Medicare Compliance Program Plan

Medicare Prescription Drug Plan – Part D
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Medicare Compliance Plan Program Governance

The Medicare Compliance Program Plan, and the Medicare Prescription Drug Plan (Part D), is a component of the Optima Health overall Compliance Program and reinforces a commitment to ethical standards of conduct. The Medicare Compliance Program Plan builds on the foundation established by the Optima Health Compliance Program, including measures related to mandatory compliance training, HIPAA Privacy program training, Fraud, Waste and Abuse (FWA) detection, prevention, and correction, a hotline for anonymous reporting, FWA training and specialized training for functional areas supported by department policies and procedures. The Medicare Compliance Program Plan is updated annually, approved and adopted by the Optima Health Compliance Committee and the Optima Health Board of Directors.

Optima Health Board of Directors is responsible for the oversight of the Medicare Compliance Program Plan to ensure that Optima Health is upholding its commitment to compliant, lawful, and ethical conduct and to the Medicare Program. This oversight requires the Board of Directors to be knowledgeable about, and either approve or delegate approval, of the content and operation of the Compliance Program, Code of Compliance, Compliance policies and procedures, and all applicable statutory and regulatory requirements. The Board of Directors has the responsibility to review reports by the Compliance Officer and Compliance Committee on the activities and status of the Compliance Program, including issues of non-compliance identified, investigated, and resolved; Compliance Program outcomes and effectiveness; results of internal and external audits; exclusion list matches; hotline calls; root cause analyses and corrective actions; Notices of Non-Compliance, Warning Letters, and formal sanctions; fraud, waste, and abuse goals and actions; and risk assessment and reduction activities.

The Board of Directors, through periodic resolutions, gives authority to the Compliance Officer to provide the Optima President and the Board with unfiltered, in-person reports, depending upon the immediate situation(s). The Board gives authority to the Compliance Officer to implement needed compliance actions and activities without waiting for their approval, provided those actions and activities are reported in the next Board meeting.

The Board of Directors delegates the following responsibilities to Optima Health Senior Leaders and the Compliance Committee:
1. Development, implementation and approval of Compliance policies and procedures;
2. Review and approval of compliance and fraud, waste and abuse training;
3. Review and approval of compliance risk assessments;
4. Review of internal and external audit work plans, audit results, and corrective action plans;
5. Review and approval of appointment and performance goals for the Compliance Officer;
6. Evaluation of the senior management team’s commitment to ethics and the Compliance Program; and
7. Review of dashboards, scorecards, self-assessment tools, and other evaluative tools.

The Board of Director meeting minutes and related documents provide evidence of their active engagement in the oversight of the Medicare Compliance Program and include documentation of the Board’s questions, follow-up on issues and actions taken to ensure an effective Compliance Program.

The Compliance Committee is responsible to Senior Management, the Chief Executive Officer and the Board of Directors for reviewing the effectiveness of the Compliance Program through
self-audits and monitoring of metrics and key indicators and to ensure that prompt and effective corrective actions are taken where deficiencies are noted. The Compliance Officer and the Compliance Committee are responsible for escalating compliance deficiencies and ongoing issues of non-compliance to Senior Management, the Chief Executive Officer and the Board of Directors.

Optima Health makes this Medicare Compliance Program Plan available to all Optima Health Employees and Board of Directors (“Directors”), as well as contractors, subcontractors, vendors, agents, and First Tier, downstream and related entities (“FDRs”) who provide services for Part D members. The Compliance Director reserves the right to amend and update components of the Medicare Compliance Program, including the material in this Medicare Compliance Program Plan, at any time based on regulatory guidance, enhancements to the program to improve effectiveness or for any other reason.

The information contained in this Medicare Compliance Program Plan is correct as of the date of publication and may change without prior notice.

THE OPTIMA HEALTH COMPLIANCE PROGRAM

Organizational integrity is at the core of values at Optima Health and begins with each individual Employee. At Optima Health, each Employee is required to observe the spirit and letter of all applicable laws and regulations, as well as demonstrate the highest standards of proper compliance and personal integrity. Employees are expected to conduct themselves in an ethical and lawful manner, both inside and outside of the workplace, by refraining from any non-compliant, illegal, dishonest or unethical activities. Proper compliance is an individual responsibility. The Optima Health Code of Compliance expresses these commitments as key values of our Company.

Optima Health considers its Compliance Program to be an essential tool for promoting regulatory compliance and ethical conduct; preventing, detecting and resolving non-compliant and illegal conduct, including fraud, waste or abuse of government programs, whether committed by Optima Health Employees or by those outside of the Company.

The Optima Health Compliance Program includes, but is not limited to, the following elements:

1. Written Policies and Procedures and Standards of Compliance;
2. A Compliance Officer hired by Optima Health and Compliance Committee;
3. Training and Education;
4. Effective Lines of Communication;
5. Auditing and Monitoring;
6. Enforcement of Standards through well-publicized disciplinary guidelines; and
7. Detecting and responding to offenses and developing Corrective Action Plans.

An effective Compliance Program has a Compliance Plan, which is a written document that describes the specific manner in which the Compliance Program elements are met for each of our lines of business including Medicare Part D. The Compliance Plan also clearly states that the Company expects Employee compliance and provides Employees with guidance in abiding by the elements of the Compliance Program.

