

SUNY DOWNSTATE MEDICAL CENTER

POLICY AND PROCEDURE

No: OCA-4

Subject: Compliance Reporting, Inquiries and Investigations

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Approved by: Compliance & Audit Oversight Committee

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- I. **Purpose:** The purpose of this policy and procedure is to provide Downstate Medical Center’s (DMC) workforce the framework for reporting compliance concerns and the general inquiry and investigative process that DMC follows in the event that a compliance concern has been reported.
- II. **Policy:** SUNY DMC requires all members of its workforce to report any known or suspected violations of laws, regulations or DMC Policies & Procedures.
- III. **Scope:**
 - A. This policy applies to DMC’s:
 - 1. Employees;
 - 2. Residents and fellows;
 - 3. Physicians and allied health professionals appointed to DMC’s Medical Staff;
 - 4. Students;
 - 5. Faculty; and
 - 6. Contractors, subcontractors or agents who, on behalf of DMC, furnish or authorize the furnishing of health care items or services, perform billing or coding functions, or who monitor the health care provided by DMC.

IV. Procedure:

A. General Categories Requiring Reporting: Individuals should report known or suspected violations pertaining to but not limited by the following:

1. Medicare/Medicaid fraud/abuse;
2. Fraudulent billing;
3. Professional & business ethics;
4. Professional standards of practice;
5. Resident work hours & supervision;
6. Patient confidentiality;
7. Patient rights;
8. Conflicts of interest;
9. Bribes/Kickbacks;
10. Substance Abuse;
11. Harassment/Discrimination;
12. Human Subject & Animal Protection;
13. Research Misconduct;
14. Other ethical/legal violations.

Reports should be submitted when a violation is suspected. Even if a caller cannot present proof, any reasonable suspicion of non-compliance should be reported.

B. Methods for Reporting: Any individual who suspects a violation of law, or general wrong doing should contact:

1. The immediate supervisor;
2. The department responsible for the concern;
3. OCAS;
4. DMC's Compliance Line.

The table below represents the various categories of complaints and the relevant departments with expertise in that area to whom such complaint should/may be referred

Referral Table				
Concerns Regarding	Department	Phone	Fax	Box
Legal Issues	OCAS	270-4033	270-4312	1248
	University Counsel	270-4628	270-6749	1258
Disciplinary Issues	Human Resources	270-1191	270-1815	53
	Labor Relations	270-3019	270-4684	1224
Patient Confidentiality	HIPAA Privacy Officer	270-7470	270-4312	1248
Security of Information Systems	Information Security Officer	270-2431	270-1271	17
Patient Abuse	Patient Relations	270-1111	270-2770	23
EEO/Diversity Issues	Office of Opportunity & Diversity	270-1738	270-2276	1220
Research Misconduct	OCAS	270-7470	270-4312	1248
	Research Administration	270-1178	270-1407	69

Concerns Regarding	Department	Phone	Fax	Box
Environmental Health & Safety	FM&D	270-1216	270-2894	13
Threats & Physical Violence	University Police	270-2626	270-4090	1201
Other Compliance Issues	OCAS	270-4033	270-4312	1248

C. DMC Compliance Line

1. DMC's Compliance Line can be utilized to make both reporter identified and anonymous complaints. The option to remain anonymous is solely at the correspondent's discretion. Reports can be made through:
 - a. Calling: 877-3490-SUNY (7869)
 - b. Web Reporting: Click on the "Compliance Line" link found at www.downstate.edu
2. Compliance Line reports, whether by phone or web, are received by independent, third party compliance specialists. Based on the information provided a written report is generated and sent to the OCAS.
3. Based on the nature of the report, OCAS will conduct an inquiry which may lead to an investigation or referral for an inquiry/ investigation to the applicable DMC Department/Administrator or legal counsel.
4. In some instances these reports fall under the protection of Attorney / Client Privilege. In such cases, OCAS will work under the direction of DMC Counsel.

D. Information to be Provided with a Report: Regardless of the method utilized to report a complaint, the same basic information will be collected:

1. **Primary issue of concern-** Reporter will be asked to identify which of the following major classifications & sub-classifications the complaint falls under:

Major Classification	Sub-Classification	Description
Customers, Vendors and Business Partners	Business Relationships	Inappropriate communications or transactions with vendors/business partners such as solicitation or acceptance of gifts, favors or other improper inducements in exchange for influence or assistance in a transaction
EEO/ Diversity Issues	Discrimination	Statements, conduct or actions based on age, race, color, national origin, sexual orientation, gender, disability or religion that are the basis for employment, promotion or compensation decisions.
Environment, Health, Safety and Physical Security	Alcohol and Drug Abuse	Substance abuse in workplace.
	Environmental Concern	Conduct, actions, policies or practices that either violate state or federal environmental laws or regulations or may cause or result in potentially hazardous conditions that impact the environment.
	Safety Concern	Safety issue that could escalate to a violation. Equipment failure, violation in procedure.
	Safety Violation	An actual violation of safety procedures or protocols.
	Threats and Physical Violence	Statements, conduct or actions which threaten acts of violence or the presence of weapons, firearms, ammunition, explosives or incendiary devices in the workplace, on company premises or in company vehicles.

