



The Mary M. Gooley Hemophilia Center, Inc. Compliance Program

Center Compliance History

The Mary M. Gooley Hemophilia Center, Inc. (“the Center”) currently has an established Compliance Program that was initiated in April 2002. This Compliance Program comprehensively oversees various compliance activities that work to provide transparency to Center operations. This is paired with development and establishment of Center policy and procedures that are created to mitigate non-compliant activities and to ensure that all Center activities are legal, honest and ethical. Center policy and procedures specifically aimed at compliance are fairly and resolutely implemented. Remedial action for any uncovered noncompliance is swiftly and meticulously carried out to correct any uncovered issues and to moderate potential for reoccurrence. The Center has a structured schedule for detection of certain compliance risk areas which includes internal (self-evaluation) and external audits that examine Center operations.

Staff participation and understanding regarding the Center compliance structure is vital to an effective, sound program. Therefore, the Center strongly encourages staff participation by frequent compliance education and updates. The Center has created an effective and open system of non-compliance reporting. The expectations of employee reporting is discussed at least annually with staff, as well as reinforced by the Center’s policy of non-retaliation against reporting.

The Compliance Officer (“CO”) acts as staff to the CEO, the Compliance Committee, and the Board of Directors by monitoring and reporting results of the compliance/audit/ethics efforts of the Center and in providing guidance for the Board and senior management team on matters relating to compliance. The Center has an active, involved Compliance Committee comprised in part of members of the Board of Directors. The CO regularly reports all compliance activity to the Compliance Committee and is expected to meet with the committee quarterly. The Compliance Committee, in turn, is expected to provide oversight and consultation to the CO. The CO, together with the Compliance Committee, is authorized to implement all necessary actions to ensure achievement of the objectives of an effective Compliance Program. In addition, the CO will meet privately with the Executive Committee of the Board at least once each year.

New York Compliance Requirements

The Office of Medicaid Inspector General (“OMIG”) established Compliance rules in Title 18 of the New York Codes, Rules, and Regulations Part 521 (Part 521) for Medical Assistance Providers that have been in effect as of July 1, 2009 and are entitled Provider Compliance Programs. It is imperative that the Center assures integration of these new rules and continues implementation of an effective, thorough Compliance Program. The mission of a Compliance Program is to enhance the integrity of the New York State Medicaid program and recover improperly expended Medicaid funds while promoting high-quality patient care.

There are seven (7) mandatory Elements to a Compliance Program (as described in New York Social Services Law Section 363-d & Part 521). These Elements as detailed more fully below were updated/revised in New York Social Services Law 363-d in April, 2020. The implementing regulations at Part 521 will be similarly revised in the future.

Element 1: Written policies, procedures and standards of conduct that:

- a) Articulate the organization’s commitment to comply with all applicable federal and state standards;**
- b) Describe compliance expectations as embodied in the standards of conduct;**
- c) Implement the operation of the Compliance Program;**
- d) Provide guidance to employees and others on dealing with potential compliance issues;**

- e) **Identify how to communicate compliance issues to appropriate compliance personnel;**
- f) **Describe how potential compliance issues are investigated and resolved by the organization;**
- g) **Include a policy of non-intimidation and non-retaliation for good faith participation in the Compliance Program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials; and;**
- h) **All requirements listed under 42 U.S.C.1396-a(a)(68)**

The Center has a reputation for conducting itself in accordance with the highest level of business and community ethics and in compliance with applicable Federal and State governing laws. The Center recognizes the problems that both intentional and inadvertent misconduct in the health care industry can pose. As a result, the Center is committed to ensuring that it operates under the highest ethical and moral standards and that all of its activities comply with all applicable requirements.

This Compliance Program demonstrates the Center's policies and commitment to honest and ethical behavior in all aspects of its delivery of services to patients and relations with third-party payors, employers, contractors, agents, and independent contractors. The Compliance Program will provide guidance to employees and health care professionals and will aid in preventing fraud, waste, and abuse while providing high quality care to the Center's patients.

The Compliance Program begins with the acknowledgment and agreement that it will comply with all applicable Federal, State, and local laws and regulations ("Legal Requirements"). The Center is committed to maintaining an effective internal program which ensures compliance with all Legal Requirements. With this Compliance Program, the Center will promote and ensure full compliance with its legal mandates and obligations, foster and assure ethical conduct, and provide guidance to each staff member and contractor of the Center for his/her conduct. The procedures and standards of conduct contained within this Compliance Program are intended to generally define the scope of conduct which the Compliance Program is intended to address but are not to be considered as all inclusive. This Compliance Program is intended to be a living document and will be updated periodically in order to keep the Center's staff members and contractors informed of the most up-to-date information relating to health care compliance requirements.

All employees/staff members (which shall throughout this Compliance Program include, but not be limited to, its executives and Board of Directors) and Center contractors/consultants have the obligation and responsibility to understand and to comply with all Legal Requirements which relate to their positions, and Center supervisors have the responsibility of ensuring that all staff members and contractors/consultants who report to them are provided with accurate, up-to-date information so that they can comply with such Legal Requirements. All staff members and contractors/consultants will be held accountable for their individual actions. It is the policy of the Center to immediately investigate any suspected violations of the Legal Requirements. If the investigation reveals that a potential violation has occurred, the Center will take appropriate corrective action which may include reporting the suspected violation to the appropriate authorities for investigation. The Center will cooperate with any governmental investigation into the circumstances surrounding an alleged violation. Additionally, any violations may result in disciplinary action by the Center, up to and including termination.

