

# Medicare/Medicaid Compliance Policies and Procedures

## TABLE OF CONTENTS

I. INTRODUCTION.....	4
II. WRITTEN POLICIES AND PROCEDURES.....	4
A. Code of Conduct .....	4
B. Policies and Procedures.....	5
III. TRAINING AND EDUCATION.....	5
A. General Compliance Training.....	5
B. Specialized Compliance Training.....	5
IV. EFFECTIVE LINES OF COMMUNICATION .....	5
A. Compliance Hotline and Other Forms of Communication .....	5
B. Anonymity.....	6
C. Non-Retaliation.....	6
D. Documentation of Reports.....	6
V. ENFORCEMENT OF STANDARDS.....	6
VI. PROMPT RESPONSES TO DETECTED OFFENSES AND CORRECTIVE ACTION .....	7
A. Internal Investigations.....	7
B. Government Investigations.....	7
C. Corrective Actions .....	7
VIII. MONITORING AND AUDITING.....	8
APPENDICES	
1. Code of Conduct	
2. Protocol for Responding to Government Investigations	
3. Policy on Monitoring and Auditing	
4. Protocol for Internal Investigations	
5. Compliance Policies and Procedures	
5A. Billing and Pricing	
5B. Privacy and Security of Protected Health Information	
5C. Dispensing	
5D. Employing or Contracting with Sanctioned or Excluded Individuals or Entities	
5E. Inducements and Kickbacks	
5F. Records Management	

## Compliance Manual

### I. INTRODUCTION

Because compliance with applicable laws and regulations is a top priority for we endorse the implementation of a Compliance Program which sets forth the standards that will ensure compliance with applicable legal requirements and foster organization-wide integrity. This Compliance Program Manual provides a description of these standards and a plan for implementing the Compliance Program. The success of compliance efforts depends on each associate's dedication to working with us to implement the Compliance Program. The Compliance Program describes expectations for associates and others associated with **\_\_TYPE NAME OF CLINIC\_\_** and provides guidance on dealing with compliance issues that may arise in the daily course of business. In particular, all associates are responsible for acting consistently with the Compliance Policies and Procedures, including the Code of Conduct. The compliance Officer responsibilities are assumed under the Compliance Officer who is **\_\_TYPE NAME OF COMPLIANCE OFFICER\_\_**.

## **II. WRITTEN POLICIES AND PROCEDURES**

**\_\_TYPE NAME OF CLINIC\_\_** has established written policies, procedures, and standards that demonstrate our commitment to complying with all applicable federal and state statutory, regulatory and other requirements. These policies and procedures are a critical component of our efforts to detect, prevent and control fraud, waste and abuse.

**\_\_TYPE NAME OF CLINIC\_\_** will update all Compliance Policies and Procedures as necessary to remain current with legal and other current developments. All new associates will receive a copy of the Manual at the time of hire. The manual will be available for all associates to review. Upon implementation of required training, all associates will acknowledge receipt and understanding of all Compliance Policies and Procedures.

### **A. Code of Conduct**

All associates must act in an ethical manner and adhere to applicable legal requirements in the course of performing their duties on behalf of **\_\_TYPE NAME OF CLINIC\_\_**. The Code of Conduct, which is attached at Appendix 1, articulates the commitment to comply with all statutory, regulatory, and other requirements. It also describes the ramifications of any failure to comply with the Code of Conduct. **\_\_TYPE NAME OF CLINIC\_\_** will also share its Code of Conduct with its vendors and other contractors and encourage them to follow a code of conduct that reflects a similar commitment to detecting, preventing, and correcting fraud, waste and abuse.

### **B. Policies and Procedures**

In addition to the Code of Conduct, **\_\_TYPE NAME OF CLINIC\_\_** has developed more detailed Compliance Policies and Procedures to guide conduct and to assist associates in addressing specific areas of possible fraud, waste and abuse. These Compliance Policies and Procedures may be found at Appendix 5 to this Manual.

## **III. TRAINING AND EDUCATION**

**\_\_TYPE NAME OF CLINIC\_\_** has implemented a training program to help associates identify, prevent, and report noncompliance. The training program is currently recommended and will be fully compliant when it is deemed required by Medicare and Medicaid programs. Failure to comply with the training content may result in disciplinary action, including possible termination. The Compliance Officer with assistance from the Training Manager will verify that all associates attend compliance training and maintain training records.

### **A. General Compliance Training**

All associates must participate in general compliance training upon initial hire or engagement and at least annually thereafter and must acknowledge attendance at each

session. Documentation of completion will be maintained by the Compliance Officer.

