



POLICIES AND PROCEDURES

SUBJECT: DHS CONFLICT OF INTEREST DISCLOSURE POLICY -
PHARMACEUTICAL

POLICY NO: 329.006

PURPOSE:

To delineate clear guidelines for Department of Health Services (DHS) healthcare providers regarding conflict of interest disclosure in regards to financial relationships with pharmaceutical and biotechnology manufacturers/vendors of drug therapy. This policy is intended to maintain a culture of ethics in pharmaceutical business relations and to require disclosure of conflicts of interest.

This policy applies to all DHS Core Pharmacy & Therapeutics (P&T) Committee members, subcommittees, and expert panel members. This policy also applies to all providers that submit formulary requests for consideration to the DHS Core P&T Committee.

It is essential that all aspects of the DHS Core P&T Formulary Selection and Maintenance Process (Policy No. 329.002) remain objective and unbiased, and that the judgment of the Committee members, or those who advise the Committee, not be influenced by individual financial circumstances. Therefore, the ability of healthcare professionals who disclose a conflict of interest will be impacted by the nature of their financial relationship, as identified in the policy below.

POLICY:

A "Conflict of Interest Disclosure Statement Form (Appendix A)" shall be completed on an annual basis by the following groups (except if the individual is already required to complete the annual Form 700 Statement of Economic Interests and has timely filed his/her Form 700): DHS Core Pharmacy & Therapeutics Committee, subcommittees and expert panel members. It is highly encouraged that DHS Facility P&T Committees adopt this policy for facility level formulary committees. Facility Chief Medical Officers (CMOs) shall consider disclosed pharmaceutical vendor conflicts of interest prior to appointment of a representative to any of these committees.

The completed disclosure statement will be returned to the DHS Chief Pharmacy Officer (also DHS Core P&T Committee co-chair). The DHS Chief Pharmacy Officer shall tabulate all disclosed conflicts and provide a report to the impacted committee for review prior to rendering formulary recommendations or decisions.

A healthcare provider with a Category I conflict of interest (considered significant conflict, as outlined below) may not participate in any DHS P&T Committee, subcommittee, or expert panel where a formulary discussion or decision is taking place, regardless of their conflicted vendor's

APPROVED BY:

EFFECTIVE DATE: January 14, 2014

REVIEW DATES: November 12, 2013
January 8, 2013

SUPERSEDES: November 12, 2013
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product. The facility CMO may assign an alternate. The DHS facility will forfeit voting privileges if an alternate is not provided.

Those individuals on the DHS Core P&T Committee, subcommittee, or expert panel with a Category II conflict of interest (considered non-significant conflict of interest, as outlined below) will have those conflicts disclosed to the DHS Core P&T Committee prior to the formulary review of an agent. The individual may not participate in the formulary discussion of, or voting on, any product/therapeutic class competitor with the conflicted pharmaceutical vendor/manufacturer at Core P&T or Facility P&T meetings. Individuals with a Category II conflict of interest are allowed to discuss but cannot vote as a facility representative in Expert Panels.

All drug formulary change requests (addition, deletion, or restriction change) forwarded to the DHS Core P&T Committee shall be accompanied by a completed "Conflict of Interest Disclosure Statement Form" (Appendix A). Any formulary change requests forwarded to the DHS Core P&T Committee without this form will be returned back to the Facility P&T Committee. Any potential conflicts of interest will be disclosed to the DHS Core P&T Committee.

It is the responsibility of the DHS Core P&T Committee, subcommittee, or expert panel member to complete an updated "Conflict of Interest Disclosure Statement Form" should his/her conflict change during the year for which the statement is valid.

CONFLICT OF INTEREST CATEGORIES:

Conflict of interest develops when an individual who serves in a position of influence with a vendor has the opportunity to influence DHS business decisions or interests.

