



DOCUMENT TITLE: Responding to Government Inquiries	SYSTEM POLICY AND PROCEDURE MANUAL
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Prepared by: Office of Legal Affairs; Office of Corporate Compliance	Notations: N/A

GENERAL STATEMENT of PURPOSE

The purpose of this document is to establish a uniform procedure for responding to government inquiries, including but not limited to informal or letter requests for records, on-site audits and investigations, requests for interviews, execution of search warrants, and service of subpoenas for documents or testimony at trial or deposition (hereinafter collectively referred to as an “Inquiry” or “Inquiries”).

POLICY

It is the policy of Northwell Health to cooperate with requests from government agencies for information pertinent to an Inquiry. Inquiries must be conducted in accordance with procedures established by law, and, because Inquiries may relate to multiple departments, all appropriate stakeholders must be notified to ensure an appropriate response. For these reasons, upon receipt, all Inquiries shall be immediately forwarded and handled as follows:

1. Except as provided in paragraphs 2 through 6 below, all Inquiries shall be faxed or transmitted electronically on the day of receipt to the Office of Legal Affairs (“Legal Affairs”) for review prior to responding to the Inquiry, and shall be handled in accordance with the process described below.
2. Audit notices shall be referred to the Chief Financial Officer of Northwell Health. *See Procedures, Section C below.*
3. Routine and non-material overpayment notices from a fiscal intermediary or carrier that are reconciled or adjusted by Finance through established policies and procedures of the payor shall be referred to Northwell Health’s Chief Financial Officer. *See Procedures, Section D below.*

4. Pre-scheduled and unannounced site visits by the N.Y.S. Department of Health, the N.Y.C. Department of Health, and/or the Connecticut Department of Public Health in response to patient complaints, reportable incidents and other public health or Article 28 compliance matters, shall be handled in the first instance by site Administration/Quality Management. See Procedures, Section E below; and also *Northwell Health Administrative Policy #100.29 Regulatory and Accrediting Agency Inspections and Surveys Policy*.
5. Requests in connection with an investigation of patient complaints, adverse event, and/or licensure of a Northwell provider, inclusive of requests by the N.Y.S. Department of Health (including the Office of Professional Medical Conduct (“OPMC”) or the N.Y.S. Department of Education (including the Office of Professional Discipline (“OPD”)), shall be referred to Quality Management, which shall thereafter re-direct the request to the relevant stakeholders and custodians of records as may be relevant to the request. See Procedures, Section F, below.
6. Inquiries related to research inspections or audits from federal or state regulatory authorities such as the U.S. Food and Drug Administration, the Office of Human Research Protections, the Office of Inspector General, the Office of Research Integrity or others should be referred to the Office of Research Compliance. Refer to *Northwell Health Research Policy #GR027 “Preparation for an External Regulatory Research Inspection or Audit as a Research Site.”*

SCOPE

This policy applies to all Northwell Health employees, as well as medical staff, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health; faculty and students of the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell or the Hofstra Northwell School of Nursing and Physician Assistant Studies conducting research on behalf of the Zucker School of Medicine on or at any Northwell Health facility; and any other Affected Individual.

DEFINITIONS

Affected Individuals: “Affected Individuals” is defined as all persons who are affected by Northwell Health’s risk areas including, but not limited to, Northwell Health’s employees, the chief executive and other senior administrators, managers, medical staff members, contractors, agents, subcontractors, independent contractors, and governing body and corporate officers.

PROCEDURE

A. **Inquiries Initiated by Mail, Fax or Email**

Except for inquiries described in paragraphs 2 through 6 of the Policy section above, the following procedures shall be followed when an Inquiry is initiated by mail, fax or email:

