

ERIE COUNTY MEDICAL CENTER CORPORATION COMPLIANCE PLAN

I. INTRODUCTION

Erie County Medical Center Corporation (and its subsidiaries and affiliates, collectively referred to as “ECMCC”) is dedicated to ensuring a culture of compliance, honesty and integrity. ECMCC is subject to a myriad of Federal, State and local laws and regulations as it carries out its mission as a leader in the areas of patient care, teaching, and research. ECMCC is committed to compliance by all affected individuals, both clinical and non-clinical (including employees, officers, senior administrators, managers, professional staff members, members of its Board of Directors, volunteers, agents and contractors). In order to enhance its collective efforts to comply, ECMCC, by action of the Board of Directors, has adopted this Corporate Compliance Plan (the “Plan”).

This Plan supersedes the previously adopted Corporate Compliance Plan, and, along with ECMCC’s Code of Conduct, is intended to be the overall framework for guiding and assisting personnel in complying with the laws and regulations that apply to our activities on behalf of ECMCC. The Plan is not designed to provide detailed guidance but rather a roadmap to the ECMCC’s compliance efforts, coupled with ECMCC’s additional detailed policies and procedures that promote compliance and ethical conduct. It is also intended to serve as a resource for Board of Directors and ECMCC officers regarding their corporate responsibilities. The Plan also describes the procedures that will be followed in enforcing compliance standards and ensuring that ECMCC stays in compliance with all applicable laws, including those listed below.

This Plan is designed to incorporate recommendations enumerated in the Department of Health and Human Services Office of Inspector General’s (“OIG”) Compliance Program Guidance for Hospitals dated February 1998, Supplemental Compliance Program Guidance for Hospitals dated January 2005, Compliance Program Guidance dated November 2023, Compliance Program Guidance for Nursing Facilities dated March 2000, Supplemental Compliance Program Guidance for Nursing Facilities dated September 2008. It also reflects the elements of an effective compliance plan as described in the Federal Sentencing Guidelines, Social Security Law Section 363-d, title 18 New York Codes of Rules and Regulations Part 521, the NYS OMIG Compliance Program Review Guidance dated January 2023, the Deficit Reduction Act of 2005 (DRA), and the New York State False Claims Act.

The Importance of the Compliance Plan

ECMCC is committed not only to providing patients with high quality care and caring medical services, but also to providing those services pursuant to the highest ethical, business and legal standards. ECMCC’s compliance efforts are designed to perpetuate a culture within ECMCC that promotes prevention, detection and resolution of instances of conduct that do not conform to federal, state and local laws and federal, state and private payor health care program requirements. This is not only the right thing to do, but it is also important for ECMCC’s continuing reputation for honesty and integrity in ECMCC’s business and medical dealings with others.

Moreover, compliance with federal and state laws, rules and regulations is essential because of the potential for civil and even criminal liability if ECMCC is found to have violated the applicable legal standards. A governmental inquiry can lead to significant financial exposure

ERIE COUNTY MEDICAL CENTER CORPORATION

COMPLIANCE PLAN

and damage to ECMCC's reputation for honesty and integrity. Prevention is certainly a prudent business plan, and that is what ECMCC's Plan is designed to accomplish.

The Plan is especially critical as an internal control in the reimbursement and payment areas. Throughout the health care industry, claims and billing operations often raise potential fraud and abuse concerns and, therefore, have been the focus of governmental reviews and sanctions.

Purpose and Execution of the Compliance Plan

The purpose of the Plan is to guide ECMCC in its management and operation of compliance-related activities by both preventing and detecting fraudulent, abusive and/or wasteful practices. This Plan reflects ECMCC's commitment to honest and responsible conduct, encourages personnel to report potential problems, and allows for appropriate internal investigation and corrective action. The Plan intends to demonstrate that it is both committed to due diligence in seeking to prevent and detect systemic problems and violations of law by developing and sustaining a rigorous compliance plan. The Plan has at its foundation seven elements that New York State and federal guidelines have deemed necessary for an effective, high-quality compliance program:

