

**UNIVERSITY OF CALIFORNIA, DAVIS
AUDIT AND MANAGEMENT ADVISORY SERVICES**

**UC Davis Health
Department Compliance Programs
Audit & Management Advisory Services Project #22-12**

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**Department Compliance Programs
AMAS Project #22-12**

MANAGEMENT SUMMARY

Background

As part of the fiscal year (FY) 2022 audit plan, AMAS reviewed the compliance programs for Clinical Laboratory, Home Health, and Hospice services at UC Davis Health (UCDH). Clinical Laboratory operations are administered by the Department of Pathology & Laboratory Medicine (Pathology). Home Care Services administers both the Home Health and Hospice programs.

The US Department of Health & Human Services Office of the Inspector General (OIG) published separate compliance program guidance for hospitals, clinical laboratories, home health agencies, and hospices to assist healthcare organizations in developing effective internal controls that promote adherence to applicable law and program requirements of Federal, State and private health plans. Voluntary compliance programs advance the prevention of fraud, abuse, and waste in health care.

The UCDH Compliance Department manages and provides oversight to the UCDH Operations Compliance Committee (OCC.) OCC is charged with the oversight of compliance related to Clinical Laboratories, Home Care Services, privacy, security, and UCDH operations compliance. OCC is also charged with recommending “policy and procedures, appropriate monitoring, audit reporting, and educational activities to ensure compliance with the UCDH Compliance and Privacy program.” OCC reports to the Chief Administrator of UC Davis Medical Center.

Clinical Laboratories under Pathology are licensed by the State of California, certified by Clinical Laboratory Improvement Amendments (CLIA), accredited and or inspected by the College of American Pathologists (CAP), American Association of Blood Banks (AABB), Food and Drug Administration and the State of California as applicable.

Home Care Services’ mission is to provide exemplary home care that responds to the diverse physical, psychosocial, and spiritual needs of patients. Home Care Services is accredited by the Joint Commission and is a member of state and national hospice and palliative care organizations.

Purpose and Scope

The purpose of this audit is to determine if appropriate compliance programs and oversight have been implemented over the Clinical Laboratories, Home Health, and Hospice operations at UCDH. We also sought to determine that a process exists to ensure that laboratory licenses and CLIA certifications are current and documented.

In order to accomplish these objectives, we examined published guidance, read meeting minutes, reviewed department policies and compliance reporting, and interviewed staff.

The timeframe reviewed was FY 2017 through the first two quarters of FY 2021.

Conclusion

We were able to verify that Home Care Services employs compliance measures consistent with a standard compliance program. It includes internal self-reviews, including billing and utilization

audits, mileage audits, staff training, and external reviews. Pathology does not currently operate a Clinical Laboratory compliance program.

We also found that the OCC has not fulfilled its charge to provide oversight for the compliance of Clinical Laboratories. We have identified areas where the OCC should improve its oversight of Home Care Services.

We determined that Pathology has a process to ensure that CLIA certifications and state licenses are current and documented.

Observations, Recommendations, and Management Corrective Actions**A. Compliance Oversight****OCC does not fulfill its duties in overseeing and monitoring department compliance programs.**

OCC is charged with monitoring the compliance programs for Clinical Laboratories and Home Care Services, as well as oversight in other areas at UCD Health. This responsibility includes providing Home Care Services and Pathology with recommendations regarding “policy and procedures, appropriate monitoring, audit reporting, and educational activities to ensure compliance with the UCDH Compliance and Privacy program, UCOP Ethics Compliance and Audit Program, and applicable compliance laws and regulations.” These functions are recommended by the OIG guidance to be performed by the compliance committee.

Home Care Services has maintained a sound compliance program and reports its compliance activities annually to the OCC. A Clinical Laboratory compliance program was operated by Pathology in past years prior to the scope period of this audit but no longer exists. In the timeframe of this review, the OCC did not perform oversight of or require compliance reporting from Pathology and therefore did not fulfill its charge.

The absence of a Clinical Laboratory compliance program and OCC oversight create risks of poor internal controls, improper billing, waste, and fraud. We recognize that Pathology performs certain compliance activities such as for its technical accreditations from CAP and CLIA, but participation in a compliance program and oversight by OCC should occur to reduce the aforementioned risks.

The OIG compliance program guidance recommends that an effective compliance program perform annual reviews to determine the program’s compliance elements have been satisfied, such as whether there has been appropriate training; ongoing educational programs; and monitoring performed. Verification of conformance with the compliance program by the OCC was not performed for neither Home Care Services nor Pathology in the years under audit.

OCC should also be reviewing and approving the department compliance program policy. Currently, the compliance program policy for Home Care Services is monitored internally by the department and not reviewed or approved by the OCC. A compliance program policy does not exist for Pathology.

Recommendations

- The Compliance Department and OCC should work with Pathology to develop and approve a compliance program policy for the department.
- Pathology and the Compliance Department should work to perform a general risk assessment of compliance areas, including those addressed in the “Publication of OIG Compliance Program Guidance for Clinical Laboratories” including Medical Necessity, Billing and Auditing, and Monitoring.

- The Director of Pathology and Laboratory Medicine should be added as a member to OCC.
- OCC should annually review and approve the compliance program policy for Home Care Services and Pathology. As part of its oversight, OCC should make an annual determination of whether practices have satisfied the program's elements and provide feedback for improvement.

Management Corrective Actions

- 1) By August 24, 2022, Pathology and the Compliance Department will work to develop a clinical laboratory compliance program to be reviewed and approved by the OCC. As part of this process, the Compliance Department and Pathology will work to assess compliance risks of clinical laboratory operations.
- 2) By March 17, 2022, the OCC will add the Director of Pathology and Laboratory Medicine as a member.
- 3) By August 24, 2022, the OCC will include as part of its operations an annual review and approval of department compliance programs. The OCC will make at least annual determinations about whether the compliance programs are sufficiently operating.

B. Notices to Physicians

Pathology and Laboratory Medicine does not apprise physicians of Medicare medical necessity policies.

The guidance for clinical laboratory compliance programs states that clinical laboratories are in a unique position to educate physician clients about Medicare policies relating to medical necessity for clinical laboratory services. The guidance recommends that clinical laboratories provide annual written notices to physician clients that set forth the following:¹

1. The Medicare national policy and Medicare contractor local medical review policy for lab tests.
2. That organ or disease related panels will only be paid and will only be billed when all components are medically necessary.
3. The Medicare laboratory fee schedule and a statement informing the physician that the Medicaid reimbursement amount will be equal or less than the amount of Medicare reimbursement.
4. Provide the phone number to the clinical consultant determined under CLIA.
5. Explain the Medicare reimbursement paid for each component of a customized profile.
6. Inform physicians that using a customized profile may result in the ordering of tests which are not covered, reasonable or necessary and will not be billed.

¹ See A.2.b "Notices to physicians" "[Publication of OIG Compliance Program Guidance for Clinical Laboratories](#)"

7. Inform physicians that the OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under law.

We have determined that this practice is not currently being performed by Compliance or Pathology and Laboratory Medicine.

Recommendation

To ensure compliance with federal guidelines, Compliance management is encouraged to enact the practice of sending annual physician notifications.

Management Corrective Action

- 1) Pathology/Compliance will develop a plan to provide an annual notice to physicians regarding Medicare policies on medical necessity of clinical laboratory services by June 30, 2022.