#### **B. Specialized Compliance Training**

Specialized compliance training is provided to employees whose actions affect submission and reimbursement of claims, including those involved in dispensing, billing and reimbursement, and pharmacy marketing. Such training is furnished upon initial hire or engagement, when substantive legal requirements change, or in response to a finding of noncompliance.

### **IV. EFFECTIVE LINES OF COMMUNICATION**

Associates are expected to report suspected violations of Compliance Policies and Procedures, including the Code of Conduct and applicable laws and regulations. An associate should make such reports to his or her supervisor, manager, or to the Compliance Officer. Such reports should contain enough information to allow investigation into the concerns raised.

#### **A. Compliance Hotline and Other Forms of Communication**

Associates are expected to report suspected violations of company policy, including the Code of Ethics, applicable laws and regulations. Associates may report the suspected violations to their supervisor or manager or to the Compliance Officer. Such reports should contain enough information to allow investigations into related questions or concerns in person or by telephone, email or other written communications. **\_TYPE NAME OF CLINIC\_** provides this toll free number **TYPE HOTLINE PHONE NUMBER\_**.

Associates may leave an anonymous voice mail if desired. Callers are encouraged to leave as much detail as possible in the message, as well as the name and/or contact number in order to enable a thorough investigation.

#### **B. Anonymity**

The identity of those reporting potential fraud, waste or abuse is generally protected if the individual wishes to remain anonymous. However, the investigation process may result in identity disclosure, particularly if federal or state enforcement authorities become involved in the investigation. **\_TYPE NAME OF CLINIC\_** cannot guarantee confidentiality when an individual discloses material evidence of a violation of the law to the Compliance Officer or if that person is identified during the normal course of an investigation. Security measures are in place to preserve the confidentiality of hotline records.

#### **C. Non-Retaliation**

**\_TYPE NAME OF CLINIC\_** will not engage in nor tolerate retaliation against individuals who report suspected wrongdoing. No reprisal, reprimand, or disciplinary action will be permitted or will be taken against anyone who discloses a compliance-related concern in good faith through the proper reporting procedures. This policy does not insulate the reporter from disciplinary action if it turns out that he or she is involved in any wrongdoing.

#### **D. Documentation of Reports**

The Compliance Officer documents and tracks all reported concerns and issues as well as the status of related investigations and corrective actions. Compliance-related questions and compliance personnel answers also are documented, dated and shared with others as appropriate.

### **V. ENFORCEMENT OF STANDARDS**

Associates are expected to comply with the Code of Conduct and to adhere to applicable legal requirements during the course of performing their duties on behalf of \_\_\_\_\_

Failure to do so may result in disciplinary action up to, and including, termination. Certain offenses may justify the immediate termination with an associate. Such wrongdoing includes, but is not limited to:

- violation of federal or state fraud and abuse laws
  - failure to report conduct that the individual knows is illegal or that a reasonable person would have known is illegal
  - intentional provision of materially false information to a customer, or a payer
  - knowing provision of false or misleading information to the Compliance Officer
- Conduct that would otherwise justify termination may result in less severe disciplinary action if the violator self-reported or if the individual cooperated fully during the investigation. However, anyone who self-reports is not immune from disciplinary action or termination.

Management will be held responsible for the actions of their associates if they facilitate or fail to appropriately forward report made to them as a result of their own negligence, carelessness or inattention.

## **VI. PROMPT RESPONSES TO DETECTED OFFENSES AND CORRECTIVE ACTION**

Through the Compliance Program, **\_TYPE NAME OF CLINIC\_** ensures prompt responses to and appropriate corrective actions for detected offenses. Responses to detected offenses vary

according to the circumstances and may include immediate referral to criminal or civil law enforcement, a corrective action plan, and/or return of overpayments.

### **A. Internal Investigations**

The Compliance Officer will conduct a timely and reasonable investigation of all credible reports of suspected noncompliance. A reasonable inquiry includes a preliminary investigation by the Compliance Officer or other compliance personnel. Associates should follow standard audit investigation processes. The protocol for internal investigations may be found at Appendix 4. If an internal investigation results in the discovery of misconduct that may violate applicable laws or regulations, the Compliance Officer will consult with human resources, loss prevention and legal counsel before deciding how to proceed.

### **B. Government Investigations**

This policy is to be forthright and cooperative when dealing with government investigations, inquiries or information requests. If a government agent or employee contacts an associate, he or she should refer to the protocol for responding to government investigations.

