

November 15, 2023

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ASSOCIATE VICE PRESIDENT
ACADEMIC HEALTH SCIENCES
UNIVERSITY OF CALIFORNIA OFFICE OF THE PRESIDENT

KYLE AHN, MD
ASSOCIATE DEAN FOR GRADUATE MEDICAL EDUCATION and
DESIGNATED INSTITUTIONAL OFFICER (DIO)
UC IRVINE SCHOOL OF MEDICINE

RE: UC Health Affiliations Review – UCI Local Report
Report No. I2023-203

In accordance with the fiscal year 2022-23 University of California (UC) audit plan, the systemwide Office of Ethics, Compliance and Audit Services (ECAS) requested the internal audit departments of all six UC campuses with academic health centers to complete an interim review of UC's progress in implementing *Regents Policy 4405: Policy on Affiliations with Healthcare Organizations that Have Adopted Policy-Based Restrictions on Care* (RP 4405).

The objective of the audit was to evaluate the University's progress in implementing all requirements stated in RP 4405 and the accompanying interim systemwide policy. The audit scope included an evaluation of the design and implementation of the processes and controls that have been implemented to-date to facilitate compliance with RP 4405 and its accompanying interim policy.

Pursuant to ECAS's request, UC Irvine Internal Audit Services (IAS) audited the processes, internal controls, and documentation currently in place to facilitate compliance with RP 4405 and the accompanying interim systemwide policy. The review also included a verification of required agreement language for any new affiliation agreements and existing affiliation agreements that have been amended as of the timing of audit fieldwork. Specific areas of focus included an assessment of the following policy requirements:

- Due diligence, review, and approval of affiliation agreements
- Required contract language
- Communication to UC patients, faculty, staff, and trainees
- Processes for receiving, evaluating, and resolving complaints or grievances
- Processes for transferring patients that require restricted services

Dr. Deena Shin McRae

Dr. Kyle Anh

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RE: Report No. I2023-203 – UC Health Affiliations Review – UCI Local Report

Based on the results of the audit test work performed for this interim review, UCI has made satisfactory progress in implementing the requirements in RP 4405 and its accompanying interim policy. Furthermore, notwithstanding the concerns noted below, UCI is well-positioned to fully implement all requirements of the aforementioned policies either before or by the UCOP-imposed deadline of December 31, 2023.

During the course of audit field work, inquiries were made to administrators in the UCI Health Contract departments as to whether they had documented all of the processes they are required to perform under RP 4405 and the accompanying interim systemwide policy. Results received from the inquiries were mixed:

- UCI Health Patient Transfer – Procedures and supporting records appear to be adequately documented. However, management indicated that any changes to RP 4405 that might occur at any time prior to the December 31 deadline would require an update to their written procedures and/or supporting records.
- UCI Health Contracting and Graduate Medical Education (GME) Administration – Procedures and supporting records have not yet been documented. However, the UCI Health Contracts Manager and the UCI School of Medicine (SOM) GME Director indicated that they will work with UCI Health General Counsel to draft written procedures in support of RP 4405 prior to December 31st.
- UCI Health Patient Experience – The Director of UCI Experience indicated that procedures and supporting records have not yet been fully documented for the various pathways that RP 4405 complaints may follow until they are fully resolved.
- UCI Health/GME Communications – The Communications policy language and templates for RP 4405 are still under review for possible revision at UCOP. UCI administrators will not be able to document procedures for UCI communications until RP 4405 revisions are finalized.

UCI administrators responsible for implementing and maintaining the aforementioned RP 4405 policy requirements need to ensure that key processes in all of their affected areas are fully documented by the December 31, 2023 deadline.

Also, for your information, we have attached a copy of the final systemwide report for UC Health Affiliations, Project No. P23A003.

Dr. Deena Shin McRae

Dr. Kyle Anh

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RE: Report No. I2023-203 – UC Health Affiliations Review – UCI Local Report

If you have any questions or require additional assistance, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Mike Bathke". The signature is written in a cursive, slightly slanted style.