This Medicare Compliance Program Plan applies to all Optima Health Employees, subcontractors, first tier, downstream, and related entities, and agents whose jobs touch upon the Medicare Part D program. For other Optima Health Employees not involved in the Medicare
program, this Medicare Compliance Program Plan is part of the overall Optima Health Compliance Program and sets forth the Optima Health commitment to compliance and provides general guidelines on Compliance Programs within the Company.

The Medicare Compliance Program Plan and Employee policies and procedures are reviewed at least bi-annually and revised when there are changes in regulatory requirements or business needs. The Medicare Compliance Program Plan includes ongoing risk assessment(s) so the program evolves in response to issues that arise with resources for oversight deployed based on business circumstances of the Company.

The Compliance Officer is responsible for oversight of the Medicare Compliance Program Plan, providing Compliance Program guidance, and reporting incidents of suspected or identified non-compliance to Senior Management and the Board of Directors.

Optima Health leaders of each functional area are responsible for maintaining overall compliance with the changing requirements of the Centers for Medicare and Medicaid Services ("CMS"). Optima Health senior leaders and the Board of Directors are accountable for the effectiveness of the Compliance Program.

The Medicare Compliance Program Plan includes processes for assessing the effectiveness of the Compliance Program, through the use of effective, two-way communications and reporting metrics. While not limited to the following, the Medicare Compliance Program may be evaluated for effectiveness by review of:

1. Structure indicators such as Medicare related hotline calls investigated within two (2) working days and resolved within sixty (60) days; annual Compliance Effectiveness Survey; reports to the Board; Code of Compliance provided yearly to 100% of staff; Medicare Regulatory Communications committee meeting at a minimum of ten (10) times per year.
2. Process indicators such as 100% of staff trained annually on Compliance/HIPAA/FWA; 100% of staff, vendors, and Board members checked monthly against LEIE/System for Award Management (SAM) database; annual survey of Medicare staff to determine Medicare training needs; compliance with 10% non-model rate.
3. Outcome indicators such as reporting requirement timelines meet; 100% of member materials filed and approved prior to distribution; 100% of advertising documents reviewed and filed with CMS prior to use.

WRITTEN POLICIES, PROCEDURES AND STANDARDS OF COMPLIANCE

The Optima Health overall expectation for Employee compliance begins with commitment to comply with all Federal and State regulations, standards and sub-regulatory guidance. Compliance training occurs as part of the new hire process and is conducted annually thereafter, as determined by the Optima Health Compliance Department. In addition, Optima Health has policies and procedures that establish expectations that Optima Health Employees, as well as FDRs, are expected to follow. Optima Health maintains an extensive library of policies and written guidelines so all Employees know and understand their individual responsibility for compliant and ethical business practices.

The Optima Health core standards are described below.
**Optima Health Code of Compliance**

The *Code of Compliance* articulates the commitment to doing business in a lawful and ethical manner in compliance with Federal and State requirements. The *Code of Compliance* is approved by the Compliance Committee. The *Code of Compliance* is designed to guide Optima Health Employees and business partners in upholding our high standards of fair and ethical practices.

All Optima Health Employees must read the *Code of Compliance* and yearly electronically sign an acknowledgement that they agree to abide by the *Code of Compliance*. A hard copy of the *Code of Compliance* is provided to all newly-hired Employees and is available to review on the Optima Health intranet ([https://wavenet.sentara.com/Pages/home.aspx](https://wavenet.sentara.com/Pages/home.aspx)) and Internet ([https://optimahealth.com](https://optimahealth.com)) sites by all Employees and FDRs.

Each Optima Health manager, director and officer of the company is responsible for reinforcing the *Code of Compliance* in their respective departments. In support of the *Code of Compliance*, Optima Health has developed written policies, which provide Employees with practical guidance in meeting standards of acceptable behavior. Employee policies are stored in Microsoft products, WaveNet, Wintergrate and Compliance 360 which are available to all Employees.

Optima Health requires that all FDRs supporting the Medicare Prescription Drug (Part D) Program abide by the Vendor *Optima Health Code of Compliance* or implement their own Code of Compliance that incorporates standards of Compliance and compliance requirements similar to the *Optima Health Code of Compliance*.

On a bi-annual basis, Optima Health reviews the *Code of Compliance* for possible revisions that may result from a change in Company policy or changes in applicable laws or regulations.

**Health Insurance Portability and Accountability (HIPAA) Privacy Program**

The HIPAA Privacy Program sets the standards for Employees in safeguarding confidential and protected health information. Optima Health is committed to complying with applicable laws, regulations and policies related to privacy of health information. All Employees are required to complete training on the Privacy Program policies and are required to perform their work duties with a conscious regard for the privacy rights of all Optima Health members.

Under the direction of the Optima Health Director of Compliance, the Privacy Program focuses on educating Employees on their ongoing responsibility to protect member privacy and secure member information. The Compliance Department manages and updates the privacy policies and procedures, which are available to all Optima Health Employees via the electronic repository.

All FDRs must abide by the Optima Health Privacy Program policies or demonstrate that they have a dedicated Privacy Officer who is responsible for ensuring that all individuals within the respective delegated entity or vendor are trained on HIPAA regulations and the process for reporting privacy breaches. The FDR’s Privacy Officer is also responsible for managing any issues related to privacy breaches and reporting to Optima Health should a privacy breach occur that impacts Optima Health members or business.