1. The development and distribution of written standards of conduct, as well as **written policies and procedures** that promote and support the hospital's commitment to compliance;
2. The **designation of a compliance officer and other appropriate bodies**, e.g. a corporate compliance committee, vested with the oversight and responsibility of operating and monitoring the compliance program, and who report directly to a senior leader and the Audit & Compliance Committee of the Board of Directors;
3. The development and implementation of regular, effective **education and training** programs for all affected personnel and persons associated with ECMCC;
4. Open and effective **lines of communication**, including an anonymous hotline available to all affected individuals, including patients and recipients of NYS Medicaid, to receive complaints and/or concerns; an incident reporting system and open door to the Compliance Officer; and a **policy of non-intimidation and non-retaliation** for good faith participation in ECMCC's Compliance Program, including reporting potential issues, investigating issues, self-evaluations, audits and remedial actions;
5. A **system to enforce appropriate disciplinary action** against personnel who have violated internal compliance policies, applicable statutes, regulations or Federal health care program requirements;
6. A **system of risk assessments, audits, monitoring and/or other evaluation techniques** utilized to monitor compliance, to assist in the reduction of potential

ERIE COUNTY MEDICAL CENTER CORPORATION

COMPLIANCE PLAN

issues, to thoroughly investigate compliance concerns, and to take the steps necessary to remediate any legal or policy violations that may be found; and

7. A **system to promptly investigate, remediate and respond to compliance issues**, including the identification and investigation of systemic problems, with corrective actions and remediated and policies developed to address and cure the non-compliance and, if associated with overpayments, to repay such overpayments to affected government agencies.

II. STANDARDS OF CONDUCT AND WRITTEN POLICIES AND PROCEDURES

It is the policy of ECMCC to comply with all laws and regulations that govern or apply to its activities, in particular, those laws and regulations that address health care fraud, waste, abuse and misconduct such as the Federal False Claims Act and applicable State law and enforcement policies. To achieve compliance, ECMCC expects that all personnel and members of its professional staff will act in accordance with this Plan, its Code of Conduct and all compliance-related policies and procedures.

In addition, ECMCC expects that all personnel will take part attentively in compliance education and training programs conducted by ECMCC and that they will conduct their daily activities in conformance with the principles conveyed through such programs. ECMCC personnel also are expected to report actual or suspected violations of law or regulations of which they become aware and to cooperate in the investigation of any reported violations. Supervisors have an obligation to report known or suspected compliance issues further up the chain of command and/or to the Compliance Officer.

All ECMCC personnel must comply with the standards of conduct set forth in the Plan, Code of Conduct and in applicable departmental compliance policies and procedures. All personnel are expected to report potential issues and raise questions as set forth in the Plan. Strict compliance with these legal and compliance standards is a condition of employment, and violation of any of these standards of conduct will result in discipline being imposed including, but not limited to, the following:

- Informing, educating and discussing with the relevant personnel both the violation and how it should be avoided in the future;
- Providing remedial education (formal or informal) to ensure that the relevant personnel understand the applicable rules and regulations;
- Conducting a follow-up review to ensure the problem is not recurring;
- Refunding any payments that resulted from improper documentation, coding or billing;
- Imposing fair and firm discipline, ranging from oral reprimand to termination;
- Suspending all billing of the services provided, as set forth below; and
- When appropriate, voluntarily disclosing to an appropriate governmental agency.

ERIE COUNTY MEDICAL CENTER CORPORATION

COMPLIANCE PLAN

Key policies and procedures, detailed further below, are intended to educate staff in proper procedures, laws, and regulations affecting key risk areas:

- **Billing Compliance Policy**

ECMCC will ensure that its billing practices comply with applicable federal and state laws, regulations, guidelines and policies. It is the policy of ECMCC that in an effort to comply with applicable federal and state law, ECMCC has billing standards and procedures that assist in ensuring that claims are timely, accurate and complete. To prevent the submission of erroneous billing claims, this policy also provides guidance to employees on certain key risk areas that affect billing for health care services:

- Medical necessity for services
- Billing for items or services not actually rendered
- Billing without adequate documentation
- Correct Coding
- Duplicate billing
- Cost Reporting
- Balance billing
- Billing discrepancies
- Discharge disposition
- Medicare secondary payer

- **Exchanges Between ECMCC and Industry Policy**

Many aspects of ECMCC's interactions with the health care industry are positive and important for promoting the educational, clinical and research missions of ECMCC. However, these interactions must be ethical and cannot create conflicts of interest or improper relationships that could endanger patient safety, data integrity, the integrity of our training programs, or the reputation of either staff members or the institution. This policy addresses circumstances and provides guidelines for when these industry interactions are both acceptable and unacceptable.

