacy Provider Services Department	<ul style="list-style-type: none"> • Pharmacy credentialing and re-credentialing • Pharmacy Network FWA training • Pharmacy terminations • Facilitates Pharmacy Grievance and Appeal Committee

Formulary Operations Department	<ul style="list-style-type: none"> • Formulary development and maintenance • Utilization Management (step therapy, quantity limit, prior authorizations) • Concurrent Drug Utilization Review (CDUR) • Part B versus Part D messaging
Medicare D Population Health	<ul style="list-style-type: none"> • Medication Therapy Management (MTM) program oversight • Medicare Part D Utilization Audits
Population Health/ Product Development	<ul style="list-style-type: none"> • Retrospective Drug Utilization Review (RDUR) • Clinical edits • CDUR

VII. PLANNING & IMPLEMENTATION PROCESS

The Navitus FWA Program document is updated annually. Planning activities include risk assessments, program revisions, and related policy and procedure updates. Medicare Part D, Managed Medicaid, and Health Exchange specific considerations, as well as other federal and state requirements, are key elements of the FWA planning process.

A. Risk Assessment

FWA risks are considered annually and periodically in a variety of ways including:

- Interactions with Navitus' management during the normal course of operations;
- Awareness of changes to client contractual and delegated terms or FWA reporting requirements;
- Review and analysis of hotline or compliance contacts and calls;
- Industry trends;
- Changes in regulations and/or regulatory focus;
- Previous internal and external audit results, including pharmacy audit and investigation results;
- Claims system modifications;
- Financial impact;
- Internally and externally identified FWA schemes;
- Quarterly data mining; and
- Management and staff turnover and organizational changes.

The Risk Assessment helps align the FWA activities with Navitus' strategic and operational goals and objectives, and takes into account the resources available to perform pharmacy audits and investigations. Throughout the year, the annual FWA Work Plan is subject to revision as risks and priorities change. Risk assessment results assist in defining FWA related projects.

B. Work Plan

Each year a FWA Work Plan is developed for anticipated activities or risk. The Work Plan is a high level overview and timeline for those projects determined to be critical to the successful implementation of the FWA Program, management of risk, and reportable to the FWA oversight committee. This Work Plan has clear objectives of what needs to be achieved during the annual period and is a component of the effectiveness measurement of the overall program.

VIII. PROGRAM COMPONENTS

A. PREVENTION

Navitus strives to prevent FWA from occurring by ensuring prevention-based controls are established to ensure the effective, efficient, and economical use of time and resources for all parties.

Prevention activities occur throughout the organization. Specific information related to each key activity is further described below.

1. FWA Training

Navitus provides FWA training upon hire to employees, temporary employees, agents, and contractors. In addition, participating pharmacies and other downstream entities must also complete training for their employees upon hire and annually to satisfy this requirement. Downstream entities are required to attest annually that they have completed the CMS Compliance and FWA or equivalent training.

2. Population Health

This Navitus department has several programs designed to prevent FWA, such as Concurrent Drug Utilization Review (CDUR) occurring at the time of claim adjudication. While these programs are primarily designed to reach the best clinical outcome for the patient, they are also important components in the fight against fraud, waste and abuse.

a. Concurrent Drug Utilization Review (CDUR)

Navitus' CDUR program checks prescriptions at the point-of-sale during claim adjudication for potential drug utilization errors. The program is a series of claims system edits designed to review the member's prescription history at point-of-sale for potential drug conflicts, such as drug-to-drug interactions, refills too soon, or therapeutic duplications.

Network Pharmacies access Navitus' claims system, online and in real-time, for CDUR. All participating pharmacies including retail, mail service, specialty, long term care, home infusion, and Indian Tribal pharmacies are subject to Navitus' CDUR edits. Each transaction submitted through Navitus becomes a part of the member's profile and claims are checked against that profile.

If a claim is flagged in the system as a potential problem, the system sends a response to the dispensing pharmacy. This response occurs before the member receives the medication and informs the pharmacy of the potential conflict. The National Council for Prescription Drug Programs (NCPDP) supports transmission of multiple CDUR messages relating to an individual claim. CDUR messages are stored for reporting purposes as part of the claims extracts.

The following CDUR edit responses may be returned to the pharmacy, depending on the client's criteria:

- **Hard Reject:** Rejects the claim, and does not allow the pharmacy to override a CDUR conflict. Only Navitus may override the rejections.
- **Soft reject:** Rejects the claim, but allows a pharmacy to override the CDUR conflict by entering the appropriate NCPDP outcome and intervention override code into the system. Navitus may also override these types of rejections.
- **Message:** Pays the claim, but sends an informational message back to the pharmacy.

i. Concurrent DUR Sample Edits

Examples of CDUR edits include those shown in the table below. Each edit is configurable by the client to return a response as defined above.

Title	Description
CDUR Type: Drug-Allergy	
Allergy Screening	DUR edit designed to verify a member allergy does not conflict with the drug dispensed. For the ALLERGY CHECK edit to work, the member's health profile record must contain the member's allergies. The allergy check is expected to be done by the pharmacy, as PBMs do not receive patient allergies.
CDUR Type: Compliance	
Drug Regimen Compliance	DUR edit verifies the patient is not underutilizing a drug. This edit checks the member's prescription history to determine if he/she has received the same drug (under the same prescription number from the same pharmacy and with the same dosage) and if he/she is receiving the new refill within a certain number of days since it was last filled.
CDUR Type: Drug-Drug/Disease Interaction	
Drug-Drug Interaction	DUR edit checks the member's prescription history for interactions between two or more drugs.
High Cumulative Dose/Care Coordination Edit	Detects members that have prescriptions for more than 90 mg, MED, have used multiple pharmacies, and multiple prescribers for active opioid claims.
Drug-Diagnosis Caution	DUR edit checks the member's health profile record for conflicts between listed diagnoses and the submitted drug or inferred health state. This check is expected to be done by the dispensing pharmacy if diagnosis is known.
Concurrent use of Opioids and Benzodiazepines	This edit will identify a member filling a prescription for an opioid and benzodiazepine concurrently by two different providers.
Initial Opioid Fill	The Initial Opioid fill edit identifies opioid claims for more than 7 days in opioid-naïve patients.
CDUR Type: Dose Check	

Dosing/ Duration	Compares dosage on the claim to recommended dosage for the member's age group and determines whether to send a response if the daily dose is exceeded. This edit also compares day supply on the claim with the recommended duration for the drug in the GPI or NDC list.
Title	Description
CDUR Type: Drug-Age/Sex	
Drug-Age Caution	The Drug-Age checking edit identifies FDA warnings and other contraindications for specified age groups such as tramadol/codeine restrictions for children.
Drug-Sex Caution	The Drug-Sex Caution Screening edit identifies contraindications based on gender.
CDUR Type: Duplicate Therapy	
Duplicate Therapy	The Duplicate Therapy edit checks for therapeutic duplications based on ingredient duplication.
Long-acting Opioid	The Long-acting Opioid Duplicate Therapy edit will identify a member filling multiple prescriptions for long-acting opioids in the same timeframe.
Buprenorphine	The Buprenorphine Duplicate Therapy edit checks for history of a buprenorphine product used to treat opioid dependence when an opioid claim is submitted.
CDUR Type: Drug-Pregnancy	
Drug-Pregnancy	This pregnancy precaution screening identifies medications that may be contraindicated when pregnant. This check is expected to be done by the pharmacy when pregnancy status is known.

ii. Other Concurrent DUR Edits (Medicare Part D)

This type of CDUR clinical information is helpful as a prevention tool, but also allows for detection of FWA trends or specific pharmacies that may have this behavior.