**Fraud, Waste and Abuse (FWA) Plan**

Optima Health maintains a FWA Plan that demonstrates a commitment to prevent, detect and correct incidents that could lead to fraud, waste and/or abuse. The FWA Plan includes initial background checks for all potential employees, Board members, physicians, and FDRs to review for felony convictions and Office of Inspector General (OIG) or General Services Administration
(GSA) sanctions or exclusions. Upon hire or initiation of a contract, all individuals listed above must agree to comply with the Optima Health Code of Compliance and complete all mandatory FWA training courses. FWA training must include laws and regulations related to Medicare FWA (False Claims Act, Anti-Kickback Statute, etc.). Employees (including temporary workers and volunteers), governing body members, and FDR employees who have involvement in delivery of Part D must receive FWA training:

1. Upon appointment of a new job or new product;
2. When requirements, regulations or laws change;
3. When employees are found to be noncompliant;
4. As a corrective action to address a noncompliance issue;
5. When an employee works in an area implicated in past FWA activities.

Optima Health uses a number of system edits and programmatic reviews of data designed to detect potential fraud. Optima Health maintains a FWA hotline for anonymous reporting and a Special Investigations Unit (SIU) that investigates all reports of potential fraud, waste and/or abuse. The SIU works with designated State and Federal agencies, the National Benefit Integrity Medicare Drug Integrity Contractor ("MEDIC"), and law enforcement to pursue individuals or organizations who may be involved in activities that fall under the FWA umbrella and will pursue prosecution of health care fraud and abuse.

Fraudulent activity may involve an Employee, member, subscriber, or health care provider who is involved in inappropriate schemes, behaviors, false documentation, inappropriate prescriptions, or falsification of conditions in order to help an individual receive an otherwise uncovered service under Medicare or other Federal programs.

All Optima Health Employees, Directors and FDRs play an important role in the Optima Health fraud prevention program and are required to report suspected fraud, waste and/or abuse through the channels provided.

Please refer to Attachment A, Optima Health Fraud, Waste and Abuse (FWA) Prevention & Detection Plan, for details on the Fraud, Waste and Abuse Plan.

**Optima Health Compliance and FWA Policies**

Optima Health policies and procedures represent its response to laws and regulations and day-to-day risks to help reduce the prospect of fraudulent, wasteful and abusive activity. Because risk areas evolve and change over time, the Optima Health policies and procedures are reviewed bi-annually and revised when there are changes in regulatory requirements or business needs.

Optima Health policies demonstrate to Employees, business partners, and the community at large, our strong commitment to honest and responsible business compliance. Optima Health published policies establish procedures and provide direction to Employees to promote compliance with laws and regulations, and to reduce the prospect of fraudulent, wasteful, or abusive activities in our daily work.

Optima Health requires that all FDRs adopt Optima Health policies and procedures or maintain similar policies and procedures that comply with current regulations or sub-regulatory guidance from CMS.
Medicare Compliance Policies and Procedures

Optima Health Operational Areas have developed Medicare Compliance policies and procedures to ensure process controls are in place to meet specific requirements of the Medicare program. The policies and procedures support the Medicare Compliance Program Plan and work in conjunction with department policies developed by and used on a day-to-day basis by Optima Health business areas.

The Optima Health Policies and Procedures are located in the Compliance 360 database and are available for all Employees to view and utilize as necessary. Each Department retains a repository of the Medicare policies which supports the Optima Health Medicare Compliance Plan and is used on a day-to-day basis by the respective Optima Health business areas. These policies are reviewed and revised bi-annually. Revisions may occur more frequently according to business needs, process and governmental regulation changes and improvements.

Delegated Entities, Vendors, Agents and First Tier, Downstream & Related Entities (FDRs)

The Optima Health network management, and vendor oversight teams oversees the Company relationships with FDRs. The teams monitor FDRs’ activities and performance to ensure they fulfill their contractual requirements for Part D, and meet established performance standards. Delegation and vendor oversight teams employ audits to validate compliance, develop corrective action plans in response to detected offenses, and report oversight activities through their respective delegation or vendor oversight committees. The delegation or oversight committees manage corrective action plans and reports to the Compliance Committee.

TRAINING AND EDUCATION

Training and education are important elements in the Optima Health overall compliance program. Optima Health requires that Employees at all levels of the company complete mandatory compliance training courses. The compliance training courses listed below must be completed within ninety (90) days of employment and must be repeated annually, unless otherwise noted.

1. Code of Compliance;
2. General Compliance;
3. HIPAA; and

Compliance Training for FDRs

All first tier, downstream and related entities that provide services to Medicare Advantage and/or Part D enrollees are required to complete compliance and fraud, waste and abuse training. Contracted providers and FDRs have the option of taking the Optima Health Compliance and Fraud, Waste and Abuse Compliance training on-line via the Optima Health provider website, request a hardcopy version of the training, complete CMS’ online training or conduct their own training. Although some FDRs may be deemed to have met the requirements for the Medicare FWA training due to their enrollment into the Medicare Program, these deemed individuals must still receive general Medicare compliance training and specialized compliance training in connection with their job responsibilities.
Tracking Required Compliance Training

At Optima Health, each member of management is responsible for ensuring their Employees complete all required compliance training.

