UC IRVINE | INTERNAL AUDIT SERVICES

Clinical Lab Compliance

Internal Audit Report No. I2021-605

September 2, 2021

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UCI Internal Audit Services

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VALERIE DIXON
CHIEF COMPLIANCE AND PRIVACY OFFICER
SCHOOL OF MEDICINE COMPLIANCE

RE: Clinical Lab Compliance Audit
Report No. I2021-605

Internal Audit Services has completed the review of Clinical Laboratory Compliance and the final report is attached.

We extend our gratitude and appreciation to all personnel with whom we had contact while conducting our review. If you have any questions or require additional assistance, please do not hesitate to contact me.

Sincerely,

Mike Bathke
Director

Attachment

C: Audit Committee
Neil Detweiler, Chief Administrative Officer – Pathology Administration
Melisand Mohseni, Regulatory and Compliance Manager – Pathology Administration

I. MANAGEMENT SUMMARY

In accordance with a request from senior leadership, Internal Audit Services (IAS) performed an audit of Clinical Lab Compliance in FY 2021. The objective was to review clinical lab operations to ensure compliance with policies, procedures, and regulations.

Based on the results of the audit work performed, some processes need improvement to fully comply with federal regulations.

The following concerns were noted:

Clinical Laboratory Compliance Program and Policies/Procedures – The Laboratory Compliance Program documentation has not been revised since 2014 and needs to be updated. Further details related to this issue are provided in Section V.1.

Notices to Physicians – There has been a lapse in the practice of sending annual physician notifications, as indicated in the Compliance Program policy. Details of this issue are discussed in Section V.2.

Clinical Laboratory Licenses and Permits – In general, the process of monitoring renewal dates for clinical lab licenses and permits appears to be functioning properly. However, certain place-of-service (POS) 11 (non-hospital, ambulatory care clinics) were either unable to provide a current license or provided an expired license. UCI does not have a have a centralized hub for monitoring clinical lab licenses and permits. This issue is discussed in Section V.3.

II. BACKGROUND

Pathology and Laboratory Medicine was established in 1968 to fulfill the clinical, research and educational missions of University of California Irvine (UCI) Health. Pathology and Laboratory Medicine faculty and staff provide clinical diagnostic services to UCI Health patients and also provide consultative and referral services to multiples of skilled nursing facilities, ambulatory clinics, community and regional hospitals.

The UCI clinical laboratories are an integral part of the UCI Medical Center and UCI School of Medicine. Almost 12 million patient specimens are tested annually. The laboratories are accredited and/or inspected by the State of California, College of American Pathologists (CAP), American Association of Blood Banks (AABB), Food and Drug Administration and/or Joint Commission on Accreditation of Healthcare Organizations. The main clinical laboratory at the UCI Irvine Medical Center is also a national referral center for specialized procedures and services for a wide range of clientele.

The Department of Pathology and Laboratory Medicine has an active clinical laboratory regulatory compliance program (Clinical Laboratory Compliance Program, or CLCP). The primary objective of the program is to ensure that clinical laboratories under the jurisdiction of Pathology and Laboratory Medicine are in compliance with all laws and regulations governing a provider's participation in federally funded health care programs. The Laboratory Compliance Officer (LCO) is responsible for developing compliance policies and standards, overseeing and monitoring laboratory compliance activities, and achieving and maintaining laboratory regulatory compliance.

The UCI Health Compliance & Privacy Office supports the Department of Pathology and Laboratory Medicine by leading the Laboratory Billing Compliance Committee and providing oversight for the development of written policies that promote the laboratory's commitment to compliance addressing specific areas of potential fraud, such as billing, marketing and claims processing; and auditing and/or other evaluation techniques to monitor compliance and ensure risk reduction and mitigation.

III. PURPOSE, SCOPE, AND OBJECTIVES

The purpose of the audit was to determine whether the Medical Center's CLCP is operating in accordance with the Health and Human Services (HHS) Office of Inspector General (OIG) "Compliance Program Guidance for Clinical Laboratories," and the UCI Pathology and Laboratory Medicine policies and procedures, as documented in the Clinical Laboratory Regulatory Compliance Program Manual.

The audit included the following objectives.

1. Determine that the Laboratory Compliance Program contains the elements defined by the OIG, as outlined in the HHS OIG "Publication of OIG Compliance Program Guidance for Clinical Laboratories" recognizing that the CLCP and the UCI Health Compliance program are jointly responsible for determining the appropriate topic areas and measures to be included in its compliance program.
2. Determine that a process exists to ensure that all laboratory licenses and Clinical Laboratory Improvement Amendments (CLIA) certifications are current and documented.
3. Verify that standard laboratory test requisitions have been developed, and include:
    a. Language that reminds physicians to order only medically necessary tests.
    b. A statement indicating that Medicare generally does not cover routine screening tests and encourages the submission of a diagnosis for lab tests.
    c. The stated condition(s) under which a reflex test will be performed.
    d. Documentation to facilitate the ordering of individual tests, unless they are part of a Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS)-defined automated multi-channel panel.