- (1) ***Notice of Inquiry.*** Any Northwell Health facility receiving a notice of an Inquiry shall immediately forward a copy of the notice by fax (516-321-6360) or electronic mail to the attorney-on-call in Legal Affairs (LegalAffairs@northwell.edu) on the day received, and shall call Legal Affairs (516-321-6650) to confirm receipt. If the Inquiry is time sensitive, the transmittal should be marked “Immediate Attention Required.”
- (2) ***Notification to Office of Corporate Compliance and Administration.*** The General Counsel, or his/her designee, shall, when applicable, inform the Chief Corporate Compliance Officer/designee, as well as the relevant facility, service line and/or business unit(s) of the Inquiry.
- (3) ***Response.*** For all such Inquiries, Legal Affairs and, when applicable, the Chief Corporate Compliance Officer/designee, shall determine who will assume primary responsibility for coordinating the response and any communication with government agencies.
- (4) ***Notification to Stakeholders.*** The individual(s) designated to coordinate the response to the Inquiry shall promptly identify and notify the facilities, departments, and entities or individuals who need to be involved in collecting records and responding to the Inquiry. Such additional parties may include Finance, Physician and Ambulatory Network Services, Risk Management, Quality Management, Health Information Management, Medical Staff Services, clinical departments, outside legal counsel and other stakeholders.
- (5) ***Preservation and Collection of Materials.*** Legal Affairs, or the individual(s) designated to coordinate the Inquiry response (in consultation with and/or at the direction of Legal Affairs), may request retention/preservation of relevant documents and/or implement a “hold” on any regularly-scheduled archiving or destruction of records. If documents have been requested or may need to be preserved, the individual(s) designated to coordinate the response shall notify those identified stakeholders of the required timeframe for collection of applicable materials.
- (6) ***Initial Meeting or Other Contact with Stakeholders.*** As soon as practical, the individual(s) designated to coordinate the response to the Inquiry will organize a meeting or call(s) with relevant stakeholders to discuss the Inquiry and Northwell Health’s response. During the meeting/call(s), the participants will define the timeframes for collecting the information, provide instructions for a review of the records, designate the individual(s) responsible for preparing the response and otherwise assign tasks to various responsible parties.
- (7) ***Extensions.*** If an extension of time is needed to respond to the Inquiry, the individual(s) designated to coordinate the response to the matter, in coordination with (and depending on the matter, under direction of) Legal Affairs, shall determine the appropriate person to request such an extension.
- (8) ***Briefing to Administrative Team.*** The individual(s) designated to coordinate the response

to the matter shall be responsible for periodically briefing facility and Northwell Health leadership as to the status of the response and any issues that may arise in connection therewith. Depending on the circumstances surrounding the Inquiry, the individual(s) may be a member of Legal Affairs, or if not, may be conducting the briefing at the direction of Legal Affairs.

B. Inquiries Initiated by Phone

Certain facilities have recently seen an increase in fraudulent and malicious calls from individuals posing to be from government agencies or law enforcement. The purpose of these calls is often to solicit sensitive information, such as professional licensing numbers and National Provider Identifier (“NPI”) numbers. Therefore, for inquiries initiated by phone from an individual who claims to be a government agency or law enforcement representative, and when it is not clear that the caller is who they say they are, the recipient of the call should ask for the individual’s contact information, including their full name and phone number. The team member should ask the caller to send a follow-up e-mail and state that someone will respond within a reasonable timeframe. The recipient of the call should report the call to the Digital IT&S Service Desk and forward all information to the Office of Legal Affairs and/or Risk Management, in order to determine who will assume primary responsibility for coordinating the response and any communication with government agencies or law enforcement.

C. On-Site Visits by Government Representatives

An appropriate response to a government on-site visit depends on the nature of the visit. As explained below in parts (1) and (2), responding to a subpoena and responding to a search warrant require separate procedures.

(1) *Responding to Search Warrants*

Search Warrant: A search warrant is a document issued by a judge that permits government agents to immediately search and seize tangible property that is specifically identified in the search warrant or located in an area specifically identified as covered by the search warrant. While most search warrants seek to seize documents or other tangible items, it can also seek to obtain physical evidence from someone’s person (e.g., blood sample from a patient).