- Acetaminophen High Dose*: Checks the total acetaminophen dose across all prescriptions that are currently being used and have remaining supply. If the calculated quantity per day supply of acetaminophen is greater than 4 grams, the claim is rejected.
- Compound Dosage Form Description*: Checks the dosage form submitted. Compounded products with a topical dosage form (ointment, cream, emulsion, lotion or shampoo) will reject.

iii. Refill Too Soon

The Navitus system provides an edit for refill limitations in which the client specifies the acceptable window for getting a prescription refilled upon receiving the same prescription number from the same pharmacy. Typically, clients require a member to use between 70 and 80 percent of their previous claim supply before allowing a refill. The allowed refill tolerance for opioids and other abused medications requires a member use between 80 and 85 percent of their previous claim supply before allowing a refill. If the member is early, it triggers a hard reject.

3. Part B vs. Part D Messaging (Medicare Part D)

For our Medicare Part D plan sponsors with drugs that may be covered under Medicare Part B or Part D (B vs. D), Navitus utilizes drug edits and messaging to the pharmacy at point of sale. The messaging advises the pharmacy if the claim will need to be reviewed to make the correct B vs. D billing decision. The Navitus claims processing system relies on benefit design, formulary setup, and eligibility file indicators to drive how the client benefit plan should pay under the appropriate Medicare benefit.

For the Commercial plans that participate in the Retiree Drug Subsidy Program (RDS), B versus D drugs are excluded from RDS processing. Submitting claims to the correct Medicare program is important to the overall reduction of waste in the healthcare system. Navitus utilizes the CMS option of “Do not submit any costs for any drugs within the following three categories of drugs” when covered by Medicare Part B:

- Drugs used for immunosuppressive therapy following a Medicare-covered transplant;
- Oral drugs used for cancer treatment; and
- Oral anti-emetic drugs when administered within 48 hours of chemotherapy.

4. Utilization Management (Quantity Limits, Prior Authorization, Step Therapy) Navitus uses a variety of measures to help ensure correct utilization of medications and prevent FWA. Within the formulary design, utilization criteria such as quantity limits, prior authorizations or step therapies are placed on certain medications to guarantee safe and effective use of these products. These edits may prevent claims from paying at the point of sale and require further information be received from the pharmacy or prescriber for approval of criteria prior to adjudication of the claim. Quality controls, such as interrater reliability, are implemented on Navitus Utilization Management processes to ensure consistent application of these criteria. Utilization criteria are approved by the Navitus Pharmacy & Therapeutics Committee and if exceeded or where a denial is prompted based on such criteria, staff may initiate a referral to SIU.

i. Quantity Limits

Navitus may limit the amount or duration of a medication that a member receives for a variety of reasons and often is based on the maximum safe dose

established for the medication. Quantity limits can also be placed on medications that are frequently targets of overuse or misuse in order to prevent such occurrences. For example, opioids may be limited to prevent large quantities from being dispensed at one time. Additionally, these edits may be applied to drugs, like Copaxone, where billing issues have arisen due to packaging to make sure that clients are not overpaying claims.

ii. Prior Authorization

Many medications have prior authorizations in place to make sure the member is using a medication that is appropriate for his or her condition. These are often high cost medications with off-label uses, such as Lyrica, which are often prescribed for conditions that are not approved by the FDA. In other cases, prior authorizations may limit which specialists can prescribe for specific medications, such as Restasis. Prior Authorizations also assure that patients are being seen by the proper type of health care provider.

iii. Step Therapy

Medications with step therapy require a trial of a preferred medication before the target medication can be obtained. In some cases, step therapy is used to promote use of less expensive, but similarly effective, medications on the formulary. Other times step therapy is used to limit overuse of medications. For antibiotics such as Dificid, step therapy is used to reserve newer agents for specific situations in an effort to reduce antibiotic resistance of certain bacteria.

5. High Dollar Claims Review

High dollar claims that are above a dollar threshold are regularly reviewed to ensure that the dispensing pharmacy is submitting the claim correctly. If it is determined that the claim may have been submitted incorrectly, Navitus will contact the pharmacy and investigate. Investigation may include requesting a copy of the prescription, a conversation between Navitus and a representative from the pharmacy, along with reprocessing of the claim. Actions that are executed are documented and noted appropriately.

6. Medication Therapy Management (Medicare Part D)

Navitus, in consultation with the Part D Plan Sponsors and with licensed practicing pharmacists and physicians, provides a Medication Therapy Management Program (MTM/MTMP) designed to optimize therapeutic outcome for targeted Medicare Part D beneficiaries.

Part D beneficiaries qualify and are automatically enrolled to receive the services of a participating plan sponsor's MTM when the following criteria are met:

- Beneficiary has a minimum number of chronic conditions; and
- Has a minimum number of paid Medicare Part D prescriptions to meet the plan sponsor's MTM threshold; and
- Has drug spend or is likely to incur an annual drug spend of the amount set each plan year by CMS on Part D medications.

MTM chronic conditions may include:

Alzheimer's Disease	Mental Health-Chronic/Disabling
Bone Disease—Arthritis	Mental Health Conditions
Osteoporosis	Mental Health-Schizophrenia
Chronic Heart Failure (CHF)	Respiratory Disease—Chronic Lung
Dyslipidemia	Acid/Reflux/Ulcers
Hypertension	Anticoagulation
Autoimmune Disorders	Stroke
Autoimmune Disorders	Anemia
Cancer	Atrial Fibrillation
Cerebrovascular Disease	Benign Prostatic Hyperplasia (BPH)
Chronic Non-Cancer Pain	Cardiovascular Disorders
End-Stage Liver Disease	Chronic Alcohol and Other Drug
HIV/AIDS	Dementia
Neurologic Disorders	Severe Hematologic Disorders
Bone Disease-Arthritis-	Bone Disease-Arthritis-Rheumatoid
Arthritis	Diabetes
End-Stage Renal Disease (ESRD)	Mental Health—Bipolar Disorder
Mental Health-Depression	Respiratory Disease-Asthma
Hepatitis C	Multiple Sclerosis

Navitus' MTM clinicians perform the following:

- Enhance member understanding through education counseling that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications;
- Increase member adherence to prescribe medication regimens; and
- Detect potential adverse drug events and patterns of over-use and under-use of prescription drugs.

Navitus' MTM services and interventions include:

- On a weekly basis, the MTM mails introduction letters with a participation form to beneficiaries meeting enrollment criteria. Completed participation forms will prompt MTM contact with beneficiaries for an interactive Comprehensive Medication Review (CMR).
 - CMR is an annual interactive medication review of the enrolled beneficiary.
 - It includes medication education on side effects, correct administration, possible over use or under use, and adherence.
 - It includes an assessment of medication therapy to identify duplicate therapy, drug-drug interactions, prescription induced side effects, under treated conditions, and generic alternatives, which optimize patient outcomes.
 - An intervention letter is sent to beneficiaries and prescribers as needed, following the initial and any subsequent CMR.
 - More than one CMR can be performed with the beneficiary by either a MTM Nurse or MTM Pharmacist, depending on the complexity of the unresolved medication issues, identified during the CMR.
- On a regular basis, the MTM utilizes pharmacy claims to perform Targeted Medication Reviews (TMRs), which assesses medication therapy for beneficiaries who are ambulatory or residing in a long term facility.

