UNIVERSITY OF CALIFORNIA, SAN FRANCISCO AUDIT AND ADVISORY SERVICES

Outside Activities Reporting Review Project #21-037

August 2021



Audit & Advisory Services

UCSF Box 0818 1855 Folsom Street San Francisco, CA 94143

tel: 415.476.3851 fax: 415.476.3326

www.ucsf.edu

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 below¹:

- Academic Personnel Manual Policy 025 (APM 025): "Conflict of Commitment and Outside Activities of Faculty Members" (rev. January 2020)
- Academic Personnel Manual Policy 670 (APM 670): "Health Sciences Compensation Plan" (July 2012)
- Academic Personnel Manual Policy 671 (APM 671): "Conflict of Commitment and Outside Activities of Health Sciences Compensation Plan Participants" (rev. September 2020)

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
- Reguest 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

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.

Category	Definition	Disclosure Requirements
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 Payments², 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 manufactures) 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.

_

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

No.	<u>Observation</u>	Risk/Effect	Recommendation	MCA
1	Multiple instances of non-compliance with	In addition to	a) For faculty who	Action Plan:
	University policy on outside activities and income	compliance risk, there	have improperly or	a) The inaccurate
	disclosures were identified. Among a sample of	is reputational risk in	incompletely	disclosures were
	20 faculty members, nearly two thirds (13) had	not ensuring that	disclosed their	reported to the
	under-reported income that totaled \$496K.	outside activities are	outside	department chairs,
		properly and	professional	who worked with the
	a) Policy Non-compliance:	comprehensively	activities,	faculty to review the
	Our analysis of Open Payments data and activities	disclosed in OATS,	departmental	discrepancies. As a
	reported for FY19 and FY20 within OATS identified	the system of record	leaders should	result, the faculty
	several faculty members who did not fully report their	for outside activities	ensure that faculty	members made
	outside activities, as required by University Policies	reporting.	update their	retroactive
	APM 025 and APM 671.		outside activities	adjustments to their
		By not applying	disclosures in	OATS disclosure
	We selected 20 faculty who had an initial variance of	consequences for	OATS.	forms.
	over \$10,000 between what was reported in Open	non-compliance, there	-> -> -> -> -> -> -> -> ->	A -4: O -4
	Payments and what was disclosed in OATS. From	may not be an	b) Focused	Action Completed
	this sample, we contacted the department chair for	incentive to change	education	b) The current FAQs
	additional information. Based on the information	behavior and to	regarding outside	on outside activities will
	reported by the chair, we concluded that 13 out of 20	ensure compliance	professional	be enhanced and made accessible to
	faculty had underreported outside earnings in	with UC policy.	activities,	
	amounts that ranged from \$1,800 to \$213,689. The total amount of underreported income was \$496,005.		particularly the distinction	faculty, department chairs and chief
	total amount of underreported income was \$490,005.		between	administrative officers.
	We noted the following reasons for the		categories, should	The FAQs will provide
	underreporting:		be considered to	greater clarity on
	2 faculty members engaged in Category I		promote more	Category II and III
	activities and made after-the-fact disclosures		accurate	activities.
	during the following fiscal year ³ (see		disclosure.	GOLVIGO.
	Observation # 3 for further details on category		diodiodalo.	
	I disclosures)			Target Completion
	i diodiodico)			Date:

³ One faculty assumed a founding or co-founding role and served on the board of directors outside the University, and engaged in these activities prior to appropriate Chancellor approval. The other faculty engaged in teaching outside the University.

No.	Observation	Risk/Effect	Recommendation	MCA
	3 faculty members miscategorized Category II		c) In addition to	December 1, 2021
	activities as Category III ⁴		training, other	
	1 faculty member did not complete a		actions should be	Responsible Party:
	disclosure due to reluctance to using OATS		considered in	SOM Vice Dean,
	6 faculty members underreported payments		order to address	Academic Affairs
	from their outside activities		structural reporting	
	1 faculty member had the impression that the		gaps, such as	c) SOM Academic
	outside activity did not need to be reported.		soliciting input	Affairs will continue
			from department	with its schoolwide
	Potential reasons for the discrepancies noted above		chairs and faculty on their	presentations,
	are that faculty did not have a clear understanding of			presentations for Chief Administrative
	the reporting requirements for non-cash		understanding of the academic	Officers, and other
	compensation such as stocks and stock options and		policies and OATS	presentations in
	erroneously classified "attending and presenting talks		disclosure,	order to enhance
	at academic colloquia and conferences" sponsored		targeted	knowledge of the
	by for-profit industry as a Category III activity when, in fact, these are Category II activities and subject to		communication,	categories of outside
	reporting requirements.		and establishment	professional
	reporting requirements.		of champions for	activities and the
	b) Policy Enforcement		outside activities	reporting
	a) I oney Emercement		reporting.	requirements. The
	APM 025 is the current UC policy regarding academic			next presentation
	appointees and conflict of commitment and outside		d) In regard to faculty	will be held by June
	activities of faculty members. Per APM 025-26 (b)		who failed to	30, 2022.
	Consequences for Non-Compliance, "failure to		disclose outside	
	comply with the policy may subject a faculty member		activities identified	Target Completion
	to discipline, corrective action, or administrative		in this audit, SOM	Date:
	remedies."		Academic Affairs	June 30, 2022
			should consider	
	While there are provisions in the policies for remedies		applicable actions	
	and disciplinary measures, currently there are limited		under APM 025	Boononcible Bertu
	consequences for late submission of disclosures,		"Consequences	Responsible Party:

_

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.

