August 27, 2021

Brian Alldredge
Vice Provost
Academic Affairs

Elena Fuentes-Afflick
Vice Dean, Academic Affairs
School of Medicine

SUBJECT: Outside Activities Reporting

As a planned internal audit for Fiscal Year 2021, Audit and Advisory Services ("A&AS") conducted a review of faculty outside activities reporting. The purpose of this review was to assess the processes and internal controls in place surrounding reporting and disclosures of outside professional activities to ensure adherence to University policies.

Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the "IIA Standards").

Our review was completed and the preliminary draft report was provided to department management in June 2021. Management provided final comments and responses to our observations in August 2021. The observations and corrective actions have been discussed and agreed upon with department management and it is management’s responsibility to implement the corrective actions stated in the report. A&AS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Board, and is not intended to be and should not be used by any other person or entity.

Sincerely,

Irene McGlynn
Chief Audit Officer
UCSF Audit and Advisory Services
EXECUTIVE SUMMARY

I. BACKGROUND

As a planned audit for Fiscal Year 2021, Audit and Advisory Services conducted a review to assess the processes and controls surrounding disclosures of outside professional activities reporting to ensure adherence to University policies and procedures.

At UCSF, the Office of Academic Affairs oversees academic policy development and implementation, including broad oversight responsibilities for faculty members’ outside professional activities and their appropriate disclosure, as regulated by the key UCSF policies below:


Faculty must self-disclose outside professional activities that are stipulated under applicable University policies and procedures regarding conflict of commitment and outside activities. A conflict of commitment (COC) occurs when a faculty member’s outside activities interfere with the faculty member’s professional obligations to the University.

Disclosure of financial interests is completed using the Outside Activities Tracking System (OATS). OATS, implemented during FY19, is a web-based application that facilitates reporting and disclosure of outside professional activities, tracks the time and earnings thresholds, and provides a mechanism to report receipt of cash and non-cash compensation for outside professional activities such as stock and stock options. The five forms available in OATS are:

- Category I Request
- Student Involvement
- Request to Exceed Threshold (time and/or earnings)
- Request to Retain Earnings above Threshold
- Annual Certification of Outside Professional Activities

Approval workflows vary, depending on the type of request. Generally, review of annual certifications is performed by designated reviewers within the faculty member’s department or school and then approved by the department chair or Dean. For

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1 According to APM 025 and APM 671, generally, the “UC policy on conflict of commitment and outside activities and the disposition of income earned from outside professional activities provides guidance for the identification and management of outside professional activities in order to avoid conflicts of commitment.” Outside professional activities, whether compensated or not, and regardless of financial interest, “are defined as those activities that are within a faculty member’s area of professional, academic expertise and that advance or communicate that expertise through interaction with industry, the community, or the public.”
Category I activities and requests to retain earnings above threshold, approval from a higher level (above the Dean) is required.

The matrix below summarizes the different categories of activities as well as corresponding disclosure requirements. For examples of outside activities within each category, please refer to Appendix A.

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Disclosure Requirements</th>
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</table>
| I        | The outside professional activity most likely to create a conflict of commitment because:  
1. They are activities related to the training and expertise that is the faculty member’s qualification for University appointment but performed for a third party; and/or  
2. Activity requires significant professional commitment | Activity requires prior approval and annual disclosure |
| II       | Typically, shorter-term outside professional activities that are outside the course and scope of University employment | Activity does not require prior approval but does require annual disclosure |
| III      | Activity within the course and scope of University employment | Does not require prior approval or annual disclosure |

Currently, the only third-party national disclosure system for outside professional activities is the Centers for Medicare and Medicaid Services (CMS) Open Payments\(^2\), which has increased awareness of the financial relationships between health care industry and providers, by collecting and reporting payments or transfers of value that medical manufacturers (pharmaceutical and device manufacturers) made to physicians or teaching hospitals. The information from Open Payments is available to the public and intended to promote a more transparent and accountable health care system. However, there is a lag in the Open Payments system and as of April 2021 the most recent available data is from Calendar Year (CY) 2019 (Jan - Dec 2019).

II. **AUDIT PURPOSE AND SCOPE**

The purpose of this audit was to assess the processes and controls surrounding reporting and disclosures of outside professional activities to ensure adherence to University policies. Reporting of conflicts of interest and compliance were outside the scope of this review.