Mike Bathke

Director

Internal Audit Services

Attachment

C: Audit Committee

Denise Burton, Executive Director – UCI Health Contracting

George Choriatis, Health Sciences Counsel – UCI Health General Counsel

Kieley Cockrell, Contracts Manager – UCI Health Contracting

Bradley Giafaglione, Director of UCI Experience - UCI Health

Daniel Kang, Assistant Dean - Graduate Medical Education

Peter Schneider, Chief Health Sciences Counsel – UCI Health General Counsel

Courtney Strayer, GME Director - SOM Medical Education

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
OFFICE OF ETHICS, COMPLIANCE AND AUDIT SERVICES



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Alexander Bustamante
SENIOR VICE PRESIDENT
CHIEF COMPLIANCE AND AUDIT OFFICER

November 9, 2023

EXECUTIVE VICE PRESIDENT RUBIN

RE: Final Report Project No. P23A003: Systemwide UC Health Affiliations

Attached is a copy of the final report for: Audit Services Project No. P23A003 Systemwide UC Health Affiliations. With the issuance of this final report, please destroy any previous draft versions. We very much appreciate the assistance provided to us by you and members of your staff during our review. If you should have any questions please feel free to contact me at 510-987-9646 (email: matthew.hicks@ucop.edu).

A handwritten signature in cursive script, appearing to read "Matt Hicks".

Matt Hicks
Systemwide Deputy Audit Officer

Attachment

cc: Senior Vice President Bustamante
Associate Vice President Nelson
Director Foster
Systemwide Associate Audit Director Bishin

UNIVERSITY OF CALIFORNIA
ETHICS, COMPLIANCE AND AUDIT SERVICES
INTERNAL AUDIT SERVICES

SYSTEMWIDE UC HEALTH AFFILIATIONS AUDIT
Project No. P23A003
October 2023

*University of California
Ethics, Compliance and Audit Services
Systemwide UC Health Affiliations Audit*

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I. Executive Summary

Introduction

In accordance with the fiscal year 2022-23 University of California (UC) audit plan, the systemwide Office of Ethics, Compliance and Audit Services (ECAS) oversaw an interim systemwide audit to assess UC's progress implementing Regents Policy 4405: Policy on Affiliations with Healthcare Organizations that Have Adopted Policy-Based Restrictions on Care. ECAS performed this audit in coordination with the internal audit departments at all campuses with academic health centers using a standard systemwide audit program.

ECAS developed this summary report based on information gathered by each location's internal audit department. It provides a consolidation of the systemwide findings and a set of corresponding recommendations to address these findings. Each location's internal audit department will issue a separate report presenting findings noted at that location, corresponding management corrective actions to address those findings, as well as management corrective actions to address each of this report's recommendations to the locations.

Objective and Scope

Objective: The objective of this audit was to evaluate the University's progress implementing the requirements in Regents Policy 4405 and the accompanying interim systemwide policy.

Scope: The scope of this audit included evaluation of the design and implementation of the processes and controls that have been implemented to date to facilitate compliance with Regents Policy 4405 and accompanying interim systemwide policy, including verification of required agreement language for any new affiliation agreements and existing affiliation agreements that have been amended as of the timing of audit fieldwork¹. The final deadline to amend all agreements subject to Regents Policy 4405 is December 31, 2023. Accordingly, ECAS will conduct a follow up audit after this deadline to verify that all applicable agreements have been appropriately amended and to verify that management has appropriately remediated the internal control deficiencies and opportunities for improvement identified in this interim audit.

The areas of focus of this audit included an assessment of processes, controls and documentation associated with the following policy requirements:

- Due diligence, review and approval of affiliation agreements
- Required contract language
- Communication to UC patients, faculty, staff and trainees
- Processes for receiving, evaluating and resolving complaints or grievances
- Processes for transferring patients that require restricted services
- Annual report to the Regents Health Services Committee
- Joint clinical advisory committee

The following areas were out of scope for this audit and deferred to the planned follow up audit:

- Monitoring and reporting on quality of care
- Termination of non-compliant agreements

¹ In anticipation of expected changes to the systemwide policy, the scope of this audit did not include affiliations with public organizations, such as Veterans Affairs and Indian Health Services.