Required training courses are delivered electronically via the Sentara University Learning Management System (PLMS), which tracks training completion rates by Employees and alerts Managers to any overdue training requirements. Through the Onelink Learning Database, attendance logs, training materials and test results are maintained for reference.

Employees and Managers receive regular reminders of their training obligations, as well as personalized email remainders of outstanding compliance training requirements. Failure to complete required compliance training subjects Employees and their Managers to performance actions, up to and including termination of employment.

FDRs must maintain documentation, including attendance logs, training materials and testing results, of all employees, contractors and volunteers who have completed the trainings either provided by Optima Health through the website (www.optimahealth.com) or their own trainings.

EFFECTIVE LINES OF COMMUNICATION

Optima Health works diligently to foster a culture of compliance throughout the organization by regularly communicating the importance of performing jobs in compliance with regulatory requirements and reinforcing the company expectations of ethical and lawful behavior.

Optima Health has systems in place to receive, record, and respond to compliance questions, or reports of potential or actual non-compliance from Employees, Members, Providers and FDRs. The areas listed below are fundamental to the Compliance Department communications strategy:

Sentara Compliance, Ethics and Privacy Hotline Hotline

The Sentara Integrity Hotline is a confidential, toll-free resource available to Employees twenty-four (24) hours a day, seven (7) days a week to report violations or raise questions or concerns relating to the Optima Health Code of Compliance.

Sentara Compliance, Ethics & Privacy Hotline
1-800-981-6667

Calls to the Sentara Hotline may be made anonymously. Calls are never traced or recorded. The Sentara Integrity Hotline is operated by a third-party vendor to ensure confidentiality.

The Corporate Compliance Department regularly promotes awareness of the Sentara Integrity Hotline through a variety of materials, published at various intervals throughout the year, including:
1. Articles on Optima Health Connect, the intranet website
2. Posters displayed in common work areas
3. Electronic newsletters and emails

Optima Health tracks calls to the Sentara Compliance, Ethics and Privacy Hotline to ensure proper investigation and resolution of reported matters; and to identify patterns and opportunities for additional training or corrective action.
All calls to the Sentara Compliance, Ethics and Privacy Hotline are investigated internally. Results of investigations are normally not provided to callers other than the fact that the investigation has been closed.

**Optima Health Fraud, Waste and Abuse Hotline and Email Box**

The Optima Health Fraud, Waste and Abuse Hotline is a confidential, toll-free resource available to Employees, Members, Providers and FDRs twenty-four (24) hours a day, seven (7) days a week to report violations, or raise questions or concerns relating to fraud, waste and abuse. A twenty-four (24) hour confidential email box is also available for this same purpose. Employees, Members, Providers and FDRs may call:

**Optima Health Fraud, Waste and Abuse Hotline**  
1-866-826-5277 or  
[www.compliancealert@sentara.com](mailto:www.compliancealert@sentara.com)

These calls and emails may be made/sent anonymously. These communications are never traced or recorded. Anyone can make a report without fear of intimidation or retaliation.

Optima Health tracks calls to the Optima Health Fraud, Waste and Abuse Hotline or email complaints to ensure proper investigation and resolution of reported matters and to identify patterns and opportunities for additional training or corrective action. All calls to the Optima Health Fraud, Waste and Abuse Hotline are investigated by the Optima Health Special Investigations Unit (SIU).

Optima Health educates Employees about the Optima Health Fraud Hotline and email box through:
1. Fraud, Waste and Abuse Training;
2. The Employee intranet website;
3. Posters displayed in common work areas;
4. Optima Health Policies and Procedures;
5. Newsletters and emails.

Members, Providers and FDRs are educated regarding the Optima Health Fraud Hotline and email box through:
1. The Optima Health internet website;
2. The Fraud, Waste and Abuse Compliance training for Providers and FDRs;
3. Provider Newsletters and Updates;
4. The Optima Health Medicare Advantage Member Explanations of Benefits (EOBs).

**Compliance Awareness Week**

Each year Optima Health targets an entire week to deliver focused, all-Employee communications designed to build compliance, privacy, information security, and ethics awareness. The week-long schedule of activities includes creative education methods and other activities designed to increase awareness of compliance expectations and rewards Employees for their ongoing compliance efforts.
Medicare Communications Committee

This Committee has the responsibility to monitor all CMS publications, revisions, new laws and regulations that may affect the delivery of Part D services and communicate these changes to the appropriate operational areas affected.

ENFORCEMENT OF STANDARDS

Optima Health, as part of the compliance program, has published the *Code of Compliance*, which established standards of compliance that all Employees must follow. Every Employee is responsible for abiding by the *Code of Compliance* and for reporting any situation where he/she believes illegal or unethical compliance may have occurred. FDRs must also comply with standards Optima Health has established or demonstrate that they have implemented similar standards of compliance.

Optima Health takes its commitment to the *Code of Compliance* very seriously and takes appropriate and immediate investigative and disciplinary action if anyone violates the *Code of Compliance*, Optima Health policies or the law.