If a staff member or contractor has any questions regarding the propriety or legality of any particular course of action, the staff member or contractor should immediately seek advice from his/her supervisor or the Center's CO. Similarly, staff members and consultants may report any perceived violations of the Compliance Program and/or Legal Requirements on a strictly confidential basis by contacting his/her superior or the Center's CO. If the matter at issue involves the individual's superior or the Center's CO, the matter can be discussed with other appropriate management staff or members of the Center's Board of Directors.

Additionally, the Center adopts a policy of non-intimidation and non-retaliation for a staff member and/or consultant's good faith participation in the Compliance Program. Specifically, the Center shall not take any adverse employment actions against any staff member or consultant for reporting potential compliance issues, for submitting self-evaluations to the Center, and/or for engaging in any authorized audits or remedial/corrective actions (unless the staff member or contractor/consultant is complicit in the compliance problem). Furthermore,

the Facility will comply at all times with the applicable provisions of New York Labor Law Sections 740 and 741 and other Legal Requirements.

With respect to compliance with the requirements under 42 U.S.C 1396-a(a)(68), the federal Deficit Reduction Act, the Center shall comply with the Deficit Reduction Act Policy.

Element 2: Designation of a compliance officer and a compliance committee who report directly and are accountable to the organization's chief executive or other senior management.

The Center has appointed a Compliance Officer/CO who has the responsibility for overseeing the day-to-day operation of the Center's Compliance Program. The Compliance Officer's responsibilities shall include, but not be limited to, understanding all aspects of this Compliance Program, educating staff members and consultants regarding compliance issues, monitoring and reporting of all of the Center's compliance activities, investigating reports of suspected non-compliance, and such other duties as are necessary to monitor developments and changes in the Legal Requirements that will affect the Center.

The Center has also appointed a compliance committee which is empowered to assist the Compliance Officer in evaluating compliance issues and making policy and procedure changes in order to ensure that the Center remains in compliance with all Legal Requirements. The Center's compliance committee should meet at least quarterly (four times each year). In addition, the Compliance Officer should privately meet with the board's Executive Committee at least once each year to have a confidential space to review any concerns.

The Compliance Officer shall be responsible for preparing reports for the Center at the Center's Compliance meetings. The Compliance Officer shall report compliance and auditing activities to the Center's governing body on a periodic basis.

Eric Iglewski is currently the Center's Compliance Officer and can be directly reached at 922-4177 or eric.iglewski@rochesterregional.org with any questions or concerns.

Element 3: Each provider shall establish and implement effective training and education for its compliance officer and organization employees, the chief executive and other senior administrators, managers and governing body members. Such training and education shall occur at a minimum annually and shall be made a part of the orientation for a new employee and new appointment of a chief executive, manager or governing body member.

The Center's staff members (including, but not limited to, its executives and Board of Directors) and its contractors/consultants will receive training and education relating to this Compliance Program at least annually, and more frequently if the Compliance Program is revised or the Legal Requirements have changed. At these training sessions, the Facility will discuss with its staff members and consultants as applicable the components of this Compliance Program, the Center's commitment to compliance, as well as staff member and consultant responsibilities. Compliance considerations will be part of the performance evaluation of all staff members and consultants, and such performance will be evaluated annually, or more frequently if the need arises or if compliance concerns are raised by any party.

All new staff members and consultants (including, but not limited to, its executives and Board of Directors) will receive a copy of the Center's Compliance Program and will receive compliance training during orientation and thereafter. All employees and health care professionals shall receive education and training based on their job functions. The Center shall ensure that all levels of personnel receive adequate and ongoing training. Attendance and description of formal training programs shall be documented.

Element 4: Establishment and implementation of effective lines of communication, ensuring confidentiality between the compliance officer, members of the compliance committee, the organization's employees, managers and governing body, and the organization's first tier, downstream and related entities. Such lines of communication shall be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

Center staff members and consultants are required, in good faith, to report behavior and conduct that may constitute a violation of this Compliance Program and/or Legal Requirements. The failure to report a compliance violation is, in and of itself, a violation of the Center's Plan. The Center strives to maintain an open line of communication and is committed to ensuring that all staff members and consultants feel comfortable communicating their concerns to the Compliance Officer or other management personnel. The Compliance Officer shall have an open door policy and maintain regular office hours (and will also schedule special appointments, if needed) in order to address compliance issues with staff members and consultants. The Compliance Officer can be notified verbally, by telephone, by e-mail or other electronic communication. There is also a confidential Compliance Lock Box (as described below further) where complaints can be deposited. Written reports, and any relevant documents, can also be placed in a sealed envelope and marked "For the Compliance Officer Only". Intentional false reports or accusations are prohibited and subject to disciplinary action.

It is the core policy of the Center that it will respect the confidentiality of any compliance communication to the greatest degree possible, acknowledging that complete confidentiality and anonymity in reporting may not be possible in order to conduct a thorough investigation and implement an appropriate plan of compliance correction. The Center's policies permit individuals to anonymously report all compliance violations, suspected compliance violations, questionable conduct, or questionable practices. The Center is committed to ensuring that there will be no retribution against any staff members and consultants when reporting a potential compliance violation committed by third parties.

Element 5: Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the Compliance Program by all affected individuals.