Except for pre-scheduled and unannounced site visits by the N.Y.S. Department of Health, the New York City Department of Health, and/or the Connecticut Department of Public Health in response to patient complaints, reportable incidents and other public health or Article 28 compliance matters, which are handled in the first instance by site Administration/Quality Management (*see Procedures, Section E, below*) and except for pre-scheduled and unannounced site visits by accrediting agencies as set forth in *Northwell Health Administrative Policy #100.29 Regulatory and Accrediting Agency Inspections and Surveys*, the following procedures shall be followed in the event of a search warrant being executed at Northwell Health:

(a) Request to see identification from the government representative(s) and write down

those individuals' names, agency, and phone number; ask for business cards from the representatives; and ask for a copy of the search warrant. If the representative does not produce an ID card or business card, ask for his/her name and title, office address and phone number and agency name and identification number.

- (b) If the government representative does not produce a search warrant and still wants to search the premises, politely ask the representative to wait in the lobby until you have an opportunity to speak with Legal Affairs. In the case of Provider enrollment related visits by representatives of CMS contracted entities, Legal Affairs should be notified.
- (c) Immediately notify Legal Affairs (via the attorney-on-call at 516-321-6650) and the appropriate site Administration representative of the visit and fax or e-mail the search warrant (if one is produced by the government representative) to the Office of Legal Affairs.
- (d) Assuming a valid search warrant is produced, politely tell the lead government representative that Northwell Health is represented by legal counsel and request that the lead government representative and any accompanying other government representatives wait in the lobby until legal counsel arrives. If the lead representative refuses to wait, offer to put the representative on the phone with the attorney-on-call. You should inform the government representative that you do not have the authority to consent to the search, but you will not prevent or obstruct them from acting immediately. Regardless of whether representatives from the government agree to wait for legal counsel or talk to legal counsel, do not prevent or interfere with any government representative's search, and at no point make physical contact with any government representative.
- (e) Legal Affairs, in consultation with the facility, will designate a representative who shall make him/herself known to the employees on-site and to the government agent in charge of the visit as the primary contact for all purposes of the visit ("Designated Liaison") who will perform the following tasks.
 - (i) Remain in close contact with Legal Affairs (or its designated legal contact) during the execution of the search warrant.
 - (ii) Immediately refer any questions or issues to Legal Affairs.
 - (iii) To the extent possible, make copies of any original documents being taken and create a search log (list or inventory) documenting any seized items and areas searched, as well as ask to retain a copy of any log created by the government. To this end, the Designated Liaison should monitor the search, if permitted by government representatives, but in no event shall the Designated Liaison interfere with the search. If possible, note in the log the lead investigator, including name and phone number, and all law enforcement

personnel and agencies involved.

- (iv) Since a search warrant does not empower the government to conduct compulsory interviews while executing the warrant, no employee is required to speak with the government during the course of the search or answer any questions except those relating to the location of documents. The Designated Liaison shall immediately notify Legal Affairs if government representatives seek to interview any Northwell Health employee. See Section 3 below for additional information regarding responding to requests for interviews by government representatives.
 - (v) If government representatives appear to be violating applicable health and safety rules or regulations, the Designated Liaison shall immediately notify Legal Affairs, shall politely notify the government representatives of the relevant health and safety regulations, and note this in the facility's search log.
 - (vi) If any documents or equipment that is being seized are immediately necessary to the care of patients, the Designated Liaison shall immediately inform the lead government representative and notify Legal Affairs. The Designated Liaison may ask the government representative if he or she may copy all the files in the equipment (e.g., computer, hard drive) to a disk before it is seized.
 - (vii) If government representatives attempt to seize documents essential to the operation of the facility or documents that are required by law to be maintained on site, the Designated Liaison shall immediately notify Legal Affairs.
 - (viii) If government representatives attempt to review or seize documents that appear to be communications with Northwell Health lawyers or work product created by Northwell Health lawyers, the Designated Liaison shall immediately notify Legal Affairs.
- (f) Under no circumstances shall any Northwell Health employee attempt to interfere in any way with the conduct of the search by government representatives, the examination of any particular area, or the seizure of equipment, documents, or any other type of evidence covered by the search warrant.

(2) *Responding to Subpoenas*

Subpoena: A subpoena is a court or administrative order issued by a government agency requiring a person to appear and testify in court or elsewhere. A subpoena *duces tecum* directs a person to produce documents to a court or government agency, which could also require the person to accompany the records and testify as a witness. In most situations, a subpoena will have a "return date" (ranging from a few days to several weeks in the

future) at which time the named person or entity has to comply with the subpoena. Therefore, acceptance of the subpoena is all that is required at the time of service.