Optima Health strong commitment to ethical values and compliance includes:

**Involvement of Chief Executive Officer, Senior Management and Board of Directors**

The President and Chief Executive Officer (CEO) of Optima, Executive Vice President and Chief Operating Officer (COO) of Optima Health, and the Board of Directors are involved in establishing Optima Health standards of Compliance.

**Enforcing Standards of Compliance**

Optima Health policies provide specific instructions for handling reports of potential violations of company policies, administrative rules, regulations, or law. Any Optima Health Employee who suspects a potential violation of policy or law is required to report the matter to any of the following:
1. Their department supervisor or manager;
2. The Director of Compliance;
3. The Sentara Compliance, Ethics and Privacy Hotline;
4. The Optima Health Fraud, Waste and Abuse Hotline;
5. The email box at [www.compliancealert@sentara.com](mailto:www.compliancealert@sentara.com).

Optima Health does not tolerate intimidation or retaliation against Employees who report potential violations in good faith. A description of the Optima Health policy on non-intimidation/non-retaliation is found in the *Code of Compliance*, and is reinforced in a number of policies, procedures, guidelines, and training materials.

**Publicizing Disciplinary Guidelines**

All Optima Health Employees are informed that violations of the *Code of Compliance*, Optima Health policies, regulations or laws may result in appropriate disciplinary action, up to and including termination of employment. Disciplinary and Sanction policies are posted on the intranet for all Employees.
MONITORING AND AUDITS

Monitoring and auditing are critical elements in the Medicare Compliance Program. Compliance-related elements are used to develop metrics for evaluating performance against regulatory standards. Monitoring and auditing allows Optima Health to identify areas that require corrective action in order to achieve compliance with specific regulatory requirements. This process of self-identification and corrective action, along with monitoring that such actions are effective, is a key element of our program.

Optima Health will ensure that the Compliance Department auditors:

1. Are independent and do not audit areas where they have responsibility or have been involved in implementation or policy development;
2. Do not audit their own processes, policies, or actions;
3. Are knowledgeable of Medicare program requirements; and
4. Have access to relevant information of the company and its FDRs.

Optima Health employs multiple methods to monitor and audit these entities, including risk assessments, on-site audits, desk reviews and monitoring of self-audit reports. Oversight activities and results are reported regularly. Departments responsible for overseeing their specific entities must ensure appropriate corrective actions are implemented on a timely basis.

Compliance risks are separately reviewed through a variety of oversight audits, including:

1. Internal Audits;
2. Third Party Data Validation Audits;
3. Business Unit Self-Audits and Monitoring;
4. Delegation Oversight Audits;
5. Vendor Oversight Audits;
6. Credentialing Audits;
7. Special Investigations Unit (SIU) Monitoring, Audits and Investigations;
8. Annual Compliance Effectiveness Audit;
9. Auditing by regulators or other external parties.

The various components that make up Optima Health monitoring and audit activities include:

Medicare Monitoring and Audit Work Plan

The work plan for auditing operational areas and FDRs includes:

1. Audits to be performed;
2. Audits scheduled for the year, including start and end dates;
3. Number of first tier entities being audited and how they were chosen (may perform risk assessment to determine sample);
4. Announced or unannounced audits;
5. Audit methodology;
6. Necessary resources;
7. Types of audit: desk or onsite;
8. Person(s) responsible;
9. Final audit report due date;
10. Follow-up activities from findings;
11. Process for responding to audit results and for conducting follow-up reviews of non-compliance to determine if the corrective actions are successful.
**Medicare Compliance Audits**

The Compliance Department audits business unit operations as part of its overall program to identify and mitigate compliance risks. The Compliance Committee performs an annual risk assessment using data and information from a variety of sources, which may include:

1. Regulatory risks based on CMS and DMAS guidance;
2. Risks as identified in the OIG work plan;
3. Audit findings from CMS;
4. Notices of Non-Compliance from CMS;
5. Complaints filed with CMS (CTMs);
6. Complaints related to sales and marketing issues;
7. Secret Shopper issues and findings identified by CMS;
8. Audit findings from business unit self-audits;
9. Identified high risk areas;
10. Corrective Action Plan monitoring;
11. Member “touch points” such as Appeals & Grievances, Claims, Member Services, Enrollment/Disenrollment, and Premium Billing.

The result of the risk assessment drives the development of the Compliance Department’s annual work plan for oversight audits. The Compliance Department may modify its audit work plan based on issues that arise within the organization, focusing on high risk areas to confirm effective corrective actions were taken based on detected areas of non-compliance or compliance risks. Medicare Compliance audits are based on regulatory guidance and, depending on the department being audited, may rely on CMS and DMAS guidance outlined in the:

1. The Medicare Managed Care Manual;
2. The Medicare Prescription Drug Benefit Manual;
3. The CMS Monitoring Guide;
4. Other applicable CMS guidance and publications;
5. DMAS publications and contract.

Similar to the process CMS uses in its audits, Compliance prepares a report of findings and the audited department(s) develops a corrective action plan. The audit report and corrective action plan are reported to the Compliance Director, the Compliance Committee, and the Audited Department’s Senior Management. In turn, the Compliance Director may report the audit findings and corrective action plan to the Senior Leadership.

**Third Party Validation Review Audits**

Optima Health contracts with independent third parties to audit processes and operations against CMS standards and requirements. The results of the third party audits are reported to Senior Management, the Director of Compliance, the Compliance Committee, CEO and the Board of Directors.

