

## A. Academic Personnel Manual (APM) 671

APM 671 is UC's policy on conflict of commitment and outside activities, and the disposition of income earned from OPAs. The policy provides guidance for the identification and management of OPAs,<sup>3</sup> in order to avoid conflicts of commitment, while assuring that Health Sciences Compensation Plan (the "Compensation Plan") participants may engage in a wide array of outside activities without unnecessary limitations. This policy specifically applies to faculty members who are participants in the Health Sciences Compensation Plan.

In relevant part, under Section 671-6(b), faculty members are responsible for:

- Obtaining prior written approval for engagement in Category I activities;<sup>4</sup>
- Maintaining a running total of annual earnings from, and time spent on, all OPAs;<sup>5</sup>
- Depositing all income that exceeds the earnings approval threshold into the Plan with the exception of income earned from Category III activities;<sup>6</sup>
- Obtaining prior written approval to engage in OPAs that may result in exceeding the total annual time and/or earnings approval thresholds;<sup>7</sup>
- Submitting annual reports of all Category I and II activities and compensation earned from such activities (or the lack thereof) to the Department Chair;<sup>8</sup>
- Attesting to adherence with the requirements of the policy in the annual report;<sup>9</sup> and Disclosing any current or prospective outside professional activity to the Department Chair if in doubt as to whether there is a conflict of commitment.<sup>10</sup>

### 1. *Accounting of OPAs*

APM 671 requires faculty to report all OPAs on an annual basis. This accounting is operationalized by faculty completing a "Report of Category I, II and III Compensated Outside Professional Activities and Additional Teaching Activities and Report of Investment Interests in Health Industry Companies." This form is maintained by the Academic Personnel Office (Academic Personnel).

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<sup>3</sup> Per APM 671: "Outside Professional Activities, compensated or uncompensated, 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. Outside additional teaching as described in APM 671-10-a-(2)-(a) is included in this definition. Outside professional activities are distinct from nonprofessional activities, i.e., activities that are part of the faculty member's private life and are not expressly governed by University regulations or by the guidelines on outside professional activities. Outside professional activities must not interfere with a faculty member's professional obligation to the University."

<sup>4</sup> See 671-6(b)(2).

<sup>5</sup> See 671-6(b)(3).

<sup>6</sup> See 671-6(b)(4) and 671-8(d)(5). Departments have the authority to distribute a portion of or the entire amounts of deposited income, after assessment, and with the exception of income set aside for academic enrichment, to the individual faculty member, consistent with applicable law and University policies.

<sup>7</sup> See 671-6(b)(5).

<sup>8</sup> See 671-6(b)(6).

<sup>9</sup> See 671-6(b)(7).

## B. Open Payments (OP)

The Physician Payments Sunshine Act (PPSA) requires medical product manufacturers to disclose to the Centers for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals.<sup>14</sup> The data disclosed by these companies is published annually in a publicly searchable database at: <https://www.cms.gov/OpenPayments>.<sup>15</sup> This database is commonly referred to as the Open Payments (OP) database.

The OP database characterizes payments made to physicians in four broad categories:<sup>16</sup>

- **General** - Payments that are not associated with a research study.
- **Research** - Payments that are associated with a research study.
- **Associated Research** - Funding for a research project or study where the physician is named as a principal investigator.
- **Ownership** - Ownership and investment interest in companies, which describes both the actual dollar amount invested and the value of the ownership or investment interest. Records may have one or both of these values associated with them.

## A. Comparison of APM disclosures and OP Data

### 1. *APM Disclosure Categories*

APM 671 defines three reporting categories under the policy:

- **Category I:** Category I activities are outside professional activities that are most likely to create a conflict of commitment because: 1) they are activities related to the training and expertise which is the individual's qualification for University appointment, but performed for a third party, and/or 2) they require significant professional commitment. Category I activities require prior approval by the Chancellor and require disclosure in annual reporting. Category I activities include, but are not limited to:
  - (a) Teaching, research, or administration of a grant at an educational institution, trust, organization, government agency, foundation, or other entity outside of the University;
  - (b) Employment outside of the University;
  - (c) Assuming a founding/co-founding role of a company;
  - (d) Assuming an executive or managerial position outside of the University.