### **C. Corrective Actions**

Corrective action aims to remedy the underlying problem that resulted in misconduct. It may include disciplinary action, prompt identification and refund of overpayments, or other actions. Each corrective action plan will be tailored to the particular misconduct identified and will include timeframes to prevent continued misconduct. The Compliance Officer will document all elements of the plan and the ramifications for non-compliance and will engage in ongoing monitoring to ensure that the plan is carried out.

## **VII. MONITORING AND AUDITING**

Internal monitoring and auditing are both important aspects of the Compliance Program. Such activities can detect and prevent compliance problems through verification of compliance with contractual agreements, applicable state and federal requirements, and

the Compliance Policies and Procedures. Compliance monitoring and auditing can be found in Appendix 3. Further, **\_TYPE NAME OF CLINIC\_** may be the subject of audits by the Centers for Medicare and Medicaid Services, other government agencies, or entities with which it contracts, such as sponsors of Medicare Part D prescription drug plans. Protocols for responding to audits conducted by outside entities is set forth in Appendix 2. The purpose of monitoring activities is to ensure corrective actions are carried out and to confirm ongoing compliance even when no specific problems are identified. The system of ongoing monitoring assesses performance in identified risk areas.

## **APPENDIX 1**

### **CODE OF CONDUCT**

#### **I. INTRODUCTION**

All associates must act in an ethical manner and adhere to applicable legal requirements in the course of performing their duties on behalf of **\_TYPE NAME OF CLINIC\_**. This Code of Conduct, which is part of our Compliance Program, is intended to be a clear and concise summary of fundamental ethical standards with which all associates must comply when conducting business on our behalf. The Compliance Policies and Procedures provide more detailed rules designed to ensure that those associated with us act legally and ethically at all times. **\_TYPE NAME OF CLINIC\_** expects all associates to read and adhere to the standards described in the Code of Conduct as a condition of employment. Any associate who violates the Code of Conduct will be subject to disciplinary action, up to and including termination.

#### **II. STANDARDS OF CONDUCT**

##### **A. Comply with Laws and Regulations**

All associates must comply with the Compliance Program, including the Compliance Policies and Procedures, and with applicable laws and regulations. If associates have questions about the laws and regulations that apply to or about the policies and procedures for complying with them, they are expected to seek guidance from supervisors or the Compliance Officer.

##### **B. Act Ethically and Avoid Conflicts of Interest**

**\_TYPE NAME OF CLINIC\_** expects all associates to conduct business on its behalf in an honest, fair, and ethical manner and in our best interests, without regard to personal considerations. Associates must refrain from participating in any activities or business endeavors that could pose a conflict with their responsibilities .

**\_TYPE NAME OF CLINIC\_** does not employ nor contract with individuals or entities that are prohibited from doing business with the federal government. As a result, every new associate must reveal any convictions related to health care or any debarment, exclusion, sanction, or other adverse action taken against him or her by any federal or state agency. **\_TYPE NAME OF CLINIC\_** will revalidate this information periodically and require all associates to give notice if any such action is initiated.

##### **C. Protect the Privacy of Customer Information and the Confidentiality of Records**

All associates must respect the confidential nature of protected health and any proprietary information received in the course of their work on behalf of **\_TYPE NAME OF CLINIC\_**. In particular, associates must comply with state and federal laws and regulations, including the Health Insurance Portability and Accountability Act (known as "HIPAA"), governing the privacy and security of protected health information.

#### **D. Prepare and Submit Accurate and Complete Claims for Payment**

Preparing and submitting accurate and complete reimbursement claims is among top priorities. **\_TYPE NAME OF CLINIC\_** expects associates to adhere to the laws, regulations, and internal policies and procedures governing the billing and claims submission process. Associates must not present, nor cause to be presented, any false or fraudulent claims for payment.

#### **E. Properly Dispense Prescriptions**

**\_TYPE NAME OF CLINIC\_** promotes full compliance with applicable dispensing requirements. All associates involved in the dispensing process must carry out their duties in accordance with legal and ethical standards and maintain a comprehensive working knowledge of all laws, regulations, and internal policies and procedures applicable to dispensing.

#### **F. Participate in Compliance and Other Training Sessions**

All associates must participate in compliance training and other professional skills development activities necessary to carry out their respective duties effectively and, if applicable, to maintain required professional licensure.

