

Applicability:	UW Medicine ¹ and UW Medicine Affiliated Covered Entity ²
Policy Title:	Government Investigations
Policy Number:	COMP.008
Superseded Policies:	VMC, Response to Government Investigations UWMC, 15-5 Response to Government Investigations and Subpoenas
Date Established:	October 11, 2017
Date Effective:	June 20, 2024
Next Review Date:	June 20, 2027

PURPOSE

The purpose of this policy is to ensure enterprise-wide consistency in responding to government investigations, reviews, or audits and subpoenas involving healthcare compliance matters. It applies to all UW Medicine entities, departments and individual workforce members. Please note, this policy does not include governmental investigations involving non-UW Medicine compliance matters such as Department of Health investigations of our licensed providers/facilities.

DEFINITIONS

See [UW Medicine Compliance Glossary](#).

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](#).

POLICY

UW Medicine cooperates fully with legally authorized government investigations and subpoenas³, involves designated institutional officials throughout the process, produces records in a timely manner and retains appropriate documentation in accordance with established record retention schedules.

I. Responsibility for Implementation

UW Medicine is a complex organization with numerous offices that have sole or matrixed responsibilities for certain issues. Responsibility for implementing this policy is shared by UW Medicine Compliance, entity leadership, UW Medicine shared services leaders and workforce members.

- A. All actions or activities in which a workforce member is approached by someone claiming to be a government investigator or agent on behalf of a government agency, or who receives a subpoena or other written, official governmental request for information (such as a Civil Investigative Demand) related to a healthcare compliance investigation must be reported as soon as possible to UW Medicine Compliance at (206) 543-3098 or comply@uw.edu.
- B. UW Medicine Compliance will take the lead coordinating and overseeing any applicable response, including, but not limited to:

Issuing required notifications regarding the visit;

- Ensuring appropriate documentation and adequate information about the purpose and extent of the visit is obtained before the investigation, review or audit commences;
- Ensuring each individual understands their role and responsibility, the authority of the external reviewers and the compliance issues in question;
- Ensuring that relevant records are gathered and produced in a timely manner;
- Ensuring appropriate communication protocols are established and maintained;
- Providing acceptable accommodations and access to the site visitors; *and*
- Developing and retaining appropriate records of all correspondence, meeting minutes, phone notes and other communications with the external investigators.

II. Prohibited Actions

- A. Destroying or altering any document or record in anticipation of a request for material by a government agency or court.
- B. Lying or making false or misleading statements to any government investigator.
- C. Failing to cooperate with a government investigation.
- D. Attempting to persuade any other individual to provide false or misleading information to a government investigator.

³ External investigators and auditors from any number of agencies may arrive at UW Medicine unannounced, including but not limited to those from the following agencies: the Office for Civil Rights (OCR); the Federal Bureau of Investigation (FBI); the Department of Justice (DOJ); the Centers for Medicare & Medicaid Services (CMS); the Food and Drug Administration (FDA); the Office of Human Research Protections (OHRP); the Office of Lab Animal Welfare (OLAW); the Environmental Protection Agency (EPA); the Office of the Inspector General (OIG), the WA Department of Social and Health Services (DSHS); the WA Department of Health (DOH); and the WA State Auditor's Office (SAO).

III. Workforce Member Rights

Government investigators or persons presenting themselves as government investigators may contact workforce members outside the workplace, during non-work hours or at home. Workforce members may choose to talk to investigators, but also have the right to contact legal counsel or the designated institutional official(s) before responding to any questions.

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).

PROCEDURE ADDENDUM(S) REFERENCES/LINKS

- [UW Medicine Compliance Glossary](#).
- [Health Sciences Risk Management, Subpoena, Deposition, and Testimony Guidelines for UW Medicine and the School of Dentistry](#) (VMC, see [VMC Risk Management](#)).
- VMC, Search Warrant Response Guidelines.
- VMC, Subpoena Response.
- UW Medicine Primary Care, Upol057 Management of Media, Governmental Agencies, and Other Third Party Inquiries.
- UWP, Subpoena for Billing Records.
- ALNW, 1106 Staff Member Rights in a Government Investigation

APPROVALS

/s/ Beth DeLair _____
Beth DeLair
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Associate Vice President for Medical Affairs, UW

6/25/2024 _____
Date