- The MTM evaluates claims for a specific look-back period to identify medication related problems such as: drug-drug; drug-age; or drug disease interactions.
- Interventions for specific medication related problems, a change in therapy, or opportunities to optimize medication use are made. The prescriber may be asked to assess the potential risk and to contact the beneficiary if necessary.

The MTM is important to the clinical health of the patient, but also assists healthcare professionals in intercepting and identifying potential incidents of fraud, waste or abuse.

7. Formulary Development

Formulary development decisions are made by Navitus' Pharmacy and Therapeutics Committee. This is a standing, independent committee reporting to Navitus' Chief Pharmacy Officer. The Committee is charged with the following functions:

- *Formulary Development and Maintenance* - the Committee develops and maintains formularies as necessary to support Navitus' clients; and
- *Advisory* - the Committee serves in an evaluative, educational and advisory capacity to the organization and Navitus' clients in matters pertaining to the use of drugs.

When drugs are reviewed for placement on the formularies, the Committee bases formulary decisions using a rigorous, evidence-based review process, applying current clinical guidelines and protocols. The Committee utilizes the following criteria:

- The safety of the drug being evaluated, with comparison to available alternatives;
- The efficacy of the drug, with comparison to available alternatives;
- Unique properties of the drug, with comparison to available alternatives;
- Market considerations (such as net-cost, generic considerations, and member impact); and
- Research, review and discussion of abuse deterrent products.

Committee members must represent various specialties and regions of the country, where possible and may be general practitioners, specialists, pharmacists, or health care administrators. A majority must be practicing physicians and/or pharmacists. Members must comply with applicable local, state and federal licensing, certification, accreditation, and registration standards and remain in good standing with applicable agencies, boards, professional licensing boards or commissions throughout the membership term.

8. Conflicts of Interest Attestations and Nondisclosure Agreements

Navitus has adopted Conflict of Interest policies and procedures in an effort to protect against FWA within Navitus' functions.

a. Pharmacy and Therapeutics Committee

Each Pharmacy & Therapeutics Committee member is required to sign the following:

- A Nondisclosure Agreement acknowledging the proprietary and non- public nature of information related to the development of, and included in, the drug formularies.
- A Conflict of Interest Disclosure

The Committee secretary reviews Statements of Disclosure and brings any potential conflicts of interest to the Appointing Authority.

A conflict of interest occurs when a member of the Committee has a personal or organizational business interest that could influence his/her decisions regarding a particular drug, drug class or policy. At each meeting, members are required to confirm verbally that they have no conflict of interest related to the topics for discussion. Sources of conflict may include:

- Stock, stock options or equity ownership in companies manufacturing or marketing products being considered by the Committee or products that compete with those being considered (does not include mutual funds);
- Receipt of consultant fees, grants, honoraria or other financial compensations from companies manufacturing or marketing products being considered;

- Participation on Speaker's bureaus or involvement in speaking engagements for Committees or products that compete with those being considered;
- Involvement in clinical trials or other research for products being considered by the Committee or products that compete with those being considered; and
- Employment by a pharmaceutical manufacturer, pharmacy benefits management company or a competing health plan during their term or for one year prior to their appointment.

b. Navitus Employees

Navitus employees including temporary employees, agents, contractors and Board of Directors are required to disclose any potential conflicts of interest. Additionally, they are required to avoid any outside personal, professional, or financial interests that might influence or appear to influence decisions or actions that are detrimental to Navitus. Navitus employees must also comply with ethical directives, code of conduct, and other behaviors set forth in the Employee Handbook which may lead to improper outcomes including potential fraud, waste, or abuse.

A new written disclosure is filed whenever a new conflict or appearance of conflict arises. The Chief Compliance Officer reviews conflict of interest disclosures, investigates as necessary, and makes the final determination regarding a potential conflict.

9. Federal and State Sanctions/Exclusion Reviews

Navitus reviews the Department of Health & Human Services, Office of Inspector General (HHS/OIG) and General Services Administration (GSA) System for Award Management (SAM), CMS list of precluded providers, and State lists required by client contract. Review includes Navitus employees (including temporary employees), agents, contractors, vendors and Board of Directors. Exclusion screening is conducted prior to hiring, contracting, or appointment and monthly thereafter. This process may use a proprietary application or a third-party vendor to compare and contrast exclusion results against the Navitus databases. Potential positive results are reviewed to confirm exclusion or remove false-positive results. Navitus researches potential positive results

using a variety of public records such as NPDES, corporate records, and state licensure records. Potential exclusion matches are tracked by Navitus' Compliance Department. The potential match as well as any research completed on the potential match is logged.

Pharmacies requesting to be added to the Navitus participating pharmacy network are checked for exclusion prior to contracting with Navitus. If a potential match is found on a pharmacy requesting to contract with Navitus, the Credentialing Department will evaluate the findings. If substantiated, the pharmacy is not added to the network. If after contracting with Navitus or joining an affiliation, a participating pharmacy is found to be excluded by the OIG, GSA or an applicable State list, the pharmacy will be terminated and pending payments suspended and/or recovered.

Additionally, Navitus reviews claims at point of sale to ensure that prescribers are not excluded. Navitus has implemented a point of sale (POS) reject edit for excluded prescribers based on the data monitored and supplied by a third-party vendor, Lexis Nexis. An excluded prescriber will reject claims prior to payment.

10. Pharmacy Credentialing and Re-Credentialing

Pharmacies in Navitus networks are credentialed before network enrollment and re-credentialed every three years. During the initial credentialing process, the pharmacy completes a network application. This application is reviewed for network integrity standards by Navitus' credentialing staff that performs the following activities:

- Verifies application is complete;
- Reviews related State Board of Pharmacy or other applicable state pharmacy licensing boards for current pharmacy, pharmacist-in-charge (PIC), license status and any disciplinary actions;
- Reviews ownership documents such as corporate business license, transfer of ownership documents, and related pharmacy ownership;
- Confirms general and professional liability insurance is current for the date of requested enrollment;
- Reviews history of license revocation, issues with record keeping or any drug related or pharmacy related offenses;
- Reviews sanction and exclusions of the pharmacy and pharmacist in charge;
- Reviews available CMS data analytics for risk score and reviews issues and/or

actions taken by other entities;

- Reviews the Social Security Death Master File via the Lexis Nexis online portal tool or an equivalent source file;
- Confirms that a physical address is provided for the pharmacy and checks if any closed or terminated pharmacies were previously located at that address;
- Compares pharmacy location to know CMS Heat Zones, additional criteria and oversight is included for any pharmacy located in these areas;
- Conducts an internet geo-search and secures a screen shot of the pharmacy building for the credentialing file;
- Verifies the address does not match a FedEx or UPS store location;
- Determines if the pharmacy appears on the Navitus watch list, indicating further attention is required before a decision is made;
- Reviews pharmacy audit history (re-credentialing only); and
- Reviews recent year FWA attestation (re-credentialing only).

Navitus' credentialing and re-credentialing processes are overseen by the Credentialing Committee. Membership includes representation from Provider Services, Clinical, Pharmacy Claims Audit, SIU, and Compliance. Pharmacy credentialing and re-credentialing are denied if Navitus' network requirements are not met.

