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COMPREHENSIVE CANCER CENTER	Policy and Procedure		
Title:		Revision:	Effective Date:
Roswell Park Comprehensive Cancer Center		10	3/17/2025
Corporate Compliance Summary Policy			
Prepared by:		Approved by:	Page:
General Counsel; Corporate Compliance Officer;			1 of 3
Assistant Vice President & Deputy General			
Counsel		Michael B. Sexton, Chief	
		Legal Officer	

A. GENERAL STATEMENT OF POLICY

It is the policy of Roswell Park Comprehensive Cancer Center and Health Research Inc, Roswell Park Division, (hereinafter collectively referred to as "Roswell Park") to comply with all applicable federal, state and local laws and regulations, both civil and criminal.

It is also the policy of Roswell Park to require staff to comply with the Roswell Park Code of Conduct (<u>Policy 125.1</u>) and additional standards of conduct which may be adopted by the Board of Directors, the Chief Executive Officer (CEO) or the Corporate Compliance Committee.

The Roswell Park Compliance Program is based upon federal and New York State guidance that hospitals take the following steps to ensure regulatory compliance:

- Establish written compliance standards, procedures, and policies.
- Assign oversight responsibility to an individual high in the organization's structure (a "compliance officer").
- Conduct effective compliance training and educational programs.
- Create a system for routine identification of compliance risk areas and utilize monitoring and auditing procedures to detect non-compliance and improve quality.
- Develop effective lines of communication for reporting violations and responding to inquiries.
- Enforce standards through well-publicized disciplinary guidelines and procedures.
- Respond appropriately and promptly to legal or regulatory violations and prevent further violations through corrective action and change in institutional and individual behaviors.
- Establish a policy of non-intimidation and non-retaliation for good faith reporting and participation in compliance program activities.

This policy summarizes the Roswell Park Corporate Compliance Program and provides information to Roswell Park staff about important federal and state laws. The provisions, standards and requirements of the program will be reviewed with each new employee and by all employees on an annual basis.

B. SCOPE

This policy applies to all employees, volunteers, contracted staff, board members, contractors, vendors, and students associated with Roswell Park.

C. ADMINISTRATION

This policy will be implemented by the Board of Directors and the President & CEO, through the Corporate Compliance Officer, the Corporation's General Counsel and other administrative and managerial staff of Roswell Park.

D. POLICY / PROCEDURE

- 1. Each Roswell Park employee, agent, contractor, vendor, and medical staff appointee will strive to act in accordance with the provisions of applicable federal, state and local laws, the Corporate Code of Conduct and Roswell Park policies, and will encourage other employees, agents, contractors, vendors, or medical staff appointees to do the same.
- 2. No Roswell Park employee, agent, contractor, vendor, or medical staff appointee has authority to act contrary to the provisions of applicable laws or the Corporate Code of Conduct or to authorize, direct or condone such action by any other employee, agent, contractor, vendor or medical staff appointee.
- 3. Any Roswell Park employee, agent, contractor, vendor, or medical staff appointee who has knowledge of activities that he or she believes may violate a law, rule or regulation has an obligation to promptly report the matter to his or her immediate supervisor, the Compliance Officer, or the Chief Executive Officer. Reports may be made anonymously and employees will not be penalized for reports made in good faith (see whistleblower protection laws described in Appendix A and Non-Retaliation Policy 103.1). Failure to report known violations, failure to detect violations due to negligence or reckless conduct and intentionally making false reports shall be grounds for disciplinary action, including termination. The appropriate form of discipline will be case-specific, and in accordance with existing collective bargaining agreements.
- 4. Roswell Park will communicate compliance standards and procedures to all employees and agents by requiring participation in training programs and by disseminating information that explains in a practical manner what is required. This will include distribution of this policy and the Code of Conduct and maintenance of a <u>Compliance website</u> with informative links and a reporting/inquiry tool.
- 5. Roswell Park will take steps to achieve compliance with its standards by utilizing monitoring and auditing systems reasonably designed to detect misconduct by its employees and agents and by having in place and publicizing a reporting system whereby employees and other agents can report misconduct within the organization without fear of retribution. The Corporate Compliance Hotline (845-3566) is one method of reporting and the Compliance website has a reporting/inquiry e-mail tool for submitting questions or concerns to the Compliance Office.
- 6. After a suspected violation has been reported, the Compliance Officer will take reasonable steps to respond appropriately and to prevent further similar violations, including making any necessary modifications to its program to prevent and detect violations of law.
- 7. All members of the Roswell Park workforce should be knowledgeable about several important federal and state laws that help to prevent and detect waste, fraud and abuse in federal health care programs such as Medicare and Medicaid. In addition, individuals who, in good faith, report suspected non-compliant behavior are protected by both federal and state law. Please see Appendix A to this policy for a description of these laws.
- 8. This policy is intended to communicate current policies regarding compliance. The Board of Directors reserves the right to change, modify, or waive all provisions herein. If any employee

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has a question concerning a particular provision contained herein or concerning any practice not addressed in this document, he or she should consult with the Compliance Officer.