The Center has a disciplinary policy in place which specifically encourages the good faith participation in the Compliance Program by all staff members and contractors/consultants. The Center may implement disciplinary action against a staff member and/or contractor/consultant when such staff members and contractors/consultants: (a) fail to report a suspected compliance concern or problem; (b) fail to comply with the Center's Compliance Program and/or Legal Requirements; (c) encourage, direct, facilitate, or permit (either actively or passively) non-compliant behavior, including, but not limited to, behavior which may impair the Center's goodwill and status in the community; (d) fail to detect a compliance problem attributable to the individual's own intentional, negligent, or reckless actions or inactions; (e) refuse to cooperate in the investigation of a suspected violation of the Compliance Program; and/or (f) retaliate against an individual for making a good faith report of a suspected violation of the Compliance Program and/or the Legal Requirements.

The Center can take disciplinary action up to and including termination. Some alternative disciplinary methods other than termination include, but are not limited to, the following: (a) oral or written warnings; (b) internal job transfer; (c) temporary probation; (d) temporary suspension (with or without pay); (e) demotion; (f) restitution/reimbursement for losses or damages; (g) mandatory or permissive reporting to the applicable governmental agency or authorities; (h) retraining of staff members or consultants; and/or (i) referral for potential criminal or civil legal actions.

The Center will consider various factors and circumstances in determining the appropriate imposition of discipline in order to ensure that its disciplinary policies are fairly and firmly enforced. Any disciplinary action shall be based on a consideration of at least the following: (a) the nature of the compliance activity or inactivity; (b) whether the individual(s) involved could reasonably have been expected to identify the activity or inactivity as non-compliant; (c) whether the individual(s) involved were in a position to implement a corrective action plan; and (d) whether the individual(s) involved were unduly influenced to participate in the non-compliant activity or inactivity.

Element 6: Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the organization's compliance with the medical assistance program requirements and the overall effectiveness of the Compliance Program.

The Center has adopted an internal audit procedure in which it will review compliance risk areas once a year and report any finding to the Compliance Committee. The Center will also hire external auditors as appropriate to address the Facility's compliance issues. The Center shall ensure that compliance requirements regarding billing, coding, claim submission, cost reporting, and Medicaid participation rules are adhered to, monitored, and enforced.

In particular, the Center has identified the following risk areas that it will self-evaluate for actual or potential non-compliance:

- Submission of accurate claims to payors
- Screening for Excluded Individuals and Entities
- Compliance with the Federal (and State) Anti-Kickback Statute
- Review of the provision of free goods and services
- Review of Services Contracts
- Review of Discounts (if any)
- Compliance with all Federal and State Physician Self-Referral Laws and Regulations
- Compliance with HIPAA Privacy and Security Rules
- The establishment and maintenance of an ethical culture

The Center shall also ensure compliance in the following risk areas: quality of care of medical assistance program beneficiaries, quality assessment and assurance, employee screening (including requirements relating to ensuring appropriate licensure and certification), and billing.

It is the Center's practice to verify the credentialing of providers and persons associated with providers and to make all necessary mandatory reports to appropriate governmental and legal authorities in a timely fashion in accordance with all Legal Requirements.

The Center will also ensure that it addresses and audits specific areas of the Medicaid program that are particularly vulnerable to improper payments, including, but not limited to, (a) claims submitted for medical services to deceased beneficiaries; (b) claims submitted after or the failure to reimburse the Medicaid program after third-party liability has been established; and (c) bills submitted to a Medicaid beneficiary for Medicaid-covered services.

Element 7: Establishment and implementation of procedures and a system for promptly responding to compliance issues are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with the medical assistance programs requirements.

When an individual fails to comply with the Center's compliance policies and/or Legal Requirements, or otherwise engages in wrongdoing that has the potential of impairing the Center's status as a compliant provider, a violation under the Compliance Program has occurred. Staff members and consultants are mandated to report potential violations to the Compliance Officer. When the Compliance Officer or other management personnel are made aware of a potential violation, a prompt investigation will be commenced in order to determine whether a material violation has occurred. If such a violation has occurred, management will take steps to mitigate and resolve the problem, report the situation to the appropriate governmental authorities in accordance with the Legal Requirements, and implement a plan of compliance correction, as necessary.

Any necessary internal investigation may include a review of some or all of the following: (a) a confidential staff member and/or consultant interview; (b) a review of the agreements with the Center's business associates and any reports drafted by those business associates; and (c) documents related to any investigations, legal and/or administrative proceedings, whether threatened or pending.

Once the investigation has been completed, the Center will draft and implement an appropriate plan of compliance correction in order to accomplish at least the following: (a) taking immediate corrective action to cure any problem and implement steps to prevent it from reoccurring; (b) making appropriate restitution; (c) conferring with legal counsel to determine what disclosures, if any, should be made; (d) initiating appropriate and fair

disciplinary action; and (e) preparing a report to the Compliance Officer and the Compliance Committee that outlines the alleged misconduct, subsequent findings, and the plan of compliance correction that was adopted or is proposed.

The Center shall report compliance issues to the New York State Department of Health/Office of Medicaid Inspector General (OMIG) in accordance with all Legal Requirements. The Center shall also make appropriate restitution (including, but not limited to, repaying any overpayments) in accordance with the Legal Requirements.

The Center shall ensure that ongoing training of employees is conducted and documented and that there is routine auditing of billing practices, quality of care issues, existing contracts, and related areas as necessary.

The Center shall also comply, to the extent applicable and practicable, with the following additional guidance issued by OMIG:

- (1) Compliance Program Self-Assessment Form (Compliance Alert 2015-02, February 12, 2015)
- (2) Federal False Claims Act Civil Penalties Increase (Compliance Alert 2016-01, July 22, 2016)
- (3) Mandatory Compliance Programs' Risk Assessments: Changes in Medicaid Reimbursement Systems (Compliance Alert 2017-1, August 31, 2017)

The Medicaid Inspector General may impose a monetary penalty if the provider fails to adopt and implement a Compliance Program which satisfactorily meets all the mandatory requirements listed above.

