Trillium Health, Inc.
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Rochester, New York 14607
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COMPLIANCE PLAN
Trillium Health, Inc., dba The Pharmacy at Trillium Health, hereby called “the organization,” is strongly committed to and has a longstanding reputation for lawful and ethical conduct. We take pride in meriting the trust of those we serve, government regulators and one another.

Given the many laws, rules and regulations governing healthcare, the organization has established a comprehensive compliance program to help us live up to our commitment to adhere to the highest ethical standards of conduct in all business practices.

The organization voluntarily implements a compliance program aimed at fraud, waste, and abuse prevention while at the same time advancing the mission of providing quality patient and client care. Our compliance efforts are aimed at prevention, detection, and resolution of variances.

The eight elements of the organization’s Compliance Plan are:

1. Commitment to Compliance
   A. Standards of Conduct
   B. Patient and Client Rights
   C. Personal Health Information/HIPAA/Article 27-F Compliance
   D. Medical Necessity
   E. Billing
   F. Compliance with Applicable HHS Fraud Alerts
   G. Marketing
   H. Anti-Kick Back/Inducements
   I. Relationships with Vendors and Suppliers
   J. Retention of Records/Documentation
   K. Medical Records/Client Record Documentation
   L. Prescription Drugs and Controlled Substances

2. Designation of a Compliance Officer/Committee
3. Conducting Training and Education Programs
4. Communication
5. Disciplinary Guidelines
6. Auditing and Monitoring
7. Corrective Action
8. Response to Special Agent’s Visit for the Purpose of Investigating Allegations of Fraud and Abuse

I. COMMITMENT TO COMPLIANCE

A. Standards of Conduct
The organization promotes adherence to the Compliance Program as an element in the performance evaluation of all staff members.
The organization’s employees are bound to comply, in all official acts and duties, with all applicable laws, rules, regulations, standards of conduct, including, but not limited to laws, rules, regulations, and directives of the federal government and the state of New York, also rules and policies and procedures of the organization. These current and future standards of conduct are incorporated by reference in this Compliance Plan.

All candidates for employment shall undergo a reasonable and prudent background investigation, including a reference and criminal background check. Due diligence will be used in the recruitment and hiring process to prevent the appointment to positions with substantial discretionary authority, persons whose record (professional licensure, credentials, prior employment, criminal record or specific “exclusion” from Medicaid funded programs) gives reasonable cause to believe the individual has a propensity to fail to adhere to applicable standards of conduct.

All new employees will receive orientation and training in compliance policies and procedures. Participation in required training is a condition of employment. Failure to participate in required training may result in disciplinary actions, up to and including, termination of employment.

Every employee is asked to sign a statement certifying they have received, read, and understood the contents of the compliance plan.

Every employee will receive an initial compliance orientation and periodic training updates in compliance protocols as they relate to the employee’s individual duties.

Non-compliance with the plan or violations will result in sanctioning of the involved employee(s) up to, and including, termination of employment.

B. Patient/Client Rights
We treat our patients/clients with respect and dignity and provide care that is both necessary and appropriate. No distinction is made in the admission, transfer, discharge or care of individuals on the basis of race, creed, religion, national origin, gender, gender expression, sexual orientation, source of payment or disability. Clinical care is provided based on identified healthcare needs and Case Management is provided based on needs identified through a uniform assessment tool, not on financial criteria, and no treatment or action is undertaken without the informed consent of the patient or an authorized representative. Patients/clients are provided with a written statement of rights which conforms to all applicable laws, and their autonomy and privacy are respected within the context of a safe congregate setting.
Employees involved in patient/client care are expected to know and comply with all applicable laws and regulations and our policies and procedures governing their particular program.

C. Personal Health Information/HIPAA/Article 27-F Compliance
The organization collects personal health information about our patients/clients to provide the best possible care. We realize the sensitive nature of this information, and are committed to safeguarding patients'/clients' privacy.

