

Applicability:	UW Medicine ¹ and UW Medicine Affiliated Covered Entity ²
Policy Title:	Compliance Risk Assessment
Policy Number:	COMP.009
Superseded Policies:	VMC, Corporate Compliance Program Assessment Policy & Procedure
Date Established:	October 11, 2017
Date Effective:	October 16, 2023
Next Review Date:	October 16, 2026

PURPOSE

This policy requires UW Medicine to engage in comprehensive and on-going formal assessments which identify and mitigate compliance risks. It applies to UW Medicine compliance departments, executive and administrative leaders and operational departments.

DEFINITIONS

See [UW Medicine Compliance Glossary](#).

POLICY

UW Medicine is committed to maintaining an effective compliance program through ongoing risk assessments which identify, mitigate and correct noncompliance. Toward that end, leadership, operations and compliance staff partner to identify, analyze and prioritize compliance risks affecting the organization, evaluate the probability of those risks occurring and their potential impact to the organization, and determine how those risks should be managed. Compliance risk areas include, but are not limited to fraud, waste, abuse, and patient information privacy and security. Risks are evaluated annually, and if appropriate, on an as needed basis. This annual risk assessment forms the basis of the Compliance Work Plan.

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](#).

At a minimum, each risk assessment considers the following factors:

- The Office of Inspector General (OIG) Workplan
- Internal and external audit results;
- Regulatory developments, rule changes, enforcement focus and other trends;
- Internal operational and structural changes;
- Compliance inquiries and consultations;
- Findings associated with compliance investigations;
- The presence or absence of internal controls;
- Factors specifically mandated by federal, state or institutional requirements; *and*
- Nature of the risks (for example, reputational damage, operational disruption, penalties and other costs).

The assessment process is coordinated by the Chief Compliance Officer or his/her designee who creates and maintains documentation of the risk assessment and corresponding Compliance Work Plan. The Compliance Work Plan is approved by the Compliance Governance Group, and includes compliance risk mitigation strategies, including but not limited to policy development and education and audit plans.

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).
- Risk Analysis, 45 C.F.R. §164.308(a)(1)(ii)(A).
- Centers for Medicare and Medicaid Services (CMS), Medicare Managed Care Manual, CMS Pub. 100-16, Chap. 21 (Rev. 110, Jan. 11, 2013); available at <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c21.pdf>.
- CMS, Medicare Prescription Benefit Manual, CMS Pub. 100-18, Chap. 9 (Rev. 16, Jan. 11, 2013); available at <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c21.pdf>.

PROCEDURE ADDENDUM(s) REFERENCES/LINKS

[UW Medicine Compliance Glossary](#)

APPROVALS

/s/ Beth DeLair
Beth DeLair
Chief Compliance Officer, UW Medicine
Associate Vice President for Medical Affairs, UW

10/20/2023
Date