**Regulatory/Corporate Compliance**

**Section:** Company and Employee Standards

**Compliance:** URAC Specialty Pharmacy 2.1

**URAC Standards:** PHARM Core 4, 27, 28

**ACHC Standards:** DRX 2-9A

**Policy ID:** 1.13

**Approved by:**

**POLICY**

To ensure compliance with all federal, state, local and private health insurance plan regulations; <insert practice name> has designed and implemented a Corporate Compliance Program. <insert practice name>’s Governing Body provides oversight of the program and has designated its Coordinator of Contracting and Auditing as Corporate Compliance Officer (CCO). The <insert practice name>/CCO with other staff responsible for compliance monitoring, have responsibility for overseeing the detailed, systematic and comprehensive plan for ensuring the ongoing compliance with all federal, state and private health insurance plans rules and regulations in addition to compliance with operational standards (internal practices and procedures). **[PHARM Core 4 (b)]**

The Compliance Program has been established to ensure that each employee has a clear understanding of their responsibilities and acts accordingly. Each employee has an obligation to know and to abide by the laws, rules, regulations, policies and procedures that are specific to their jobs and to abide by Ethics Policies established by <insert practice name>. **[PHARM Core 27 a, b, c, d, e, f)] [PHARM Core 28 (c)]**

The goal of <insert practice name>’s Compliance Program is to provide reasonable assurance that <insert practice name> conducts its business activity in full compliance with all federal, state and local laws and regulations. **[PHARM Core 4 (a)]**

The essential elements of the Regulatory Compliance Program include:

* Implementation of adherence to all applicable laws, regulations, written policies, procedures and the Code of Conduct **[PHARM Core 4 (b)]**
* Tracking applicable laws and regulations in the jurisdictions where <insert practice name> conducts business **[PHARM Core 4 (a)]**
* Ensuring compliance with applicable laws and regulations through: **[PHARM Core 4 (b)]**
  + Designation of a Compliance Officer to manage the compliance program and activities
  + Monitoring of changes in applicable laws and regulations and adapting practices as necessary
  + Development and implementation of effective training and education programs for all staff
  + Enforcement of the expected code of conduct and publicized disciplinary actions
  + Development of effective lines of communication throughout the compliance process
* Establishment of procedures that allow for prompt, thorough investigation of possible misconduct or non-compliance and prompt implementation of corrective action of detected problems **[PHARM Core 4 (c)]**

Each employee has a personal obligation to: **[PHARM Core 27 a, b, c, d, e, f)] [PHARM Core 28 (c)]**

* Uphold <insert practice name>’s mission and values
* Become familiar with <insert practice name>’s Code of Conduct and how it pertains to the laws and regulations, policies and procedures relative to each employee’s job
* Conducts all activities in accordance with the highest ethical standards and in a manner which shall uphold the reputation and standards of <insert practice name>. No employee will make false or misleading statements to any patient, person or entity doing business with <insert practice name>
* Report known or suspected violations of the Code, law or regulations or any other <insert practice name> policy or practice (whether intentional, inadvertent or accidental) using the chain of command. If uncertainty exists, individuals will report the issue to their supervisor or to the Pharmacy Manager so that the violation can be investigated and resolved

Participate in the investigation of the alleged violation and where appropriate provide solutions to prevent further occurrences of violations

**PROCEDURE**

1. **Federal, State and Local Regulations**

The Pharmacy Manager is responsible for acquiring and maintaining required pharmacy licensing or certification and ensuring compliance to federal, state, and local laws governing the business. The Corporate Compliance Officer takes action on any reports or recommendations of authorized planning, regulatory, and inspection agencies. These laws and regulations include, but are not limited to: **[PHARM Core 4 (a, b)]**

* OSHA
* FDA
* DOT
* State Board of Pharmacy
* Professional Certifications
* ADA
* Equal Opportunity Act
* Fair Labor Standards Act
* Title VI of the Civil Rights Act of 1964
* Medicare Regulations
* Medicaid regulations and policies
* Omnibus Budget Reconciliation Act 1987
* Balance Budget Act of 1997
* Public Health Regulations related to infectious disease
* HIPAA