The organization has created the Privacy Officer position in accordance with the HIPAA Privacy Rule. The Privacy Officer is responsible for development and implementation of policies, procedures and educational programs that will ensure that the organization will continue to be compliant with the Privacy regulations and will also ensure that protected health information is secure.

In order to ensure that confidentiality is maintained, employees and their representatives must adhere to the following rules:

- Do not discuss protected health information (PHI)/client information in public areas such as elevators, hallways, common gathering areas.
- Limit release of PHI/client information to the minimum reasonably necessary for the purpose of the disclosure.
- Do not disclose PHI without an appropriate consent signed by the patient/client unless it is related to the person’s care, payment of care, or health care operations of the organization. In an emergency situation, a patient’s consent may not be required when a healthcare provider treating the patient requests information, but the name and affiliation of the person requesting the information must be confirmed and documented in the medical record.
- Honor any restrictions on uses or disclosure of information placed by the patient/client.
- Make sure PHI/client information stored in the computer system is properly secured.
- Be familiar with and comply with special confidentiality rules governing the disclosure of HIV/AIDS, alcohol, substance abuse and mental health treatment.

D. Medical Necessity
The organization will take reasonable measures to ensure that only claims for services that are reasonable and necessary, given the patient’s condition/client’s needs are billed.

Documentation will support the determinations of medical necessity/client need when providing services.
The organization is aware that private and governmental third party payers will only pay for tests that meet the coverage criteria and are reasonable and necessary to treat or diagnose a patient. Therefore, the organization’s Providers will use prudent ordering practices.

In requesting diagnostic procedures or tests, the organization’s Providers will make an independent medical necessity decision with regard to each item ordered. A diagnosis will be submitted for all tests ordered. Documentation of findings and diagnoses will support the medical necessity of the service.

The organization’s Providers understand that private and governmental third party payers generally have limitations on laboratory and diagnostic tests; therefore, the prior authorization process will be followed.

The organization’s providers will order tests or services that are medically necessary for the appropriate treatment of the patient.

**E. Billing**

All claims for services submitted to private and governmental third party payers or other health benefits programs will correctly identify the services ordered. Only those tests ordered by an authorized Provider that are performed and that meet private and governmental third party payer’s criteria will be billed.

Intentionally or knowingly up coding (the selection of a code to maximize reimbursement when such code is not the most appropriate descriptor of the service offered) may result in immediate termination. The organization’s providers must provide documentation to support the current CPT and ICD codes used based on medical findings and diagnoses.

Immediate disciplinary action, up to and including termination will be implemented for instances of intentional misrepresentation of any service provided that results in over billing.

All individuals who provide billing information and billing department employees who prepare or submit billing statements must comply with all applicable laws, rules and regulations and the organization’s policies.

The organization will promptly return to payers any payments which we determine do not conform to our policies and applicable laws.

If erroneous claims have been made to Medicaid from the Health Homes or Adult Day Health programs, the applicable AIDS Institute contract manager will be notified.

As healthcare/human service Providers, our business involves reimbursement under government programs which require submission of certain reports of our
costs of operations. The organization complies with all federal and state laws and regulations relating to cost reports, which define what costs are allowable and describe the appropriate methodologies to claim reimbursement for the cost of services provided to program beneficiaries. Given the complexity of this area, all issues related to the completion and settlement of cost reports must be communicated through or coordinated with the Chief Financial Officer as well as the Chief Compliance Officer.

F. Compliance with Applicable HHS Fraud Alerts
The Compliance Officer will review the Medicaid/Medicare Fraud Alerts.

The Compliance Officer will ensure that any conduct disparaged by the Fraud Alert is immediately ceased, implement corrective actions, and take reasonable actions to ensure that future violations do not occur.

G. Marketing
The organization will promote only honest, straightforward, fully informative, and non-deceptive marketing. We use marketing to educate the public, increase awareness of our services and recruit employees. All marketing materials must accurately describe our services and programs. In order to ensure that no incorrect information is disseminated, employees must coordinate all marketing materials with and direct all media requests to the Vice President of Organizational Advancement or Sr. Vice President of Administration, if the former position is vacant. The Organization will only use and/or disclose any patient/client protected health information for marketing activities if a written prior authorization is obtained.