Pursuant to policy, faculty must obtain approval prior to engaging in a Category I activity and all such activities must be reported on the disclosure form.

- **Category II:** Category II activities are typically shorter term outside professional activities that are outside the course and scope of University employment. Category II activities have a lesser potential for a conflict of commitment than do Category I activities. Category II activities require disclosure in annual reporting under this policy, but do not require prior approval. Category II activities count toward the faculty member's time allotment for outside professional activities. Examples of Category II activities include, but are not limited to:
  - (a) Additional University-compensated teaching, including teaching for UNEX courses and programs;
  - (b) Consulting under the auspices of the University of California;
  - (c) Consulting or testifying as an expert or professional witness;
  - (d) Consulting for for-profit entities;
  - (e) Consulting for non-profit entities;
  - (f) Consulting for non-profit health or education-related organizations;

- (g) Consulting for government agencies;
- (h) Serving on a board of directors outside of the University whether compensated or uncompensated
- (i) Providing or presenting a workshop for industry;
- (j) Providing outside consulting or compensated professional activities performed for entities such as the Los Alamos and Lawrence Livermore National Laboratories;
- (k) Other income-generating activities specified in approved Implementing Procedures.

All Category II activities must be disclosed on the disclosure form.

- Category III: Category III activities are within the course and scope of University employment. As such, they are unlikely to raise conflict of commitment issues. Category III activities, even if compensated, do not require disclosure in annual reporting or prior approval under this policy, do not count toward the faculty member's time threshold for outside professional activities, and the income does not count toward the earnings approval threshold. Examples of Category III activities include, but are not limited to:
  - (a) Serving on government or professional panels or committees or as an officer or board member of a professional or scholarly society;
  - (b) Reviewing manuscripts; acting in an editorial capacity;
  - (c) Attending and presenting talks at university/academic colloquia and conferences; and
  - (d) Developing scholarly or creative works.

APM 671 also characterizes "Other Activities" that do not require repayment by faculty to the Compensation Plan. Payment from these activities does not count toward the earnings approval threshold; time related to these activities does not count toward time limits. "Other Activities" includes:

- Prizes, defined as gifts in recognition of personal achievements and not for services rendered;
- Royalties, defined as shares of proceeds for contributions as authors or inventors, as allowed under the University's copyright and patent policies;
- Honoraria, defined as payments by agencies outside the University for occasional lectures and similar public appearances beyond normal academic responsibilities to the University of California and which are not in return for other services, whether given directly or indirectly;
- University honoraria, defined as payment for occasional lectures or similar services performed on a University of California campus as permitted by Academic Personnel
- Administrative stipends;
- Income from a profession unrelated to the training and experience which is the individual's qualification for University appointment.
  - *OP Reporting Categories*

The OP Database captures 12 reporting categories for payments by companies to physicians. The OP reporting categories and examples are included in the table below.

Table 4: OP Reporting Category Definitions

Nature of payment	Definition	Examples
Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.	Payments made to physicians for speaking, training, and education engagements that are not for continuing education.	A physician who frequently prescribes a particular drug is invited by the company that makes that drug to talk about the medicine to other physicians at a local restaurant. The physician is paid for preparation time as well as the time spent giving the talk.
Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.	Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.	Drug company Y gives money to a teaching hospital to help pay for the hospital's annual course for its physicians. The course is an update on the latest treatments for diseases.
Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.	Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.	Drug Company X gives money to a society to organize a continuing education program on a particular condition that Drug Company X produces a drug to treat. The company recommends Dr. C be chosen as one of the lecturers. Because the company specifically recommended the use of Dr. C, they must report the speaking fee under Dr. C's name.
Grant	Payments to a physician or teaching hospital in support of a specific cause or activity.	Company A gives a grant to a teaching hospital to pay for part of the cost of special training for physicians who want to learn more about how to perform surgeries to give patients Company A's device.
Royalty or license	Royalty or other payment based on sales of products that use a physician's intellectual property.	A device manufacturer may promise a certain amount of payment in royalties – 1% of all device sales, for example – to a physician who worked with the device manufacturer to invent a new product.
Honoraria	Similar to consulting fees, but generally reserved for a one-time, short duration activity. Also distinguishable in that they are generally provided for services which custom prohibits a price from being set.	A medical device manufacturer representative goes to a medical meeting and asks some physicians there for an hour of their time to talk about features they would like to see to improve a particular device. This representative pays each physician a one-time honorarium.
Gift	A general category, which will often include anything provided to a physician or teaching hospital that does not fit into another category.	Promotional items such as clocks or flash drives that have the company's name printed on them.
Entertainment	Attendance at recreational, cultural,	Tickets to sporting events, concerts or theater shows.