There are seven (7) areas to which mandatory Compliance Programs must be applicable (18 NYCRR Section 521.3(a)):

- 18 NYCRR 521.3 (a)(1): Billing
- 18 NYCRR 521.3 (a)(2): Payments
- 18 NYCRR 521.3 (a)(3): Medical necessity and quality of care
- 18 NYCRR 521.3 (a)(4): Governance
- 18 NYCRR 521.3 (a)(5): Mandatory reporting
- 18 NYCRR 521.3 (a)(6): Credentialing
- 18 NYCRR 521.3 (a)(7): Other risk areas that are or should with due diligence be identified by the provider

The Center shall also comply with OMIG's Compliance Program Review Guidance (issued on October 26, 2016).

Compliance Program Summary Structure/Overview

Billing (18 NYCRR 521.3 (a)(1))

The Center's staff members and consultants shall only apply business practices that are legal, ethical and honest in creating and maintaining records and in billing. Dishonest reporting, both internal and external to the Center, will not be tolerated. This includes reporting or organizing information in an attempt to mislead or misinform. Accordingly, staff members and consultants will do the following:

- Prepare and maintain company records and reports accurately and honestly. This includes reporting of time worked, business expenses incurred, revenue received, and all documentation of business or service related activities.
- Prepare and maintain patient records and reports accurately and honestly and bill only for services actually rendered and that are fully documented in a patient's medical record.
- Cost reports filed with third party payors shall reflect appropriate costs incurred for furnishing health care services.
- Not make any entries on the Center's books and records that intentionally hide, mislead, or disguise the true nature of any transaction.

- Before making any payment for services or goods, require documentation that the services were, in fact, provided or received.
- Accurately specify the services to be provided or benefits to be received in all contracts. All contracts will be reviewed before issuance, consistent with policy directives.
- Take due care to assure that all claims submitted to any government programs or private health care program, individual, department or agency are accurate and conform to all Legal Requirements. Submit claims that accurately reflect services or products actually rendered, medically necessary and supported by relevant documentation. Any type of inaccurate billing, whether intended or not, can subject the Center and the involved staff members and consultants to severe civil and criminal penalties. The Center is only entitled to reimbursement for products or services that have been delivered or performed, were medically necessary, and are in accord with the customary charges for such products or services.

Any staff member or consultant knowingly presenting or causing to be presented claims for payment or approval that are false, fictitious, or fraudulent will be subject to immediate termination of employment.

For questions or concerns regarding record keeping or billing compliance, a staff member or consultant should contact his/her supervisor. If a staff member or consultant suspects or is aware of any violations, he/she should contact the Center's CO at 922-4177.

Payments (18 NYCRR 521.3 (a)(2))

The Center's staff members and consultants shall faithfully and accurately record payments received for healthcare services and products. Any and all receipts shall be deposited in the organization's designated banking institution consistent with internal policies and procedures and accounted for using Generally Accepted Accounting Principles. Records of payments made to the organization shall reflect:

- Payer
- Amount
- Date of payment
- Purpose of payment (with reference documentation)

An accurate "accounts receivable" balance shall be reported regularly on the organization's financial statements. Good faith efforts will be made to collect all funds owed to the organization in accordance with approved business policies and procedures.

Likewise, payments made by the Center to suppliers and other business associates of the Center should be tracked accurately, held to the same recording standard (as "accounts payable") and reported in full on financial statements.

Any person (employee or otherwise) who has knowledge of payments made by or intended for the Center that have been diverted to a recipient other than the Center or the Center's intended recipient, or used or deposited in any way outside of approved business practices has knowledge of fraudulent activity – it must be immediately reported to the Center's CO at 585-922-4177.

In April 2020, New York Social Services Law Section 363-d was amended by adding new wording that addresses overpayments and self-disclosure. If the Center receives an overpayment under the medical assistance program, it must report and return the overpayment to OMIG and notify OMIG in writing of the reason for the overpayment. An overpayment must be reported and returned by the later of (1) the date which is sixty days after the date on which the overpayment was identified or (2) the date any corresponding cost report is due, if applicable. Any overpayment retained by the Center after the deadline for reporting and returning the overpayment shall be subject to a monetary penalty. OMIG may waive interest of any overpayment reported, returned and explained; furthermore, the Center's good faith participation in the self-disclosure program may be considered as a mitigating factor in the determination of an administrative enforcement action.

Ensure Accuracy of Documentation and Billing for Physicians

The Center will assure that bills for payment of services rendered accurately reflect those services and are fully and accurately justified by appropriate documentation.

1. **Practice Standards and Procedures:** The Center has and will maintain practice standards and procedure manuals to define the work done and services delivered
2. **Documentation for Reimbursement Claims:** The Center, regularly and as a rule, documents all care, procedures, encounters and clinical information fully, clearly and accurately. A properly documented medical record verifies condition of the patient, diagnosis, what services were provided, site of service, accuracy of the billing and identity of the caregiver. Furthermore, claims are submitted only at the level of documentation found in the chart.
The Center will review (self-audit) documentation and billing procedures quarterly to assure compliance with payers' guidelines for E/M (Evaluation and Management) to determine whether:
 - Bills are accurately coded and reflect the services provided (as documented in the medical records);
 - Documentation is complete and accurate;
 - Services or items provided are reasonable and necessary; and
 - Incentives for unnecessary services exist.
3. **Improper Inducements:** Neither the Center, nor any consultants associated with the Center, will accept, ask for or suggest remuneration for referrals. That illegal activity can distort medical decision making, waste resources, increase cost to federal health care programs, and result in unfair competition by shutting out competitors who are unwilling to pay for referrals. In addition, purchases of clotting factor products are not dependent upon or associated with program support from any outside entity, including suppliers of clotting factor products, but rather with medical need and product availability. The Anti-kickback statute prohibits knowingly and willfully giving and receiving anything of value to induce referrals. Waiving of co-pay or deductibles for a service rendered or failing to make reasonable efforts to collect the cost-sharing amount is prohibited unless a determination is made that the patient is in financial need.