No.	<u>Observation</u>	Risk/Effect	Recommendation	MCA
	failure to submit conflict of commitment disclosure forms or having inaccurate information on the forms. When omissions of disclosures become known, remediation action typically includes faculty revising their disclosures forms and/or a settlement is reached whereby faculty pay a percentage of their undisclosed outside income into the compensation plan. Therefore, the current practice does not seem to be effective in encouraging behavior change and policy compliance.		for Non- Compliance".	SOM Vice Dean, Academic Affairs
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. 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. 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.	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.	a) At the campus level, a process should be developed and implemented to verify faculty member's outside reporting disclosures against the Open Payments. 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	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. Target Completion Date: April1, 2022

No.	<u>Observation</u>	Risk/Effect	Recommendation	MCA
			in during the calendar year.	Responsible Party: Vice Provost,
				b) In the event that a direct connect between Open Payments and OATS is not implemented as a multi-campus solution, the Task Force identified above will provide its recommendations to the Chancellor's Executive Team.
				Target Completion Date: June 30, 2022
				Responsible Party: Vice Provost, Academic Affairs
3	Permission for Category I activities is not always requested in a timely fashion.	Not seeking approval prior to commencing Category I activities	a) Establish a process to monitor compliance with	Action Plan: a) On a quarterly basis the Office of
	Per APM 025 and APM 067, UCSF policies governing outside activities reporting, prior approval by the	precludes the ability to determine whether the	pre-approval requirements for	Technology Management and
	Chancellor is required for Category I activities, or activities most likely to create a conflict of commitment.	activity creates a conflict of commitment for the faculty.	category I activities, such as reporting by OTM of start-up	Advancement (OTMA) will provide Academic Affairs with a list of
	We obtained a listing from the Office of Technology Management (OTM) of faculty members that had	The many levels of review and approval	activities to the Office of	university IP licensed to start-up

No.	Observation	Risk/Effect	Recommendation	MCA
	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. 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. 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 preapproval 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.	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.	Academic Affairs to alert them of potential Category I activities. b) Re-evaluate the current preapproval 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. c) Management should establish and communicate expectations to faculty regarding lead-time needed for pre-approvals of Category I activities.	companies including the relevant UCSF faculty member. The first report will be provided in December 2021 and quarterly thereafter. Target Completion Date: December 30, 2021 Responsible Party: Assistant Director, Patent Prosecution and Business b) Communications to faculty members to reinforce policy requirements on seeking prior approval for Category I activities will occur. c) The pre-approval process for Category I activities will be reevaluated to identify improvements to streamline the approval process. d) A process will be developed to

<u>No.</u>	<u>Observation</u>	Risk/Effect	Recommendation	<u>MCA</u>
				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

V. <u>OPPORTUNITIES FOR IMPROVEMENT</u>

<u>No.</u>	<u>Observation</u>	Risk/Effect	<u>Recommendation</u>
1	Faculty should be encouraged to use OATS for on-going tracking	By not utilizing OATS to	Academic Affairs and
	of outside activities and income, not solely for the annual	report outside activities	the departments should
	disclosure process.	throughout the year, the	continue to promote
		annual disclosure process	OATS to be used as an
	Though faculty engage in outside activities throughout the year, they	may be more time-	ongoing tracking tool
	are required to report their activities only once, through the annual	consuming and there is	for outside activities.
	disclosure report. Though there may be a lag between engaging in	increased risk of errors and	
	activities and receiving payment, it may be challenging for faculty to	omissions.	
	remember all of the activity details they've engaged in during the year		
	when completing their annual disclosures. Therefore, utilizing OATS to		
	track their activities as they occur could help the disclosure process be		
	less burdensome and help faculty monitor their activities in real time		
	with the aim of more accurate activities reporting.		

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:
 - Academic Personnel Manual Policy 025 (APM 025): "Conflict of Commitment and Outside Activities of Faculty Members" (rev. January 15, 2020)
 - Academic Personnel Manual Policy 670 (APM 670): "Health Sciences Compensation Plan" (July 2012)
 - Academic Personnel Manual Policy 671 (APM 671): "Conflict of Commitment and Outside Activities of Health Sciences Compensation Plan Participants" (rev. September 23, 2020)
 - Outside Activities Tracking System Guidelines: "UCSF Requirements for Requesting Prior Approval to Engage in Category I Activities" (rev. July 1, 2019)
- 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
 - o Affiliations, Outreach and Compliance Coordinator, School of Medicine
 - o 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