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# **COMPLIANCE PROGRAM 2023**

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## Executive Summary (URAC v5.0 RM 1-1:a,b,c, 2-1:a)

A compliance program is a formalized system of policies and procedures developed and implemented to prevent, detect, and correct conduct that is inconsistent with applicable federal and state laws, rules and regulations that govern a healthcare organization. A compliance program is a living document that addresses risks and changes to the laws.

The US Department of Health and Human Services – Office of Inspector General (HHS-OIG) recommended that healthcare providers establish compliance programs to prevent and mitigate violations of federal healthcare rules and regulations in the late 1990's.

In 2010, the Affordable Care Act (ACA) amended the US Social Security Act to authorize the Secretary of HHS to mandate compliance programs as a condition for enrollment for Medicare and Medicaid providers. Providers that are not required to have compliance program, by law, should adopt a program to create an ethical environment that promotes adherence to state and federal law and payor requirements that in turn protects the organization from fraud, waste, and abuse as well as other liability. Annually, WNYBC certifies that we have satisfied the requirements of having an effective compliance program.

The benefits of a compliance program are proper submission and payment of claims, reducing billing errors, avoiding the potential for fraud, waste, and abuse, promoting patient safety and quality of care, provide protection against audits by HCFA or the OIG and avoid conflicts with the self-referral and anti-kickback statutes.

This compliance program contains seven components identified by OMIG (Office of the Medicaid Inspector General) Compliance Program Requirements 2023 and OIG (Office of the Inspector General) Compliance Program Guidance for Individual and Small Group Physician Practices Federal Register

1. Written policies, procedures, and standards of conduct
2. Designating a Compliance Officer, compliance committee, and high-level oversight
3. Training and education
4. Open lines of communication
5. Enforcing disciplinary standards through well-publicized guidelines
6. Auditing and monitoring
7. Prompt response and corrective action to compliance issues

This compliance program applies to all WNYBC staff, providers, contractors, agents, independent contractors, sub-contractors, consultants, and board of directors.

## I. Written Policies and Procedures and Standards of Conduct

The written compliance policies and procedures provide a clear explanation of WNYBC's compliance expectations and obligations to adhere to the Federal, state, and other program requirements, standards, and regulations to mitigate risk to the patient and the organization. The organization's policies and procedures are available online in PolicyStat. It is the responsibility of everyone to have the knowledge and comprehension of the policies and procedures and refer to them often.

### A. Conflict of Interest Policy and Disclosure Statement

*(See the Conflict-of-Interest Policy in PolicyStat)*

WNYBC requires that all staff and board members review the Annual Conflict of Interest policy and complete the discloser statement with actual and potential conflicts of interest. The statements are reviewed on an annual basis or when circumstances change. WNYBC expects all staff and board members to conduct their business according to the highest ethical standards of conduct and to comply with all applicable laws.

### B. Other Written Policies and Procedures

#### **Annual Work Plan**

The Compliance Officer will prepare an Annual Work Plan after reviewing the latest NYS OMIG and the US OIG priorities, recent enforcements and updates, recent internal and external audit findings and reported incidents. The Work Plan will include the top five risk areas. For 2022-2024, the top five risk areas are:

1. Billing (lack of policies and procedures, lack of reporting aging claims, lack of management oversight/presence and visibility of processes, separation of duties with cash deposits)
2. Pharmacy compliance (lack of policies and procedures, adherence to regulations),
3. Pharmacy/Clinic quality assurance,
4. Inappropriate access rights to the network, and
5. Compliance Officer oversight and input (Contracts, BAAs, External Audit requests to billing, OIG Exclusion)

#### **Ad Hoc Policy and Procedure Development**

The Compliance Officer will work with other departments to develop and revise policies and procedures to reflect new/updated requirements, corrective actions to incidents and/or concerns that arise.