Major Classification	Sub-Classification	Description
HR Administration and Actions	Disciplinary Action	Issues pertaining to unfair terminations, suspensions, or other disciplinary actions.
Legal and Regulatory Issues	Accreditation Issues	Information pertaining to a healthcare facility's evaluation and/or accreditation by TJC or other federal, state or local regulatory agencies. May pertain to evaluation visits or pending visits by agency representatives or information presented to these agencies. May also include information about practices or individual actions that violate regulatory standards and thus jeopardize a facility's accreditation if the specific potential impact on accreditation applies.
	Billing and Coding Issues	Policies, practices or individual actions regarding the billing of patients or payors for health care services, when such practices are unlawful, fraudulent, deceitful or in violation of a contract. "Coding" refers to the way services are described to a payor, such as Medicare or an insurance company, within the bill sent to the payor.
	Conflict of Interest	Potential situation in which a conflict exists between an employee's personal or professional interests conflicts with his/her obligations to the company.
	Drug/Medication Control	Policies, practices or individual actions regarding the handling of drugs and medication. Includes storage, documentation, transport and administration to patients.
	Falsification of Documents	Willful perversion of facts in a company document that has already been released.
	Fraud	Deliberate deception practiced in order to secure unlawful or unfair gain.
	Patient Care	Policies, practices or individual actions causing unacceptable quality of care given to patients. Includes negligence, medical errors, accidents and abuse.
	Patient Confidentiality	The unauthorized or illegal disclosure of personal data which includes but is not limited to employment, medical, financial and individually identifiable health information in violation of HIPAA.
	Research Misconduct	A violation of the standard codes of scholarly conduct and ethical behavior in professional scientific research.
	Sexual Harassment	Statements, conduct or actions expressing unwelcome sexual advances, requests for sexual favors, unsolicited physical contact or propositions, unwelcome flirtations or offensive verbal or visual expressions or physical conduct of a sexual nature.
	Violations of Law	Conduct, actions, policies or practices that violate federal, state or local laws not specifically referred to by other allegation definitions.
Other - Non-allegations	Media Contact	Request for a statement to the press or a caller's threat to reveal information to the press.
	Other	Any allegation, concern, question or inquiry that does not fall within the other categories.
	Request for Guidance	Request for guidance or clarification on matters of concern to employees involving possible violations of company's code of conduct or the law.
Other – Violations or Concerns	General Concern	Statements, conduct, actions or policies that concern the caller but are not currently resulting in harm, injury or corporate liability.
Protecting Company Assets	Equipment Maintenance	Condition and maintenance of equipment used in administering patient care.

Major Classification	Sub-Classification	Description
Cont'd Protecting Company Assets	Theft Impending	Theft that has not yet occurred, but is anticipated to occur.
	Theft Previously Committed	The unauthorized removal or taking of supplies, equipment, furniture, fixtures, products, cash, merchandise or other tangible company product.
	Time Abuse	Theft of company time by an employee who is falsifying timekeeping records.
Workplace Conduct Issues	Workplace Conduct	Concerns about inappropriate conduct in the workplace.

2. **Persons Involved** - Reporter will be given an opportunity to provide their name and contact information. *NOTE: Reporter may also opt to remain anonymous.* Reporter should also provide the names and job titles of other parties involved.
3. **Incident Details** – Reporter will be asked to state their relationship to Downstate (e.g. Employee, contractor, patient) and to provide a full, detailed description of the issue.
4. **Location of Incident** – Reporter will be asked to provide the location in which the issue is occurring.
5. **Other Details** – Reporter will be asked to provide other details pertinent to the complaint, as determined on a case by case basis.
6. **Report Follow Up**- Reporter will be provided with information as to how s/he can obtain follow up information. For Compliance Line callers or web reporters, a reference number is generated which allows the reporter to check back on his/her complaint to review follow up actions taken, to determine whether a complaint has been referred to another department/ area of expertise, to view requests for more information or to establish that a case has been closed.