All professional, personal, or financial affiliations (including those of immediate family) with pharmaceutical companies or organizations must be disclosed. These potential conflicts are segregated into two categories:

Category I - Significant Conflict of Interest: This category is considered a "significant" conflict of interest enough to require recusal from discussion or voting on the DHS P&T Core Committee, DHS Facility P&T Committee, or expert panels. An individual with a Category I conflict may present his/her expert opinion to a DHS Expert Panel, but will not participate in any subsequent discussion or voting. Additionally, individuals with a Category I conflict may submit DHS Formulary Change Requests. Significant conflicts of interest include the following:

- A member of the Board of Directors or Advisory Board for a pharmaceutical vendor/manufacturer within the past 12 months.
- Participation in a pharmaceutical company sponsored Speaker's Bureau (defined as more than one lecture affiliated with the same company in the past 12 months).

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- Receipt of income, including but not limited to income from direct employment, speaking on behalf of a pharmaceutical vendor/manufacturer, or consulting activities from a pharmaceutical vendor/manufacturer > \$1,000 annually.
- Personal financial holdings in the form of stocks (excluding mutual funds) or royalties affiliated with pharmaceutical companies > \$1,000 annually.
- Receipt of pharmaceutical vendor/manufacturer research funding (NOT income to the individual) > \$49,999 annually. For Phase I, II, or III research, the DHS Core P&T Committee has discretion to review relevance of conflict. Phase IV research is considered a conflict in the aforementioned funding amounts.
- Receipt of pharmaceutical vendor/manufacturer educational grants, scholarships, or awards, including funds by a third-party > \$1,000 annually.
- Receipt of income from a non-pharmaceutical vendor/manufacturer as a result of presenting continuing education, professional speaker fees, or contracted education programs > \$1,000 annually. The DHS Core P&T Committee has discretion to review relevance of conflict.
- Receipt of personal gifts, meals, pens, honoraria, compensation or rewards from pharmaceutical companies in the past 12 months > \$1,000 annually.

Category II - Non-significant Conflict of Interest: Individual DHS Core or Facility P&T Committee members that have a Category II conflict shall recuse themselves from discussing and voting on any decision involving the vendor of a similar therapeutic class or clinical indication for which the member has a conflict. Individuals with a Category II conflict may participate in discussion and voting as facility representatives of an expert panel. Additionally, individuals with a Category II conflict may submit DHS Formulary Change Requests. The following are considered non-significant conflicts of interest:

- Author of company-sponsored publications, including books and periodicals without direct monetary payment.
- Receipt of income, including but not limited to income from direct employment, speaking on behalf of a pharmaceutical vendor/manufacturer, or consulting activities from a pharmaceutical vendor/manufacturer > \$99 annually (but ≤ \$1,000).
- Personal financial holdings in the form of stocks (excluding mutual funds) or royalties affiliated with pharmaceutical companies > \$99 annually (but ≤ \$1,000).
- Receipt of pharmaceutical vendor/manufacturer research funding (NOT income to the individual) > \$9,999 annually (but ≤ \$49,999). For Phase I, II, or III research, the DHS Core P&T Committee has discretion to review the relevance of conflict as it pertains to participation in discussion or voting. Phase IV research is considered a conflict in the aforementioned funding amounts.
- Receipt of pharmaceutical vendor/manufacturer educational grants, scholarships, or awards, including funds by a third-party > \$99 annually (but ≤ \$1,000).
- Receipt of income from a non-pharmaceutical vendor/manufacturer as a result of presenting continuing education, professional speaker fees, or contracted education programs > \$99

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annually (but ≤ \$1,000). The DHS Core P&T Committee has discretion to review relevance of conflict.

- Receipt of personal gifts, meals, pens, honoraria, compensation or rewards from pharmaceutical companies in the past 12 months > \$99 annually (but ≤ \$1,000).

The DHS Core P&T Committee shall, on a case by case basis, decide individual conflicts of interest exceptions. For example, if a specific physician is on the speaker’s bureau for the treatment of diabetes, their conflict of interest with a potential pharmaceutical product (manufactured by the same vendor) for radiological pharmaceutical diagnosis may not be relevant. Individual DHS Core P&T Committee members that have a Category II conflict shall recuse themselves from discussing and voting on any decision involving the vendor of a similar therapeutic class or clinical indication for which the member has a conflict.