Procedures performed as part of the review included interviews and walkthroughs with relevant personnel; review of applicable policies and procedures; data analysis between OATS disclosures and Open Payments, validation testing of a sample of OATS disclosures to ensure accuracy and completeness of disclosure of outside activities; and an assessment of the OATS system to effectively manage outside activities disclosures and COCs.

For more detailed steps, please refer to Appendix B.

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\(^2\) The Open Payments program was created by CMS in 2015 as part of the Affordable Care Act “Physician Payments Sunshine Act,” to provide a mechanism for public reporting of certain physician and teaching hospital financial relationships with industry.
The scope of the review included transactions and outside professional activities during FY19 and FY20 and Open Payments data from CY19. Work performed was limited to the specific activities and procedures described above. As such, this report is not intended, nor can it be relied upon, to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in May 2021.

III. SUMMARY

The University recognizes the value of allowing faculty members to participate in outside professional activities in support of its mission in education, delivering quality clinical care, advancement of research and collaboration and innovation with private industry. In general, the controls to ensure the completion of annual disclosures are working well, as the compliance rate for FY20 was 98%. However, there are opportunities for enhanced control in the areas of ensuring the accuracy of disclosures and a need for education and enhanced enforcement of policy requirements on reporting outside activities.

The specific observations from this review are listed below:

1. Multiple instances of non-compliance with University policy on outside activities and income disclosures were identified. Among a sample of 20 faculty members, nearly two thirds (13) had under-reported income that totaled $496K.

2. To ensure accuracy of reported information, there is no existing mechanism or process to periodically verify disclosures reported in OATS against an independent source of publicly available data.

3. Permission to engage in Category I activities is not always requested in a timely fashion.

Additionally, during the course of this review, a potential opportunity for improvement was identified relating to leveraging OATS as an on-going tracker of outside activities rather than as a vehicle for annual disclosures.
## IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS

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<thead>
<tr>
<th>No.</th>
<th>Observation</th>
<th>Risk/Effect</th>
<th>Recommendation</th>
<th>MCA</th>
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<tbody>
<tr>
<td>1</td>
<td><strong>Multiple instances of non-compliance with University policy on outside activities and income disclosures were identified.</strong> Among a sample of 20 faculty members, nearly two thirds (13) had under-reported income that totaled $496K.</td>
<td>In addition to compliance risk, there is reputational risk in not ensuring that outside activities are properly and comprehensively disclosed in OATS, the system of record for outside activities reporting. By not applying consequences for non-compliance, there may not be an incentive to change behavior and to ensure compliance with UC policy.</td>
<td>a) For faculty who have improperly or incompletely disclosed their outside professional activities, departmental leaders should ensure that faculty update their outside activities disclosures in OATS. b) Focused education regarding outside professional activities, particularly the distinction between categories, should be considered to promote more accurate disclosure.</td>
<td>Action Plan: a) The inaccurate disclosures were reported to the department chairs, who worked with the faculty to review the discrepancies. As a result, the faculty members made retroactive adjustments to their OATS disclosure forms. Action Completed b) The current FAQs on outside activities will be enhanced and made accessible to faculty, department chairs and chief administrative officers. The FAQs will provide greater clarity on Category II and III activities.</td>
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### Outside Activities Reporting

#### Project #21-037

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<tr>
<td>1</td>
<td>3 faculty members miscategorized Category II activities as Category III⁴</td>
<td>c) In addition to training, other actions should be considered in order to address structural reporting gaps, such as soliciting input from department chairs and faculty on their understanding of the academic policies and OATS disclosure, targeted communication, and establishment of champions for outside activities reporting.</td>
<td>December 1, 2021</td>
<td>Responsible Party: SOM Vice Dean, Academic Affairs</td>
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<td>2</td>
<td>1 faculty member did not complete a disclosure due to reluctance to using OATS</td>
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<td>3</td>
<td>6 faculty members underreported payments from their outside activities</td>
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<td>4</td>
<td>1 faculty member had the impression that the outside activity did not need to be reported.</td>
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Potential reasons for the discrepancies noted above are that faculty did not have a clear understanding of the reporting requirements for non-cash compensation such as stocks and stock options and erroneously classified “attending and presenting talks at academic colloquia and conferences” sponsored by for-profit industry as a Category III activity when, in fact, these are Category II activities and subject to reporting requirements.