H. Anti-Kickback/Inducements
The organization will not participate in nor condone the provision of inducements or receipt of kickbacks to gain business or influence referrals. The organization's Providers will consider the patient/client's interests in offering referral for treatment, diagnostic, or service options.

Federal and state laws prohibit any form of kickback, bribe or rebate, either directly or in directly, in cash or in kind, to induce the purchase or referral of goods, services or items paid for by Medicare or Medicaid.

Self-referral laws prohibit a Provider from referring a patient for certain types of health services to an entity with which the Provider or members of his or her immediate family has a financial relationship.

Since violations of these laws may subject both the organization and the individual involved to civil and criminal penalties and exclusion from government-funded healthcare programs, all proposed transactions with healthcare providers must be reviewed with legal counsel.
Any employee involved in promoting or accepting kickbacks or offering inducements may be terminated immediately.

I. Relationships with Vendors and Suppliers
The organization is committed to employing the highest ethical standards in its relationships with vendors and suppliers with respect to source selection, negotiation, determination of contract awards, and administration of purchasing activities. All vendors and suppliers are to be selected solely on the basis of objective criteria; personal relationships and friendships play no part in the selection process. The organization does not knowingly contract or do business with a vendor that has been excluded from a government-funded healthcare program. Any vendor or supplier who has access to the Organization’s PHI and is not a covered entity, will be required to enter into a Business Associate Agreement to comply with HIPAA rules and the HITECH Act.

J. Retention of Records/Documentation
The organization will ensure that all records required by federal and/or state law are created and maintained. All records will be maintained for a period of no less than seven years.

Documentation of compliance efforts will include staff meeting and committee minutes, audit reports, memoranda concerning compliance protocols, problems identified and corrective actions taken, the results of any investigations, and documentation supportive of assessment findings, diagnoses, treatments, and plan of care.

K. Medical Record Documentation
Timely, accurate and complete documentation is important to clinical patient care. This documentation not only facilitates high quality patient care, but also serves to verify that billing is accurate as submitted.

The organization requires that Providers follow these documentation guidelines:
- The medical record/ client record is complete and organized.
- Documentation is timely
- The documentation of each patient encounter includes the reason for the encounter, any relevant history, physical examination findings, prior diagnostic test results, assessment, clinical impression or diagnosis, plan of care, and date and legible identity of the observer.
- CPT and ICD-9 codes used for claims submission are supported by documentation in the medical record.
- Appropriate health risk factors are identified. The patient’s progress, his or her response to treatment.
- Care management encounters will be documented per New York State Department of Health guidelines.

L. Prescription Drugs and Controlled Substances
The organization's employees routinely have access to prescription drugs, controlled substances and other medical supplies. In accordance with federal, state and local laws, it is strictly prohibited to divert prescription drugs and controlled substances to unauthorized individuals, to administer them without proper orders, to distribute adulterated, misbranded, mislabeled or expired drugs or devices, or to fail to report significant adverse events. Any employee of the organization who becomes aware of a potential lapse in security or the improper diversion of drugs must report the incident immediately to his/her supervisor or the Compliance Officer.

II. DESIGNATION OF A COMPLIANCE OFFICER AND/OR A COMPLIANCE COMMITTEE

The organization designates the Sr. Vice President, Chief Financial Officer to serve as the Compliance Officer and coordinator of all compliance activities.