Requirements for various levels of DHS P&T participation based on reported conflicts are detailed in Table 1.

Table 1

Level of DHS P&T Participation	Category I Conflict Permitted	Category II Conflict Permitted
DHS Core P&T Committee Member-representing DHS facility	No	No
DHS Facility P&T Committee Chair	No	No
DHS Facility P&T Committee Members	Yes with disclosure to Facility P&T Committee, but will not participate in discussion and voting if a conflict exists	Yes with disclosure to Facility P&T Committee, but will not participate in discussion and voting if a conflict exists
DHS Core P&T Expert Panel Member-representing DHS facility	May present information to DHS Core P&T expert panel, but will not participate in subsequent discussion and voting	May participate in discussion but cannot vote
DHS Formulary Request Submitter	Disclose conflict that will be presented to Core P&T Committee members and expert panels during review	Disclose conflict that will be presented to Core P&T Committee members and expert panels during review

This policy shall be reviewed annually and updated as necessary by the DHS Core P&T Committee.

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APPENDIX A (See attachment): DHS Conflict of Interest Disclosure Statement Form

REFERENCES:

Form 700: A Public Document, Statement of Economic Interests. California Fair Political Practices Commission. 2012/2013. <http://www.fppc.ca.gov>

Form 700 Statement of Economic Interests: Reference Pamphlet. California Fair Political Practices Commission. 2012/2013. <http://www.fppc.ca.gov>

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**COUNTY OF LOS ANGELES - DEPARTMENT OF HEALTH SERVICES
 PHARMACY AND THERAPEUTICS COMMITTEE
 CONFLICT OF INTEREST DISCLOSURE STATEMENT FORM**

As a healthcare provider that participates in a DHS pharmaceutical formulary committee, or is submitting a request for formulary review, you are required to disclose pharmaceutical vendor/manufacture conflicts of interest that may exist.

Name (please print):			
Title:			
Department:		Contact telephone number:	
Email address:			
DHS Facility:			
<input type="checkbox"/> LAC+USC MC	<input type="checkbox"/> EI Monte CHC	<input type="checkbox"/> Humphrey CHC	<input type="checkbox"/> OV/UCLA MC
<input type="checkbox"/> Hudson CHC	<input type="checkbox"/> H/UCLA MC	<input type="checkbox"/> MLK MACC	<input type="checkbox"/> Mid-Valley CHC
<input type="checkbox"/> Roybal CHC	<input type="checkbox"/> Long Beach CHC	<input type="checkbox"/> High Desert MACC	<input type="checkbox"/> San Fernando CHC
	<input type="checkbox"/> Wilmington CHC	<input type="checkbox"/> Rancho LA NRC	<input type="checkbox"/> Other: _____
Reason for Disclosure:			
I am completing this disclosure form for the following committee and/or purpose: (Check all that apply)			
<input type="checkbox"/> Submitting Drug Request to be reviewed by DHS Core P&T Committee			
<input type="checkbox"/> DHS Core Pharmacy & Therapeutics Committee			
<input type="checkbox"/> DHS Facility Pharmacy & Therapeutics Committee			
<input type="checkbox"/> DHS Expert Panel (List): _____			
Disclosure Statement:			
I have read and understand the Los Angeles County DHS Conflict of Interest Disclosure Policy- Pharmaceutical, and hereby disclose the following (Please check one of the following):			
<input type="checkbox"/> I have "NO" conflicts of interest to disclose. (Please sign the form on the last page)			
<input type="checkbox"/> I do have existing conflicts of interest, either currently or within the last 12 months.			

The following is a list of my potential conflicts of interest (Check all that apply).

I or my immediate family (i.e., spouse/domestic partner or dependents) have/has been a member of the Board of Directors or Advisory Board for a pharmaceutical vendor/manufacture within the past 12 months.