## II. Designating a Compliance Officer, Compliance Committee, and High-Level Oversight

*(See the Compliance Officer Job Description in the References section below and the Compliance Committee Charter in PolicyStat)*

The OMIG requires WNYBC to designate a Compliance Officer to carry out and enforce compliance activities. The Compliance Officer should function as an independent and objective person that reviews and evaluates organizational compliance and privacy/confidentiality issues and concerns. Duties include but are not limited to overseeing and monitoring the adoption, implementation and maintenance of the compliance program, work plan, policies, and procedures, designing and coordinating internal investigations, coordinating, and implementing the fraud, waste, and abuse prevention program and chair the compliance committee.

The compliance committee is responsible for coordinating with the Compliance Officer to ensure the organization is conducting business in an ethical and responsible manner, consistent with the compliance program.

## III. Training and Education

*(See the Compliance Training and Education Policy in PolicyStat)*

The training and education program includes all hired staff, contractors, volunteers, students, fellows, and interns according to job role. Training begins on the date of hire and continues annually thereafter and as needed and applicable for all hired staff. All training addresses HIPAA, OSHA, OMIG requirements, cyber security as well as organizational risk areas through online modules, in-person training, webinars and/or onsite conferences and seminars. Online modules include a test of knowledge and comprehension that requires a passing grade of 80%.

The Board of Directors will receive high level compliance training. In 2023-2024 the board will receive in-depth training on the responsibilities of the board.

## IV. Open Lines of Communication

*(See Compliance Incident and Violation Reporting and Investigating Process in PolicyStat)*

### A. Open Lines of Communication

Having an effective compliance program includes the availability and access to the Compliance Officer to express compliance, quality, and other concerns and/or suggestions without fear of retaliation.

Any potential problem or questionable practice of laws, rules, regulations, policies, billing and collection of revenue, and any associated requirements regarding documentation, coding, supervision, and other professional or business practices must be reported to the Compliance Officer. Reporting is not limited to the staff of WNYBC. Patients, visitors, agents, contractors, independent contractors, students, fellows, interns, etc. should also report concerns to the Compliance Officer. Reports may be made verbally, in writing, compliance hotline (716-218-4005) or on the WNYBC website anonymously.

Online: [www.wnybloodcare.org](http://www.wnybloodcare.org)

Email: [kheimback@wnybloodcare.org](mailto:kheimback@wnybloodcare.org)

Hot line: 716-218-4005

Fax: 716-218-4010

Phone: 716-218-4002

Mail: Western New York BloodCare, 1010 Main Street, Suite 300, Buffalo, NY 14202, Attention: Kimberly Heimback, Compliance Officer

The Compliance Officer will promptly document and investigate reported matters. Legal counsel will be engaged for guidance of complex legal and management issues.

Suspected Fraud or Abuse in connection with **Federal** health care programs (**Medicare**) may contact US Department of Health and Human Services Office of Inspector General: [Fraud | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services \(hhs.gov\)](#)

Suspected Fraud or Abuse in connection with **State** health care programs (**Medicaid**) my contact the NYS Office of the Medicaid Inspector General hotline: 1-877-873-7283 or file a claim [File an Allegation | Office of the Medicaid Inspector General \(ny.gov\)](#)

B. Exit Interviews

An exit interview with the Compliance Officer, CEO, and/or a Board member is available and encouraged to all staff that are leaving WNYBC voluntarily or involuntarily.

## V. Enforcing Disciplinary Standards Through Well-Publicized Guidelines

*(See the Disciplinary Process for Employees policy in PolicyStat)*

All staff will be held accountable for failing to comply with applicable compliance standards. Compliance adherence is part of an employee's annual review. The supervisor/manager, or any staff member is responsible for reporting non-compliance to the Compliance Officer as soon as it is discovered. The Disciplinary Process for

Employees policy will be followed. The disciplinary process will be administered according to the policy.

The Compliance Officer will report the findings of the investigation to the supervisor/manager, CEO, and human resources. If the violation is significant, the findings will also be reported to the Board of Directors. The Compliance Officer will never be involved in imposing discipline but does have the authority to, for a reasonable time, suspend or discontinue the access rights to the person(s) involved in the violation, to reduce the likelihood of any further violations.