Compliance Officer:
The responsibilities of the Compliance Officer are:

• Chair the Compliance Committee and serve as a spokesperson for the Committee.
• Overseeing and monitoring the implementation of the compliance program.
• Reporting periodically to the Compliance Committee, the President and the Board of Directors on the progress of implementation of compliance initiatives, corrective actions and recommendations to reduce the vulnerability to allegations of fraud, waste, and abuse.
• Developing and distributing all written compliance policies and procedures to all affected employees.
• Periodically revising the program in light of changes in the needs of the organization and in the law; and changes in policies and procedures of government and private payer health plans.
• Developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program and seeks to ensure that all employees are knowledgeable of, and comply with, pertinent federal, state, and private payer standards.
• Coordinating with the Human Resources Department to ensure that employees do not appear in any of the “excluded, debarred or suspended” personnel listings published by Medicare and Medicaid.
• Ensuring that all Providers/Care Management Staff are informed of compliance program standards with respect to coding, billing, documentation, and marketing, etc.
• Assisting in coordinating internal compliance review and monitoring activities, including annual or p.r.n. reviews of policies.
• Review the results of compliance audits, including internal reviews of compliance, independent reviews and external compliance audits.
• Independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations.
• Developing policies and programs that encourage managers and employees to report suspected fraud and other improprieties without fear of retaliation. (See Whistleblower Policy)
• Interacting with external legal counsel to discuss the Organization’s initiatives on regulatory compliance.
• Handling inquiries by employees, volunteers, affiliates, consumers and family members regarding compliance issues.

The Compliance Officer has the authority to review all documents and other information relative to compliance activities, including, but not limited to HR/Perso

Compliance Committee:
The organization will designate a Compliance Committee to advise the Compliance Officer and assist in the implementation of the compliance program as needed. The Compliance Committee will consist of at least the Chief Financial Officer, Chief Medical Officer and one or more Board members. The Compliance Officer will also select designees representing Human Resources and other Departments/Divisions as needed. The Chair of the Compliance Committee will report periodically to the Board of Directors.

The functions of the Compliance Committee are:

• Analyzing the Organization’s regulatory environment, the legal requirements with which it must comply, and specific risk areas.
• Assessing existing policies and procedures that address risk areas for possible incorporation into the Compliance Program.
• Working within the Organization’s standards of conduct and policies and procedures to promote compliance.
• Recommending and monitoring the development of internal systems and controls to implement standards, policies, and procedures as part of the daily operations.
• Determining the appropriate strategy/approach to promote compliance with the program and detection of any potential problems or violations.
• Developing a system to solicit, evaluate, and respond to complaints and problems.

III. CONDUCTING EFFECTIVE TRAINING AND EDUCATION

The organization requires all employees to attend specific training upon hire and on an annual and p.r.n. basis thereafter. This will include training in federal and state statutes, regulations, program requirements, policies of private payers, and
corporate ethics. The training will emphasize the Organization’s commitment to compliance with these legal requirements and policies.

The training programs will include sessions highlighting the Organization’s Compliance Program, summaries of fraud and abuse laws, discussions of coding requirements, claim development, claim submission processes, and marketing practices that reflect current legal and program standards.

The Compliance Officer or other designated staff member will document the attendees, the subjects covered, and any materials distributed at the training sessions.

Basic training will include:
- Government and private payer reimbursement principles.
- General prohibitions on paying or receiving remuneration to induce referrals.
- Proper translation of narrative diagnoses.
- Only billing for services ordered, performed, and reported.
- Examples of fraud, waste, and abuse.
- Duty to report misconduct.

IV. DEVELOPING EFFECTIVE LINES OF COMMUNICATION

The organization will protect whistle-blowers from retaliation. The organization will not retaliate against employees who, in good faith, have made a protest or raised a complaint against some practice of the organization, or of another individual or entity with whom the organization has a business relationship, on the basis of a reasonable belief that the practice is in violation of law, or a clear mandate of public policy.

The organization will establish a procedure so that employees may seek clarification from the Compliance Officer/committee in the event of any confusion or questions regarding a policy or procedure.

A hot line has been established so that employees may anonymously consult with the Compliance Officer with questions or report violations.

The organization’s staff meeting will be used to communicate responses to anonymous inquiries or reports, as well as to communicate other information regarding compliance and compliance activities.