Audit fieldwork was conducted at all six campuses with academic health centers (UC Davis, UC Los Angeles, UC Irvine, UC Riverside, UC San Diego and UC San Francisco).

Background

In July 2021, the Board of Regents approved Regents Policy 4405: Policy on Affiliations with Healthcare Organizations that Have Adopted Policy-Based Restriction on Care², which governs affiliations between health care organizations that have policy-based restrictions on care and the University, including University of California Health's academic health centers and health professional schools. The Regents Policy requires that UC providers at affiliates with restrictive policies are able to offer patients a choice in reproductive and other types of care; expands and protects the options for UC providers and patients at covered affiliates; and gives UC providers and patients ways to address barriers to providing the full spectrum of evidence-based care. The Regents Policy and an accompanying systemwide policy providing more detailed implementation direction are intended to protect the ability of UC clinicians and trainees working at those organizations to provide evidence-based, appropriate care to all patients.

The full text of Regents Policy 4405 is as follows:

1. Advancing the University's Public Mission. Prior to approving or executing any new or renewed affiliation with a health organization that has adopted policy-based restrictions on care (a "covered organization"), the sponsoring location must: (i) document the rationale for the affiliation, including any anticipated benefits or risks to the University's education, research, and service missions and to the broader patient community; and (ii) verify that access to policy-restricted services such as abortions, contraception, assisted reproductive technologies, gender-affirming care, and end of life care will be maintained or improved as a result of the affiliation. Under no circumstances may such an organization be granted responsibility or authority to operate or manage any University facility or program on behalf of the University.
2. Documenting Adherence to University Policies and Standards in all Affiliation Agreements. Agreements with covered health organizations must recite the University's role as a public entity and commitment to non-discrimination and evidence-based care; and must require all parties to comply with all federal and state anti-discrimination laws, including Cal. Civ. Code § 51 (prohibiting discrimination on the basis of sex [including pregnancy and childbirth as well as gender, gender identity, and gender expression], race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status), and to offer any procedure or service they choose to provide at their respective facilities or through their respective employees on a non-discriminatory basis. The University may not enter agreements with provisions that purport to require the University or its personnel or trainees to enforce or abide by policy-based restrictions on care including, but not limited to, religious directives, or that include any "gag clauses" interfering with their ability to counsel all patients on their treatment options. The University must retain the option to terminate such agreements if the University determines in its sole discretion that continued performance would be incompatible with its policies or values or that the affiliate has breached its promises to not restrict University providers' freedom to advise, refer, prescribe, or provide emergency items and services without restrictions, including any

² <https://regents.universityofcalifornia.edu/governance/policies/4405.html>

necessary items and services to any patient for whom referral or transfer to another facility would risk material deterioration to the patient's condition.

3. Strengthening Patient and Provider Protections. Each University location contracting with healthcare organizations that have adopted policy-based restrictions on care must develop and implement a process to inform UC patients, faculty, staff, and trainees: (i) about such restrictions at sites to which they may be referred or assigned; (ii) that such referrals or assignments are voluntary; and (iii) and that information about alternative sites for care, practice, and training will be provided upon request. Each location must also develop a process to transfer patients who need restricted services to a UC or other location where the services can be provided. Processes for receiving, evaluating, and resolving complaints or grievances must also be developed and implemented.
4. Ensuring Reporting and Transparency. Each University location (including the Office of the President with respect to systemwide or multi-campus agreements) must provide an annual report to the Regents Health Services Committee: (i) listing all new or renewed arrangements with covered organizations; (ii) summarizing complaints or grievances received from patients, students, faculty, and staff, as well as their resolution; (iii) providing quality monitoring data consistent with systemwide quality guidelines; and (iv) reporting on any identified noncompliance with the above standards. The first report, due in June 2022, must list all current arrangements with such institutions³.
5. Implementation and Accountability. The President shall issue a systemwide policy to implement these requirements after consultation with the chancellors and representatives of the Academic Senate and UC Health. One year after implementation of that policy, the Office of Ethics, Compliance, and Audit Services shall conduct an audit of an appropriate sample of then-current contracts with covered affiliates to ensure their compliance with such policy. Thereafter, the frequency and scope of audits shall be determined by ECAS in consultation with the chairs of the Audit & Compliance Committee and the Health Services Committee. The University shall not enter into any new affiliation that fails to meet these requirements after July 1, 2021; any existing affiliation that does not meet these requirements must be amended to comply with this policy or phased out no later than December 31, 2023.