#### **G. Report Compliance Violations**

Associates must report suspected violations of Compliance Policies and Procedures or applicable laws and regulations. **\_TYPE NAME OF CLINIC\_** encourages associates to come forward even if they are unsure of whether any misconduct has occurred. **\_TYPE NAME OF CLINIC\_** will not engage in nor tolerate retaliation against an associate who reports suspected wrongdoing and will allow anonymity to the extent appropriate.

#### **H. Cooperate with Internal and External Investigations**

The Compliance Officer will conduct a timely and reasonable investigation of all credible reports of suspected noncompliance, and expects everyone affiliated with it to cooperate fully with these investigations. Outside entities, such as government agencies and private third party payers, also may conduct investigations related to suspected noncompliance, and **\_TYPE NAME OF CLINIC\_** encourages everyone to be forthright and cooperative.

### **III. CONSEQUENCES OF NONCOMPLIANCE**

Failure to meet expectations for compliance with any law, regulation or internal policy may result in the imposition of discipline, up to and including termination.

#### **APPENDIX 2**

#### **PROTOCOL FOR RESPONDING TO GOVERNMENT INVESTIGATIONS**

##### **PURPOSE:**

Our policy is to cooperate fully with all appropriate government inquiries. It is our intent to respond to inquiries in a complete, timely and properly coordinated manner so that the rights of those involved are protected. Examples of state or federal agencies that may make inquiries include, but are not limited to, the following:

- Drug Enforcement Agency
- Federal Bureau of Investigation
- Centers for Medicare and Medicaid Services
- Medicaid Fraud Control Units
- Medicaid Programs
- Department of Health and Human Services Office of Inspector General
- State Attorney General's Office

##### **PROCEDURE:**

The government may contact an associate directly to request an interview about information relating to **\_TYPE NAME OF CLINIC\_** or its business affiliates. The associate must notify the Compliance Officer or other personnel as instructed. When contacted by a government investigator, the associate should ask to see proper identification. An associate can refuse or stop an interview until legal counsel is present. Associates are entitled to have someone, like an attorney, with them during the interview and are encouraged to take notes.

### **APPENDIX 3**

#### **POLICY ON MONITORING AND AUDITING**

##### **PURPOSE:**

An internal monitoring and auditing system protects from fraud, waste, and abuse. In addition, ongoing evaluation of compliance with applicable statutes and regulations will promote the provision of high quality services.

**\_TYPE NAME OF CLINIC\_** endeavors to monitor, audit, and evaluate its compliance with internal and external rules.

##### **PROCEDURE:**

**\_TYPE NAME OF CLINIC\_** will employ a dedicated third party auditor if necessary when routine auditing finds any discrepancies in the compliance of its associates with state and federal regulations. The company also conducts routine checks for compliance by the Supervisors in charge and managers. Daily sales analysis reports are generated to focus on questionable third party claims and an investigation of these claims is performed if necessary

### **APPENDIX 4**

#### **PROTOCOL FOR INTERNAL INVESTIGATIONS**

##### **PURPOSE:**

The Compliance Officer will assess the validity of all credible reports of suspected wrongdoing and will determine whether a comprehensive investigation is warranted.

##### **PROCEDURE:**

The Compliance Officer will conduct a timely and reasonable investigation of suspected noncompliance. The Compliance Officer may determine that a compliance-related matter is an emergency requiring immediate action or that a certain matter is extremely sensitive or confidential. If an internal investigation results in the discovery of misconduct that may violate applicable laws or regulations, the Compliance Office will consult with legal counsel and human resources before deciding how to proceed. When the Compliance Officer determines that an allegation does not merit further investigation, he will document this decision with an analysis of the facts that resulted in the conclusion.

### **APPENDIX 5A**

#### **BILLING AND PRICING**

##### **PURPOSE:**

This policy sets forth the billing and reimbursement policies and procedures with which all associates must comply.

##### **POLICY:**

Accurate pricing, billing, and claims submission is a top priority. We are committed to ensuring that all medical, prescription, and related services are furnished in accordance

with applicable federal and state laws, regulations, and directives and with the requirements of all public and private third party payers.

## **PROCEDURE:**

### **I. ACCURATE AND COMPLETE CLAIMS DOCUMENTATION**

Associates must ensure that billing documentation is accurate and complete and that it conforms to the applicable payer's requirements. All requests for reimbursement must contain only true and accurate data.

### **II. DOCUMENT RETENTION**

Associates are expected to maintain documentation demonstrating that all services rendered were prescribed, dispensed and received. Payers often take the position that a service was not performed unless there is documentation supporting that fact. Consequently, documentation must be obtained and retained for all services furnished and in accordance with records management policy and with all applicable legal and contractual requirements.