Governance (18 NYCRR 521.3 (a)(4))

The Center is a New York not-for-profit corporation incorporated as a 501(c)(3), governed by a community Board of Directors. The Center is a health care provider regulated by the NYS Department of Health under Article 28 of NYS Public Health law and as such is a recipient of Medicare and Medicaid reimbursement for claims. In addition, the Center functions as a chapter of the National Hemophilia Foundation and Hemophilia Federation of America.

Excerpted from By Laws:

The business of the Corporation shall be managed by its Board of Directors, which may exercise all such powers of the Corporation and do all such lawful acts and things as are not prohibited by statute or by the Certificate of Incorporation or by these by-laws directed or required to be exercised or done by persons other than the Board. The Board shall be responsible for the general management and oversight of the affairs of the Corporation and without limitation thereto, shall have powers to:

- *Select, hire, appoint and evaluate the President and Chief Executive Officer (President/CEO) and to delegate to such person executive authority and responsibility to operate the Center in furtherance of the policies established by the Board of Directors.*

- *Establish health care and other programs and policies as needed to achieve the organization's mission and vision.*
- *Periodically review, evaluate and as needed change, create or eliminate programs of the Center.*
- *Appoint the members of the Medical and Dental Staff and, upon the recommendation of the President/CEO, appoint from such Staff a physician as Medical Director.*
- *Maintain a formal liaison with the Medical and Dental Staff, primarily through the Medical Director.*
- *Review and approve the Policies and Procedures of the Medical and Dental Staff.*
- *Enter into contracts for the provision of health care services by independent medical and dental contractors only when such contractors or the medical and dental personnel agree to apply for formal appointment to the Medical and Dental Staff and upon appointment and entering into their duties agree to adhere to the Policies and Procedures of the Staff. Nothing herein shall constitute such independent medical and dental contractors to be the employees of the Corporation.*
- *Define the Committees of the Board of Directors and of the Corporation and the Committees' functions.*
- *Define expectations for the role of individual board members.*
- *Assure that the Center operates in compliance with all applicable federal, state and local laws.*
- *The Board, in exercise of its powers and authority, shall not enter into any agreement limiting its responsibility for the establishment of policies and for the management and operation of the Center as outlined herein and by applicable law.*

Staff shall ensure the Board is fully apprised of any and all matters related to its role (above) and shall regularly report on the health and well-being of patients, both clinical and non-clinical programs and services and the organization's financial results.

Mandatory Reporting (18 NYCRR 521.3 (a)(5))

The Center's commitment to integrity is demonstrated by its development of a Regulatory Compliance Program to promote compliance with Legal Requirements. Although "compliance" may be broadly defined as adherence with all Legal Requirements, the focus herein concerns compliance in billing and reimbursement from Medicare, Medicaid, other government programs, and private insurers. The purpose of the Compliance Program is to provide a framework that reduces the likelihood of noncompliance, and provides a process for effectively diminishing and resolving regulatory compliance risks. In order for the Center's Compliance Program to be effective, Center staff members and consultants must be informed about the stated areas of potential compliance concern. The Department of Health and Human Services' Office of the Inspector General has identified several areas of concern related to compliance which merits more attention and oversight such as compliance with government health care programs such as Medicare, Medicaid, and TRICARE. Among the areas of concern are:

- Billing for items or services not actually rendered
- Providing medically unnecessary services
- "Upcoding" of a billing code that provides a higher rate than the code that reflects the actual service
- "Diagnostic Related Group creep" or using a DRG code that provides a higher payment rate than the code that reflects the service furnished

- Outpatient services rendered with inpatient stays
- Duplicate billing
- False cost reports
- "Unbundling" or the practice of submitting bills in a piecemeal fashion to maximize reimbursement for services or tests that are required to be billed together
- Patient's freedom of choice
- Failure to refund credit balances
- Incentives that violate the anti-kickback statute or other similar federal or state statute
- Joint ventures
- Financial arrangements between hospitals and hospital-based physicians
- Violation of the Stark physician self-referral law
- Knowingly failing to provide covered services or necessary care to HMO members

Provide all Staff Members and Consultants with Written Standards of Conduct

The Center's staff members and its consultants will receive standards of conduct annually, and more frequently if revised, at the staff meeting in which annual mandatory education is provided. The components of the Center's Regulatory Compliance Plan, the commitment of the Center to compliance, and staff responsibility will be discussed. The Center's CO, and methods for reporting non-compliance will be identified. Compliance will be a part of staff members and consultant's performance evaluated annually or more frequently if concerns arise. All new staff members/consultants will receive standards of conduct and above discussion during orientation.

Reporting System for Potential Incidents of Non-Compliance

The Center's CO is responsible for handling all matters related to fraud and abuse, and billing compliance for private and public payors. The CO also provides information and guidance about these regulations.