Any potential problem or questionable practice which is, or is reasonably likely to be, in violation of, or inconsistent with, federal or state laws, rules, regulations, or directives or the organization rules or policies relative to the delivery of healthcare services, or the billing and collection of revenue derived from such services, and any associated requirements regarding documentation, coding,
supervision, and other professional or business practices must be reported to the Compliance Officer.

Any person who has reason to believe that a potential problem or questionable practice is or may be in existence should report the circumstance to the Compliance Officer. Such reports may be made verbally or in writing, and may be made on an anonymous basis.

The Compliance Officer will promptly document and investigate reported matters that suggest substantial violations of policies, regulations, statutes, or program requirements to determine their veracity.

The Compliance Officer will work closely with legal counsel who can provide guidance regarding complex legal and management issues.

V. DISCIPLINARY GUIDELINES

All members of the organization will be held accountable for failing to comply with applicable standards, laws, and procedures. Supervisors and/or Managers will be held accountable for the foreseeable compliance failures of their subordinates.

The Supervisor or Manager will be responsible for taking appropriate disciplinary actions in the event an employee fails to comply with applicable regulations or policies. The disciplinary process for violations of compliance programs will be administered according to Organization protocols (generally oral warning, written warning, suspension without pay, and may lead to termination) depending upon the seriousness of the violation. The Compliance Officer is to be consulted, and may consult legal counsel in determining the seriousness of the violation. However, the Compliance Officer should never be involved in imposing discipline.

If the deviation occurred due to legitimate, explainable reasons, the Compliance Officer and supervisor/manager may want to limit disciplinary action or take no action. If the deviation occurred because of improper procedures, misunderstanding of rules, including systemic problems, the organization should take immediate action to correct the problem.

When disciplinary action is warranted, it should be prompt and imposed according to written standards of disciplinary action.

Within 30 working days after receipt of an investigative report, the supervisor and/or V.P. of Human Resources or their designee shall determine the action to be taken upon the matter. The action may include, without limitation, one or more of the following:
1) Dismissal of the matter.
2) Verbal counseling.
3) Issuing a warning, a letter of admonition, or a letter of reprimand.
4) Entering into and monitoring a corrective action plan. The corrective action plan may include requirements for individual or group remedial education and training, consultation, proctoring, and/or concurrent review.
5) Reduction, suspension, or revocation of clinical privileges.
6) Suspension or termination of employment.
7) Modification of assigned duties.
8) Reduction in the amount of salary compensation.

The President, CEO or Sr. V.P., Chief Medical Officer shall have the authority to, at any time, suspend summarily the involved employee or contractor’s privileges or to summarily impose consultation, concurrent review, proctoring, or other conditions or restrictions on the assigned duties of the involved party in order to reduce the substantial likelihood of violation of standards of conduct.

VI. AUDITING AND MONITORING

The Compliance Officer will conduct ongoing evaluations of compliance processes involving thorough monitoring and regular reporting to the officers of the organization.

The Compliance Officer will develop an annual audit plan that is designed to address the Organization’s key compliance risks, including but not limited to laws governing kickback arrangements, physician self-referral prohibition, CPT and ICD coding and billing, claim development and submission, reimbursement, marketing, reporting, and record-keeping. The Pharmacy will have a Quality Assurance program in place to monitor medication errors and drug interactions. Reversed claims for unclaimed filled prescriptions will be tracked to ensure appropriate billing.

The audit work program steps will inquire into compliance with specific rules and policies that have been the focus of Medicaid and Medicare fiscal intermediaries or carriers as evidenced by the Medicare Fraud Alerts, OIG audits, and evaluations and publicly announced law enforcement initiatives. Audits should also reflect areas of concern that are specific to the organization.

The Compliance Officer or designee shall conduct exit interviews of personnel in order to solicit information concerning potential problems and questionable practices.