### **III. SUSPECTED OR IDENTIFIED BILLING DISCREPANCIES**

Examples of potential billing or reimbursement fraud, waste, and abuse include, but are not limited to, the following:

- filling a prescription with a cheaper generic drug, but billing the payer for the more costly brand name drug
- billing for non-existent services or prescriptions
- billing multiple payers for the same service or prescription
- billing a payer more than once for the same service or prescription
- failing to return credit balances to payers and/or customers
- intentionally providing less than the prescribed quantity without telling the customer, or arranging to provide the balance of the prescription, and then billing for the full prescription
- billing for prescriptions that are never picked up and therefore returned to stock
- splitting prescriptions in order to receive additional dispensing fees
- illegally diverting pharmaceuticals

Any associate who identifies such discrepancies with respect to claims already submitted must report them immediately in accordance with the requirements of the Compliance Program. Prompt reporting is crucial because these and other billing and reimbursement discrepancies can lead to violations of the federal False Claims Act and other state and federal health care fraud and abuse laws. Associates can learn more about these laws by reading the policy on Inducements and Kickbacks (Appendix 5E).

### **IV. PRICING**

**\_TYPE NAME OF CLINIC\_** prices its products fairly, competitively, and in accordance with applicable contract provisions and legal requirements, including laws requiring to provide usual and customary prices to state Medicaid programs.

**\_TYPE NAME OF CLINIC\_** offers discounts only for proper business reasons and in accordance with applicable laws and regulations and its third party contracts.

**\_TYPE NAME OF CLINIC\_** accepts discounts from suppliers and vendors on items to be furnished to federal health care program beneficiaries only if the arrangement complies with a safe harbor under the federal Antikickback Statute.

**\_TYPE NAME OF CLINIC\_** strives to ensure that all communication to outside individuals and entities is truthful, accurate and complete. The prices advertised or otherwise

communicated to customers and others are the prices ultimately charged at the point of sale.

With respect to Medicare Part D, **\_TYPE NAME OF CLINIC\_** negotiates the prices it will charge with each Medicare Part D plan sponsor. As required by federal law, and offers Part D beneficiaries the price negotiated with his or her plan sponsor.

-  
**APPENDIX 5B  
PRIVACY AND SECURITY OF  
PROTECTED HEALTH INFORMATION**

**PURPOSE:**

This policy sets forth expectations for the privacy and security of protected health information.

**POLICY:**

**\_TYPE NAME OF CLINIC\_** expects associates to protect the privacy and security of protected health information and its proprietary information in accordance with applicable state and federal laws and regulations and all policies and procedures.

**PROCEDURE:**

**\_TYPE NAME OF CLINIC\_** requires every associate to respect the confidential nature of health and personal information and to use or disclose such information as allowed by law.

**APPENDIX 5C**

**DISPENSING**

**PURPOSE:**

Various federal and state statutes and regulations govern the dispensing process, and the purpose of this policy is to articulate clear requirements for those involved in the dispensing process.

**POLICY:**

**\_TYPE NAME OF CLINIC\_** promotes full compliance with applicable dispensing requirements by mandating that all individuals involved in the dispensing process maintain high ethical standards and a strong knowledge of all laws and regulations applicable to dispensing.

**PROCEDURE:**

**\_TYPE NAME OF CLINIC\_** associates are bound by the rules and regulations of the state in which they practice. Furthermore, associates are required to adhere to all state and federal regulations specific to their practice. To prevent fraud, waste, and abuse, **\_TYPE NAME OF CLINIC\_** prohibits all associates from engaging in any of the following activities:

- dispensing any service or prescriptions without proper authorization
- knowingly creating or dispensing a false service or prescription
- concealing or attempting to conceal a dispensing error
- altering a prescription to increase or decrease the quantity prescribed or the number of refills without the prescriber's permission
- dispensing a prescription drug that was not stored or handled in accordance with manufacturer or FDA requirements
- dispensing a prescription that is beyond its expiration date or is not refillable according to applicable legal requirements
- charging a patient or billing a third party payer for the full amount of a prescription, but providing less than the prescribed quantity without

informing the patient or making arrangements to provide the full balance

- giving inappropriate pricing discounts
- knowingly billing a third party plan for a false or nonexistent prescription or exceeding authorized parameters of a prescription plan

#### **APPENDIX 5D**

#### **EMPLOYING OR CONTRACTING WITH SANCTIONED OR EXCLUDED INDIVIDUALS OR ENTITIES**

##### **PURPOSE:**

This policy establishes the process for ensuring that it does not employ nor contract with individuals or entities that are banned from doing business with the government. By not employing or contracting with such parties, **\_TYPE NAME OF CLINIC\_** protects itself, and those with whom it does business, from fraud, waste and abuse, and also ensures that **\_TYPE NAME OF CLINIC\_** is eligible for reimbursement from government programs.