**Monitoring and Auditing of First Tier, Downstream, and Related Entities (FDRs)**

Optima Health contracts with various parties to administer and/or deliver Medicare Advantage Part D benefits. These first tier parties and their downstream contractors must abide by specific Optima Health contractual and regulatory requirements. Various Optima Health departments are responsible for overseeing the ongoing compliance of the FDRs including, but not limited to:
1. Credentialing;
2. Pharmacy;
3. Provider Network;
4. Accounting;
5. Medicare Operations;
6. Medicare Sales;
7. SIU.

Optima Health will perform internal auditing and monitoring and external audits, as appropriate, to evaluate the FDRs compliance with CMS requirements as well as overall effectiveness of the compliance program.

FDR audit selection criteria consists of a risk assessment to identify the highest risk FDRs so that a reasonable number will be selected to audit from the group(s) that pose the highest risk.

**Medicare FDR Oversight Committee**

This Committee has the responsibility to monitor all CMS publications, revisions, new laws and regulations that may affect the delivery Part D services regarding our FDRs and communicate these changes to the appropriate FDR operational areas affected.

**Special Investigations Unit Monitoring, Audits and Investigations (Fraud, Waste and Abuse Issues)**

The Optima Health Special Investigations Unit (“SIU”) is responsible for investigating issues of possible Medicare fraud, waste and/or abuse. The SIU also develops and implements training and awareness programs to promote commitment to ethical compliance for all Employees, contracted Providers, and FDRs. The SIU is the focal point for FWA investigations and works with the Medicare Drug Integrity Contractor (“MEDIC”), law enforcement and other agencies, as required.

The SIU employs analytical data mining to identify referral patterns, possible payment errors, utilization trends and other indicators of potential fraud, waste, and abuse.

Results of SIU investigations are reported to the FWA Committee, the Director of Compliance, the Compliance Committee and the Compliance Officer. The SIU Director and the Director of Compliance work together to report all applicable Medicare fraud, waste and abuse issues to the Compliance Committee and Senior Leadership Committee.

**Auditing by Federal Agencies or External Parties**

Optima Health views regulatory audits and reviews as an opportunity to confirm that our ongoing compliance efforts, supported by the Board, are effective and successful. In cases where an audit outcome indicates we have not met a regulatory requirement, Optima Health will use the audit findings to perform root cause analysis and develop corrective action plans to address identified areas of non-compliance. Optima Health may also contract with external companies to perform compliance related reviews and assist with programmatic changes to help drive compliance.

Optima Health cooperates with federal agencies and external parties when audits are completed and provides auditors access to information and records related to business processes and those
First Tier, Downstream and Related Entities. Optima Health allows access to all documentation and records for audits and maintains all records for ten (10) years.

The Compliance Department serves as the point of contact for all audits related to the Medicare Advantage Part D program and coordinates auditor requests with all internal departments. Staff from other Optima Health departments is charged with coordinating state audits or reviews, and the Compliance team may assist in those audits to the extent they apply to specific issues related to the Medicare products.

**Sales Producer & Broker Monitoring and Auditing**

Sales Producers and Brokers are audited through review of member complaints, secret shopping, review of company websites for unapproved advertising, ride-alongs, review of exclusion databases, disenrollment rates, and review of BOI complaints or licensure issues. Complaints against a Sales Producer may be received through a variety of sources including beneficiary complaints filed with CMS, the CMS regional office, Member Call Center, Customer Service Department, Medicare Compliance, the hotline or through the Appeals and Grievance Department. An “at fault” finding requires Optima Health to implement prompt corrective action with the Sales Broker, such as re-training, re-testing or ride-along, or it may involve specific sanctions such as suspension of sales production, or termination of employment or the Broker Agreement.

**CORRECTIVE ACTION PROCEDURES**

Optima Health takes corrective actions whenever there is a confirmed incident of non-compliance. Optima Health may identify the incident of non-compliance through a variety of sources, such as self-reporting channels, CMS audits, internal audits, hotline calls, external audits, regional collaborative work groups or member complaints, either directly to the Plan or through CMS. Whenever Optima Health identifies an incident of non-compliance or fraud, waste and abuse, it is followed through the risk assessment process.

The Director of Compliance (in conjunction with SIU and other key staff) is responsible for reviewing cases of non-compliance related to the Medicare programs and, when applicable, for disclosing such incidents to CMS. Because of the complex nature of some of the cases that may be involved, particularly fraud investigations, the Director of Compliance may delegate all or a portion of this responsibility to the appropriate internal expert, for example to the SIU, for the detailed reporting to the MEDIC or law enforcement.

Any time an incident of non-compliance is discovered or a department’s process or system results in non-compliance with CMS requirements, the business area is required to submit a Corrective Action Plan (CAP) to the Compliance Department. A CAP represents a commitment from the business unit to correct the identified issue in a timely manner. Corrective actions may include revising processes, updating policies or procedures, retraining staff, reviewing systems edits and other root causes. The CAP must achieve sustained compliance with the overall CMS requirements for that specific operational department.