1. All applicable licenses will be posted at each location for the general public to easily review
2. All rules and regulations and laws that require posting by federal and state mandate will be posted for easy review by all employees. (5 in 1 Poster)
3. <insert practice name> will maintain or have ready access to current copies of applicable rules and regulations for all services provided such as state licensure regulations, care regulations, and acceptable industry standards
4. All outcomes from reviews and/or audits from a regulatory organization that might affect operation /or accreditation will be reported to the Governing Body within 48 hours and to URAC within 30 days or as required by applicable law
5. All requests for information from a regulatory organization will receive a full report by the Governing Body within the required time frame, but not to exceed 30 days
6. **Corporate Compliance**

Elements of <insert practice name>’s Corporate Compliance Program include: **[PHARM Core 4 (b)]**

* Initial review of Board of Pharmacy regulations upon issuance of a permit by each respective Board of Pharmacy.
* Review of all newsletters and other communications received by Board of Pharmacy.
* Maintaining policy and procedures utilized to detect non-compliant conduct by employees;
* Promoting organizational culture to encourage ethical conduct and a commitment to compliance with the law;
* Oversight by the Governing Body;
* Designation of individuals accountable for the Compliance Program;
* Ensuring that system in place for both hiring and compensation practices encourages the creation and maintenance of a compliant workforce;
* Mechanism for the appropriate reporting and disciplinary mechanisms for instances of misconduct;
* Ongoing training of employees and management on <insert practice name> standards; **[PHARM Core 27 (a)] [PHARM Core 28 (c)]**
* Monitoring and auditing to detect misconduct;
* Yearly evaluation of the Compliance Program;
* Post hoc analysis of instances of misconduct to determine whether a systemic change is suggested by the problem; and
* Periodic assessment of risk and establishment of compliance priorities

The primary responsibilities of the Corporate Compliance Officer (CCO) are: **[PHARM Core 4 (b)]**

* Overseeing and monitoring the implementation of the compliance program;
* Maximizing <insert practice name>’s efficiency and quality of service, while reducing the company’s vulnerability to fraud, abuse, and waste;
* Periodically revising the program in light of organizational changes, regulatory changes, and changes in payer health plans;
* Reviewing employees’ certifications and their agreement to abide by the Code of Conduct/Ethics;
* Developing, coordinating, and participating in an educational program of full breadth;
* Investigating those applicants and potential employees who have been excluded from participation in the Medicare program on a monthly basis. (OIG Exclusion List)
* Promptly responding to all allegations of illegal/improper activities
* Independently acting on information from investigations, complaints, and suspected violations;
* Strengthening lines of communication to encourage trust and a corporate culture of openness;
* Maintaining the momentum and adherence to the objectives of the corporate compliance plan.

The Corporate Compliance Officer will have access to all patient files, billing records, supplier documents, marketing literature and brochures, contractual relationships, and employee records. Further, the CCO will be copied on all internal audit reports, all monitoring activities, and on all trends that may require a change in policy.

1. **Auditing and Monitoring [PHARM Core 4 (b)]**

An ongoing evaluation process is critical to a successful compliance program. Compliance reports created by internal monitoring and auditing become the backbone of the <insert practice name>’s Corporate Compliance Program. The Corporate Compliance Officer (CCO) is responsible for the ongoing maintenance of these auditing functions and the resulting reports.

The audits are designed to address <insert practice name>’s compliance with, at a minimum:

* laws governing kickback arrangements
* The physician self-referral prohibition
* Pricing
* Contracts
* Claims development and submission
* Reimbursement
* Sales and marketing

Further, audits should be conducted to monitor the ongoing adherence to the specific rules and policies of the Medicare DMERC, as well as any other federal, state, or private payer.