##### **POLICY:**

**\_TYPE NAME OF CLINIC\_** policy is to hire, contract with, and retain trustworthy individuals and entities and makes a reasonable and prudent effort to avoid submitting to government entities claims for products or services furnished by any person or entity excluded from doing business with the government.

##### **PROCEDURE:**

**\_TYPE NAME OF CLINIC\_** reasonably inquires into the background of new associates, vendors and contractors. In addition, periodically confirms that these individuals and entities have not been convicted of a criminal offense related to healthcare or have not been excluded or sanctioned by a federal or state agency. Prospective associates, vendors and other contractors must, among other things, reveal any convictions of criminal offenses related to health care or any debarment, exclusion, sanction, or other adverse action taken against the individual or entity by government health care programs or any other federal or state agency. Before employment, Human Resources Department will determine whether the individual at issue appears on the relevant lists of excluded individuals and entities compiled by the Office of Inspector General (“OIG”) and other government agencies.

**\_TYPE NAME OF CLINIC\_** will refuse to be associated with any individual or entity that appears on these exclusion lists. Although **\_TYPE NAME OF CLINIC\_** reviews the relevant lists of excluded individuals and entities prior to its association with an individual, **\_TYPE NAME OF CLINIC\_** also checks those lists at least annually for the names of current associates.

#### **APPENDIX 5E**

#### **INDUCEMENTS AND KICKBACKS**

##### **PURPOSE:**

This policy outlines the rules regarding offering, providing, soliciting or receiving something of value in connection with the referral of federal health care program business to or by **\_TYPE NAME OF CLINIC\_**.

##### **POLICY:**

**\_TYPE NAME OF CLINIC\_** is committed to compliance with federal laws prohibiting health care fraud and abuse. Generally, the laws described below govern our relationships with federal health care program customers and referral sources, and these laws are implicated most often in the context of inducements and kickbacks.

## **APPLICABLE FEDERAL LAWS:**

### **I. ANTI-KICKBACK STATUTE**

The federal Anti-Kickback Statute prohibits the provision or receipt of any remuneration to induce a referral for, or for ordering, services covered by a federal health care program. "Remuneration" includes anything of value. Soliciting or accepting remuneration is as illegal as offering or paying such remuneration.

Violation of the Anti-Kickback Statute can result in substantial criminal and civil penalties. Such penalties may include imprisonment for up to five years, fines of up to \$25,000, not including fines applicable to corporations as a result of application of the federal corporate sentencing guidelines, and exclusion from the federal health care programs. The Civil Monetary Penalties Law, discussed below, establishes additional penalties for Anti-Kickback Statute violations, including payment of up to three times the amount of remuneration involved and \$50,000 for each item or service at issue. The False Claims Act also has been used to sanction Anti-Kickback Statute violations, and it can result in the imposition of treble damages, plus \$5,500 to \$11,000 penalties for each false claim. The Civil Monetary Penalties Law and the False Claims Act are both discussed in more detail below.

### **II. CIVIL MONETARY PENALTIES LAW**

The Civil Monetary Penalties Law ("CMP Law") allows the Office of Inspector General for the Department of Health and Human Services ("OIG") to impose civil monetary penalties against any person or entity that presents or causes to be presented a claim to a federal or state agency that the person or entity knows, or should know, was not provided as claimed or was false and fraudulent. It also prohibits the following conduct:

- offering remuneration to a state or federal health care program beneficiary that the person knows, or should know, is likely to influence the beneficiary to obtain items or services billed to a state or federal health care program
- knowingly employing or contracting with an individual or entity that the provider knows, or should know, is excluded from participation in a federal health care program
- billing for services requested by an unlicensed physician or an excluded provider
- billing for medically unnecessary services

The penalties for violating the CMP Law include fines of up to \$10,000 per item or service; payment of up to three times the amount billed, depending on the nature of the offense; and exclusion. As mentioned above, it also provides for additional penalties for Anti-Kickback Statute violations.