11. Ongoing Awareness Communications to Employees

In addition to annual FWA training, the SIU team provides communication to employees on recognizing and preventing potential fraud or abuse activity. This communication is presented in a variety of forms, including email notices, posters, training, Member Service alerts, meetings, lunch and learn sessions, newsletter articles, and marketing items. Topics covered include recent FWA trends or schemes as well as ways to identify potential fraudulent or abusive activity.

12. Ongoing Awareness and Education to Participating Pharmacies

Navitus provides ongoing education and awareness to participating pharmacies including the Navitus Pharmacy Provider Manual. Examples of ongoing education include pharmacy newsletters, and conference calls with the Navitus pharmacy advisory panel that provides updates on common drug billing errors to watch for and new drugs being

released to the market. The use of fax blasts to participating pharmacies are also helpful for when there is a need for notification of an industry wide drug or billing issue.

Navitus Pharmacy Audit team also provides pharmacy specific education during desktop and onsite audits including education on billing errors, prescription documentation, and other pharmacy specific education needs. Periodic correspondence with pharmacies in the form of quarterly newsletters and bulletins reinforces errors, issues or trends that have been recently noted in audits.

13. System Security Measures and Controls

Intrusion and cybersecurity activities have increased in recent years with system breaches and related events occurring more frequently in the healthcare industry. As part of the FWA program, Navitus requires data confidentiality and security of its information systems to reduce improper access that may lead to FWA.

Navitus has written privacy, security, and confidentiality policies and/or documented procedures on unauthorized data use, access, prevention of breaches electronic resource monitoring, log in attempts, and network perimeter security. These also help control the sharing of information and limit access to sensitive data in non-sanctioned work environments for Navitus as well as healthcare providers.

B. MONITORING, DETECTION AND INVESTIGATION

The Navitus FWA program includes procedures and practices aimed at effective and ongoing monitoring, detection, and best practice investigation technique. This ensures that risks of potential FWA are identified early and rapid intervention and resolution occurs. While many of these areas revolve around pharmacy claims which are the largest risk, there are other areas that Navitus evaluates as well. Key monitoring and detection elements are as follows:

1. FWA Hotline

Navitus has established an FWA hotline (855-673-6503) that can be utilized internally and externally to report allegations of potential FWA. This hotline contact information is published on Navitus' corporate website for the general public, clients, pharmacies, members, and prescribers and is included in employee training, communication, and

outreach materials. The FWA hotline number and verbiage advising members to report fraud to Navitus are also published in appropriate member publications, at the discretion of the client. There is also an established email address for internal reports of potential FWA. The SIU team monitors FWA calls and/or emails received by Navitus. Reported incidents are triaged and, when appropriate, Navitus SIU initiates an investigation.

2. Data Analyses

Navitus uses data from multiple sources to assist in monitoring and detecting potential FWA. Examples of sources include:

Report Name	Purpose	Level	Used by
SIU Data Mining Tool	Evaluate outliers and patterns across claims data against a defined set of risk areas and thresholds for potential investigation targets including but not limited to opioid targets, prescriber specialty, drug combinations, claim rejects, fill too soon/frequent billing; brand drugs, NPI status, and geolocation.	Member; Pharmacy; Prescriber	SIU
Prepayment Claims Data	Identify significant pharmacy data entry errors related to price and/or quantity	Pharmacy	Pharmacy Network
CMS Quarterly High Risk Pharmacy Report	Identify potential fraud schemes based on pharmacy outlier data and practices	Pharmacy (Med-D)	Audit, SIU
CMS Quarterly High Risk Prescriber Report	Identify potential fraud schemes based on prescriber outlier data and practices	Prescriber (Med-D)	Audit, SIU
CMS Quarterly Drug Trend Analysis	Identify potential fraud schemes based on sudden changes in claims utilization, member utilization and total amounts paid for specific drug classes and categories	Pharmacy; Prescriber	Formulary , Audit, SIU
CMS FWA Pharmacy Invoice Report	Identify potential drug shortages based on previous audits and invoice reconciliation reviews.	Pharmacy (Med-D)	SIU
CMS FWA Tracking	Identify trends health plans are identifying with reference to Med-D activity	Pharmacy; Prescriber	SIU

Healthcare Fraud Prevention Partnership	Identify trend, schemes and alerts by other health plans	Pharmacy; Prescriber	SIU
Listserv	List serve monitoring for identification of prescribers and pharmacies. Sources include: US Attorney, DOJ, OIG, NCHAA and other fraud activity alerts, Fierce, Google and other news article key word searches related to FWA	Pharmacy; Prescriber	SIU
Industry Alerts	Identifying alerts from FWA sources that publish investigations, allegations, and fraud initiatives and schemes	Pharmacy; Prescriber; or Member	SIU
FWA Watch Lists	Identify pharmacies, prescribers, and/or members that may require additional research if related to a credentialing issue, audit, or investigation.	Pharmacy; Prescriber; or Member	Pharmacy Network, Audit, SIU
Ad hoc Reports	Varies based on reason for report	Pharmacy; Prescriber; or Member	Audit

3. Population Health

This Navitus program provides important data for raising awareness of and detecting potential FWA schemes. These clinical programs utilize data-driven analysis to identify potential pharmacy and physician “shoppers,” drug collusions, and diversions. When Population Health identify suspected but still unsubstantiated member fraud, additional referrals to SIU may occur. SIU can engage in more in- depth monitoring and evaluation where patterns are sustained or further substantiated through data mining.

a. Retrospective Drug Utilization Review (RDUR)

RDUR uses program-specific logic to detect member utilization patterns by querying paid claims and/or member eligibility databases. These are not confirmed instances of FWA. Navitus sends interventions with member profiles and potential recommendations to appropriate providers on those members exhibiting the identified patterns including those, which may contribute to FWA. Examples of RDUR programs include:

- **Controlled Substance Monitoring Program (CSM)**

This program identifies members receiving multiple prescriptions for controlled medications (Schedule II, III, and IV) from more than one provider and filled at more than one pharmacy during a pre-defined time period.

- **CSM Repeat Alerts**

Navitus also identifies members who have been included in the CSM program at least four times in the last two years. CSM Repeat Alert is an extension of the CSM program for members with regular, high utilization of controlled medications. A sample of the Controlled Substance Retrospective DUR methodology is as follows:

- *Targeting method:* RDUR uses program-specific logic to detect member utilization patterns by querying paid claims and/or member eligibility databases.
- *Intervention:* Patterns indicating potential inappropriate and/or unsafe utilization prompts communication to the member's prescribers, pharmacists and/or the member.
- *Effectiveness Evaluation/Response Monitoring:* Navitus measures the effectiveness of each intervention in our RDUR programs by the number of members identified and the number of members for whom our recommendations were adopted. The measurement includes a pre-Implementation and post-Intervention review.

- **Expanded Fraud-Waste-Abuse:** Identifies members receiving multiple prescriptions for drugs with high potential for abuse. Drug categories for this program include: muscle relaxants, migraine medications, and other medications that are not scheduled (not included in CSM), but have potential for overuse or abuse.

- **Multi-Prescriber:** Identifies members receiving treatment from multiple health care providers. This program improves coordination of care and member adherence to drug therapy, as well as helps reduce adverse drug events and

duplicate therapies.