Monitoring techniques at <insert practice name> will include sampling protocols that permit the Corporate Compliance Officer (COO) to identify and review variations from an established baseline, or a pre- determined “snapshot”. Significant variation from the baseline is cause to conduct a reasonable inquiry to determine the cause of the deviation.

If the deviation is caused by improper procedures, misunderstanding of rules, or fraud and abuse systematic problems, the Corporate Compliance Officer (COO) will take immediate and deliberate steps to remediate the situation. **[PHARM Core 4 (c)]**

Any overpayments found as a result of an audit will be returned to the payer immediately.

Other monitoring techniques utilized by <insert practice name> may include:

* Testing billing staff of their knowledge of reimbursement coverage criteria and official billing guidelines;
* Ongoing risk analysis and vulnerability assessment of operation;
* Assessment of existing relationships with physicians, and other potential referral sources;
* Unannounced audits, mock surveys and investigations;
* Examination of complaint logs;
* Employee interviews;
* Solicitation of employee feedback through questionnaires;
* Review of medical necessity documentation;
* Utilization and trend analyses that uncover deviation, positive or negative;

All efforts by <insert practice name> will be documented and retained as part of <insert practice name>’s Corporate Compliance Program.

All employees will train on ways in which to identify, report and prevent Fraud, Waste and Abuse (FWA) in pharmacy claims. Employees must retrain at least annually. Records of both will be maintained. Additionally, this training will include a discussion of the False Claims Act (FCA) and their right and responsibility to report fraud to the Corporate Compliance Officer without recourse. Examples of fraud include: **[PHARM Core 27 a, b, c, d, e, f)] [PHARM Core 28 (c)]**

* Billing for services not rendered;
* Requesting, offering, or receiving a kickback, bribe, or rebate;
* Using an incorrect or inappropriate provider number in order to be paid;
* Selling or sharing patients’ Medicare numbers so false claims can be filed; or
* Falsifying information on applications, medical records, billing statements, and/or cost reports or on any statement filed with the government.

1. **Corrective Action [PHARM Core 4 (c)]**

**Policy:**

<insert practice name> employees are expected to adhere the established policies and procedures and perform their duties in accordance with <insert practice name>’s Code of Conduct/Ethics. Violations of <insert practice name>’s policies and procedures or Code of Conduct/Ethics will be investigated by the Pharmacy Manager and if warranted, violators will be sanctioned.

**Procedure:**

1. The Pharmacy Manager or designee will investigate all suspected violations of <insert practice name>’s policies, procedures and Code of Conduct/Ethics
2. The investigation of a suspected violation will include a review of the following:
   1. Appropriate personnel file
   2. Circumstances of the violation
   3. Previous sanctions or actions for similar violations
3. The Pharmacy Manager or designee will consult with employee’s immediate supervisor and the Human Resources Department, if applicable, to establish the appropriateness and legality of enforcing sanctions against the individual(s) up to, and including, termination
4. Based on the severity of the occurrences, sanctions may include:
   1. Verbal Warning: The verbal warning will indicate to the employee that a change in behavior is required. A verbal warning is always documented in writing and will contain specific facts relating to the incident or that standard that has not been met. The verbal warning will include a plan for improvement of performance or a plan to prevent a violation of work standards with specific timeframe for compliance and then re-assessment
   2. Written Warning: A written warning is issued if an earlier verbal warning has not resulted in expected behavior changes, or if the incident is severe enough to warrant it
   3. Final Written Warning: A final written warning is issued if an earlier written warning has not resulted in expected behavior changes or if the incident is severe enough to warrant it
   4. Suspension: Employee is sent home without pay for the number of days specified for each improper conduct
   5. Termination: Employee is terminated/discharged from <insert practice name>
5. Based on the violation and investigation findings, additional employee training may be required to prevent repeated violations <insert practice name>’s Corrective Action Process will be enforced for all employees
6. For all violation incidents, detailed documentation will be completed to include investigation outcome and results and reviewed with employee who will sign documentation to confirm understanding of the incident and subsequent results. Documentation is kept in secure Human Resources file

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