The elimination and ongoing prevention of fraud, abuse and waste in health care billing are critical goals for the Center. In order to provide quality care to all patients, the Center is heavily dependent upon federal and state funding. In return, the United States and New York State governments require strict compliance with laws and regulations governing the provision of public funds.

Therefore, all staff members and consultants are under obligation to promptly report all incidents of perceived noncompliance where there is a reasonable basis to believe that noncompliance has occurred. The Center will promptly evaluate and investigate all reports received. Records of such matters and any subsequent investigations shall be retained, in confidence, by the CO, so far as possible. Such records shall be subject to disclosure only as required by Center policy, through advice of counsel, or as otherwise required by Applicable Law.

The following reporting options are available to all staff members and consultants: Contact the CO directly by telephone at 922-4177 or meet directly with the CO who has an open-door policy. In addition, employees may anonymously report any compliance concerns or issues in writing by placing them in the Compliance Lock Box located in the Center's break room (checked daily by the CO). There will be appropriate follow-up by the CO. If staff wish to remain anonymous, anonymity will be maintained to the extent allowable by Applicable Law. The Center is committed to creating an environment where employees feel safe to report compliance issues and concerns. Intimidation – any behavior or action that is meant to prevent someone from reporting a compliance issue or participating in a compliance investigation – is strictly forbidden and is in violation of the Center's code of conduct and New York Labor Law.

“Whistle Blowing”

Pursuant to New York Labor Law (740/741) the Center will not take any retaliatory action against an employee if they disclose information about the Centers policies, practices, or activities to a regulatory, law enforcement or other equivalent agency. Protected disclosures are those that allege that the Center is in violation of a law that creates a “substantial and specific danger to the public health and safety or which constitutes health care fraud”, with a specific aim to defraud a claim for payment that intentionally has false omissions (NYS Law). Other Protected disclosures are those made in good faith, based on the employee’s belief of improper quality of patient care.

Credentialing (18 NYCRR 521.3 (a)(6))

Members of the medical staff have a contractual relationship with the Center’s Board of Directors, which, under NYS Public Health Law, holds ultimate responsibility for the quality of care delivered by the corporation. The medical staff will deliver medical services pursuant to contracts, consistent with the Center’s by-laws, established with and approved by the Board of Directors. The Board will ensure that staff periodically verifies the credentials of each clinician practicing medicine on behalf of the Center. Such verifications shall include, but not be limited to, licensure, educational background, reports of adverse claims, events or practices, past and ongoing employment and/or affiliations with other medical providers.

Other Risk Areas (18 NYCRR 521.3 (a)(7))

Ensure Accuracy of Factor Inventory

The Center will maintain accurate clotting factor inventory both internally and externally (clotting factor is kept in the Center, in the RGH and Strong Memorial Pharmacies, and in the homes of those patients on the Home Infusion Program). Factor is billed to insurance carrier as per regulations and carrier-specific agreements.

Factor is purchased by the Center under 340B pricing for outpatients and billed to insurance carriers under those prices plus a per-unit mark up to cover administrative and program costs. In addition, the Center supplies hospitals factor at non-340B prices for use in their institutions plus a per-unit mark up to cover administrative and program costs. The Center bills hospitals directly for the cost of factor plus the per-unit mark-up. The hospitals in turn bill the insurance carrier.

Ensure Clinical Accuracy and Timeliness of Patient Treatment Plans

In order to provide comprehensive care with continuity, patients will have a detailed treatment plan to include condition, diagnosis, treatment orders, viral history, allergies, past infusions for bleeds, dental needs, and psychosocial history. All bleeding disorder patient treatment plans/problem sheets will be accurate and updated when a patient has a comprehensive care visit. Problem sheets will be updated as problems occur for patients not attending clinic.

This Compliance Program is hereby adopted by the Center in accordance with all Legal Requirements.

EXHIBIT A

Mary M. Gooley Hemophilia Center, Inc. Deficit Reduction Act Policy

PURPOSE

The Mary M. Gooley Hemophilia Center, Inc. (“Center”) is committed to its role in preventing health care fraud and abuse and complying with applicable state and federal laws related to health care fraud and abuse. The Federal Deficit Reduction Act of 2005 requires health care providers which receive or make \$5 million or more in Medicaid payments during a Federal fiscal year to establish written policies and procedures informing and educating their employees, agents, and contractors about the Federal False Claims Act and other laws, including state laws, which deal with fraud, waste, abuse, and whistleblower protections regarding those issues.

While the Center does not receive or make \$5 million or more in Medicaid payments during a Federal fiscal year, recent changes to New York State Social Services Law Section 363-d require that the Center’s compliance program shall include written policies, procedures, and standards of conduct including all requirements under 42 U.S.C. 1396-a(a)(68), which is the Federal Deficit Reduction Act of 2005.

In order to ensure compliance with such laws, the Center has policies and procedures in place to detect and prevent fraud, waste, and abuse, and also to support the efforts of Federal and State authorities in identifying incidents of fraud and abuse. This policy sets forth information concerning the Center’s existing policies and procedures, including avenues for reporting concerns internally, and contains an overview of the Federal Civil False Claims and Program Fraud Civil Remedies Acts and applicable state laws.

As detailed more fully in the Center’s existing Compliance Plan, to which this Deficit Reduction Act Policy is attached and incorporated herewith, the Center is committed to maintaining an effective internal program which ensures compliance with all applicable legal requirements.