- **Triple Threat:** Identifies members who have concurrent use of opioids, benzodiazepines/hypnotics and skeletal muscle relaxants in the past four months. This combination of drugs can be subject to abuse as it produces euphoric sensations, similar to the effects of heroin.
- **Compound:** Identifies members who have been prescribed a topical analgesic, antifungal and/or antimicrobial compound that includes an ingredient that does not meet the definition of a covered Medicare Part D drug.
- **Multi-Prescription:** Identifies members with multiple drug regimens. The program improves coordination of care and informs prescribers of potentially unsafe drug utilization.
- **Duplicate Therapy:** Identifies members prescribed multiple medications with similar therapeutic purpose. This program can potentially reduce adverse drug events.
- **Cost:** Identifies members prescribed medications that have generic alternatives, lower cost alternatives, tablet splitting and/or dose consolidation.

b. Retrospective Opioid Overutilization Case Management Program

Navitus also offers an RDUR Opioid Overutilization Program using a Morphine Equivalent Dose (MED) report to perform case management for members. This methodology identifies those most at risk for safety and abuse concerns related to overutilization of this drug category, and helps identify potential fraudulent prescriptions or drug diversions.

For members with excessive opioid overutilization, the enhanced RDUR Opioid Overutilization Program provides telephonic outreach to prescribers every four months. Members are eligible for this program if their morphine equivalent dose

(MED) exceeds 120 mg in a specific timeframe determined by a reviewing clinician/clinical pharmacist, and have used more than three prescribers and more than three pharmacies during the same timeframe. The reviewing clinician may also add suggested interventions that may be beneficial.

c. Specialty Split-Fill Program (Medicare Part D and Commercial)

Navitus provides its clients with a Specialty Split-Fill Program that helps to reduce waste by limiting a days' supply to 15-day intervals for qualifying high-cost specialty medications that typically have high discontinuation rates within the first three months of therapy. This prevents unnecessary dispensing of two weeks of therapy, should therapy be discontinued. This program also allows our specialty pharmacy to initiate earlier clinical interventions due to medication side-effects that require dose modification or therapy discontinuation.

d. Prescriber Insight Report

Navitus provides reporting by individual prescriber and specialty for health plans to monitor patterns of prescribing including opioid volume, peer comparison, and payment amounts. This enables the health plan to participate in monitoring of member prescription activity and provide education and outreach to prescribers to promote appropriate utilization and management.

3. Pharmacy Audits

The Navitus Pharmacy Audit team is responsible for monitoring pharmacy compliance, verifying the integrity of claims submitted to Navitus, identifying instances of potential FWA, and taking corrective action when errors are identified. The audit scope includes those risks identified internally by Navitus, as well as measures included on the High Risk Pharmacy Assessment List, produced quarterly by CMS.

a. Daily Claims Pre-Payment Review

Navitus monitors claims data daily to correct individual quantity and pricing errors on a pre-payment basis. This process educates pharmacies and helps reduce retroactive audit recoveries that could result from a pharmacy desktop or onsite audit. The pre-payment report reviews quantity outliers, day supply issues, package size and other criteria as appropriate. In the event of an overpayment identification, Navitus will request that the pharmacy reverse and reprocess the claim.

While a pre-payment review is typically considered preventive, we also consider it a FWA detection element because it could also identify patterns of FWA at a particular pharmacy or for a particular member. The pre-payment claims review complements the desktop and onsite audit processes and is not intended to review audit elements considered in a desktop or onsite audit. Such data would allow an expanded review during a full desktop or onsite audit. These types of pre-payment reviews also provide the audit team with vital information about a specific pharmacy that may have frequent instances of incorrect billing, resulting in the pharmacy being included on the desktop or onsite audit list.

b. Audit Selection

In addition to the patterns of incorrect billing identified during prepayment audits, other situations could trigger a desktop or onsite audit. These include:

- Request or inquiry by a client, prescriber, plan sponsor, member or government agency;
- Pharmacy general billing history;
- Untimely or insufficient response to issues identified through the pre-payment inquiry or pre-payment daily claims review;
- Referral from the Navitus Compliance or SIU team;
- Routine audit of pharmacies selected on a random basis; and
- CMS High Risk Pharmacy Assessment

The Navitus audit plan is reviewed regularly and revised as needed based on new trends, recommendations from the Credentialing Committee, client needs, drug manufacturer alerts, or CMS FWA alerts.

c. Desktop Audits

On a monthly basis, passes 100% of post-payment claims through its software with algorithms that identify risks such as inappropriate billing, incorrect use of dispense-as-written coding, aberrant quantity vs day supply, or partial package billing. This allows Navitus to identify if there is a safety impact or if error trends suggest potential FWA.

If the algorithm shows an error, the Audit team will then request the hard copy prescription from the pharmacy and compare the prescriber's request with the claim submission by the pharmacy. These desktop audits remediate pharmacy billing errors; identify potential FWA; and detect opportunities to educate pharmacists on billing practices that comply with Federal and State requirements, the Pharmacy Participation Agreement, and the Navitus Pharmacy Provider Manual.

d. Onsite Audits

Onsite audits are broader in scope than desktop audits and may be applicable where further review of a pharmacy is indicated. In addition to reviewing claims and identifying FWA, the onsite audit also considers operational deficiencies and reviews the pharmacy's compliance with the network contract, the provider manual and state and federal regulatory requirements such as licenses and privacy.

During an onsite audit, the auditor reviews or inquires on items related to prescriptions, signage, licensing, medication storage and handling, FWA and compliance training, exclusion screening of pharmacy employees, and other operational compliance. The auditor provides the participating pharmacy with a written audit report, which includes details of any discrepancies, concerns or relevant audit findings and education on the types of errors.

4. External Audits

Additionally, Navitus may contract or collaborate with external auditors to support audit activities or to consider the effectiveness of internal controls that mitigate FWA risk. Audits

that assess the control environment consider the design, implementation, and effectiveness of the controls. FWA controls may include segregation of duties for financial reporting and auditing; authorization or review of transactions by appropriate person(s); retention of records; physical safeguards such as cameras or locks; software and network access restrictions; system edit accuracy training and education; and reviews of reports comparing actual performance versus plans or goals.

Each year, Navitus engages an external and independent audit firm to conduct an SSAE 16 SOC 1 and SOC 2 audit (formerly known as SAS 70), to validate internal controls, ownership of operational activities and appropriate assignment of duties.

Clients may request a copy of the most recent report by contacting the Navitus Chief Compliance Officer.

Navitus performs additional auditing activities as risks are identified.

5. Other Compliance Reviews, Audits and Control Validations

Navitus engages in many other activities which can be used to detect FWA or other improper activity that negatively affects Navitus internally or its associates such as actions by staff, vendors, or pharmacies. These may be identified through reported incidents related to other non-compliance or privacy/security; reported conflicts of interest; financial audits; human resources and expense/payroll actions; and agency reviews or inquiries such as Better Business Bureau or insurance commissions. Navitus will apply the tools of this FWA Plan to such events to detect instances of prohibited activity such as kickbacks, code of conduct violations, embezzlement, forgery, and theft.