The status of open Corrective Action Plans is reported to the Director of Compliance and the Compliance Committee on a monthly basis or a frequency determined by the Compliance Director. The Compliance Department monitors CAP implementation and requires that the business department regularly report the completion of all interim action steps. Once a CAP is
complete, the Compliance Department validates the CAP by monitoring individual action items over a period of time to demonstrate sustained compliance was achieved, and the CAP was effective.

The Compliance Committee is charged with reviewing ongoing activity to ensure that CAPs being undertaken are timely and effective and to report ongoing non-compliance risks to Senior Management.

Optima Health delegation and vendor oversight of FDRs includes a requirement that they submit a Corrective Action Plan when deficiencies are identified through oversight compliance audits, ongoing monitoring or self-reporting. Optima Health takes appropriate action against any contracted organization that does not comply with a CAP or does not meet its regulatory obligations, up to and including termination of their agreement. The FDRs are delegated to perform specific administrative or plan functions. They are bound contractually through written agreements with Optima Health that stipulate compliance with CMS requirements and provisions for removal of delegation or termination for failure to cure performance deficiencies.

The Optima Health Medicare Compliance Program Plan is effective in promoting compliance, and controlling fraud, waste and abuse at both the sponsor and FDR levels in the delivery of Part D benefits to Medicare beneficiaries. For operational assistance, please refer to the Medicare Compliance Policies and procedures, located on the Optima Health intranet Compliance 360, website.
Overview
Optima Health does not tolerate fraud, waste or abuse (FWA) of Medicare program (Part D) resources and has implemented this FWA Plan to help prevent, detect and correct areas where FWA activity may occur. All Optima Health Employees, Directors, and First Tier, Downstream and Related Entities (FDRs) are prohibited from committing or participating in fraudulent, wasteful or abusive activities.

The Optima Health FWA Plan outlines various methods Optima Health employs to detect and prevent fraud, waste or abuse. The Optima Health FWA Plan includes prevention through awareness, screening, training, and disciplinary standards that are built upon the foundation of the Optima Health Code of Compliance.

The FWA Plan includes written policies and procedures on detecting and preventing FWA, as well as policies related to FWA investigations and reporting.

Optima Health maintains a Fraud Hotline and email box for anonymous reporting of suspected FWA, as well as a Special Investigations Unit (SIU) that follows up on all reported potential offenses. The SIU works with designated state and Federal regulatory agencies, the Medicare Integrity Contractor (“MEDIC”) and law enforcement in pursuit of individuals who may be involved in activities that fall under FWA oversight.

Fraudulent activity raises the cost of care for all individuals. Fraudulent activity may involve an Employee, member, subscriber, or health care provider who is involved in inappropriate schemes, behaviors, false documentation, inappropriate prescriptions, or falsification of conditions in order to help an individual receive an otherwise uncovered service under Medicare or other Federal programs. All Optima Health Employees, Directors, and Entities play an important role in preventing Medicare fraud, waste, and abuse, and are required to immediately report any suspected instances of fraud, waste or abuse (FWA).

Elements of Fraud Prevention
The Optima Health FWA Plan is a subset of the overall Compliance Program at Optima Health, which includes Compliance, HIPAA Privacy and Security, and the Medicare Program. Elements of the prevention activities are integrated into the overall compliance program to address each of the seven (7) elements of an effective compliance program:
1. Written Policies and Procedures and Standards of Compliance;
2. Compliance Officer and Compliance Committee;
3. Training and Education;
4. Effective Lines of Communication;
5. Enforcement of Standards through well-published disciplinary guidelines;
6. Monitoring and Auditing;
7. Prompt Responses to detected offenses and corrective action procedures.

Optima Health employs the following processes to detect potential fraudulent activity:
1. Monitoring and auditing performed by the Compliance Department, SIU, business units and departments responsible for overseeing the ongoing compliance of First Tier, Downstream and Related Entities;
2. Raising Employee awareness of potential fraudulent activities through required Employee training, posters, Compliance Week activities, policies and procedures and the Medicare Folder on the intranet site (SAL);
3. Publicizing communication channels such as the 24 (twenty-four) hour Optima Health Fraud, Waste and Abuse Hotline and email box and the Sentara Compliance, Ethics and Privacy Line;
4. Regular communications to Employees, which reinforce their role in identifying fraudulent activities in their course of performing their daily work.

**Definition of Fraud, Waste and Abuse**

**Fraud:** Fraud is the intentional misrepresentation of data for financial gain. Fraud occurs when an individual knows or should know that something is false and makes a knowing deception that could result in some unauthorized benefit to themselves or another person.

**Waste:** Waste is overutilization: the extravagant, careless or needless expenditure of healthcare benefits or services that result from deficient practices or decisions.

**Abuse:** Abuse involves payment for items or services where there was no intent to deceive or misrepresent but the outcome of poor insufficient methods results in unnecessary costs to the Medicare program.

**Examples of Fraud, Waste and Abuse**

Optima Health investigates and pursues prosecution of health care related fraud and abuse. In addition to potential fraud identified internally by employees and externally by members and FDRs, fraudulent or abusive practices may be identified by review of data to look for patterns of over-, under-, or inappropriately-based utilization, including issues identified through systems edits such as:

1. Claim systems edits to look at age and gender;
2. Edits and controls to look at Medicare Secondary Payer and COB;
3. Controls on early pharmacy refills outside of long-term care settings;
4. Edits to prevent payment for statutorily excluded drugs;
5. Limits on the number of times a prescription can be refilled;
6. Brand name versus generic drugs;
7. Number of prior authorizations;
8. Real time contraindication (e.g. drug interactions);
9. Therapeutic edits;
10. Excessive claims for controlled substances;
11. Insufficient or excessive dosage edits;
12. Step therapy edits;
13. Identifying drugs provided outside of the Part D benefit by Patient Assistance Programs.