4. Determine that an Advance Beneficiary Notice of Non-Coverage (ABN) waiver process is in place and ABN policies include a training program to instruct physicians and hospital registration, phlebotomy and billing staff in the practice of obtaining a proper ABN.
5. Determine that the CLCP provides its physician clients with an annual written notice that includes:
   a. The Medicare national policy and Medicare contractor local medical review policy for lab tests.
   b. Instructions that organ or disease related panels will only be paid and will only be billed when all components are medically necessary.
   c. The Medicare laboratory fee schedule and a statement informing the physician that the Medi-Cal reimbursement amount will be equal to or less than the amount of the Medicare reimbursement.
   d. The phone number of the clinical consultant.

IV. CONCLUSION

The UCI Health Chief Compliance & Privacy Officer, who leads the UCI Health Compliance & Privacy program, plans to carefully review the Laboratory Compliance Plan and work with the LCO to ensure that there is compliance oversight for the School of Medicine clinical laboratories outside of the jurisdiction of the Department of Pathology and Laboratory Medicine, non-affiliated UCI clinical laboratories, and UCI School of Medicine research laboratories. It is noted that the position of Compliance Specialist is currently vacant. This role is critical to serve as the liaison with the CLPC. Until such time as the position of Compliance Specialist is filled, the UCI Health Compliance program will establish an audit program for clinical lab billing to ensure that internal and compliance controls are strong, roles and responsibilities are determined and documented, employees are adequately trained in their roles and responsibilities, compliance policies and procedures are fully vetted, created and/or updated, verifiable objectives are established, and specific employees are held accountable for achieving the objectives.

In a planned phase II endeavor of continuous improvement efforts, the Compliance & Privacy Office will complete the following remediation plan:

1) Perform a functional assessment of the current laboratory compliance program. The assessment goals will be to provide:
   a. A delineation of the Pathology and Laboratory Medicine Compliance Program versus the UCI Health Compliance program responsibilities.
   b. A current listing of the laboratory billing locations.

2) Within the reimbursement and payment areas, claims and billing operations are often the source of fraud and abuse and, historically, have been the focus of government regulation, scrutiny, and sanctions. Compliance will work with key stakeholders to identify current UCI policies, as well as standard operation procedures for the creation, addition, and physical movements for both Hospital

and School of Medicine business lines. Opportunities identified through this process will be used to create a sustainable process used to ensure regulatory, financial and operational considerations are addressed in a proactive manner. Deliverables will include, but not be limited to:

a. Updated policies and procedures for clinical lab billing.
b. Updated standard operating procedures.
c. Updated repository of UCI licensed locations.
d. Updated training to key stakeholders.

Finally, certain compliance controls need immediate improvement in order to fulfill federal guidelines for clinical laboratories, Pathology and Laboratory Medicine compliance policies and procedures, and/or best practices. Observation details and recommendations were discussed with management, who formulated action plans to address the issues. These details are presented below.

V. OBSERVATIONS AND MANAGEMENT ACTION PLANS

1. Clinical Laboratory Compliance Program and Policies/Procedures

Background

HHS OIG compliance program guidance is intended to assist hospitals, including their clinical laboratories, in developing effective internal controls that promote adherence to applicable federal and state law, and the program requirements of federal, state, and private health plans. The adoption and implementation of voluntary compliance programs significantly advance the prevention of fraud, waste, and abuse in these health care plans while at the same time furthering the fundamental mission of all hospitals, which is to provide quality care to patients.

Observation

Pathology and Laboratory Medicine management and Laboratory Compliance management completed an internal control questionnaire (ICQ) to determine the status of the CLCP. IAS developed follow-up questions, as necessary, to confirm that actual practices align with management assertions documented in the ICQ.

Completion of the ICQ and additional discussions with management disclosed the following concerns.

1. The CLCP documentation has not been reviewed and revised since 2014, and needs to be updated.

2. Some Clinical Laboratory Compliance policies and procedures (P&P) may not be up-to-date and/or may not reflect current governmental requirements/ private program guidelines and/or best practices.

To ensure compliance with current federal, state, and private program requirements, UC/UCI P&P, and best practices, it is important to review and update the CLCP documentation annually. Similarly, Clinical Laboratory Compliance P&P should be reviewed and updated when changes are warranted and/or at least once per year.

Management Action Plan

Management will review and make the necessary revisions to the CLCP and Clinical Laboratory Compliance P&P to assure alignment with current governmental and regional requirements and best practices.