6. Investigations

a. Framework

When potential fraud is identified or suspected, the Navitus SIU conducts a confidential investigation. SIU investigators may collaborate with the Pharmacy Audit team or other departments to gather additional information for the investigation. The SIU Investigator may also work with a client's SIU team to gather additional information as needed.

b. Mechanisms

SIU uses a variety of mechanisms to prompt reporting, detect and investigate FWA across all lines of business and with downstream entities. Some activities include:

- Ensuring that policies and procedures are reviewed and updated annually;
- Working with the compliance staff to develop effective training programs and outreach materials for employees including temporary employees, agents, pharmacies, contractors and vendors to bring awareness to the current FWA environment and recognize FWA schemes;
- Monitoring the FWA confidential hotline number and SIU referral email account;
- Ensuring timely logging, triaging and tracking of referrals and allegations received to investigate and identify trends;
- Posting SIU Hotline on the Navitus website, training materials and in the Pharmacy Provider Manual.
- Responding to inquiries and data requests from government authorities or law enforcement;
- Coordinating and cooperating with MEDICs, CMS, Medicaid Fraud Control Units (MFCU), State Attorneys General, State OIG, and law enforcement requests for information regarding potential fraud schemes;
- Providing periodic trend reports to Navitus leadership to ensure investigation results are considered when developing and revising the Work Plan;
- Providing clients with SIU metrics; and
- Providing documentation to support CMS Compliance Program Effectiveness (CPE) audits.

c. Referral Process

Any individual or entity including members, pharmacies, prescribers, law enforcement, clients, and Navitus departments may submit referrals. Complaints from pharmacies, prescribers, members or other entities may also constitute a referral to SIU where such a report also includes concerns about integrity, utilization, or improper activity. SIU provides Navitus Customer Care, Greivance and Appeals, Pharmacy Relations and other

staff with key indicators that might suggest FWA and protocols for referring this information to SIU. In addition to calling the Hotline or emailing the SIU team Navitus referral sources may also use a referral form that includes specific information to aid the investigator in assessing the issue.

Once a referral is received, every referral is triaged which allows each referral to be vetted, scored, and assessed for risk and prioritized for investigation. The risk assessment process identifies relevant scope and/or claims, Medicare or Medicaid impact, and scores the likely potential for fraud, waste or abuse to enable effective assignment to the investigators. Triaging contemplates the nature of the referral, the medications involved, and the source and conditions leading up to the referral. Triaging also rapidly identifies opportunities to communicate trends, provide education, and detect schemes.

d. Investigative Process

SIU conducts standard investigations using accepted methods established by the Association of Certified Fraud Examiners (ACFE), National Health Care Anti-Fraud Association (NHCAA), The Institute of Internal Auditors (IIA), and the National Association of Drug Diversion Investigators (NADDI). The process includes:

- **Gathering Evidence**

SIU will make a reasonable inquiry into all referrals of potential FWA from individuals or entities including but not limited to clients, providers, members government entities, law enforcement, and internal Navitus departments. For referrals of FWA allegations related to Navitus employees, SIU will escalate the matter to the Chief Compliance Officer and a determination as to whether the matter will be investigated internally or outsourced will be made on a case-by- case basis.

SIU analyzes claims reports through its proprietary tools and conducts risk assessments to gather evidence for an investigation. This enables SIU to identify the level of risk for potential FWA. If the risk assessment results indicate the investigation poses a moderate to high level of risk SIU will perform a more in- depth review of

documentation and will determine if additional information is needed from internal and/or external sources.

- **Validating or Substantiating the Allegation of FWA, by Considering:**
 - Quality “root cause analysis”
 - The nature of the issue;
 - Prior violations, sanctions, exclusions etc.;
 - Willingness to cooperate;
 - Who is involved in the fraud;
 - Pertinent affiliate and ownership relationships;
 - Who made the allegation and why;
 - Member complaints;
 - Client validation, supporting evidence;
 - What the direct evidence supports;
 - Any indirect evidence that is present;
 - Evidence of attempted improper behavior (i.e. Claims testing);
 - Absence of expected evidence;
 - How long the activity has been in progress;
 - Whether the individual was trained or informed of appropriate practices; and
 - Internal control environment, including systemic controls.

- **Determining Recommendations for Successful Mitigation and Corrective Action to reduce or eliminate FWA and Prevent Recurrence by Considering:**
 - Patterns and likelihood of ongoing activities;
 - Entities to effect correction, e.g., Client; law enforcement
 - Resolution options including pharmacy education or corrective action, member case management, medical necessity review and prescriber interventions
 - Availability of deterrents, e.g. Lock-in Program; and
 - Level of sophistication of activity.

□ **Additional In-depth Review**

- Navitus uses a variety of additional sources when further analyzing data for

investigation. Some of these sources include:

- Pharmacy audit results
- Pharmacy network credentialing activity – license, insurance, etc.
- Proactive/expanded investigations
 - Social media sources
- Exclusion screening
- Pharmacy affiliation mapping
- CMS Fraud Alerts
- CMS Open Payments
- CLEAR Investigational Background Tool
- Corporate business listings – state and social media
- License and board sites
- Court sites where available
- Retrospective Drug Utilization Review letter responses from prescribers
- FWA Outlier Letter responses

7. FWA Watch Lists

The SIU team maintains a FWA Watch List that includes prescribers, pharmacies, and members flagged for patterns that may be emerging as potential FWA, identified in industry reports, publications or fraud alerts. The individuals and entities on the FWA Watch List are reviewed, after a designated period of time depending on the issue, for claims screening that may reveal potential FWA activity. The SIU team additionally maintains a list of drugs that are frequently associated with FWA activity. This list may be influenced based on industry trends, alerts, list serve notices, and Navitus claims experience.

The Pharmacy Audit Team maintains a Watch List of Pharmacies who have been previously terminated from the Navitus network, are currently being monitored or investigated by Navitus for certain activities, are sanctioned or investigated by external agencies as result of an audit or allegation, are identified in industry reports, or have a prior debarment, conviction, loss of license, or Board action. The list is utilized internally by the Pharmacy Network team when credentialing new pharmacies or re-credentialing existing pharmacies. The Watch List helps prevent previously terminated pharmacies or pharmacies from becoming part of the Navitus Participating Pharmacy Network again.

8. Industry Participation and Trend Identification

Navitus participates in several industry associations that are sources of information related to fraud schemes in the healthcare industry, including the National Association of Drug Diversion Investigators (NADDI), the Health Care Compliance Association (HCCA), and the Association of Certified Fraud Examiners (ACFE). These organizations offer ongoing FWA training as well as frequent emails and newsletters with information about current trends and news relating to pharmacy FWA.

In addition, the SIU and Audit teams and other departments also receive information from a variety of experts dedicated to anti-fraud practices such as the National Health Care Anti-Fraud Association (NHCAA) and the CMS Part D MEDIC Taskforce. These organizations provide an opportunity for members to share information on potential fraudulent situations and emerging fraud schemes. Navitus coordinates with its Part D Sponsor clients related to information sharing with the CMS MEDIC and with Managed Medicaid Organizations for information sharing and reporting for Medicaid.

C. MITIGATION AND CORRECTIVE ACTION

1. Corrective Action Plans Resulting from Audits

Navitus may notify pharmacies of FWA patterns or place pharmacies on corrective action plans due to findings of non-compliance. Navitus performs follow up audits related to pharmacies placed on corrective action plans. Corrective action plan audit results have the following outcomes:

- Improvement noted – CAP is closed;
- Some improvement noted – CAP is extended;
- No improvement noted – Pharmacy reviewed for potential network termination or CAP is extended, if appropriate; or
- Increased issues noted – Pharmacy reviewed for potential network termination.

2. Corrective Action Plan Resulting from Investigations

Where the SIU team has identified potential or actual FWA across members, pharmacies and/or prescribers, investigation reports are provided with recommendations to clients for corrective actions and effective means of curtailing the issues that were identified during the investigation.