#### b) Policy Enforcement

APM 025 is the current UC policy regarding academic appointees and conflict of commitment and outside activities of faculty members. Per APM 025-26 (b) Consequences for Non-Compliance, “failure to comply with the policy may subject a faculty member to discipline, corrective action, or administrative remedies.”

While there are provisions in the policies for remedies and disciplinary measures, currently there are limited consequences for late submission of disclosures.

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⁴ Though Category III activities are not reportable, there is an option to populate these activities in OATS when entering activities for the annual disclosure. However, only Category I and Category II activities are reflected on the final OATS disclosure.
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<td></td>
<td>failure to submit conflict of commitment disclosure forms or having inaccurate information on the forms.</td>
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<td>for Non-Compliance”.</td>
<td>SOM Vice Dean, Academic Affairs</td>
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<tr>
<td>2</td>
<td><strong>To ensure accuracy of reported information, there is no existing mechanism or process to periodically verify disclosures reported in OATS against an independent source of publicly available data.</strong></td>
<td>Currently, it is not a requirement for faculty to review their activities against an independent source, and there is not an administrative unit at UCSF to perform any validation of the activities disclosed. Faculty are expected to report in good faith and there is no existing mechanism to compare activities reported with outside sources, such as Open Payments or media publications.</td>
<td>Independent verification of payments and activities from external source provides more assurance that disclosures are being made compliantly, ultimately reducing reputational risk for the University.</td>
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<td></td>
<td>Our analysis revealed several discrepancies between OATS disclosures and Open Payments data. While it is acknowledged that there are noted variances in the timeframe between Open Payments and OATS, it still is an independent source of outside activities information that is not currently being leveraged.</td>
<td>a) At the campus level, a process should be developed and implemented to verify faculty member’s outside reporting disclosures against the Open Payments.</td>
<td>b) Annual disclosure notification from OATS should remind faculty members to check Open Payments and their Form 1099 when completing their disclosures as a consideration of alignment of activities engaged.</td>
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<td>Action Plan: a) UCSF Academic Affairs will work with other UC campuses to explore a multi-campus approach for augmentation of OATS to include Open Payments data for validation. If such an option is not feasible or pursued, other options will be explored via a Task Force to be convened by Academic Affairs.</td>
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<td>Target Completion Date: April 1, 2022</td>
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<td></td>
<td><strong>Permission for Category I activities is not always requested in a timely fashion.</strong></td>
<td></td>
<td>a) Establish a process to monitor compliance with pre-approval requirements for category I activities, such as reporting by OTM of start-up activities to the Office of</td>
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<td></td>
<td>Per APM 025 and APM 067, UCSF policies governing outside activities reporting, prior approval by the Chancellor is required for Category I activities, or activities most likely to create a conflict of commitment.</td>
<td></td>
<td>b) On a quarterly basis the Office of Technology Management and Advancement (OTMA) will provide Academic Affairs with a list of university IP licensed to start-up</td>
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<td>We obtained a listing from the Office of Technology Management (OTM) of faculty members that had</td>
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<td>Not seeking approval prior to commencing Category I activities precludes the ability to determine whether the activity creates a conflict of commitment for the faculty.</td>
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<td>The many levels of review and approval</td>
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**Responsible Party:**
Vice Provost, Academic Affairs

**Target Completion Date:**
June 30, 2022

**Action Plan:**
a) On a quarterly basis the Office of Technology Management and Advancement (OTMA) will provide Academic Affairs with a list of university IP licensed to start-up
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<td>1</td>
<td>formed start-up companies and had entered into an agreement with the University during FY19 and FY20. A sample testing of 10 start-ups revealed that 5 faculty had not obtained prior approval from the Chancellor before engaging in Category I activities.</td>
<td>for Category I activities creates significant delays in the approval process, making it less likely that faculty can comply with the prior approval requirement when submitting the approval request.</td>
<td>Academic Affairs to alert them of potential Category I activities.</td>
<td>companies including the relevant UCSF faculty member. The first report will be provided in December 2021 and quarterly thereafter.</td>
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<tr>
<td></td>
<td>Additionally, our analysis of retroactive reviews of the Category I activities showed that it took between 90 - 304 days for the requests to be reviewed and approved from the initial submission to final approval by the Chancellor. Category I activities submitted into OATS go through as many as 5 levels of review and approval that can contribute to the extended time in obtaining approvals.</td>
<td>b) Re-evaluate the current pre-approval process to determine how it might be streamlined or improved in order to reduce the time it takes for faculty to receive final approval/denial for Category I activities.</td>
<td>b) Communications to faculty members to reinforce policy requirements on seeking prior approval for Category I activities will occur.</td>
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<td></td>
<td>Faculty disclose Category I activities in which they have already engaged, even if they did not comply with the requirement for prior approval. Academic Affairs management indicated that the initial goal is to use OATS to educate faculty about policy requirement related to APM 025/671 and the pre-approval requirements for Category I, exceeding thresholds and retaining earnings. Additionally, there is an internal timing challenge due to the University’s encouragement to commercialize Intellectual Property (IP) arising from faculty start-ups, creating a misalignment of incentives.</td>
<td>c) Management should establish and communicate expectations to faculty regarding lead-time needed for pre-approvals of Category I activities.</td>
<td>c) The pre-approval process for Category I activities will be re-evaluated to identify improvements to streamline the approval process.</td>
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<td>d) A process will be developed to</td>
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Target Completion Date: December 30, 2021