- **Detecting and Preventing Fraud, Waste, Abuse and Misconduct**

It is ECMCC's obligation to prevent and detect any actions within the organization that are illegal, violative of federal and state health care programs, fraudulent, or in violation of any applicable ECMCC policy. To help satisfy this obligation, ECMCC utilizes this policy to educate our work force regarding the requirements, rights and remedies of federal and state laws, including the rights of employees to be protected as whistleblowers under such laws and the importance of submitting accurate claims and reports to federal and state governments.

- **340B Compliance**

The Public Health Services Act (PHSA) 340B Drug Discount program entitles ECMCC to purchase drugs for outpatient use at a reduced price. ECMCC has specific policies listed below governing program monitoring, testing and maintenance:

- 340B Contract Pharmacy Oversight
- 340B Covered Patient Definition, Monitoring, Maintenance and Billing
- 340B Drug Storage and Procurement
- 340B Program Education and Competency
- 340B Program Enrollment, Recertification, and Change Request

ERIE COUNTY MEDICAL CENTER CORPORATION COMPLIANCE PLAN

- Reporting 340B Non-Compliance
- **Non-Retaliation and Non-Intimidation**

Any individual who, in good faith, reports a potential violation of the Plan, law, regulation, policy, procedure, Public Authority's Code of Ethics, the Code of Conduct, or other instances of potential wrongdoing within ECMCC will not be subjected to retaliation, intimidation, retribution or harassment. This policy describes ECMCC's commitment to this in further detailing, including prohibiting individuals from engaging in retaliation, retribution, or any form of harassment against an employee for reporting a compliance related concern.
- **Conflict of Interest**

In all dealings with and on behalf of ECMCC or any affiliated entity, all employees and contractors are held to a strict standard of honest and fair dealing and are prohibited from using his or her position, or knowledge gained there from, in such a manner as to create a conflict, or the appearance of a conflict, between the interest of the ECMCC or any affiliated entity and the interest of such person. This policy describes this in further detail.
- **Physician Compensation Policy**

ECMCC must comply with federal and state laws that prohibit illegal remuneration, such as kickbacks, bribes, improper or excessive payments, free or below market rents or fees for administrative services, or interest-free loans. To that end, this policy requires that each ECMCC financial relationship with a physician or a physician's immediate family member meet applicable Stark Law and Antikickback Statute requirements for compliant physician relationships.
- **Sanction Screening Policy**

This policy sets forth the process by which ECMCC screens individuals to prohibit their employment, appointment, or contracting if they have been declared ineligible based off state and federal lists.

This list represents only key policies; ECMCC holds additional policies related to its Compliance program, all of which can be accessed by all staff on the ECMCC Intranet.

III. COMPLIANCE OVERSIGHT

ECMCC Compliance oversight consists primarily of a Compliance Officer, Board Audit & Compliance Committee, and separate employee Compliance Committee, as more specifically set forth below.

Compliance Officer

The ECMCC Board has designated the Compliance Officer to assist it in coordinating the development, implementation, communication and monitoring of the Plan. The Compliance Officer reports directly to senior management and to the Chair and Board of ECMCC's Audit & Compliance Committee.

ERIE COUNTY MEDICAL CENTER CORPORATION

COMPLIANCE PLAN

The Compliance Officer is vested with the responsibility for the day-to-day operation of the Plan and with the power to investigate instances of possible non-compliance with laws or regulations or other provisions of the Plan. All ECMCC personnel are required to cooperate fully with the Compliance Officer in connection with any such investigative activities. The Compliance Officer will generally assist and coordinate all compliance activities including education and training and the compliance monitoring activities discussed below. The Compliance Officer shall serve as chairperson of the Compliance Committee (a separate and distinct committee from the Audit & Compliance Committee).