## VI. Auditing and Monitoring

*(See the Self-Disclosure Program Policy and the WNYBC Compliance Audit Standards policy in PolicyStat)*

The Compliance Officer will coordinate and oversee ongoing internal and external federal and state government audits as well as third-party payer audits. These audits are designed to detect fraudulent activity and are designed to address key compliance risks, and patient safety including but not limited to laws, medical record documentation, coding and billing, medical necessity, reimbursements, denials, overpayments, and self-disclosure.

The audit program criteria will be dependent on Medicare Fraud Alerts, OIG audits and work plans, OMIG audits and work plans and law enforcement initiatives, and vulnerabilities within the organization.

The Compliance Officer will monitor patterns and trends for risk areas and systemic problems.

The Pharmacy Director will have a Quality Assurance program to monitor quality and safety of dispensations and reduce the number of errors.

## VII. Responding to Compliance Issues and Corrective Action Initiatives

*(See the Compliance Incident and Violation Reporting and Investigating Process Policy in PolicyStat)*

When the organization determines a possible violation with WNYBC's policies, the compliance program or state and federal law, the Compliance Officer must be notified immediately. Violations of a compliance program, failures to comply with federal or state law, and other types of misconduct threaten the organizations' reliability, reputation, honesty, and trustworthiness.

The Compliance Officer will promptly review the reported incident/violation and investigate the allegations. The Compliance Officer will document the investigation with the following information:

- A. Alleged violation(s)
- B. Description of the investigative process
- C. Copies of interview notes and other documents essential for demonstrating a complete and thorough investigation
- D. Disciplinary action taken
- E. Corrective action(s) implemented

If the investigation identifies credible evidence that federal and/or state law, rules or regulations have been violated, the Compliance Officer will promptly report the violation(s) to the appropriate governmental entity and keep all copies with the documentation of the investigation.

## VIII. Non-Intimidation and Non-Retaliation Policies

*(See the following policies in PolicyStat: Sexual Harassment Policy for All Employers in New York State, Code of Ethics and Business Conduct, Patient Confidentiality and Compliance Policy for Employees, Students, Fellow, Contractors, and Volunteers and the Fraud and Abuse Laws and Regulations policy)*

WNYBC will not retaliate against employees who, in good faith, have raised a potential violation or concern against a practice/process of the organization, an individual or an entity that the organization has a business relationship with, based on a reasonable belief that a violation of company policy(ies) or law has occurred.

Any person that works for or represents the organization is obligated to report to the Compliance Officer any activity that is believed to be inconsistent with the organization's policies, the Compliance Program or federal and/or state law. Every representative of WNYBC is protected by the Qui Tam provision in the False Claims Act from being discharged, demoted, discriminated against, intimidated, harassed or any other retaliation. Any employee who retaliates against someone who has reported a violation in good faith is subject to discipline up to and including termination of employment.

Reports of violations or suspected violations will be kept confidential to the extent possible, consistent with the need to conduct an adequate investigation. All notifications to the Compliance Officer will be acknowledged as quickly as possible, promptly investigated, and appropriate corrective action will be taken accordingly.

## IX. WNYBC's Commitment to Compliance

*(See the Compliance Training and Education policy on PolicyStat)*

### A. Standards of Conduct

*(See the Code of Ethics and Business Conduct policy in PolicyStat)*

All employees are required to observe the highest standard of business and personal ethics in the conduct of their duties and responsibilities. As a representative of the organization, employees must practice honesty and



integrity in fulfilling responsibilities and comply with all applicable laws, regulations, and internal policies.

All new employees will receive orientation and training in compliance policies and procedures. Required training completion is a condition of employment. Failure to participate in the required training, upon hire and annually thereafter, may result in disciplinary actions, up to and including termination of employment.