POLICIES AND PROCEDURES

The Center takes health care fraud and abuse very seriously. It is our policy to provide information to all employees, contractors, and agents about the Federal and State false claims acts, remedies available under these provisions and how employees and others can use them, and about whistleblower protections available to anyone who claims a violation of the Federal or State false claims acts. We also advise our employees, contractors, and agents of the steps the Center has in place to detect health care fraud and abuse.

FEDERAL AND STATE FALSE CLAIMS LAWS

The Role of Federal and State Laws in Preventing Fraud, Waste, and Abuse: The Centers for Medicare & Medicaid Services (“CMS”) defines “fraud” as the intentional deception or misrepresentation that an individual knows to be false (or does not believe to be true) and makes, knowing that the deception could result in an unauthorized benefit to himself or another person. CMS defines “abuse” as incidents or practices of providers that are inconsistent with sound medical practice and may result in unnecessary costs, improper payment, or the payment for services that either fail to meet professionally recognized standards of care or are medically unnecessary.

The Federal Government and the State of New York have enacted criminal and civil laws pertaining to the submission of false or fraudulent claims for payment or approval to the Federal and State governments and to the private payors. These false claims laws, which provide for criminal, civil, and administrative penalties, provide governmental authorities with broad authority to investigate and prosecute potentially fraudulent activities, and also provide anti-retaliation provisions for individuals who make good faith reports of waste, fraud, and abuse.

The Federal Civil False Claims and Program Fraud Civil Remedies Acts, applicable State laws, and anti-retaliation provisions are summarized in the following sections. A more complete copy and listing of the applicable Federal and New York Statutes Relating to Filing False Claims is also attached to this policy and made a part hereof. These statutes can also be located at the following website (which website may be amended from time to time):

<https://omig.ny.gov/media/54411/download>

This listing of statutes is supplemented by the relevant Compliance Alerts from the New York Office of the Medicaid Inspector General which can be located at:

<https://omig.ny.gov/compliance-alerts>

As applicable, the Center shall also comply with the following guidance:

<https://omig.ny.gov/sites/default/files/document/DRAFAQsfinal.pdf>

<https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD032207Att1.pdf>

FEDERAL CIVIL FALSE CLAIMS ACT

The Civil False Claims Act (31 U.S.C. §3729 et seq.) is a statute that imposes civil liability on any person who:

- knowingly presents, or causes to be presented, a false or fraudulent claim, record or statement for payment or approval,
- conspires to defraud the government by getting a false or fraudulent claim allowed or paid,
- uses a false record or statement to avoid or decrease an obligation to pay the Government, and
- engages in other fraudulent acts enumerated in the statute.

The term “**knowingly**” as defined in the Civil False Claims Act (“FCA”) includes a person who has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required.

The term “**claim**” includes any request or demand for money or property if the United States Government provides any portion of the money requested or demanded.

Potential civil liability under the FCA currently includes penalties of between five thousand five hundred and ten thousand per claim (adjusted for inflation), treble damages, and the costs of any civil action brought to recover such penalties or damages.

The **Attorney General of the United States** is required to diligently investigate violations of the FCA, and may bring a civil action against a person. Before filing suit the Attorney General may issue an investigative demand requiring production of documents and written answers and oral testimony.

The FCA also provides for **Actions by Private Persons** (qui tam lawsuits) who can bring a civil action in the name of the government for a violation of the Act. Generally, the action may not be brought more than six years after the violation, but in no event more than ten. When the action is filed it remains under seal for at least sixty days. The United States Government may choose to intervene in the lawsuit and assume primary responsibility for prosecuting, dismissing or settling the action. If the Government chooses not to intervene, the private party who initiated the lawsuit has the right to conduct the action.

In the event the government proceeds with the lawsuit, the qui tam plaintiff may receive fifteen to twenty-five percent of the proceeds of the action or settlement. If the qui tam plaintiff proceeds with the action without the government, the plaintiff may receive twenty-five to thirty percent of the recovery. In either case, the plaintiff may also receive an amount for reasonable expenses plus reasonable attorneys' and costs. These percentages may be amended periodically.

If the civil action is frivolous, clearly vexatious, or brought primarily for harassment, the plaintiff may have to pay the defendant its fees and costs. If the plaintiff planned or initiated the violation, the share of proceeds may be reduced and, if found guilty of a crime associated with the violation, no share will be awarded the plaintiff.

Whistleblower Protection. The FCA also provides for protection for employees from retaliation. An employee who is discharged, demoted, suspended, threatened, harassed, or discriminated against in terms and conditions of employment because of lawful acts conducted in furtherance of an action under the FCA may bring an action in Federal District Court seeking reinstatement, two times the amount of back pay plus interest, and other enumerated costs, damages, and fees (as amended).

FEDERAL PROGRAM FRAUD CIVIL REMEDIES ACT OF 1986

The **Program Fraud Civil Remedies Act of 1986** ("Administrative Remedies for False Claims and Statements" at 38 U.S.C. §3801 et seq.) is a statute that establishes an administrative remedy against any person who presents or causes to be presented a claim or written statement that the person knows or has reason to know is false, fictitious, or fraudulent due to an assertion or omission to certain federal agencies (including the Department of Health and Human Services).

The term "**knows or has reason to know**" is defined in the Act as a person who has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required.

The term "**claim**" includes any request or demand for property or money, e.g., grants, loans, insurance or benefits, when the United States Government provides or will reimburse any portion of the money.

The authority, i.e., federal department, may investigate and with the Attorney General's approval commence proceedings if the claim is less than one hundred and fifty thousand dollars. A hearing must begin within six years from the submission of the claim. The Act allows for **civil monetary sanctions** to be imposed in administrative hearings, including penalties incurred per claim and an assessment, in lieu of damages, of not more than twice the amount of the original claim (as amended).