Audit & Compliance Committee

The Audit & Compliance Committee (the “Audit Committee”) maintains oversight of and collaborates with the Compliance Officer on ECMCC’s establishment, maintenance and operation of a comprehensive compliance plan. The Audit Committee is a subcommittee of the ECMCC Board of Directors and consists of four independent (as defined by law) members of ECMCC’s Board of Directors. The Audit Committee is also attended by the Chief Executive Officer, Chief Operating Officer, and Chief Financial Officer of ECMCC, as well as other individuals as requested. The role of the Audit Committee is set by the Audit Committee charter, which is reviewed and approved by the Committee on an annual basis. The Audit Committee meets at least quarterly and complies with the OIG’s General Compliance Program Guidance for Board involvement and oversight of the Plan. The Compliance Officer holds a direct reporting line to the Board via this Committee. In addition to quarterly reports, the Compliance Officer shall be authorized to engage the Chair of the Audit Committee on an as-needed basis, as well as, when necessary, the Chief Executive Officer of the Corporation and the Chair of the Board of Directors, as determined in the Compliance Officer’s discretion.

Specifically, the Audit Committee is tasked with:

- Overseeing the Compliance Officer and the Compliance Committee and receiving and reviewing information necessary to understand ECMCC’s compliance risks;
- Ensuring that the Compliance Officer has direct and uninhibited access to the Board of Directors at all times;
- Analyzing the legal requirements and specific risk areas of the health care industry;
- Assessing existing policies that address legal requirements and risk areas for possible incorporation into the ECMCC Compliance Plan;
- Working with ECMCC departments to develop standards of conduct and policies and procedures to promote compliance with the ECMCC Compliance Plan;
- Recommending and monitoring the development of internal systems and controls to carry out ECMCC’s standards, policies and procedures as part of its daily operations;
- Determining appropriate strategy to promote compliance with the Plan and detection of possible violations, including fraud reporting mechanisms; and
- Developing a system to solicit, evaluate and respond to complaints and problems.

ERIE COUNTY MEDICAL CENTER CORPORATION

COMPLIANCE PLAN

The Compliance Committee

The Compliance Committee (the “Committee”) consists of individuals from senior management positions at ECMCC representing key risk areas. The individuals shall be identified in the Committee charter, which shall be reviewed and approved by the Committee on an annual basis. The Committee consists of voting and non-voting members, with non-voting members being asked to present and opine as issues as they arise.

Unlike the Audit Committee, the Compliance Committee’s role is not to supervise or oversee the activities of the Compliance department, but rather to support Compliance activities within the organization and assist in the identification of risk areas. The Committee meets at least quarterly and complies with the OIG’s General Compliance Program Guidance for Compliance Committees as well as the requirements of 18 NYCRR § 521-1.4(c). The Committee is among other items charged with reviewing and approving key compliance documents; ensuring that training topics are timely completed; ensuring communication and cooperation by affected individuals on compliance related issues and internal or external audits; advocating for the allocation of sufficient funding, resources and staff for the compliance program; ensuring that the required provider has effective systems and processes in place to identify compliance program risks, overpayments and other issues, and effective policies and procedures for correcting and reporting such issues; and advocating for adoption and implementation of required modifications to the compliance program.

IV. EDUCATION AND TRAINING

ECMCC is committed to providing training and education on this Plan. ECMCC has various policies and education programs designed to teach affected individuals about the Compliance Department, explanation of the structure and operation of the Plan and their individual compliance responsibilities.

One such policy establishes a mandatory training program for personnel. ECMCC employees receive compliance training upon hire and annually thereafter. In addition, the Plan and Code of Conduct are provided to new hire employees at orientation and available to all employees at any time on the ECMCC intranet. Compliance training includes: the Plan, risk areas, role of the Compliance Officer and Committees, lines of communication (including the Compliance & HIPAA Anonymous Hotline), fraud, waste, abuse, the Code of Conduct, and key policies. Participation in training may be a factor in each employee’s performance appraisals. Advance notice of training programs is given to ensure attendance. Participation in programs is documented and retained by Human Resources’ LMS system and/or the Compliance Department. For high-risk areas or areas on concern, additional training are provided as applicable.

Compliance training and education may be provided in a variety of ways, including educational programs conducted by knowledgeable ECMCC personnel, Compliance staff, programs conducted by reputable professional consultants, and/or attendance at outside professional conference/seminars.