- (a) All individuals seeking to serve subpoenas on Northwell Health should be directed to Administration to accept service of a subpoena by an authorized person in the Administration Department, including signing the receipt of service (the “Administration Representative”).
- (b) Upon acceptance of service, the Administration Representative shall request identification of the individual serving the subpoena. The Administration Representative shall immediately notify Legal Affairs (via the attorney-on-call at 516-321-6650) of the visit and fax (516-321-6360) or e-mail the subpoena to the Office of Legal Affairs at LegalAffairs@Northwell.edu.
- (c) A subpoena or a subpoena *duces tecum* ordinarily does not entitle government representatives to seize documents immediately or to conduct compulsory interviews at the time of service. As such, you do not need to provide the individual serving the subpoena with any information or documents. If, however, a government representative requests interviews or documents at the time of service, the Administration Representative should politely ask the serving individual(s) or government representative to wait in the lobby while the Administration Representative contacts Legal Affairs. See Section 3 below for additional information regarding these requests for interviews.
- (d) Once the government representative, or serving party, has left the facility, Legal Affairs and, when applicable, the Chief Corporate Compliance Officer, or his/her designee, shall determine who will assume primary responsibility for coordinating the response. Thereafter, the procedures outlined in Section A, parts (4) through (9) shall apply.

(3) *Responding to Requests for Interviews*

- (a) A government representative may visit Northwell Health employees at home or work and request to interview them about some aspect of his/her employment. Each employee has the right to decide whether to speak with a government representative. However, the employee also has the right to request that the interview take place at a future date after the employee has an opportunity to prepare for the interview and decide if the employee wants to be represented by an attorney during the interview.
- (b) Northwell Health may provide legal counsel to assist the employee prepare for an interview with the government and/or attend the interview with the employee. An employee may consult with an outside attorney on their own, but Northwell Health requests that the employee contact Legal Affairs prior to engaging outside legal counsel.

- (c) If an employee chooses to be interviewed by a government representative before contacting Legal Affairs, the employee is requested to contact Legal Affairs as soon as possible after the interview. The employee should also not disclose information covered by Northwell Health's attorney-client privilege.
- (d) If an employee is asked to sign an affidavit on behalf of Northwell Health, the employee should not comment on it, but should explain that the employee is not authorized to sign any document on behalf of Northwell Health prior to review by Legal Affairs.

(4) *Responding to News Media*

Except as outlined in this policy, Northwell Health employees should not discuss matters related to a government investigation with anyone other than Northwell Health team members and representatives responsible for investigating the matter on behalf of Northwell Health. In matters conducted under the attorney-client privilege, Northwell Health employees shall only discuss the investigation with Legal Affairs or with individuals acting on behalf and at the direction of Legal Affairs.

All media inquiries related to a government investigation shall be directed to Northwell Health's Office of Public Relations. No Northwell Health employee shall speak with the media or respond in any manner to inquiries from the media about matters pertaining to government investigations unless specifically authorized to do so by the Office of Public Relations.

D. Audits

The following procedures shall be followed upon receipt of notice of a government-initiated audit:

- (1) ***Notice of Audit.*** A copy of the audit notice shall be immediately forwarded to the Chief Financial Officer and Chief Corporate Compliance Officer of Northwell Health.
- (2) ***Response to Audit.*** Finance shall assume primary responsibility for coordinating the response to all audits, in consultation with Legal Affairs, the Office of Corporate Compliance and/or any other relevant business unit as appropriate and necessary.
- (3) ***Audit Log.*** Finance shall maintain a log of all audit notices received by Northwell Health. This log shall include a summary of the audit findings and the amounts of any repayments made as a result thereof. This log shall not include routine and non-material overpayments that are routinely reconciled or adjusted by Finance through established policies and procedures of the payor. A copy of this log shall be provided to the Office of Corporate Compliance on a monthly basis.