NEW YORK STATE FALSE CLAIMS LAWS AND WHISTLEBLOWER PROVISIONS FALSE CLAIMS AND STATEMENTS - CIVIL MONETARY PENALTIES:

The New York Social Services Law imposes civil liability for anyone that knowingly makes a false statement or representation, or by deliberate concealment of any material fact, on behalf of him or herself or others, to obtain payment from public funds for services or supplies furnished under a Social Services program (such as Medicaid). The government can recover civil damages for a violation of this statute equal to **three** times the amount falsely overstated or **three** times the amount incorrectly paid.

Additionally, the Department of Health may require the payment of an additional monetary penalty as restitution to Medicaid by any person who fails to comply with the standards of the Medicaid program when such person knew, or had reason to know, that: (1) the payment involved the providing or ordering of care, or supplies that were medically improper, unnecessary or in excess of the medical needs of the person to whom they were furnished; (2) the care, services or supplies were not provided as claimed; (3) the person who ordered or prescribed care, services or supplies which were medically improper was suspended or excluded from Medicaid at the time the care, services or supplies were furnished; or (4) the services or supplies for which payment was received were not, in fact, provided.

The New York False Claims Act (State Finance Law §§187-194) is similar to its federal counterpart in that it imposes civil penalties upon parties who knowingly file false and fraudulent claims for payment from any state or local government. This New York law allows private individuals to file lawsuits in state court. If the lawsuit results in repayment to the government, the individual commencing the action may be able to recover a percentage of the proceeds.

FALSE CLAIMS AND STATEMENTS - CRIMINAL PENALTIES:

The New York State Social Services Law also imposes criminal penalties against any person who by means of a false statement, or by deliberate concealment of any material fact, or by other fraudulent device, obtains or aids or abets any person to obtain public assistance or care to

which he or she is not entitled, or does any willful act designed to interfere with the proper administration of public assistance and care.

Such a person shall be guilty of a **misdemeanor**, unless the act is a violation of the New York Penal Law, in which case he or she shall be punished in accordance with the Penal Law. Furthermore, it is also fraudulent for any person who, with intent to defraud, presents for payment any false or fraudulent claim for furnishing services or merchandise, or who knowingly submits false information to obtain greater compensation than legally entitled, or who knowingly submits false information to obtain authorization for furnishing services or merchandise under the New York State Social Services Law. Such a person is guilty of a **Class A misdemeanor**, unless the act constitutes a violation of the New York Penal Law.

While various criminal statutes in New York can potentially be applied to the Medicaid program, Penal Law Article 177 focuses specifically on crimes involving health care fraud. A person is guilty of health care fraud when, with intent to defraud a publicly or privately funded health insurance or managed care plan or contract (such as Medicaid), an individual knowingly and willfully provides false information or omits material information for the purpose of requesting payment from a health plan for health care items or services that the

person is not otherwise entitled to receive. The criminal penalty imposed on such a person corresponds to the amount of payment wrongfully received from a single health plan in a one-year period.

NEW YORK WHISTLEBLOWER PROTECTIONS:

Under certain circumstances, whistleblower protection is available for employees under New York Labor Law (Section 740). It is illegal for employers to take any retaliatory actions (such as discharge, suspension, demotion or other adverse employment action in the terms and conditions of employment) against an employee who discloses, or threatens to disclose to a supervisor or to a public body an activity, policy or practice of the employer that is in violation of law, rule or regulation which violation creates and presents a substantial and specific danger to the public health or safety, or which constitutes health care fraud (as defined in Penal Law Article 177).

An employee who is the subject of such retaliatory action may commence a civil court action within 1 year after the alleged retaliatory action was taken. Such relief may include: (1) an injunction to restrain continued violation; (2) the reinstatement of the employee to the same or equivalent position held before the retaliatory action; (3) the reinstatement of full fringe benefits and seniority rights; (4) the compensation for lost wages, benefits and other remuneration; and (5) the payment by the employer of reasonable costs, disbursements and attorneys' fees.

EXAMPLES OF POSSIBLE FALSE CLAIMS

- Making false statements regarding a claim for payment;
- Falsifying information in the medical record;
- Double-billing for items or services; and/or
- Billing for services or items not performed or never furnished.

WHAT SHOULD BE DONE IF A FALSE CLAIM HAS BEEN MADE

The Center strives to maintain an open line of communication and is committed to ensuring that all staff members and consultants feel comfortable communicating and reporting their concerns regarding false claims internally to the Compliance Officer or other management personnel. The Compliance Officer shall maintain regular office hours (and will also schedule special appointments) in order to address compliance issues with staff members and consultants. The Compliance Officer can be notified verbally, by telephone, e-mail or other electronic communication whenever a compliance issue arises. Compliance Officer can also be contacted via a written statement using either paper or a compliance report form which is available in the Center's business office, whenever a compliance issue arises.

Individuals are not required to report a possible false claims act violation to the Center first. A report can be made directly to the applicable Federal or State authorities. However, in many instances the Center believes that the use of its internal reporting process is a better option because it allows the Center to quickly address potential issues. In any event, the Center will not retaliate against any individual for informing the Center or the Federal or State government of a possible false claims act violation.

An employee with questions regarding this policy should contact the Center's Compliance Officer, Eric Iglewski, at (585) 922-4177 or eric.iglewski@rochesterregional.org.

Effective Date: April 16, 2021