Pharmaceutical Vendor / Manufacturer	Position Held (category 1 conflict)

I or my immediate family (i.e., spouse/domestic partner or dependents) have/has been appointed to a pharmaceutical company sponsored Speaker's Bureau (defined as more than one lecture affiliated with the same company in the past 12 months).

Pharmaceutical Vendor / Manufacturer	Specific Drug / Agent (category 1 conflict)

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I or my immediate family (i.e., spouse/domestic partner or dependents) have/has been an author of company-sponsored publications, including books and periodicals without direct monetary payment.

Pharmaceutical Vendor / Manufacturer	Publication Title (category 2 conflict)

I or my immediate family (i.e., spouse/domestic partner or dependents) have/has received income, including but not limited to income from direct employment, speaking on behalf of a pharmaceutical vendor/manufacture, or consulting activities from a pharmaceutical vendor/manufacture.

Pharmaceutical Vendor / Manufacturer	Position Held	Amount received >\$1,000 (category 1 conflict)	Amount received >\$99 (category 2 conflict)

I or my immediate family (i.e., spouse/domestic partner or dependents) have/has personal financial holdings in the form of stocks (excluding mutual funds) or royalties affiliated with pharmaceutical companies.

Pharmaceutical Vendor / Manufacturer	Specify Financial Holdings Type	Valuation Amount >\$1,000 (category 1 conflict)	Valuation Amount >\$99 (category 2 conflict)

I or my immediate family (i.e., spouse/domestic partner or dependents) have/has received pharmaceutical vendor/manufacture research funding (NOT income to the individual). For Phase I, II, or III research, the DHS Core P&T Committee has discretion to review the relevance of conflict as it pertains to participation in discussion or voting. Phase IV research is considered a conflict in the aforementioned funding amounts.

Pharmaceutical Vendor / Manufacturer	Specific Drug / Agent	List Trial Phase (i.e., I, II, III, or IV)	Amount Received >\$49,999 (category 1 conflict)	Amount Received >\$9,999 (category 2 conflict)

I or my immediate family (i.e., spouse/domestic partner or dependents) have/has received pharmaceutical vendor/manufacture educational grants, scholarships, or awards, including funds by a third party.

Pharmaceutical Vendor / Manufacturer	Grant or Contract Title (include specific agent)	Amount received >\$1,000 (category 1 conflict)	Amount received >\$99 (category 2 conflict)

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I or my immediate family (i.e., spouse/domestic partner or dependents) have/has received income from a non-pharmaceutical vendor/manufacturer as a result of presenting continuing education, professional speaker fees, or contracted education programs that focused on a specific drug or drug class. The DHS Core P&T Committee has discretion to review relevance of conflict.

List topic of speaking engagement	Name of Drug or Therapeutic Class Involved	Amount received >\$1,000 (category 1 conflict)	Amount received >\$99 (category 2 conflict)

I or my immediate family (i.e., spouse/domestic partner or dependents) have/has received personal gifts, meals, pens, honoraria, compensation or rewards from pharmaceutical companies in the past 12 months.

Pharmaceutical Vendor / Manufacturer	Type	Amount received >\$1,000 (category 1 conflict)	Amount received >\$99 (category 2 conflict)

I or my immediate family (i.e., spouse/domestic partner or dependents) have/has been involved in any **other** potential conflict of interest as defined below:

Pharmaceutical Vendor / Manufacturer	Description

I have reviewed "DHS Conflict of Interest Disclosure Policy-Pharmaceutical" and have submitted all of my known disclosures, as stipulated in this policy. I understand that it is my obligation to fully disclose all potential conflicts of interest. If my conflicts of interests change, or if I become aware of any additional potential conflicts, I understand that is my responsibility to submit an updated disclosure form to the DHS Core Pharmacy & Therapeutics Committee.

Signature

Date

Please return the completed form to:

DHS Pharmacy Affairs
 313 N. Figueroa Street, Suite 701
 Los Angeles, CA 90012

You may fax form to:

Attention: DHS Pharmacy Affairs
 (213) 975 – 9623

Approved by:

DHS Core P&T Committee

Effective Date: 1/14/14

Last Updated: 1/14/14