Medical staff members receive annual compliance education through the medical staff office. The Compliance Department provides the training to the medical staff department to be distributed to all medical staff members. In addition, the Compliance Department is available to

ERIE COUNTY MEDICAL CENTER CORPORATION

COMPLIANCE PLAN

all medical staff for any questions or concerns regarding compliance and/or the Code of Conduct. Additional trainings can and will be provided when necessary or when requested.

Vendors are required to complete annual compliance training as well. Compliance annually distributes this training to vendors for completion in various avenues:

- ECMCC Vendor Compliance Training is available on the ECMCC external-facing webpage; or
- Vendors and/or contractors receive as part of their onboarding through ECMCC's vendor credentialing system policies and the expectations related to their commitment to compliance with all federal and state health care program requirements.

In addition, vendors and/or contractors are contractually obligated to comply with all pertinent laws, HIPAA, compliance training, sanction/exclusion monitoring, health and background screening, and agree to work in conjunction with the facility/entity they are servicing.

V. OPEN LINES OF COMMUNICATION

The reputation and integrity of both ECMCC and our personnel are valued. ECMCC is committed to the timely identification and resolution of all issues that may adversely affect employees, patients, providers or the organization.

ECMCC's live Compliance & HIPAA Hotline (the "Hotline"), available at 855-222-0758, is a 24/7 avenue maintained by ECMCC by which ECMCC employees, as well as patients, medical staff, contractors, subcontractors, agents, volunteers, Board members, students, and other persons performing work for or at ECMCC (collectively, "Affected Individuals") may report known or suspected violations of federal and state criminal, civil or administrative law, ECMCC ethics or Code of Conduct requirements, and ECMCC's Compliance plan. Reports made utilizing the Hotline may be made anonymously. Affected Individuals are encouraged to report any problem or concern either anonymously or in confidence via the Hotline as they deem appropriate. Affected individuals also have the option of contacting the Office of Corporate Compliance directly via telephone at 716-898-6439 or fax at 716-898-5178 during regular business hours, by e-mail at dlnesbitt@ecmc.edu, or in-person on ECMCC's 3rd Floor.

When reporting a violation in good faith, it is imperative to the investigation to provide as much detail as possible, including:

- The date and time of the questionable action;
- A description of the questionable action;
- The circumstances around the situation; and
- If known, the consequence, if any, of the action as it relates to patient care, staff or hospital operations.

Individuals need not identify themselves when calling the hotline. Anonymity will be maintained. If an individual chooses to identify themselves, their identity will be preserved within the limits of the law unless doing so prevents us from fully and effectively investigating the

ERIE COUNTY MEDICAL CENTER CORPORATION

COMPLIANCE PLAN

suspected violation. ECMCC personnel may report instances of actual or suspected non-compliance in confidence and without fear of retaliation or retribution.

VI. PENALTIES IN THE EVENT OF NON-COMPLIANCE

ECMCC has established procedures for responding to compliance issues as they are raised. All personnel have a duty to report suspected or known compliance issues and are encouraged to assist in their resolution. ECMCC will not take any adverse action against an affected individual for reporting a compliance issue. Comparatively, all ECMCC employees will be subject to disciplinary action for failure to comply with ethical standards, legal requirements, ECMCC's Code of Conduct and ECMCC's Compliance Plan. Any violation of these will result in appropriate sanctions. Human Resources will be engaged to ensure consistent and appropriate disciplinary action. Non-employees' behavior is also a reflection of ECMCC and failure to adhere to organization values, performance standards, or Policies and Rules may result in disciplinary action. ECMCC shall enforce its disciplinary standards fairly and consistently, and the same disciplinary action shall apply to all applicable individuals and entities.

There may be additional reporting to and cooperating with governmental authorities with respect to violations of law or regulation in appropriate circumstances after obtaining the advice of counsel. Further corrective actions (i.e. policy changes, system changes, training and education) will be undertaken as necessary.

VII. MONITORING COMPLIANCE & ASSESSING COMPLIANCE RISKS

Auditing and Monitoring

The most effective means to determine whether a compliance plan is successful is monitoring activities in relation to applicable laws and regulations to determine if those activities are being conducted in a compliant manner. To this end, the Compliance Officer will conduct various monitoring and auditing activities – both internal and external through third party auditing consultants – to measure compliance. Such activities may include, for example, unannounced audits of certain patient records and periodic and systematic auditing of various areas by the Compliance Department, Revenue Integrity or outside consultants. All personnel are expected to cooperate fully with any such monitoring activities. The purpose of monitoring is constructive as it provides an opportunity to identify and correct any systemic problems or misunderstandings about regulatory requirements so that the same incident of non-compliance does not recur.