(4) **OMIG Compliance Program Reviews.** Nothing shall preclude or limit OMIG's ability to determine if a required provider has an effective Compliance Program. OMIG may, at any time, review to determine if a required provider has adopted, implemented and maintained a compliance program as required by 18 NYCRR § 521 Compliance program reviews to confirm that:

- (a) The adopted compliance program satisfies the requirement of an effective compliance program;
- (b) The adopted compliance program has been implemented and that Northwell Health has continuously operated such program for the entire period under review;
- (c) That Northwell Health met the criteria requiring the adoption, implementation and maintenance of such programs; and
- (d) The adopted, implemented and maintained compliance program is effective.

E. **Overpayment Notices**

Routine and non-material overpayment notices received from a fiscal intermediary or carrier that are reconciled or adjusted by Finance through established policies and procedures of the payor shall be referred to the Chief Financial Officer of Northwell Health immediately upon receipt. Finance shall notify the Office of Legal Affairs and the Corporate Compliance Office only if Finance deems it necessary or appropriate to do so in the circumstances (e.g., in cases where there is a large sample size or the fiscal intermediary or carrier has performed an extrapolation).

N.Y.S. Self-Disclosure Protocol

This is a process by which persons who have identified an overpayment under the Medical Assistance program, report, return and explain overpayments to the Medical Assistance program. The Self-Disclosure statement shall be signed by Northwell Health's Compliance Officer. OMIG shall acknowledge receipt and review the Self-Disclosure and consider any written requests.

F. **Site Visits by N.Y.S. Department of Health, the N.Y.C. Department of Health, and/or the Connecticut Department of Public Health**

Pre-scheduled and unannounced site visits by the N.Y.S. Department of Health, the N.Y.C. Department of Health, and/or the Connecticut Department of Public Health in response to patient complaints, reportable incidents, public health issues and other public health or Article 28 compliance matters, shall be handled in the first instance by site Administration/Quality Management. Quality Management shall notify Risk Management whenever any site visit involves a patient complaint or other incident that may result in a liability claim. In addition, if Quality Management deems it necessary or appropriate in the circumstances, Legal Affairs and/or the Corporate Compliance Office also shall be notified.

New York State Department of Health visits may result in citation of Article 28 deficiencies, which require future response by the Northwell Health facility. Quality Management shall

coordinate the preparation of all Plans of Correction in response to any Statement of Deficiencies.

G. Inquiries Requesting Medical, Quality Assurance, Peer Review and Credentials Records

Inquiries, including document requests, by the N.Y.S. Department of Health, the N.Y.C. Department of Health, and/or the Connecticut Department of Public Health that pertain to patient complaints, reportable incidents, credentialing and/or quality records, public health issues and other public health or Article 28 compliance matters, shall be handled in the first instance by site Administration/Quality Management.

Quality Management. Quality Management shall notify Risk Management whenever any Inquiry involves a patient complaint or other incident that may result in a liability claim. In addition, if Quality Management deems it necessary or appropriate in the circumstances, Legal Affairs and/or the Corporate Compliance Office also shall be notified.

The following procedures shall be followed upon receipt of an Inquiry requesting patient medical records, quality assurance, peer review or credentialing files:

- (1) Health Information Management, Quality Management and Medical Staff Services shall each maintain a log of all such Inquiries received and the individuals/offices to whom copies of each such Inquiry is sent in accordance with paragraph (2) below.
- (2) Any individual or office receiving such an Inquiry shall scan and email it, or fax it, as follows:
 - (a) To Legal Affairs for review to determine whether the requesting government agency has the authority to request the records and that the request is in accordance with law, and whether the Inquiry may be related to any matter being handled by Legal Affairs.
 - (b) To Quality Management and Risk Management for review to determine whether the Inquiry may be related to any matter being handled by one or more of those offices/departments. If there is a clear indication that the record request relates to a quality-of-care issue, then Quality Management also shall review the records and notify Legal Affairs and Risk Management of its findings.
 - (c) If medical records are being requested:
 - (i) To Health Information Management for retrieval of the records and review thereof to ensure they are in proper order and contain only the relevant information requested; and
 - (ii) If applicable, to the Assistant Vice President for Clinical Documentation Management, or other appropriate staff, in Finance, who shall review the records to ensure that the billing was appropriate.