E. DISTRIBUTION

This Policy and Procedure will be distributed to all Roswell Park Managers via the Roswell Park internal web page and to holders of backup hard copies of the manual. Managers are responsible for communicating policy content to pertinent staff.

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Appendix A Compliance with Federal and State Laws

It is the policy of Roswell Park Comprehensive Cancer Center (Roswell Park) that all personnel (including employees, directors, physicians, consultants, contractors and agents who provide healthcare and billing and coding services) shall comply with all applicable federal and New York State false claims laws and regulations. Roswell Park has various policies and procedures which are available in the policy section of the internal Roswell Park website to ensure compliance with these laws and to assist Roswell Park in preventing fraud, waste and abuse in federal and State health care programs. Several important federal and state laws are summarized below. Roswell Park Staff are encouraged to consult with the Compliance Officer if they have questions about the meaning or application of these laws.

In general, the regulatory activity of federal and State agencies is directed toward detecting and eliminating fraud, waste and abuse in the health care industry. Fraud is defined as an intentional act of deception, misrepresentation or concealment in order to gain something of value. Waste is the over-utilization of services or mismanagement of resources including incurring unnecessary costs because of inefficient or ineffective practices or systems. Abuse is defined as excessive or improper use of services or actions that are inconsistent with acceptable business or medical practice.

Examples of provider fraud, waste and abuse include the following:

- billing for services that were not provided;
- duplicate billing such as billing Medicare or Medicaid and then also billing private insurance and/or the patient;
- requiring the patient to return for more visits when additional appointments are not necessary;
- taking unnecessary x-rays, blood work, etc.;
- upcoding, e.g., providing a simple office visit and billing for a comprehensive visit;
- having an unlicensed person perform services that only a licensed professional should render, and then billing as if the professional provided the service;
- billing for more time than actually provided;
- accepting payment from another provider, including sharing in the reimbursement paid by the Medicare or Medicaid program, as a result of referring a patient to the other provider.

Federal Laws:

<u>False Claims Act (31 USC §§3729-3733)</u>. Under the False Claims Act ("FCA"), those who knowingly submit or cause another person or entity to submit false claims for payment of government funds are liable for three times the government's damages plus civil penalties of \$14,308 to \$28,619 per false claim.

While the False Claims Act imposes liability only when the claimant acts "knowingly," it does not require that the person submitting the claim have actual knowledge that the claim is false. A person who acts in reckless disregard or in deliberate ignorance of the truth or falsity of the information, also can be found liable under the Act. 31 U.S.C. 3729(b).

In sum, the False Claims Act imposes liability on any person who submits a claim to the federal government that he or she knows (or should know) is false. An example may be a physician who submits a bill to Medicare for medical services she knows she has not provided. The False Claims Act also imposes liability on an individual who may knowingly submit a false record in order to obtain payment from the government. An example of this may include a government contractor who submits records that he knows (or should know) are false and that indicate compliance with certain contractual or regulatory requirements. The third area of liability includes those instances in which someone may obtain money from the federal government to which he may not be entitled, and then uses false statements or records in order to retain the money. An example of this so-called "reverse false claim" may include a hospital who obtains interim payments from Medicare throughout the year, and then knowingly files a false cost report at the end of the year in order to avoid making a refund to the Medicare program.

In addition to its substantive provisions, the FCA provides that private parties may bring an action on behalf of the United States. 31 U.S.C. 3730 (b). These private parties, known as "qui tam relators" or whistleblowers, may share in a percentage of the proceeds from an FCA action or settlement.

Section 3730(d)(1) of the FCA provides, with some exceptions, that a qui tam relator, when the Government has intervened in the lawsuit, shall receive at least 15 percent but not more than 25 percent of the proceeds of the FCA action depending upon the extent to which the relator substantially contributed to the prosecution of the action. When the Government does not intervene, section 3730(d) (2) provides that the relator shall receive an amount that the court decides is reasonable and shall be not less than 25 percent and not more than 30 percent.