**B. Patient Rights**

WNYBC adheres to all nineteen rights, consistent with New York State law in the Patients' Bill of Rights for Diagnostic and Treatment Centers (Clinics). All employees involved in patient care are expected to know and comply with all applicable laws and regulations and our policies and procedures.

**C. HIPAA Compliance**

*(See the Patient Confidentiality and Compliance Policy for Employees, Students, Fellow, Contractors, and Volunteers policy)*

WNYBC takes the privacy and protection of our patient's personal health information seriously. The Compliance Officer is responsible for the development and implementation of policies, procedures, and education of staff to ensure compliance with all Privacy and Security Rules.

Employees must adhere to the following rules to ensure confidentiality is maintained:

1. Do not discuss PHI in public areas such as elevators, hallways, common gathering areas or waiting rooms.
2. Limit release of PHI to the minimum necessary for the purposes of the disclosure.
3. Do not disclose PHI without an appropriate consent signed by the patient unless related to the patient's care, payment of care, or healthcare operations. In an emergency, a patient's consent may not be required when a healthcare provider treating the patient requests information, but the name and relationship with the person must be confirmed and documented in the patient's medical record.
4. Honor any restrictions noted on the HIPAA Disclosure Statement signed by the patient.
5. Ensure ePHI is properly secured.
6. Comply with special confidentiality requirements that apply to HIV/AIDS, alcohol, substance abuse and mental health treatment.

**C. Medical Necessity**

WNYBC will take reasonable measures to ensure only claims for services that are reasonable and necessary, given the patient's condition, are billed. Medicare and Medicaid will only pay for tests that meet the coverage criteria and are

reasonable and necessary to treat or diagnose a patient. All documentation will support the determinations of medical necessity when providing services.

Some services have limited coverage; therefore, the prior authorization process will be followed.

D. Coding and Billing

All claims for services billed to private and governmental third-party payers or other health benefits programs will correctly identify the services ordered. All criteria outlined in each contract will be met before billing for the services. The providers must provide documentation that supports the current CPT and ICD codes based on medical findings and diagnoses.

Intentionally or knowingly up-coding, unbundling, duplicating billing, or misrepresenting any service that results in over billing may result in immediate termination.

All billing staff that prepare or submit billing statements must comply with all applicable laws, rules and regulations and the organization's policies and procedures.

When an overpayment made by Medicare and/or Medicaid is identified, prompt repayment should be made within 60 days of the identification, the reason for the overpayment to the OMIG and follow the self-disclosure process per Medicare and Medicaid standards.

[Self-Disclosure Submission Information and Instructions | Office of the Medicaid Inspector General \(ny.gov\)](#)

WNYBC receives reimbursement for services provided to government beneficiaries which requires us to submit reports of our cost of operations. Federal and state laws and regulations define what costs are allowable and describe the methodologies to claim reimbursement for the cost of services provided to beneficiaries. The CFO will complete the cost reports.

E. Compliance with Applicable OIG Fraud Alerts

The Compliance Officer will review the OIG Fraud Alerts on a regular basis and ensure any conduct or processes that put the organization at risk, with the current fraud activity, will be immediately ceased and discontinued. All pertinent information will be communicated to the appropriate staff.

F. Marketing

WNYBC will promote only honest, straightforward, fully informative, and non-deceptive marketing. We use marketing to educate the public, increase awareness of our services and to recruit new employees. All marketing materials must describe our services and programs accurately. All marketing materials and

media must be approved by the COO. Patient protected health information will only be disclosed for marketing purposes if a signed written prior authorization is obtained.

G. Anti-Kickback (AKS)/Inducements and Self-Referrals (Stark Law)  
*(See the Fraud and Abuse Laws and Regulations policy in PolicyStat)*

Unlawful activity of “remuneration” to induce or reward patient referrals or generate business that includes payment by the Federal health care programs is strictly prohibited.