NO RIGHT OF ACTION

This policy is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the University of California or its Board of Regents, individual Regents, officers, employees, or agents.

On September 22, 2021, the Office of the President issued an interim systemwide policy to implement the requirements of Regents Policy 4405 (Interim Policy: Affiliations with Certain Healthcare Organizations⁴). The purpose of this policy was to establish standards for affiliation with organizations with policy-based restrictions on care that protect and advance the University's values, as well as its commitment to inclusion, diversity, equity, and accountability, and ensure such affiliations do not compromise the University's commitment to evidence-based care for all patients.

³ UC Legal has interpreted this requirement to mean current arrangements that have been amended or negotiated to be in compliance with policy.

⁴ <https://policy.ucop.edu/doc/5000698/AffiliationHealthcareOrganizations>

To promote complete and consistent application of the policy requirements at each location, UC Health convened a working group comprised of representatives from each UC health center. This group coordinated with sub-groups, committees, leadership, and individuals at each location to implement and operationalize measures within the policy.

Overall Conclusion

At the completion of audit fieldwork, Internal Audit observed that UC Health and the UC academic medical centers had taken the following actions to implement Regents Policy 4405:

Affiliation agreements

- All affiliation agreements sampled for testing had been amended to comply with the requirements of Regents Policy 4405 and the interim systemwide policy or were in the process of being renegotiated.
 - Any deviations from the standard language were appropriately escalated and approved as required by policy.
- For the agreements that have been amended to comply with Regents Policy 4405, the rationale for the affiliation was appropriately documented as required by policy.

Communications

- UC Health developed and distributed draft communications to be used by the academic medical centers to inform UC patients, faculty, staff, trainees and volunteers about the restrictions, requirements and provisions of Regents Policy 4405.
 - These templates have not been finalized because the systemwide policy is currently under revision, and these revisions may impact required communications to UC Patients, Faculty, Staff and Trainees.
 - Some academic medical centers have begun to implement some of these communications locally, while others are awaiting finalization of communication templates from UC Health.

Complaint resolution

- UC's academic medical centers had implemented processes for receiving, evaluating, and resolving complaints and grievances from UC trainees, faculty, staff and patients related to Regents Policy 4405, generally relying on previously established processes.
 - Internal Audit did not identify any such complaints or grievances that had been received by the academic medical centers and therefore did not perform any testing to verify that they were appropriately evaluated and resolved.

Transfers

- UC's academic medical centers have developed and implemented processes to inform patients being transferred from a UC to a covered facility about the covered facility's restrictions and alternative options at UC Health or other facilities

Monitoring and reporting

- UC Health prepared an annual report in a timely manner and distributed this report to the Regents Health Services Committee. The report generally contained the information

required by Regents Policy 4405 at the time of audit fieldwork⁵.

Joint committee

- UC Health established a joint clinical advisory committee to review reports when issued, solicit feedback from stakeholders, and provide feedback on UC Health's policies on affiliations with institutions that have adopted policy-based restrictions on care.
- The Executive Vice President for UC Health and the Chair of the Academic Senate are co-chairs of the joint clinical advisory committee, and the composition of the committee conforms to the interim systemwide policy's requirements.
- The committee meets periodically throughout the fiscal year, as deemed necessary by the co-chairs.