- Medicare investigations will be reviewed and a case triaged within two weeks of receipt by Navitus and will be completed within a reasonable time.
- Preliminary investigations with potential FWA originating at Navitus will be communicated to the client in order for the client to meet any reporting requirements enforced by state agencies.
- Other reports with client specific findings are prioritized and moved promptly through the investigative process to meet or exceed Medicare investigation standards.

Other FWA reports are also provided to clients per contractual or delegation requirements or upon request. Metric reporting is provided monthly, quarterly, or annually depending on the type of report and client contractual requirements. Clients may request a copy of a specific, non-confidential report, by contacting the Chief Compliance Officer or the Compliance/SIU Manager. Remediation with pharmacies, prescribers, or members may include one or more of the following:

a. Administrative Actions

- Pharmacy retraining and education;
- Pharmacy written corrective action plan;
- Pharmacy notification of potential FWA outlier behavior with request for response;
- Pharmacy contract termination;
- Recommendations for Plan Sponsors for Part D MEDIC reporting;
- Recommendations for Medicaid Program Integrity, e.g., lock-in program;
- Reports to external agencies such as State Boards of Pharmacy, the Drug

Enforcement Agency (DEA) and US Food and Drug Administration (FDA) reporting;

- Recommendations to plan/client for prescriber intervention;
- Recommendations to plan/client for member intervention;
- Recommendation for reviews of medical necessity or medical services;
- Placement of pharmacy, prescriber or member on FWA Watch List;
- Increased monitoring and auditing; and/or
- Recommendations and coordination with clients, e.g., referrals to investigative agencies and authorities.

Internal corrective actions may also be taken to address the root cause of findings such as:

- Systemic fixes;
- Retraining on processes and procedures for staff;
- Revision or development of documentation, including policies and procedures, process flows, etc.;
- Reporting to the appropriate internal personnel or committees;
- Recommendations to Health Strategies team to address utilization issues regarding covered services including but not limited to observances on prior authorization, quantity limits, or step therapy;
- Requests to Drug Information Pharmacists to evaluate formulary status and conditions for coverage associated with findings related to specific medications;
- Correcting claim configurations for transactions;
- Consequences or disciplinary actions, as necessary; or
- Monitoring to verify reoccurrences are prevented.

3. Prescriber Alerts and Blocking

Where the SIU team identifies a prescriber as part of our regular publication and listserv monitoring, an alert notification will be sent to clients with claims impact. The notification will indicate any actions taken such as further investigation or placement on the FWA Watch List. If the prescriber meets certain criteria such as a fraud conviction or license revocation, Navitus may block the prescriber from processing claims.

4. Financial Actions

Pharmacies who engage in activities that result in improper or overpayments may be subject to payment actions which may impact reimbursement amounts or the stream of reimbursement for claims submitted. Navitus will track all such actions. Examples may include but are not limited to the following.

Claims Correction or Recovery

- o Audit corrections, adjustments, or recoveries – Such corrections are initiated on the basis of audit findings and are requested per transaction. These may be the result of billing, quantity, dose or other errors found in desktop, onsite or other audits. Where a pharmacy does not voluntarily make the correction or cannot correct due to system limitations, Navitus will submit the correction for the pharmacy.

- o SIU recoveries – Such corrections are initiated on the basis of an investigation and confirmation by the client as a credible allegation. Recoveries may not be pursued by Navitus if a client or program directive initiates the recovery through its own processes. This is the result of an investigation pattern, trend, or repeated behavior which is identified over a specified period. This may be accomplished through direct payment by the pharmacy or offset of future claims.

- o All adjustments and recoveries are submitted through Navitus claims team for manual processing of the correction. Each submission includes the claims history, impacted dates and affected pharmacies. All such recoveries are returned in full to the designated client or plan.

- o Pharmacies will receive notice in advance (directly or via contract representative) of any intended correction, adjustment or recoveries.

- o Payment Suspension – This is a short or long term action which may be implemented by Navitus, a client, or at the request of a program authority to hold payments for claims where a pharmacy's claims activity must be further confirmed or the pharmacy's participation status is in question.

5. Appeals

Participating Pharmacies may be provided with audit findings or adverse credentialing decisions by the Credentialing Committee. Pharmacies may appeal these determinations in writing and provide any supporting documentation related to determination. Appeals are reviewed by the Pharmacy Grievance and Appeals Committee to determine the outcome of the appeal based on a comparison between the original documentation and appeal documentation.

D. FWA REPORTING

In addition to the audit and investigative activity described above, FWA activities and outcomes are reported internally to employees, Committees including Compliance and FWA Oversight, and Board of Directors and Executive Committee, as applicable:

On a regular basis, the FWA Oversight Committee meets and is provided a quantitative and qualitative report on metrics, corrective action plans, trends, watch-list data, hotline activity, FWA training issues, changes to the Work Plan, external referrals, and recommendations for policy or procedure revisions

Navitus provides standardized FWA metric and trend reporting to its clients as well as additional reports based on the specific needs and requirements, including written reports, regular update meetings, Medicaid/Medicare program reporting, and other interactions as necessary.

Furthermore, Navitus will cooperate with state and federal authorities who are pursuing information regarding individuals and entities who may be the subject of or involved in fraud, waste and abuse. Such cooperation shall include but is not limited to meetings, sharing investigation materials and evidence, producing claims and contracts, maintaining confidentiality, or providing other investigative support. Navitus will fulfill subpoenas and requests for information within the time requested from authorities unless extensions or other allowances are mutually agreed upon.

E. FDR OVERSIGHT

1. Monitoring

As a first tier entity, Navitus provides ongoing monitoring of the downstream entities, including pharmacies and vendors. The monitoring considers the types and levels of risk that the vendor poses to the Navitus FWA Program and whether the vendor qualifies as a first tier, downstream or related (FDR) entity. Factors considered in determining the risks associated with the FDRs include the amount of work completed by the FDR, complexity of the work, training, and past compliance issues.

The Navitus Medicare Compliance team executes an annual FDR audit plan which identifies which downstream entities are audited and describes the scope and timing of each audit.

The plan will include:

- The number of audits to be performed;
- The FDRs to be audited and audit schedules, including start and end dates;
- Necessary resources;
- Person(s) responsible;
- Final audit report due date to Compliance Officer; and
- Follow up activities from findings.

The results of the annual FDR audits are shared with the FDR Oversight Committee, Compliance Committee, and Quality Management Committee.

2. Education, Training, and Exclusion Review

The Compliance department ensures oversight of specific aspects of the FDR or vendor relationship, including Code of Conduct distribution, compliance and FWA training, exclusion screening, offshore activities, document retention, and breach notifications, among others.

On at least an annual basis, Navitus seeks attestation from downstream entities on completion of the CMS Compliance and FWA training and other Medicare Part D requirements. Additionally, Navitus conducts monthly exclusion reviews of vendors, and network pharmacies to ensure that no excluded entities conduct business with Navitus.

APPENDIX A
DEFINITIONS

Fraud:

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

OR

An intentional Act or Omission for the purpose of obtaining something of value through Deception, Misrepresentation or Concealment

Waste:

Overutilization of services or other practices that, directly or indirectly, result in:

- Unnecessary costs to the health care system, including the Medicare program
- Improper payment for services
- Payment for services that fail to meet professionally recognized standards of care
- Services that are medically unnecessary

It is not generally considered to be caused by criminally negligent actions, but by the misuse of resources.