- (d) If credentialing records are being requested, to Medical Staff Services for retrieval of

the records and review thereof to ensure they are in proper order and contain only the relevant information requested.

- (3) If the individual/office that received the Inquiry is not the individual/office responsible for maintaining or retrieving the requested record(s), then the request shall be immediately forwarded to the appropriate person or office, and the offices/individuals identified in paragraph (2) above shall be notified.
- (4) The individual/office responsible for maintaining the requested records shall arrange for their retrieval; is responsible for ensuring that the above-described reviews are conducted in a timely fashion; and is responsible for ensuring that the records are ready for production to the government prior to the deadline stated in the Inquiry, or any extension thereof.
- (5) After the above reviews have been completed, any issues concerning the records shall be discussed with Legal Affairs and/or Corporate Compliance, as appropriate.
- (6) *Extensions.* If an extension of time is needed to respond to the Inquiry, then the individual responsible for maintaining or retrieving the requested records shall, in consultation with Legal Affairs, determine the appropriate person to request such an extension.

REPORTING AND ENFORCEMENT

All violations of this policy shall be reported to the appropriate manager/supervisor/director or to the Office of Corporate Compliance (516-465-8097) for appropriate resolution of the matter. The HelpLine is available 24 hours a day, seven days a week at (800) 894-3226 or online at www.northwell.ethicspoint.com, is accessible to all Affected Individuals and allows for questions regarding compliance issues to be asked and for compliance issues to be reported. Reports of potential fraud, waste and abuse and compliance issues also may be made directly to the Chief Corporate Compliance Officer or designee in person, in writing, via email, mobile device via a QR code, or by telephone. All reports received by the Office of Corporate Compliance are investigated and resolved to the fullest extent possible. The confidentiality of persons reporting compliance issues shall be maintained unless the matter is subject to a disciplinary proceeding, referred to, or under investigation by Medicaid Fraud Control Unit, U.S. Department of Health and Human Services (HHS), Office for Civil Rights, HHS, Office of Inspector General Office of Medicaid Inspector General or law enforcement, or disclosure is required during a legal proceeding, and such persons shall be protected under Northwell Health's policy for non-intimidation and non-retaliation. Violations of this policy will be subject to disciplinary action as outlined in the Human Resources Policy and Procedure Manual and *Northwell Health Policy #800.73 – Compliance Program Disciplinary Standards for Non-Employees*.



REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- Northwell Health Administrative Policy #100.16 – Service of Legal Papers
- Northwell Health Administrative Policy #GR027 – Preparation for an External Regulatory Inspection or Audit at a Research Site
- Northwell Health Administrative Policy #100.29 – Regulatory and Accrediting Agency Inspections and Surveys.
- Northwell Health Corporate Compliance Policy #800.42 – Confidentiality of Protected Health Information.
- Northwell Health Policy #800.73 – Compliance Program Disciplinary Standards for Non-Employees
- Northwell Health Administrative Policy #900.11 – Electronic Communications Policy
- Northwell Health Human Resources Policy and Procedure Manual, Part 5-3 – Workforce Conduct – Progressive Discipline
- NY Office State Comptroller - Responding to an OSC Audit Report: Audit Responses and Corrective Action Plans - <https://www.osc.state.ny.us/local-government/audits/responding-osc-audit-report-audit-responses-and-corrective-action-plans>
- NYS OMIG Audit Protocols - <https://omig.ny.gov/audit/audit-protocols>
- OMIG Compliance Program Guidance, Title 18 NYCRR § 521 – Fraud, Waste and Abuse Prevention (March 28, 2023)
- 18 NYCRR § 517 – Provider Audits
- 18 NYCRR § 518 – Recovery and Withholding of Payments or Overpayments
- SOS § 363-D – Provider compliance program

CLINICAL REFERENCES/PROFESSIONAL SOCIETY GUIDELINES

N/A

ATTACHMENTS

N/A

FORMS

N/A

APPROVAL:	
Service Line/Department Review	07/10/2025
Northwell Health Policy Committee	07/22/2025❖
System PICG/Clinical Operations Committee	07/22/2025❖

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