### **III. SAFE HARBORS**

The OIG has promulgated safe harbor regulations specifying types of conduct that will not subject individuals or entities to sanctions under the Anti-Kickback Statute, certain provisions of the CMP Law, and the exclusion authorities. To obtain safe harbor protection, each aspect of the arrangement or conduct at issue must satisfy all the requirements of the applicable safe harbor. Failure to fall within the strict parameters of a safe harbor does not necessarily mean that the specified conduct or business arrangement is illegal. However, if all applicable safe harbor requirements are not met, the OIG will

analyze the situation based on its particular facts and circumstances. **\_TYPE NAME OF CLINIC\_** considers and seeks to comply with the safe harbor regulations whenever they are applicable to its activities or business arrangements.

#### **IV. FALSE CLAIMS ACT**

The False Claims Act (“FCA”) forbids knowing and willful false statements or representations made in connection with a claim submitted for reimbursement to a federal health care program, including Medicare or Medicaid. The FCA extends to those who have actual knowledge of the falsity of the information as well as those who act in deliberate ignorance or in reckless disregard.

Examples of a false claim include submitting a claim for a service that was not rendered or billing multiple payers for the same service. Penalties include fines from \$5,500 to \$11,000 per false claim, payment of treble damages, and exclusion.

The FCA includes a whistleblower provision, which allows someone with actual knowledge of alleged FCA violations to file suit on the federal government’s behalf. After the whistleblower files suit, the case is kept confidential while the government conducts an investigation to determine whether it has merit. The government may decide to take over the case, but, if it declines to do so, the whistleblower still may pursue the suit. A whistleblower who prevails may qualify for 15 to 30 percent of the amount recovered on the government’s behalf as well as attorney’s fees and costs.

The FCA prohibits associates from retaliating against employees who file or participate in the prosecution of a whistleblower suit. An employee who suffers retaliation may, for example, qualify for back pay or reinstatement.

#### **PROCEDURE:**

#### **I. RELATIONSHIPS WITH ACTUAL OR POTENTIAL REFERRERS AND THEIR FAMILY MEMBERS**

##### **A. General Prohibition on Paying, Offering, Soliciting, or Receiving Remuneration**

Associates must never provide or offer a bribe to induce the referral of federal health care program business by a person or entity to **\_TYPE NAME OF CLINIC\_**. Similarly, associates must never solicit or receive a bribe from any person or entity in exchange for referring federal health care program business to that person or entity. Such activities are prohibited because they could result in violation of the Anti-kickback Statute and other health care fraud and abuse laws. Any compensation paid to a referrer or a family member of a referrer must be based on the fair market value of services provided and may not be related to the volume or value of any business referred to **\_TYPE NAME OF CLINIC\_**.

##### **B. Interaction with Medicare Part D Plan Sponsors**

Ordinarily, neither **\_TYPE NAME OF CLINIC\_** nor its associates may accept inducements in connection with the referral of potential enrollees to any Medicare Part D, Medicare Advantage (“MA”), or Medicare Advantage prescription drug (“MA-PD”) plan. All payments made by plans to **\_TYPE NAME OF CLINIC\_** for its services will be fair market value, consistent with an arm’s length transaction, and for bona fide and necessary services, and will otherwise comply with all relevant laws and regulations, including the federal Anti-kickback Statute. Specifically, an associate cannot accept remuneration meant to induce or reward the associate to:

- switch federal health care program customers to different drugs
- influence prescribers to prescribe different drugs

- steer patients to particular Medicare Part D plans

### **C. Discounts**

All discounts received from suppliers and vendors must comply with third party contracts and applicable laws and regulations. **\_TYPE NAME OF CLINIC\_** will accept discounts from suppliers and vendors on items to be furnished to federal health care program beneficiaries only if the arrangement complies with the federal discounts safe harbor under the federal Antikickback Statute.

### **D. Professional Courtesy**

The offering of professional courtesy is a practice that government officials believe may constitute an illegal inducement. The term “professional courtesy” includes a number of different practices, such as: (1) the waiver of all or part of the fee for services provided to prescribing physicians or other referral sources, their families, or their employees, and (2) the waiver of coinsurance obligations or other out-of-pocket expenses for the same groups (often referred to as “insurance only” billing). If a professional courtesy is extended in a way that directly or indirectly takes into account the recipient’s ability to affect past or future federal or state health care program referrals, the federal Antikickback Statute may be implicated. Consequently, **\_TYPE NAME OF CLINIC\_** does not offer professional courtesy waivers nor discounts to federal health care program beneficiaries nor to actual or potential sources of federal health care program referrals, their families, or their employees.