Administrative Remedies for False Claims (31 USC Chapter 38§§ 3801–3812).

This statute allows for administrative recoveries by federal agencies. If a person submits a claim that the person knows is false or contains false information, or omits material information, then the agency receiving the claim may impose a penalty of up to \$5,000 for each claim. The agency may also recover twice the amount of the claim.

Unlike the False Claims Act, a violation of this law occurs when a false claim is submitted, not when it is paid. Also unlike the False Claims Act, the determination of whether a claim is false, and the imposition of fines and penalties is made by the administrative agency, not by prosecution in the federal court system.

Anti-Kickback Statute (42 USC 1320a-7b. This statute provides that whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe or rebate (directly or indirectly, overtly or covertly), in cash or in kind: (i) in return

for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under [Medicare] or a State health care program; or (ii) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or in part under [Medicare] or a State health care program shall be guilty of a felony and, upon criminal conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than ten years, or both.

Remuneration may include gifts, payments, bribes or rebates. Certain exceptions or safe harbors, such as group purchasing agreements and price reductions to health plans, among others, are excluded from this prohibition.

<u>Stark Law (42 USC 1395nn).</u> Section 1877 of the Social Security Act prohibits physicians from referring Medicare/Medicaid patients for certain designated health services to an entity with which the physician, or a member of the physician's immediate family, has a financial relationship – unless an exception applies. Section 1877 also prohibits an entity from billing for designated health services that were furnished as a result of a prohibited referral.

Privacy and Security of Protected Health Information. Health Insurance
Portability and Accountability Act (HIPAA) (45 CFR, Part 160 and Subparts A, C and E of Part 164). HIPAA's Privacy Rule establishes Federal standards regarding the use and disclosure of protected health information (PHI) by healthcare providers and other "covered entities." As required by the Privacy Rule, Roswell Park's Workforce Members (including employees, trainees, students and volunteers) shall not use or disclose PHI (in any format, including paper, electronic or spoken word) except (1) for purposes of treatment, payment and healthcare operations; (2) with a patient's written authorization or (3) as otherwise specifically permitted by HIPAA. Additionally, Roswell Park Workforce Members may use and disclose PHI only to the minimum extent necessary for a proper purpose – and only to the extent that such use or disclosure falls within the scope of the Workforce Member's official job responsibilities. Examples of PHI include but are not limited to:

- 1. Patient demographic information such as name, address, SSN:
- Information about a patient's health care tests, diagnosis and treatment;
- 3. Patient's bills, payment status or other patient financial information; and
- 4. Other information identified by patient name, number, SSN or other identifier.

HIPAA's Security Rule establishes additional requirements that specifically apply to electronic PHI (which includes PHI on computers, PDAs, floppy disks, thumb drives and similar media). As required by the Security Rule, Roswell Park has adopted policies and procedures to ensure the confidentiality, integrity and availability of electronic PHI. For example, there are specific policies governing the use of PHI in e-mails. Workforce Members must comply with these policies in using electronic devices, computers and PHI in any electronic format.

Violations of HIPAA are punishable by significant fines (up to \$1,500,000) and criminal convictions. Employees, Workforce Members or Agents who become aware of a

suspected or actual improper use or disclosure of PHI shall immediately report it to the Privacy Officer, Security Officer or Compliance Officer.

New York State Laws:

New York's false claims laws fall into two categories: civil/administrative and criminal laws. Some apply to recipient false claims and some apply to provider false claims, and while most are specific to healthcare or Medicaid, some of the "common law" crimes apply to areas of interaction with the government.

Civil and Administrative Laws:

NY False Claims Act (State Finance Law, §§187-194). The NY False Claims Act closely tracts the federal False Claims Act. It imposes penalties and fines on individuals and entities that file false or fraudulent claims for payment from any state or local government, including health care programs such as Medicaid. The penalty for filing a false claim is \$6,000 -\$12,000 per claim and the recoverable damages are between two and three times the value of the amount falsely received. In addition, the false claim filer may have to pay the government's legal fees.

The Act allows private individuals to file lawsuits in state court, just as if they were state or local government parties. If the suit eventually concludes with payments back to the government, the person who started the case can recover 25-30% of the proceeds if the government did not participate in the suit of 15-25% if the government did participate in the suit.