Violations of these laws may subject the organization and the individual to civil and criminal penalties and exclusion from government-funded healthcare programs. All proposed transactions with healthcare providers must be reviewed with legal counsel. The payers and/or recipients of kickbacks intent is a key element of the liability under the AKS.

H. Vendor and Collaboration Relationships

WNYBC 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 WNYBC’s PHI and is not a covered entity, will be required to enter into a Business Associate Agreement to comply with applicable federal and state confidentiality and data protection rules, including HIPAA and 42.C.F.R. Part 2, federal regulations that govern the confidentiality of drug and alcohol abuse treatment, mental health, and HIV/AIDS.

I. Record Retention/Document Destruction

*(See the Medical Record Retention Policy, the Business Records Retention Policy and the Compliance Documentation Retention Policy in PolicyStat)*

WNYBC will ensure that all records required by federal and/or state law are created and maintained. All medical records will be maintained for a period of no less than ten years. Business records will be maintained for a period of no less than six years.

Compliance documentation will include, but are not limited to, staff meeting and committee minutes, audit reports, incident reports and investigations, identified problems, and corrective actions taken and training records for no less than six (6) years from the date the program was implemented. Documentation will also be retained in accordance with the retention periods specified in our MMCO contract.

All documents due for destruction should be discarded in accordance with the HIPAA Rules, in secure Shred-it recycling bins located throughout the facility.

Shred-it, Inc uses on-site cross-cut shredding technology, which destroys the confidential materials into confetti-sized pieces so they can never be reconstructed. Shred-it, Inc is scheduled to come on site monthly.

J. Medical Record Documentation

Timely, accurate and complete documentation is important for patient care, accurate billing and to satisfy HIPAA regulations. Providers are required to follow these documentation guidelines:

1. Documentation is timely, complete, and organized
2. Each patient encounter includes
  - Reason for the encounter
  - Relevant history
  - Allergies and adverse drug reactions
  - Medications
  - Current weight
  - Physical examination findings
  - Prior diagnostic test results
  - Times documented
  - Biographical data
  - Assessment
  - Plan of care
  - Legible signature and date of the physician
3. Each Record Set will contain:
  - Signed Informed Consent form
  - Current Notice of Privacy Practices and acknowledgement
  - Current Patient Bill of Rights attestation
  - HIPAA Communication Consent form
  - PHI Authorization form
  - Region I Hemophilia Program Patient Choice policy

A monthly medical record audit and a quarterly peer review audit are conducted to validate these requirements are fulfilled.

K. Pharmacy/Medications

WNYBC maintains all medications and medical supplies in the pharmacy, which has limited employee access (access limited to only the necessary staff needed to dispense medications). In accordance with federal, state, and local laws, legend medications require a valid New York State prescription for dispensation to patients. All prescriptions are reviewed by pharmacists licensed in the State of New York to confirm compliance with federal, state, and local laws prior to dispensation to patients. WNYBC pharmacy maintains policies and procedures to prevent the dispensation of medications and medical devices that are deemed adulterated, misbranded, counterfeit, damaged, expired, mislabeled or

otherwise unacceptable for use by patients. Dispensation of medications including controlled substances to unauthorized individuals by WNYBC staff is strictly prohibited.

Staff are strictly prohibited from diverting prescription drugs and controlled substances to unauthorized individuals or to administer them without proper orders. WNYBC staff are educated and required to report significant adverse events to proper state, local and federal authorities. Any employee of the WNYBC who becomes aware of a potential lapse in security, or the improper diversion of drugs must report the incident immediately to his/her supervisor.

**References:**

[Compliance Library | Office of the Medicaid Inspector General \(ny.gov\)](#)

<https://omig.ny.gov/information-resources/laws-and-regulations>

[OMIG POSTS COMPLIANCE RESOURCES AND INFORMATION | Office of the Medicaid Inspector General \(ny.gov\)](#)

[OIG Compliance Program for Individual and Small Group Physician Practices \(hhs.gov\)](#)

**Author:** Kimberly Heimback, Compliance Officer of Western New York BloodCare 8/30/23