Abuse:

Providing products or services that are inconsistent with accepted practices or are clearly not reasonable or necessary, example billing for a non-covered service or prescribing drugs in a manner or quantity that may cause safety concerns.

Anti-Kickback Statute:

Provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce or reward the referral of business reimbursable under any of the Federal health care programs, such as Medicare, Medicaid or Affordable Care Act.

Appeal:

A process whereby a person with Medicare (or such person's representative) exercises the right to request a review of a contractor claim determination to deny Medicare coverage or payment for a service in full or in part.

CMS: The Centers for Medicare and Medicaid Services, an agency within the Department of Health and Human Services, responsible for oversight of the Medicare and Medicaid FWA program

Commercial Client: a pharmacy benefit plan sponsored by an employer/union group, third party administrator or fully insured health plan that is not implemented by or on behalf of a government program such as Medicare or Medicaid.

Edit: Logic within the claims processing system that selects certain claims, evaluates or compares information on the selected claims or other accessible source, and depending on the evaluation, takes action on the claims, such as pay in full, pay in part, or suspend for manual review.

Exchanges: An electronic marketplace to purchase health insurance from participating health plans as provided for by the Affordable Care Act.

Exclusion: A person or entity that has been excluded from participating in or receiving payment from any federal healthcare program including Medicare and Medicaid.

False Claims Act: A Federal law that imposes liability on anyone who knowingly submits, or causes another to submit, a false or fraudulent claim to the United States. The term "knowingly" includes actions taken with actual intent, or one that is taken in reckless disregard or in deliberate ignorance of the truth.

Formulary: The entire list of drugs covered by a health plan, including commercial plans, Medicare Part D sponsors or Medicaid.

Government Plan Sponsor: any pharmacy benefit plan, which have contracted directly with CMS to become prescription drug plans (PDP) or Medicare Advantage plans (MA-PD) for their own members, pursuant to a CMS waiver. Also includes plans being offered and sold to employer/union groups by PDPs, MA-PD Organizations, and other Plan Sponsors, pursuant to CMS waivers; or a Prescription Drug Plan implemented by a state Medicaid Program.

HHS: HHS means Health and Human Services and may refer to either the Federal agency or a particular state agency.

Medicaid: Medical assistance provided under a state plan approved under Title XIX of the Act.

Medicare: The health insurance program for the aged and disabled under Title XVIII of the Act.

Medicare Advantage (MA): A public or private entity organized and licensed by a state as a risk-bearing entity (with the exception of provider sponsored organization receiving waivers) that is certified by CMS as meeting the Medicare Advantage contract requirements. (42 C.F.R. § 422.2)

Medicare Advantage Prescription Drug Plan (MA-PD): An MA plan that provides qualified prescription drug coverage. (See 42 C.F.R. § 423.4).

Office of the Inspector General (OIG): OIG means the Office of the Inspector General for the Department of Health and Human Services.

Part D Plan: A prescription drug plan (PDP), an MA-PD plan, or a PACE plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. This includes employer- and union-sponsored plans. (See 42 C.F.R. § 423.4).

Part D Plan Sponsor: Refers to an organization offering a MA-PD plan, including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage. This includes employer- and union-sponsored plans. (See 42 C.F.R. § 423.4).

Pharmacy & Therapeutics (P&T) Committee: A committee, the majority of whose members shall consist of individuals who are practicing physicians or practicing pharmacists (or both), that is charged with developing and reviewing a formulary. Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom is independent and free of conflict with respect to the Sponsor and at least one practicing physician and at least one practicing pharmacist who have expertise in the care of elderly or disabled persons. (See 42 C.F.R. § 423.120(b) (1)).

Provider: Any Medicare or Medicaid provider or supplier such as physician, pharmacist or home health agency.

APPENDIX B
FWA Oversight Committee Charter
Description and Responsibilities

Purpose

1. Ensure that Navitus complies with Local, State and Federal legislation and regulatory entities governing our clients and any Navitus operations as it relates to FWA.
2. Ensure appropriate controls, processes, policies and procedures are developed, implemented and adhered to, in order to ensure the integrity of business operations and legal, regulatory and contractual compliance.
3. Ensure C-suite level involvement in FWA Program oversight and monitoring and that adequate resources are invested in the Navitus FWA Program.
4. Coordinate cross-functional FWA efforts between Compliance, Special Investigation Unit (SIU), Clinical Programs, and Pharmacy Network departments and provide a mechanism for collaboration.
5. Ensure appropriate FWA oversight, monitoring, auditing and training of downstream entities (pharmacies).
6. Ensure opportunities for continuing process improvement and implementation of best practices

Committee Responsibilities

1. Review FWA Program and Plan annually, provide input, and monitor effectiveness of prevention, detection, investigation and correction efforts and initiatives.
2. Review FWA and auditing policies and procedures to ensure compliance with CMS, Federal and State laws, rules and regulations and client contractual requirements related to FWA.
3. Assist Compliance and SIU with assessment, identification and mitigation and/or remediation of potential fraud, waste and abuse risks.

4. Identify, implement and monitor strategies and controls to minimize or mitigate potential fraud, waste and abuse risks and vulnerabilities.
5. Identify training opportunities to promote prevention and detection of fraud and abuse and ensure training is accurately targeted, executed and documented.
6. Assist Compliance department with efforts to communicate FWA initiatives, including training programs/written materials which promote awareness/understanding of FWA, applicable laws and regulations, reporting requirements and consequences of non-compliance.
7. Review external pharmacy audit results for trends and opportunities, including but not limited to recommending potential claims processing system edits to reduce billing errors and potential FWA.
8. Review current clinical programs/system edits for trends and opportunities to prevent and detect FWA.
9. Participate as needed in external regulatory audits involving FWA.
10. Assist Compliance and SIU with assessment of trends identified from referrals and hotline activity.

Membership

Sr. VP, Customer Operations and CCO (Chair) Sr. VP,
Provider Services
Director, Corporate Compliance Compliance/SIU
Manager (Facilitator)
Associate Director, Provider Network Management
Associate Manager, Provider Credentials Supervisor,
Pharmacy Audit
Compliance Analyst II
SIU Investigators SIU
Associate II Clinical RPh

Meetings

Meetings are held every other month or more frequently if needed. Meetings shall be scheduled and ordered by the Facilitator with use of an agenda; and Minutes shall be created, distributed and maintained. To the degree possible, pre-read material shall be distributed prior to the meeting.

Relationships/Reporting

The FWA Oversight Committee is accountable to the Compliance Committee.

The Chief Compliance Officer will share a summary of activities, findings and recommendations with the Navitus Executive Committee on a periodic basis. An annual summary of FWA program effectiveness and activities will be included in an annual Compliance Program evaluation shared with the Board of Directors annually. All compliance-related corrective action plans will be documented and reported to the Executive Committee in a timely manner when proposed corrective actions require Executive Committee approval for execution. Further reporting of FWA-related corrective action plans will be forwarded by the Chief Compliance Officer or his or her designee and to the Director of Corporate Compliance at the respective Plan Sponsor upon request.

In addition, the Facilitator for the Oversight Committee will provide an update report at each Oversight meeting. The substance of the report shall depend on activity, but may include plans, outcomes, impact, trends and recommendations related to:

Training Auditing
Case Management Hotline
External Referrals
Client Reports
Compliance Committee Reports Marketing
Specific Projects

Approval: February 2021