Nature of payment	Definition	Examples
	sporting or other events that would generally have a cost.	
Food and beverage	Food and beverage.	A sales person from a drug manufacturer asks a physician if they can talk with them about a new drug. They meet over lunch, and the salesperson pays for the meal.
Travel and lodging	Travel and lodging.	A medical device company does yearly training events for physicians on how to use their device on patients. The company flies physicians to their headquarters for the training and pays for their hotel rooms.
Education	This category generally includes payments or transfers of value for classes, activities, programs or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a profession. This category can include things like textbooks and medical journal articles.	Companies that produce or sell drugs or devices for a particular medical condition may offer textbooks to physicians, free of charge, related to the latest treatments for that condition.
Consulting fee	Payments made to physicians for advice and expertise on a particular medical product or treatment, typically provided under a written agreement and in response to a particular business need. These payments often vary depending on the experience of the physician being consulted.	<p>Example 1: Company A has developed a drug to treat patients with a particular disease and wants advice from physicians on how to design a large study to test the drug on patients. Dr. J has a large number of patients with this disease and has experience doing research on how well medicines work for this condition. Company A asks Dr. J if he would spend about 10 hours per month to work with other physicians to create a new research study. Dr. J agrees and is paid for his time.</p> <p>Example 2: Company C has designed a new tool for surgeons to use when they are doing heart surgery. The company pays some physicians to give the new tool a “test drive” on a computer-simulated patient at the company headquarters. The physicians are paid an hourly fee for their time testing the tool and giving advice on how to make it work better. They are also paid for flights, hotel rooms and meals.</p>

- *Alignment of the OP Categories and the APM Disclosure Categories*

The requisite disclosures under APM 671 do not directly mimic the OP Reporting categories. As such, Compliance developed a crosswalk between the APM and OP categories to assess whether a reporting category in OP *could* align with an APM required disclosure. This resulted in identifying four OP payment categories that aligned with the required APM reporting categories, Categories I & II, and one category that could potentially align (i.e., Honoraria.)

Table 5: OP Categories and APM Disclosure Categories Crosswalk

<b>OP Category: Nature of payment</b>	<b>OP Category Definition</b>	<b>OP Examples of Activities that fit into that Category</b>	<b>Aligned APM Disclosure Category</b>
Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.	Payments made to physicians for speaking, training, and education engagements that are not for continuing education.	A physician who frequently prescribes a particular drug is invited by the company that makes that drug to talk about the medicine to other physicians at a local restaurant. The physician is paid for preparation time as well as the time spent giving the talk.	II
Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.	Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program	Drug company Y gives money to a teaching hospital to help pay for the hospital's annual course for its physicians. The course is an update on the latest treatments for diseases.	II
Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.	Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program	Drug Company X gives money to a society to organize a continuing education program on a particular condition that Drug Company X produces a drug to treat. The company recommends Dr. C be chosen as one of the lecturers. Because the company specifically recommended the use of Dr. C, they must report the speaking fee under Dr. C's name.	II
Consulting fee	Payments made to physicians for advice and expertise on a particular medical product or treatment, typically provided under a written agreement and in response to a particular business need. These payments often vary depending on the experience of the physician being consulted.	Company A has developed a drug to treat patients with a particular disease and wants advice from physicians on how to design a large study to test the drug on patients. Dr. J has a large number of patients with this disease and has experience doing research on how well medicines work for this condition. Company A asks Dr. J if he would spend about 10 hours per month to work with other physicians to create a new research study. Dr. J agrees and is paid for his time.	II

Honoraria	Similar to consulting fees, but generally reserved for a one-time, short duration activity. Also distinguishable in that they are generally provided for services which custom prohibits a price from being set.	A medical device manufacturer representative goes to a medical meeting and asks some physicians there for an hour of their time to talk about features they would like to see to improve a particular device. This representative pays each physician a one-time honorarium.	II (Potentially) <sup>17</sup>
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