Responsible Party: Assistant Director, Patent Prosecution and Business
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<tr>
<th>No.</th>
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<tr>
<td>1</td>
<td><em>Faculty should be encouraged to use OATS for on-going tracking of outside activities and income, not solely for the annual disclosure process.</em></td>
<td>By not utilizing OATS to report outside activities throughout the year, the annual disclosure process may be more time-consuming and there is increased risk of errors and omissions.</td>
<td>Academic Affairs and the departments should continue to promote OATS to be used as an ongoing tracking tool for outside activities.</td>
<td>communicate to faculty members any significant delays with their Category I approval request.</td>
</tr>
</tbody>
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Responsible Party:
Vice Provost Academic Affairs

Target Completion Date:
January 31, 2022

V. **OPPORTUNITIES FOR IMPROVEMENT**

| No. | Observation                                                                 | Risk/Effect                                                                 | Recommendation                                                                 |
|-----|------------------------------------------------------------------------------|------------------------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------|
| 1   | *Faculty should be encouraged to use OATS for on-going tracking of outside activities and income, not solely for the annual disclosure process.* | By not utilizing OATS to report outside activities throughout the year, the annual disclosure process may be more time-consuming and there is increased risk of errors and omissions. | Academic Affairs and the departments should continue to promote OATS to be used as an ongoing tracking tool for outside activities. | communicate to faculty members any significant delays with their Category I approval request. |

Responsible Party:
Vice Provost Academic Affairs

Target Completion Date:
January 31, 2022

UNIVERSITY OF CALIFORNIA

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APPENDIX A – Examples of Outside Professional Activities

Examples of Category I Outside Professional Activities:

- Administration of a grant outside the University
- Assuming an executive or managerial position outside of the University
- Assuming founding or co-founding role of a company
- Employment outside the University
- Research outside the University
- Teaching outside the University

Examples of Category II Outside Professional Activities:

- Consulting or testifying as an expert witness or professional witness
- Consulting for a domestic or foreign government agency
- Consulting for a for-profit entity
- Consulting for a non-profit entity
- Consulting for non-profit health or education-related organization
- Consulting under the auspices of UC
- Providing outside consulting or compensated professional activities performed for Los Alamos National Security and Lawrence Livermore National Laboratories
- Additional University-compensated teaching (CME & UNEX) or self-supporting UC degree programs
- Other income-generating activities specified in approved Implementing Procedures
- Providing or presenting a workshop for industry
- Serving on board of directors outside the University

Examples of Category III Outside Professional Activities:

- Attending and presenting talks at university/academic colloquia and conferences
- Developing scholarly or creative works
- Reviewing manuscripts, acting in an editorial capacity
- Serving on government or professional panels or committees or as an officer or board member of a professional or scholarly society
APPENDIX B – Procedures Performed

To conduct our review, the following procedures were performed:

- Review of the following relevant UCSF policies and guidelines on outside activities reporting and Conflict of Commitment:

- Interviews of key personnel to gain an understanding of current processes:
  - Associate Vice Provost for Academic Affairs
  - Director of Academic Affairs
  - Academic Business Processes Coordinator
  - Vice Dean for Academic Affairs and Faculty Development, School of Medicine
  - Affiliations, Outreach and Compliance Coordinator, School of Medicine
  - Chief Administrative Officer, Department of Orthopedic Surgery

- Comparison of data from Open Payments and OATS disclosures

- Review reporting of outside professional activities for a sample of Compensation Plan participants