Internal Audit identified the following actions as still outstanding that are required for full policy implementation. These actions include:

- Finalizing the systemwide policy
- Amending all affiliation agreements subject to Regents Policy 4405 to comply with policy and terminating all non-compliant agreements by December 31, 2023
- Implementing all stakeholder communications required by Regents Policy 4405 and the systemwide policy at all UC Health locations
- Monitoring and reporting on the quality of care provided at affiliates' facilities

Further, opportunities for improvement in local internal controls related to Regents Policy 4405 were observed at certain academic medical centers.

These observations are described in detail in this report. In the follow-up audit scheduled for early 2024, Internal Audit will assess the implementation of the outstanding actions and opportunities for improvement.

⁵ Per the Interim Systemwide Policy, standardized quality indicators were not due until August 2023. This deadline was subsequently changed to September 2023 via a revision to the Regents schedule. As noted in observation 3, there are opportunities to provide clearer guidance on reporting affiliation agreements in the annual report.

II. Observations on Policy Implementation Status

1. Outstanding Actions for Full Implementation of Regents Policy 4405 and the Systemwide Policy

Internal Audit observed that the following actions are outstanding for full implementation of Regents Policy 4405 and the systemwide policy:

Systemwide Policy

UC Health should finalize the systemwide policy ("Affiliations with Certain Healthcare Organizations"), which is currently classified as an interim policy.

Affiliation Agreements

UC Health and the academic medical centers should complete an analysis to identify all affiliation agreements subject to Regents Policy 4405 and amend them to include the policy's required language by December 31, 2023 as required. All agreements that are not compliant with Regents Policy 4405 should be terminated by December 31, 2023.

Communication to UC Patients, Faculty, Staff and Trainees

As required by Regents Policy 4405 and the interim systemwide policy, UC Health has developed and distributed draft communications to be used by the academic medical centers to inform:

- UC patients, faculty, staff, and trainees:
 - i. about restrictions at sites to which they may be referred or assigned;
 - ii. that such referrals or assignments are voluntary; and
 - iii. that information about alternative sites for care, practice, and training will be provided upon request.
- Faculty, staff, or trainees who may be invited to staff or train at a covered affiliate's site:
 - i. of the site's policy-based restrictions on care;
 - ii. of any requirements the site has adopted that such individuals certify adherence to policy-based restrictions on care and the contractual agreements that nevertheless protect their rights to make clinical decisions, counsel, prescribe, and refer or transfer, as well as to provide emergency items and services, without limitation, including any necessary items and services to any patient for whom referral or transfer to another facility would risk material deterioration to the patient's condition; and
 - iii. that working or learning at the Covered Affiliate site is entirely voluntary and that if they have an objection, alternative sites will be identified.
- Personnel and trainees voluntarily performing services or training at such facilities of the expectation that they adhere to evidence-based standards of care and their professional judgment wherever they are providing services.

These templates have not been finalized because the systemwide policy is currently under revision, and these revisions may impact required communications to UC Patients, Faculty, Staff and Trainees. Some academic medical centers have begun to implement some of these communications locally, while others are awaiting finalization of communication templates

from UC Health.

UC Health should finalize and distribute templates to the academic medical centers addressing the various communications to UC patients, faculty, staff, trainees, and volunteers required by the final versions of Regents Policy 4405 and the systemwide policy.

The academic medical centers should implement the final versions of these required communications locally.

Monitoring and Reporting

The interim systemwide policy requires that each UC Health location monitor the quality of care for UC services provided at a covered affiliate's facility, consistent with existing system-wide quality guidelines for UC Health affiliations. Regents Policy 4405 requires that the annual report to the Regents Health Services Committee include quality monitoring data consistent with systemwide quality guidelines for each University location (including the Office of the President with respect to systemwide or multi-campus agreements).

These policy provisions were not included in the scope of this interim audit because the implementation of these provisions was still in process and the proposed revisions to the interim systemwide policy may impact these requirements.

The academic medical centers should implement processes to monitor the quality of care for UC services provided at a covered affiliate's facility, consistent with existing system-wide quality guidelines for UC Health affiliations.

UC Health should include in future annual reports to the Regents Health Services Committee quality monitoring data consistent with systemwide quality guidelines for each University location (including the Office of the President with respect to systemwide or multi-campus agreements).