Social Services Law §145-b False Statements. It is a violation to knowingly obtain or attempt to obtain payment for items or services furnished under any Social Services program, including Medicaid, by use of a false statement, deliberate concealment or other fraudulent scheme or device. The State or the local Social Services district may recover three times the amount incorrectly paid. In addition, the Department of Health may impose a civil penalty of up to \$10,000 per violation. If repeat violations occur within 5 years, a penalty up to \$30,000 per violation may be imposed if they involve more serious violations of Medicaid rules, billing for services not rendered or providing excessive services.

<u>Social Services Law §145-c Sanctions</u>. If any person applies for or receives public assistance, including Medicaid, by intentionally making a false or misleading statement, or intending to do so, the person's family's needs are not taken into account for 6 months if a first offense, 12 months if a second (or once if benefits received are over \$3,900) and five years for 4 or more offenses.

Criminal Laws:

<u>Social Services Law §145 Penalties</u>. Any person who submits false statements or deliberately conceals material information in order to receive public assistance, including Medicaid, is guilty of a misdemeanor.

<u>Social Services Law § 366-b, Penalties for Fraudulent Practices</u>. Any person who obtains or attempts to obtain, for himself or others, medical assistance by means of a false statement, concealment of material facts, impersonation or other fraudulent means is guilty of a Class A misdemeanor.

Any person who, with intent to defraud, presents for payment and false or fraudulent claim for furnishing services, knowingly submits false information to obtain greater Medicaid compensation or knowingly submits false information in order to obtain authorization to provide items or services is guilty of a Class A misdemeanor.

Penal Law Article 155, Larceny. The crime of larceny applies to a person who, with intent to deprive another of his property, obtains, takes or withholds the property by means of trick, embezzlement, false pretense, false promise, including a scheme to defraud, or other similar behavior. It has been applied to Medicaid fraud cases. Fourth degree grand larceny involves property valued over \$1,000 and is a Class E felony. Third degree grand larceny involves property valued over \$3,000 and is a Class D felony. Second degree grand larceny involves property valued over \$50,000 and is a Class C felony. First degree grand larceny involves property valued over \$1 million and is a Class B felony.

<u>Penal Law Article 175, False Written Statements</u>. Four crimes in this Article relate to filing false information or claims and have been applied in Medicaid fraud prosecutions:

§175.05, Falsifying business records involves entering false information, omitting material information or altering an enterprise's business records with the intent to defraud. It is a Class A misdemeanor.

§ 175.10, Falsifying business records in the first degree includes the elements of the §175.05 offense and includes the intent to commit another crime or conceal its commission. It is a Class E felony.

§175.30, Offering a false instrument for filing in the second degree involves presenting a written instrument (including a claim for payment) to a public office knowing that it contains false information. It is a Class A misdemeanor.

§175.35, Offering a false instrument for filing in the first degree includes the elements of the second degree offense and must include an intent to defraud the state or a political subdivision. It is a Class E felony.

Penal Law Article 176, Insurance Fraud. This statute applies to claims for insurance payment, including Medicaid or other health insurance and contains six crimes. Insurance Fraud in the 5th degree involves intentionally filing a health insurance claim knowing that it is false and is a Class A misdemeanor. Insurance fraud in the 4th degree is filing a false insurance claim for over \$1,000 and is a Class E felony. Insurance fraud in the 3rd degree is filing a false insurance claim for over \$3,000 and is a Class D felony. Insurance fraud in the 2nd degree is filing a false insurance claim for over \$50,000 and is a Class C felony. Insurance fraud in the 1st degree is filing

a false insurance claim for over \$1million and is a Class B felony. Aggravated insurance fraud is committing insurance fraud more than once and is a Class D felony.

Penal Law Article 177, Health Care Fraud. This statute applies to claims for health insurance payment, including Medicaid, and contains five crimes. Health care fraud in the 5th degree is knowingly filing, with intent to defraud, a claim for payment that intentionally has false information or omissions and is a Class A misdemeanor. Health care fraud in the 4th degree is filing false claims and annually receiving over \$3,000 in aggregate and is a Class E felony. Health care fraud in the 3rd degree is filing false claims and annually receiving over \$10,000 in the aggregate and is a Class D felony. Health care fraud in the 2nd degree is filing false claims and annually receiving over \$50,000 in the aggregate and is a Class C felony. Health care fraud in the 1st degree is filing false claims and annually receiving over \$1 million in the aggregate and is a Class B felony.