Due date: December 31, 2021

2. Notices to Physicians

Background

In providing guidance to clinical laboratory compliance programs, the Centers for Medicare and Medicaid Services (CMS) has stated that clinical laboratories are in a unique position to educate their physician clients about Medicare policies as they relate to clinical laboratory services. Among other recommendations, the CMS recommends that clinical laboratories provide all of their physician clients with annual written notices that set forth:

1. The Medicare national policy and contractor local medical review policy for laboratory tests;

2. Requirements that organ or disease-related panels will only be paid and will only be billed when all components are medically necessary; and

3. The Medicare laboratory fee schedule and a statement informing the physician that the Medi-Cal reimbursement amount will be equal to or less than the amount of Medicare reimbursement.

The Pathology and Laboratory Medicine - Clinical Laboratory Regulatory Compliance Program Manual states that "A Physician Notice explaining Medicare medical necessity shall be provided to all clients on an annual basis." The manual also states that, "The Laboratory Compliance Office maintains, on file, copies of all Physician Notices plus a distribution schedule."

Observation

IAS performed a review to determine the extent to which notices are sent at least annually to client physicians, and physician notices are retained for management/ third-party review.

Discussions with compliance management disclosed that there has been a lapse in the practice of sending annual physician notifications, as indicated in the Compliance Program policy.

To ensure compliance with CMS guidelines, and the Pathology and Laboratory Medicine - Clinical Laboratory Regulatory Compliance Program Manual, Laboratory Compliance management is encouraged to resume the practice of sending annual physician notifications, including the retention of electronic copies of all distributed Physician Notices and the distribution schedule.

Management Action Plan

Annual Notice Letter to physicians is in its final review process. Moving forward, the annual physician notification letter will be mailed to physicians on an annual basis, including retention of electronic copies of distributed physician notices and the distribution schedule.

Due date: December 31, 2021

3. Clinical Laboratory Licenses and Permits

Background

An audit was conducted to determine whether a centralized Clinical Laboratory Improvement Amendments of 1988 (CLIA) certification registry and tracking mechanism is being utilized to ensure that all licenses and CLIA certificates are not allowed to expire for any location. UCI maintains labs at the Medical Center as well as satellite offices and a transfusion center. In addition, there are approximately 24 off-site point of care testing ambulatory clinics.

Observation

In general the process of monitoring licensure and records management along with critical renewal dates appears to be functioning properly. All of the licenses for CLIA and State as requested and tested were valid and in order.

However, IAS noted that the Tustin Multi Specialty unit had a State license that expired on June 27, 2020. This license is pending renewal and is not currently valid. Likewise, IAS also did not receive the license for Primary Care Network – Yorba Linda, so this is also pending renewal and not currently valid.

UCI does not have a have a centralized hub for monitoring the licenses. Each site submits their renewal application form with fees. Practice managers for each site are responsible for the renewal process. Some sites will reach out to lab compliance for assistance with the renewal process. An Ambucare administrative email address of ambucareadmin@hs.uci.edu was set up to manage the renewal

notifications since the notification were going to the emails of employees who were no longer with UCI.

Laboratory best practices, as recommended by CLIA, include the utilization of a centralized certification registry and tracking mechanism to ensure that CLIA and State certifications are not allowed to expire for any location where laboratory testing is performed.

Management is encouraged to maintain a central hub and periodically update licensure and accreditation information in the summary list and licensure book to strengthen the Lab Compliance office's monitoring efforts over those clinical labs under the jurisdiction of Pathology and Laboratory Medicine.

Management Action Plan

Management will centralize the administration of CLIA and CA state license renewals for UCI Health off-site ambulatory clinics. An automated email notice will be generated from ambulatory care administration to Path-Point of Care (POC) and Ambulatory Care distribution groups with the upcoming license expiration notices for each POC testing site three months in advance of the license expiry date on a recurring annual frequency. The clinic's practice manager and director will initiate the online license renewal process. All clinics will use the ambucareadmin@hs.uci.edu email address on the license renewal forms as the designated contact email. Renewed licenses will be emailed to the Ambucare admin email address that will then be forwarded to the appropriate clinic's practice manager.

During their monthly site audits, POC group will check for current licensure and record the license expiry dates in their audit checklist form. The ambulatory administrative group will maintain a current list of ambulatory clinics performing POC testing. Ambulatory administration will be responsible for practice manager training with CLIA and CA State license renewals by incorporating the training as part of the onboarding activities.

Note: CA State license applications and renewals are completed online. Practice managers will create an online account on the CDPH-LFS site to submit renewal forms and the ambucareadmin@hs.uci.edu email address will be defined as the contact email address. Ambulatory administration will determine the mechanism to facilitate online fee payment for license renewal.

Due date: September 30, 2021