The Compliance Officer shall coordinate corrective actions and timely responses to remedy identified deficiencies. This shall include timeframes for completion of corrective actions as well as provision of the corrective action plan to those personnel charged with implementing it. The Compliance Officer shall retain all reports and corrective action plans for six years.

Any identified over-billings, under-billings, or documented deficiencies will be adjusted or remedied in accordance with applicable laws and regulations.

Annual Risk Assessment

A formal risk assessment shall be performed by the Compliance department annually and reviewed at least once midway through the year. Key stakeholders who shall be interviewed include the Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, Chief

ERIE COUNTY MEDICAL CENTER CORPORATION

COMPLIANCE PLAN

Medical Officer, Senior Vice President of Nursing, General Counsel, and members of the Compliance Committee. In addition, Compliance shall compile a list of issues identified from other organizations regionally and nationally and review as part of its risk assessment for determining whether these items should be included in its annual workplan. Compliance shall also annually compile a list of all known compliance risks at the organization to determine and re-prioritize them based on current risk level.

Annual Work Plan

On an annual basis, the Compliance Officer shall prepare two work plans: one for the medical center, and one for its Terrace View Longterm Care Facility. The work plans are developed from a variety of sources and inputs such as identified risk areas, ECMCC internal department interviews, past investigations and audits, the annual risk assessment, and information available from the HHS OIG Annual Work Plan and New York State Medicaid Plan and other outside sources – most notably, authoritative publications from agencies within the federal government such as the OIG, the Centers for Medicare and Medicaid Services, and Medicare and Medicaid contractors. Workplans shall be approved by both the Compliance Committee and Audit Committee of the Board. Ongoing items shall be added to the Compliance Workplan throughout the year regardless of whether they were identified in the initial risk assessment.

Annual Evaluation of Compliance Program Effectiveness

The Compliance department shall annually analyze and prepare a report on the following (the “Effectiveness Report”):

- I. Is ECMCC’s compliance program well designed?
- II. Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
- III. Does ECMCC’s compliance program work in practice?

The Effectiveness Report shall be based on guidance from the U.S. Department of Justice’s “Evaluation of Corporate Compliance Programs” document (last updated March 2023), shall also meet the requirements of 18 NYCRR § 521-1.4(g)(2), and shall include a review of the effectiveness of the Compliance Officer and the resources allocated to the Compliance function of the organization. The Effectiveness Report shall be approved by both the Compliance Committee and Audit Committee.

Additional quarterly reports shall further be provided to the Audit Committee on the Compliance Program’s effectiveness as well as progress of the risk assessment, Workplan, and key issues that have been identified during the quarter.

VIII. INVESTIGATING AND RESPONDING TO COMPLIANCE ISSUES

All complaints and/or allegations of fraud, waste, abuse and misconduct are reviewed and investigated. The Compliance Officer (or his or her designee) will investigate instances of possible non-compliance which come to the attention of the Compliance Officer. If the investigation reveals there has been non-compliance with laws, regulations, or provisions of the Plan, the Compliance Officer will take appropriate steps to investigate, report, and remediate the violation or non-

ERIE COUNTY MEDICAL CENTER CORPORATION COMPLIANCE PLAN

compliance. The Compliance Officer will conduct a fair and impartial inquiry that may include documentation review, interviews, audit and other investigative techniques. Interim measures may be taken during an investigation into possible misconduct to protect the integrity of the investigation and respect the due process rights of the involved individuals. These measures, to be taken in accordance with applicable laws, collective bargaining agreements etc., may include temporary reassignments or leaves.

Appropriate remediation steps may include, but are not limited to, recommending changes in policies or procedures to prevent recurrence, recommendations for appropriate personnel action to be taken with respect to persons involved in non-compliant activity, reporting investigation results to ECMCC's CEO, General Counsel, and/or Audit & Compliance Committee. Verified overpayments will be repaid, as required by law. A log of all investigations by the Compliance Department, and their outcome, will be maintained by the department.

Approved by:

ECMCC Board of Directors

Date: September 24, 2024