Protection for Whistleblowers:

Federal False Claims Act (31 U.S.C. §3730(h)). The FCA provides protection to whistleblowers or qui tam relators who are discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of their employment as a result of their furtherance of an action under the FCA. 31 U.S.C. 3730(h). Remedies include reinstatement with comparable seniority as the qui tam relator would have had but for the discrimination, two times the amount of any back pay, interest on any back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees.

NY False Claim Act (State Finance Law §191). The False Claim Act also provides protection to whistleblowers or qui tam relators who are discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of their employment as a result of their furtherance of an action under the Act. Remedies include reinstatement with comparable seniority as the qui tam relator would have had but for the discrimination, two times the amount of any back pay, interest on any back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees.

New York Labor Law §740. An employer may not take any retaliatory action against an employee (including former employees and independent contractors) if the employee discloses information about the employer's policies, practices, or activities to a federal, state or local court, agency, law enforcement office, or executive branch. Retaliatory action includes actions or threats to take actions that would adversely impact a former employee's current or future employment, and contacting or threating to contact immigration authorities. Protected activities include a report or threat to report an action, policy, or practice by the employer that the employee reasonably believes: (i) violates <u>any</u> federal, state, or local law, rule, or regulation; or (ii) poses a substantial and specific danger to the public health or safety. The employee can make (or threaten to make) such reports to any federal, state, or local court, agency, law enforcement officer, or executive branch. The employee is protected even if such reporting is outside of the scope of his or her employment duties. Moreover, the employee is protected even if he

or she incorrectly believed the employer's actions to constitute a violation of the law, so long as his or her belief in that regard was reasonable. The employee must only demonstrate a "good faith effort" to bring the matter to the supervisor's attention before making the external report. Further, employees are not required to make any internal report "where: (a) there is an imminent and serious danger to the public health or safety; (b) the employee reasonably believes that reporting to the supervisor would result in a destruction of evidence or other concealment of the activity, policy, or practice; (c) such activity, policy, or practice could reasonably be expected to lead to endangering the welfare of a minor; (d) the employee reasonably believes that reporting to the supervisor would result in physical harm to the employee or any other person; or (e) the employee reasonably believes that the supervisor is already aware of the activity, policy, or practice" and will not correct it. If an employer takes retaliatory action, the court may order money damages (specifically, front pay) as an alternative to reinstatement of the employee. In addition, allow civil penalties not to exceed \$10,000 and if the employer's violation is found to be willful, malicious, or wanton; uncapped punitive damages.

New York Labor Law §741. A health care employer may not take any retaliatory action against an employee if the employee (including former employees and independent contractors) discloses certain information about the employer's policies, practices or activities to a federal, state or local court, agency, law enforcement office, or executive branch. Retaliatory action includes actions or threats to take actions that would adversely impact a former employee's current or future employment, and contacting or threating to contact immigration authorities. Protected activities include a report or threat to report an action, policy, or practice by the employer that the employee reasonably believes: (i) violates any federal, state, or local law, rule, or regulation; or (ii) poses a substantial and specific danger to the public health or safety. The employee can make (or threaten to make) such reports to any federal, state, or local court, agency, law enforcement officer, or executive branch. The employee is protected even if such reporting is outside of the scope of his or her employment duties. Moreover, the employee is protected even if he or she incorrectly believed the employer's actions to constitute a violation of the law, so long as his or her belief in that regard was reasonable. The employee must only demonstrate a "good faith effort" to bring the matter to the supervisor's attention before making the external report. Further, employees are not required to make any internal report "where: (a) there is an imminent and serious danger to the public health or safety; (b) the employee reasonably believes that reporting to the supervisor would result in a destruction of evidence or other concealment of the activity, policy, or practice; (c) such activity, policy, or practice could reasonably be expected to lead to endangering the welfare of a minor; (d) the employee reasonably believes that reporting to the supervisor would result in physical harm to the employee or any other person; or (e) the employee reasonably believes that the supervisor is already aware of the activity, policy, or practice" and will not correct it. If an employer takes retaliatory action, the court may order money damages (specifically, front pay) as an alternative to reinstatement of the employee. In addition, allow civil penalties not to exceed \$10,000 and if the employer's violation is found to be willful, malicious, or wanton; uncapped punitive damages.

Additional Information and Resources (click to follow links) https://oig.hhs.gov/

Centers for Medicare and Medicaid Services (CMS):

CMS Information about the Physician Self Referral Law:

Office of the New York State Medicaid Inspector General