E. Allegation Inquiry Phase

1. Based on the information reported, an inquiry will be conducted to determine whether an investigation is warranted. In instances where OCAS does not have the requisite expertise in the subject matter of the inquiry, it will triage the inquiry to the responsible party/ department and may, in addition, serve as the Compliance Administrator for the inquiry; including providing staffing for the inquiry review, establishing the inquiry structure, researching the relevant regulatory information and facilitating the non- expert related aspects of the review.
2. The inquiry examiner(s) will evaluate the data, including any statements, listing of parties involved or other evidence provided by the Reporter. Interviews may be conducted in the course of an inquiry as necessary.
3. Based upon this review, a determination will be made as to whether a formal investigation is warranted. The results of the inquiry will be communicated to the relevant parties and the Compliance Line database will be updated accordingly.
4. When an inquiry determines that an investigation is not warranted, the Reporter will be notified via the method in which their issues were communicated. Compliance

Line reports will be updated with this determination and the case will be marked 'unsubstantiated' and subsequently closed.

5. In some instances, an inquiry will determine that further information is needed. The Reporter may be asked to provide additional facts (via the method in which their issues were communicated).

F. Allegation Investigation Phase

1. Upon conclusion of an inquiry and a consensus of its determination, an investigation should commence as soon as reasonably practical. The purpose of an investigation is to develop a factual record by exploring the allegation(s) in detail and examining the evidence in depth in order to identify findings on whether a violation has occurred, by whom and to what extent. An investigation may also determine whether additional instances of a violation have occurred that would justify broadening the scope beyond the initial allegations.
2. Investigations will be conducted by individuals who have the appropriate expertise to evaluate the evidence and issues related to the allegation(s), interview relevant parties as appropriate and sufficiently document their review.
3. Investigators must:
 - a. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented, including an examination of all relevant records and evidence;
 - b. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
 - c. Interview all listed parties and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation;
 - d. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible violations, and continue the investigation to completion.
4. An investigation report will typically include the following:
 - a. A description of the nature and specifics of the allegation(s), including a listing of relevant parties identified;
 - b. The names, titles and departments of the investigation team;
 - c. A listing of all interviews conducted with summaries of any relevant information obtained;
 - d. Identification of and summary of the records and evidence reviewed;
 - e. A statement of findings for each alleged violation identified during the investigation;
 - f. A listing of recommended mitigation if a violation has been determined; and
 - g. A listing of other recommendations and/ or disciplinary action referral if a violation has been determined.
5. A summary of the investigation results will be entered into the Compliance Line database. The Reporter will be notified of the investigation's outcome via the method in which their issues were communicated. Based on the outcome of the

investigation, the case will be marked Substantiated, Partially Substantiated or Unsubstantiated and subsequently closed.

G. Disciplinary Action

1. OCAS reports the results of the investigation to senior management who makes a determination as to whether disciplinary action is necessary. In such instances, a referral is made to the Office of Labor Relations who is responsible for executing the appropriate disciplinary measure.
2. Disciplinary actions taken will be determined dependent on the circumstances of the violation. Particular measures will be used to establish appropriate disciplinary action, including:
 - a. Whether the violation was negligent or intentional;
 - b. Whether the violation was isolated or repeated;
 - c. The nature and extent of harm caused by the violation;
 - d. Whether the violation involved personal gain;
 - e. Whether and to what extent the person assisted to discover and remedy the violation;
 - f. The hierarchical level and degree of discretionary authority of the offender; and
 - g. Whether lesser or alternative forms of redress fully address the violation and meet the goals of an effective compliance program.
3. The purpose in appropriately responding to and administering disciplinary measures is to prevent the reoccurrence of non-compliant behavior.

H. Confidentiality

1. Individuals who report in good faith are granted confidentiality to the extent possible. However, a reporting individual's identity may become known during the normal course of an inquiry or investigation.
2. All individuals involved in an inquiry or investigation must maintain confidentiality during the course of their review and any subsequent determination thereafter.

I. Non- Intimidation and Non- Retaliation- No supervisor, manager or other employee is permitted to engage in retaliation, retribution, intimidation or harassment against an individual for reporting a concern.

J. Reporting and Refunding of Overpayments- The results of the inquiry/investigation will determine whether any reporting is required to external agencies/oversight bodies. OCAS will coordinate such reporting at the direction of or in tandem with SUNY DMC Counsel, as well as assist in identification of any potential overpayments for refund.

K. References – SUNY Downstate Compliance Program

L. Associated Documents - Compliance Line Brochure, Compliance Inquiry Template, Compliance Investigation Template

Date Reviewed	Revision Required (Circle One)		Responsible Staff Name and Title
12/2016	(Yes)	No	Alexandra Bliss