

Applicability:	UW Medicine ¹ and UW Medicine Affiliated Covered Entity ²
Policy Title:	Compliance Investigations
Policy Number:	COMP.005
Superseded Policies:	PP-05 Complaints and Incidents Related to Privacy and Information Security HMC, 135.3 Compliance Program Investigations, Enforcement and Prevention HMC, 135.15 Compliance Corrective Actions and Sanctions NWH, Compliance Issue Resolution VMC, Corporate Compliance Issue Remediation Policy & Procedure VMC, Compliance Investigations Policy & Procedure UWMC, 15-48 Performance Management and Corrective Actions UWMC, 15-9 Organizational Response UWNC, Compl011 Organizational Response to Compliance Violations UWP, C-006 Addressing Reported Concerns
Date Established:	October 11, 2017
Date Effective:	November 9, 2023
Next Review Date:	November 9, 2026

PURPOSE

This policy establishes the framework for managing and responding to alleged, suspected, or potential violations of UW Medicine compliance policies or related state and federal laws and regulations. It applies to all UW Medicine compliance departments and related designated institutional officials who participate in the investigative process.

¹ UW Medicine is an integrated clinical, research and learning system with a single mission to improve the health of the public. This policy applies to the UW Medicine workforce and also those employees in shared services and the UW Medicine central leadership who support the clinical operation of UW Medicine. The clinically integrated parts of UW Medicine consist of the following:

- Airlift Northwest
- Fred Hutchinson Cancer Center (* Please note, the UW Medicine Compliance Program and this policy apply to UW faculty. Fred Hutch employees who are not also UW faculty are required to comply with Fred Hutch compliance policies only.)
- Harborview Medical Center
- UW Medical Center
- UW Medicine Primary Care
- UW Physicians
- UW School of Medicine
- Valley Medical Center

² The University of Washington (UW) is a hybrid covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), comprised of healthcare and non-healthcare components. For the purposes of HIPAA, the UW has designated healthcare components, and further designates a group of healthcare components to be one affiliated covered entity known as UW Medicine Affiliated Covered Entity (UW Medicine ACE). Healthcare components of the UW Medicine ACE are represented in [101.G1 University of Washington \(UW\) HIPAA Designation](#) – UW Medicine – Affiliated Covered Entity.

For specific procedures related to compliance investigations involving UWP billing providers, please see [UWP Reported Concern Investigations: Standard Operating Procedures](#).

DEFINITIONS

See [UW Medicine Compliance Glossary](#).

POLICY

1. The compliance department investigates compliance concerns and potential or suspected violations within its scope and jurisdiction.³ Concerns and suspected violations may be reported by workforce members, patients or the public, conveyed by regulatory agencies, discovered in compliance audits or identified from other types of information.
2. Investigations are coordinated by the compliance Director with scope and jurisdiction over the issue. Investigations are completed in a timely manner, consistent with best practices and are documented. Investigations satisfy regulatory timelines and requirements, meet applicable federal and state laws and adhere to internal procedures. Reasonable and appropriate methods are used to determine relevant facts and circumstances, and external auditors, legal counsel, human resources, information technology and other experts are engaged as necessary throughout the investigative process.
3. When a concern or issue is received, the Director or his/her designee, conducts an evaluation and assigns a priority ranking based on the criteria below. The Director may revise the priority ranking as appropriate to the circumstances. The priority for addressing any compliance concern is the prompt and accurate identification of the issue and its scope. Complex compliance issues/concerns may take additional time to accurately identify the issue and scope. Privacy investigations may have unique regulatory timelines.

High risk concerns will be communicated to the appropriate UW Medicine leadership.

Priority Ranking	Criteria	Timeline Goal
High	<p>Investigation involves urgent issue, resolution needed as soon as possible due to potentially damaging impact to the organization or an individual (continued incorrect billing of high-volume service; patient information would continue to be vulnerable to improper disclosure if issue were to remain unaddressed).</p> <p>There is credible evidence of fraud.</p> <p>Not an isolated incident but is systemic within the organization.</p>	<p>Issues of this level warrant the highest priority. Investigations should be initiated as soon as possible.</p>

³ Issues reported to compliance but not within its scope and jurisdiction are referred to designated institutional officials with the appropriate scope and jurisdiction.

Medium	Investigation involves important issue/problem and should be addressed as soon as feasible.	Issues at this level are important and investigation should be initiated as soon as feasible, preferably within 5 business days of notification.
Low	Investigation involves non-urgent issue, that can be scheduled.	Initiate investigation within 10 business days of notification.

4. During an investigation, the compliance Director or designee collaborates with the manager or supervisor of the individual or department under investigation. Managers and supervisors determine role-based activities, participate in fact-finding, receive findings, determine corrective actions, implement corrective actions, and report completion of corrective actions.
5. Human Resources administers and advises managers and supervisors regarding personnel related policies and procedures, employment contracts and appropriate disciplinary action, also conducting investigations when needed. Human Resources participates in and leads interviews with managers and unions when the conduct of an employee is under investigation.
6. Findings are determined by compliance staff and are reported in writing to designated institutional officials who have responsibility for enforcement, discipline and corrective actions.⁴ Findings are in writing, and at a minimum, identify the relevant policy and whether or not a violation has occurred. Certain findings are reporting requirements may be subject to the following additional policies:
 - Billing and coding errors must be promptly reported and remediated in accordance with [COMP.204 Identifying, Reporting and Returning Overpayments Related to Government Reimbursement](#).
 - Privacy breaches must be promptly managed in accordance with [COMP.105 Breach Notification](#).
 - See [UWP Reported Concern Investigations: Standard Operating Procedures](#) for additional requirements related to compliance investigations of UWP billing providers.
7. Subjects of an investigation are:
 - Treated fairly, respectfully, and consistent with institutional protection policies.
 - Informed about the nature of concerns being investigated.
 - Expected to cooperate fully with investigations and respond to requests for information within a reasonable time frame.
 - Provided with information throughout the investigation when doing so would not compromise the integrity of the process.
 - Placed on administrative leave during the investigation if warranted.
8. Documents, including those created or compiled during the investigation, are maintained in accordance with UW Medicine records retention policies.

⁴ See [COMP.006 Corrective Actions](#).

REGULATORY/LEGISLATION/REFERENCES

- United States Sentencing Commission, [Guidelines Manual](#), §8B2.1 (Nov. 2016).
- Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (February 23, 1998).
- Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (January 31, 2005).
- [Centers for Medicare and Medicaid Services \(CMS\), Medicare Managed Care Manual, CMS Pub. 100-16, Chap. 21 \(Rev. 110, Jan. 11, 2013\)](#).
- [CMS, Medicare Prescription Benefit Manual, CMS Pub. 100-18, Chap. 9 \(Rev. 16, Jan. 11, 2013\)](#)

PROCEDURE ADDENDUM(s) REFERENCES/LINKS

- [UW Medicine Compliance Glossary](#).
- [005.G1 Compliance Investigations: Standard Operating Procedures](#).
- [005.G2 UWP Reported Concern Investigations: Standard Operating Procedures](#).

APPROVALS

/s/ Beth DeLair

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1/12/2024

Date