

<b>Applicability:</b>	UW Medicine <sup>1</sup> and UW Medicine Affiliated Covered Entity <sup>2</sup>
<b>Policy Title:</b>	Government Investigations
<b>Policy Number:</b>	COMP.008
<b>Superseded Policies:</b>	VMC, Response to Government Investigations UWMC, 15-5 Response to Government Investigations and Subpoenas
<b>Date Established:</b>	October 11, 2017
<b>Date Effective:</b>	February 2, 2021
<b>Next Review Date:</b>	February 2, 2024

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## **PURPOSE**

The purpose of this policy is to ensure enterprise-wide consistency in responding to government investigations and subpoenas involving healthcare compliance matters. It applies to all UW Medicine entities, departments and individual workforce members.

## **DEFINITIONS**

See [UW Medicine Compliance Glossary](#).

## **POLICY**

UW Medicine cooperates fully with legally authorized government investigations and subpoenas<sup>3</sup>, 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 entity leadership, managers, workforce members, UW Medicine shared services departments and other designated institutional officials.

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<sup>1</sup> UW Medicine refers to the seven UW Medicine entities: Harborview Medical Center, Valley Medical Center, UW Medical Centers (UWMC-Montlake and Northwest campuses), UW Medicine Primary Care, UW Physicians, UW School of Medicine, and Airlift Northwest.

<sup>2</sup> 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](#).

<sup>3</sup> 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).

- A. Each entity is responsible for developing its process to address and advance government investigations and subpoenas in collaboration with the appropriate UW Medicine shared services departments that have scope and jurisdiction over the issue. Each entity shall have a designated institutional official to liaise and assist in the identification of the appropriate parties to manage an issue.

Designated institutional officials responsible for specific issues will:

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

- B. Any workforce member who is approached by someone claiming to be a government investigator, external auditor or site reviewer, or who receives a subpoena or other written, official governmental request for information (such as a Civil Investigative Demand) must immediately report it in accordance with entity-based reporting requirements.

## 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.

## 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.](#)
- [University of Washington Regulatory Response Guidance.](#)

- [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.
- UWNC, 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

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2/16/2021

Date