The Compliance Officer should be aware of patterns and trends in deviations identified by the audit that may indicate a systemic problem.
VII. RESPONDING TO DETECTED OFFENSES AND DEVELOPING CORRECTIVE ACTION INITIATIVES

Violations of the organization’s compliance program, failure to comply with applicable state or federal law, and other requirements of government and private health plans, and other types of misconduct may threaten the Organization’s status as a reliable, honest, and trustworthy provider, capable of participating in federal healthcare programs. Detected, but uncorrected, misconduct may seriously endanger the mission, reputation, and legal status of the Organization. Consequently, upon reports or reasonable indications of suspected noncompliance, the Compliance Officer must initiate an investigation to determine whether a material violation of applicable laws or requirements has occurred.

The steps in the internal investigation may include interviews and a review of relevant documentation. Records of the investigation should contain documentation of the alleged violation, a description of the investigative process, copies of interview notes and key documents, a log of witnesses interviewed and the documents reviewed, results of the investigation, and the corrective actions implemented.

If an investigation of an alleged violation is undertaken, and the Compliance Officer believes the integrity of the investigation may be hampered by the presence of employees under investigation, those employees should be removed from their current work activities pending completion of that portion of the investigation. These employees will be temporarily suspended with pay pending the outcome of the investigation.

Additionally, the Compliance Officer must take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the investigation.

If the results of the internal investigation identify a problem, the response may be immediate referral to criminal and/or civil law enforcement authorities, development of a corrective action plan, a report to the government, and submission of any overpayments, if applicable. If potential fraud or violations of the False Claims Act are involved, the Compliance Officer should report the potential violation to the Office of the Inspector General or the Department of Justice.

When making a repayment for an overpayment, the Organization should inform the payer of the following: (1) the refund is being made pursuant to a voluntary compliance program; (2) a description of the complete circumstances prompting the overpayment; (3) the methodology by which the overpayment was determined; (4) any claim-specific information used to determine the overpayment; and (5) the amount of the overpayment.
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If erroneous claims have been made to Medicaid from the Health Home or Adult Day Health program, the applicable AIDS Institute contract manager will be notified.

The President, CEO of the Organization shall have the authority and responsibility to direct repayment to payers and the reporting of misconduct to enforcement authorities as is determined, in consultation with legal counsel, to be appropriate or required by applicable laws and rules.

If the President, CEO of the Organization discovers credible evidence of misconduct, and has reason to believe that the misconduct may violate criminal, civil, or administrative law, then the Compliance Officer will promptly report the matter to the appropriate government authority within a reasonable time frame, but not more than 60 days after determining that there is credible evidence of a violation.

Office of Inspector General Hotline: 1-800-HHS-TIPS (1-800-447-8477)
When reporting misconduct to the government, the Compliance Officer should provide all evidence relevant to the potential violation of applicable federal or state laws and the potential cost impact.

VIII. RESPONSE TO SPECIAL AGENTS VISIT FOR THE PURPOSE OF INVESTIGATING ALLEGATIONS OF FRAUD AND ABUSE

In the event special agents visit the Organization for the purpose of investigating fraud and abuse allegations:

- Request a copy of the search warrant and the affidavit supporting it.
- Record names of all agents and agencies they represent.
- Ask the agent to secure the premises but to delay the search until counsel can be notified. If this request is refused, do not deny admission to the premises, which could be construed as obstruction of justice.
- Ask for a delay until all patients have been seen.
- Accompany the agents during the search.
- Record beginning and ending times of the search, items taken, areas searched, types of documents taken, photographs taken, questions asked or comments made, and requests made by agents.
- Identify and request copies of items essential to daily operation.
- If employees are interviewed, debrief them after the search.

This plan has attempted to provide the foundation for development of an effective and cost-efficient compliance program.

This Compliance Plan may be altered or amended in writing only with the concurrence of the Compliance Committee of the organization. The adoption of
this Compliance Plan has been approved and authorized as designated below, effective this 13th day of February, 2015.

Trillium Health, Inc.

By: Margaret Russell, Chief Compliance Officer Date: 2/13/2015

Village Care of New York, Code of Conduct, 11/5/01