## **II. RELATIONSHIPS WITH CUSTOMERS**

### **A. Reduction or Waiver of Copayments and Other Payment**

#### **Responsibilities**

The federal Anti-Kickback Statute makes it illegal to offer, pay, solicit, or receive anything of value as an inducement to generate business payable by federal health care programs. In addition, federal law forbids offering or giving something of value to a federal health care program beneficiary if it likely will influence the beneficiary’s choice of provider. **\_TYPE NAME OF CLINIC\_** therefore does not reduce customer copayment obligations or payment responsibilities absent an individualized, good faith determination of financial need or a legal requirement.

### **B. Medicare Part D Promotional Activities**

**\_TYPE NAME OF CLINIC\_** serves customers who are enrollees of various Part D plans. As such, associates may receive requests to educate potential enrollees on their plan choices or otherwise assist them with enrollment. When providing this assistance, associates are prohibited from steering enrollees to particular plans by offering them inducements or pressuring them in other ways. **\_TYPE NAME OF CLINIC\_** requires all associates to follow certain guidelines established by the Centers for Medicare and Medicaid Services (“CMS”), the federal agency that oversees administration of the Medicare prescription drug benefit. Associates may assist a potential or actual enrollee with an objective assessment of his or her needs and plan options that may meet those needs. To this end, associates may engage in discussions with beneficiaries who seek information or advice regarding their options but should do so in strict compliance with policies and procedures. When communicating with beneficiaries about plan options, associates cannot attempt to switch or steer them to a specific plan or group of plans to further the financial or other interests of **\_TYPE NAME OF CLINIC\_**. To that end, associates cannot:

- accept enrollment applications or offer inducements to persuade beneficiaries

to join particular plans

- direct, urge, or attempt to persuade beneficiaries to enroll in a specific plan
- offer anything of value to induce plan enrollees to select **\_TYPE NAME OF CLINIC\_** as their provider

Associates may inform prospective enrollees where they can obtain information on the full range of plan options. Possible sources of information include, but are not limited to:

- the State Health Insurance Assistance Programs
- plan marketing representatives
- the State Medicaid Office
- the local Social Security Administration Office
- <http://www.medicare.gov/>
- 1-800-MEDICARE

Plans or plan agents may conduct sales presentations and distribute and accept enrollment applications as long as the activity takes place in common areas, such as the space outside

of where customers wait for services or interact with employees and obtain medications.

In sum, when interacting with current or potential Part D plan enrollees, associates can:

- provide the names of plans in which **\_TYPE NAME OF CLINIC\_** participates
- provide information and assistance to beneficiaries in applying for low income subsidies
- distribute Part D plan marketing materials in accordance with policies
- furnish objective information regarding specific plans, such as covered benefits, cost sharing, and utilization management tools
- provide objective information on specific plan formularies, based on a particular customer's medications and health care needs
- refer customers to other sources of objective information provided by third parties, such as state and federal agencies
- use marketing materials comparing plan information created by a nonbenefit service providing third-party

When interacting with current or potential Part D plan enrollees, associates cannot:

- direct, urge or attempt to persuade any prospective enrollee to enroll in a particular plan or to insure with a particular company based on **\_TYPE NAME OF CLINIC\_** financial or other interests
- collect enrollment applications
- offer inducements to persuade beneficiaries to enroll in a particular plan
- health screen when distributing information to patients, because health screening is a prohibited marketing activity
- offer anything of value to induce plan enrollees to select the organization as its provider
- expect compensation in consideration for the enrollment of a beneficiary
- expect compensation directly or indirectly from the plan for beneficiary enrollment activities

## **APPENDIX 5F**

### **RECORDS MANAGEMENT**

#### **PURPOSE:**

This policy aims to ensure that **\_TYPE NAME OF CLINIC\_** retains records for appropriate periods of time; destroys records that are no longer useful; and establishes a system and efficient method for storing retained records.

**POLICY:**

**\_TYPE NAME OF CLINIC\_** policy is to retain records in accordance with applicable statutes and regulations, its business needs, and its contracts.

**PROCEDURE:**

**\_TYPE NAME OF CLINIC\_** will adhere to the record retention policies set forth by Medicare/Medicaid, State Boards of Pharmacy, Drug Enforcement Agency, State Pharmacy Agencies, and (but not limited to) HIPAA Privacy regulations. The Compliance Officer will determine that the storage procedures are appropriate and in compliance with regulations. **\_TYPE NAME OF CLINIC\_** will conduct an annual cleanup of records and the clean up will adhere to the policies set forth by **\_TYPE NAME OF CLINIC\_**. Records will be boxed appropriately and will be shredded.