In the follow-up audit scheduled for early 2024, Internal Audit will assess the implementation of these outstanding actions.

Management Response:

Systemwide Policy

The final draft of the Presidential Policy: Affiliations with Certain Health Care Organizations is under systemwide review through October 13, 2023, and is planned for finalization and publication in December 2023.

Affiliation Agreements

UC Health locations have identified all existing agreements with covered affiliates. A status update on compliance for all identified affiliation agreements will be provided in the UCH FY22-23 Annual Report on Affiliations. All agreements will be brought into compliance with the policies, or terminated by December 31, 2023.

Communication to UC Patients, Faculty, Staff and Trainees

UC Health distributed standardized language to academic health centers once the final draft of the Presidential Policy was available. Communications for faculty, staff and trainees were distributed and incorporated into ongoing communication and training processes. The communication provides an overview of the policy and expressly conveys the University's expectation that UC personnel and trainees make clinical decisions consistent with the standard of care and their independent professional judgment.

All UC Health locations have established communication channels for UC patients to inform them about options when receiving care at a covered affiliate site, including establishment of patient websites.

Once the systemwide policy is finalized, additional communications will be provided to align with published guidance as needed.

Monitoring and Reporting

As part of the FY21-22 annual report, UC Health defined quality standards for covered hospitals that align with the quality domains of the Institute of Medicine, key elements of the reporting scorecard used by UC Health locations, and requirements of affiliation policies. Included in the FY22-23 annual report, the UC Health Covered Affiliations Quality Metrics Scorecard was finalized, and locations participated in quality metrics reporting on performance. All data sourced for quality metrics reporting is publicly available through the Center for Medicare and Medicaid Services and the California Department of Healthcare Access and Information (HCAI).

2. Opportunities for Improvement in Internal Controls at Academic Medical Centers

The following opportunities for improvement in internal controls deficiencies were observed in local internal audit fieldwork at the academic medical centers:

- Documented local policies or procedures to address the location's implementation requirements for certain requirements in Regents Policy 4405 have not been developed or are insufficient:
 - Contracting with healthcare organizations with policy-based restrictions on care (four locations)
 - Complaints escalation process for patients, faculty/staff and trainees, including, but not limited to, how the complaint will be identified, escalated and resolved (five locations)
 - Communicating out guidance on currently covered affiliates and/or, as necessary, updates to the list of covered affiliates to all appropriate parties responsible for compliance requirements (five locations)
- The documented rationale for some affiliations subject to Regents Policy 4405 did not include all rationale elements required by policy (one location)
- Standard Contracting Language and Affiliations Checklists and accompanying documentation required by policy were not submitted to the Chancellor designee

for review and approval prior to the execution of the affiliation agreement for several agreements (one location)

- One Standard Contracting Language and Affiliations Checklist was not signedⁱ (one location)

In the follow-up audit scheduled for early 2024, Internal Audit will assess the implementation of these identified opportunities for improvement.

Management Response:

UC Health locations will review the individually identified areas of improvement.

In addition, UC Health will share templates to document internal processes for 1) management of complaints, and 2) contracting which includes communicating changes in the list of covered affiliates. All locations will update outstanding internal procedures by December 31, 2023.

3. Opportunity for Additional Guidance from UC Health

In our review of the UC Health Fiscal Year 2021-22 Report on Covered Affiliations to the Regents Health Services Committee, we identified an opportunity for additional guidance from UC Health in order to ensure consistency in reporting between UC locations. We observed that UC Health could provide clearer instructions on the criteria for consolidating multiple agreements with the same affiliated entity into a single line item in the list of agreements in the reporting of affiliation agreements included in the annual report. It is recommended that UC Health issue guidance to UC locations that clarifies these criteria.

Management Response:

UC Health shares reporting instructions with locations and consults individually with each campus as part of the data collection. Going forward, UC Health will enhance instructions for reporting on covered affiliation agreements as part of future report requests to health locations to clarify criteria for reporting.

ⁱ Management took immediate action to sign this agreement's checklist once the issue was identified by Internal Audit.