Optima Health separately reviews potential marketing or sales agent fraud, and receives referrals from operational areas, such as the Member Call Center, Appeals and Grievances, Claims, Pharmacy Services and Enrollment/Disenrollment.

Examples of Provider fraud may include:

1. Billing for services not furnished;
2. Billing for services at a higher rate than is actually justified;
3. Soliciting, offering or receiving a kickback, bribe or rebate;
4. Deliberately misrepresenting services, resulting in unnecessary cost, improper payments or overpayment;
5. Violation of the physician self-referral (“Stark”) prohibition.

Examples of Provider abuse may include:
1. Excess of charges for services or supplies;
2. Providing medically unnecessary services;
3. Providing services that do not meet professionally recognized standards;
4. Billing Medicare based on a higher fee schedule than is used for patients not on Medicare.

Examples of waste include:
1. Over-utilization of services;
2. Misuse of resources.

**FWA Training Programs**

Optima Health requires all new Employees complete a mandatory training course on fraud, waste and abuse prevention and detection within the first ninety (90) days of employment.

All Employees must attend training on an annual basis. Similar training is required of all Providers and FDRs. Optima Health makes its FWA training program available via the Optima Health website (www.optimahalth.com). FDRs may complete the Optima Health training, develop and provide their own training or the CMS Fraud, Waste and Abuse Training. If the FDR develops and provides their own FWA training, they must submit the training to Optima Health for approval prior to administering to their employees. All FDRs must maintain adequate records of their employee training, including attendance logs, training materials and results of any testing.

**Medicare Fraud, Waste and Abuse Risk Assessment**

The Compliance Department performs an annual risk assessment, which includes, but is not limited to, an assessment of the various ways FWA and non-compliance can occur (or has occurred) by and against Optima Health. FWA risk assessment also considers the ability to override, deter or remediate potential schemes that may have circumvented existing control activities by Optima Health. The results of the risk assessment are reported to the Compliance Committee, Senior Leadership and the Board of Directors, along with appropriate recommendations for additional education, FDR oversight, system edits, new or revised policies, procedures, or processes, and/or enhanced audit protocols.

**Identification and Reporting**

Optima Health requires all Employees and FDRs to report suspected FWA immediately. Reports may be made through the Fraud, Waste and Abuse Hotline or email box (www.compliancealert@sentara.com), the Sentara Compliance, Ethics and Privacy Line, to the SIU Director, Director of Compliance, or to an Employee’s Supervisor or Manager. Optima Health also identifies potential FWA through member and provider calls, complaints filed with CMS, appeals and grievances, claims processing, enrollment activities or through various system edits and reviews.
Optima Health performs prospective and monthly screenings of Employees, Directors, Senior Management, FDRs, Agents, Providers and Entities against the General Administration Services (GSA) and the Office of the Inspector General (OIG) exclusion lists.

Optima Health departments with responsibility for overseeing delegated entities and vendors perform regular oversight audits and reviews, which include areas such as claims, where patterns and trends are reviewed for potential FWA implications. All suspected incidents of FWA are referred to the Optima Health Special Investigations Unit.

**Special Investigations Unit (“SIU”)**

Optima Health is committed to reducing health insurance costs through the detection, investigation, prevention and civil/criminal prosecution of fraud, waste and abuse. This commitment has been continuously reinforced at Optima Health through the development of policies and procedures and the allocation of resources for anti-fraud efforts.

The Special Investigations Unit (“SIU”) works with various Optima Health business units to investigate suspected incidents of fraud and work with law enforcement and the MEDIC to pursue prosecution.

The SIU maintains case related information in a dedicated database, which allows the SIU to track, profile and accurately obtain qualitative and complete data concerning FWA investigations.

The SIU may independently receive reports of FWA through other areas, such as:

1. The Member/Provider Services Department;
2. The Appeals and Grievances Department;
3. The Pharmacy Department;
4. The Claims Department;
5. The Enrollment Department;
6. The Compliance Department;
7. The Fraud, Waste and Abuse Hotline and email box;
8. The Sentara Compliance, Ethics and Privacy Hotline;
9. Law Enforcement;
10. The MEDIC.

The SIU is staffed by Optima Health Employees with coding and claims processing expertise which allows them to perform a variety of investigations and review different data queries. SIU Reviews may include claims data, pharmacy data, and member or provider data indicating fraudulent activity.

If the SIU determines that potential FWA or non-compliance related to the Medicare program has occurred within or at the FDR level, the SIU will refer the case to the MEDIC as soon as possible, but no later than sixty (60) days after the determination that a violation may have occurred. The overall Optima Health FWA program is enhanced by partnering with the MEDIC. The MEDIC can help identify and address patterns across multiple sponsors and coordinate with the OIG, law enforcement and/or Department of Justice related to any scams or schemes.