

Appendix 15: CHBRP's Conflict-of-Interest Policies: General Disclosure Form and NAC Disclosure Form

In order to avoid conflicts of interest, the Legislature requested the University of California to develop and implement conflict-of-interest provisions to prohibit a person from participating in any analysis in which the person knows or has reason to know he or she has a material financial interest, including but not limited to a person who has a consulting or other agreement with a person or organization that would be affected by the legislation.

CHBRP's authorizing statute includes the following provision:

Section 127663. In order to avoid conflicts of interest, the Legislature requests the University of California to develop and implement conflict-of-interest provisions to prohibit a person from participating in any analysis in which the person knows or has reason to know he or she has a material financial interest, including, but not limited to, a person who has a consulting or other agreement with a person or organization that would be affected by the legislation.

The following clarifies the process by which the California Health Benefits Review Program (CHBRP) implements this provision.

General request for conflict-of-interest (COI) form completion process:

- When a new CHBRP staff or faculty member is hired or designated to work on CHBRP analyses, the CHBRP Director sends them the standard form letter requesting them to complete a COI form. This letter contains instructions and the due date.
- The same applies for content experts or special reviewers requested to conduct analysesspecific work. However, the lead analyst may also send a request letter. In addition, the lead analyst and/or the lead from the CHBRP medical effectiveness team should initially screen the potential content expert by querying him/her about any potential conflicts of interest. (See Appendix 9: Content Expert Identification, Screening, and Selection Protocol)
- The CHBRP Program Specialist, and the CHBRP Director and the lead CHBRP analyst (if specific to a bill) should be carbon copied on the COI request e-mail.

General submission process:

- When a new or revised COI form is submitted, the original goes to the CHBRP Program Specialist, who will provide it to the CHBRP Director.
- The CHBRP Director will update the tracking database with the new information, and contact the person submitting the COI form to clarify any questions, if necessary.

• The CHBRP Director will consult the Academic Affairs, Director of Research Policy Development if there are any potential conflicts that require further vetting.

Ongoing Review of potential conflicts- reviewing and tracking:

- *Bill-specific conflicts of interest:* When the Legislature requests a new bill analysis, as part of the initial Faculty Task Force conference calls, CHBRP staff will ask potential team members for the bill analysis to assess potential conflicts of interest, and update their file, if necessary, before the analysis starts. Files can be updated with an e-mail providing information about the conflict. Both potential conflicts and recusals from a specific bill analysis should be documented in the file. The CHBRP Director will notify CHBRP staff (and sometimes the Faculty Task Force) when a conflict has been identified and when a recusal is confirmed. If a recusal applies for a specific bill analysis, the lead analyst is responsible to ensure that the appropriate recusal notations are made in the preface or back matter of the final report.
- Ongoing tracking: The CHBRP Program Specialist and the CHBRP Director are to check the database regularly to identify any missing forms or individuals that need follow up. They are to identify who must submit a form and keep track of who has/has not submitted their form. Appropriate follow up will be done to ensure completed and updated COI forms are maintained.
- Annual Updates of COI forms: Updates of all COI forms occur on an annual basis.
 - The CHBRP Director will review the current form and determine whether updates need to be made.
 - The CHBRP Program Specialist and CHBRP Director will work together to complete an update request to all CHBRP affiliated faculty and staff during the last quarter of the calendar year. If the information that was submitted the previous year is the same, individuals may check a box that stated "same as last year" and return it with their signature page.
 - CHBRP Program Specialist will e-mail to faculty, CHBRP staff, NAC members, and other affiliated researchers and contractors a request to update and return all COI forms by the end of the calendar year.
 - CHBRP Director will complete a review of all updates by the beginning of the Legislative session, or no later than January 30 of each year.

Forms:

- All CHBRP staff, faculty, affiliated researchers, analyst, actuaries, librarians, and content experts will complete the Standard COI Disclosure form (Attachment 1)
- All NAC members will complete NAC COI Disclosure form (Attachment 2).

Attachment 1: STANDARD COI DISCLOSURE FORM

University of California (UC)

Form for Obtaining Background Information and Conflict-of-Interest Disclosure for Activities Related to the California Health Benefits Review Program¹

NAME:	
TELEPHONE:	
ADDRESS:	
E-MAIL ADDRESS:	
CURRENT EMPLOYER:	
THE DECLARATIONS	IN THE ATTACHED FORM APPLY TO DECLARANT'S CONFL

THE DECLARATIONS IN THE ATTACHED FORM APPLY TO DECLARANT'S CONFLICTS OF INTERESTS IN REGARD TO HEALTH INSURANCE BENEFIT MANDATE REVIEWS CONDUCTED UNDER THE AUSPICES OF THE CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM (CHBRP) BEGINNING JANUARY 1, 2013 AND ENDING DECEMBER 31, 2013.

There are two parts to this form, Part I—Background Information, and Part II—Conflict of Interest Disclosure. Please complete both parts, **sign** and **date** this form on the last page, and return the form to the CHBRP administrator who requested your participation in the activity to which this form applies. **Please retain a copy for your records**.

You may opt to submit a copy of your curriculum vitae as your response, to Questions I-V, which follow on the next page.

PART I—BACKGROUND INFORMATION

Please provide the information requested below regarding **relevant** organizational affiliations, government service, public statements and positions, research support, and additional

¹ This form was modeled closely on a background and conflict of interest disclosure form designed by the National Academies of Sciences (NAS) for use with respect to studies relating to government regulation. The University of California and CHBRP are grateful to the NAS for extending its permission to use the NAS form. This CHBRP form may be subject to change. A substantially similar version of this form, *"For Activities Related to Government Regulation"*, is to be used for members of scientific advisory panels that UC convenes at the request of the State and for UC-recommended experts whose reports and/or advice are to be provided to the state for official use in a government regulatory process. CHBRP is grateful also to the UC Office of Research for its assistance in developing this form.

This form and the information provided by you therein may be disclosable to the public under applicable state laws and regulations.

information (if any). Information is "relevant" if it is related to—and might reasonably be of interest to others concerning—your knowledge, experience, and personal perspectives regarding the subject matter and issues to be addressed by the activity (e.g., service as a health insurance benefits mandate evaluator) for which this form is being prepared.

I. ORGANIZATIONAL AFFILIATIONS. Report your *relevant* business relationships (as an employee, owner, officer, director, consultant, etc.) and your relevant remunerated or volunteer non-business relationships (e.g., professional organizations, trade associations, public interest or civic groups, etc.).

II. GOVERNMENT SERVICE. Report your *relevant* service (full-time or part-time) with federal, state, or local government in the United States (including elected or appointed positions, employment, advisory board memberships, military service, etc.).

III. RESEARCH SUPPORT. Report *relevant* information regarding both public and private sources of research support (other than your present employer), including sources of funding, equipment, facilities, etc.

IV. PUBLIC STATEMENTS AND POSITIONS. List your *relevant* articles, testimony, speeches, etc., by date, title, and publication (if any) in which they appeared, or provide relevant representative examples if numerous. Provide a brief description of relevant positions of any organizations or groups with which you are closely identified or associated.

V. ADDITIONAL INFORMATION. If there are *relevant* aspects of your background or present circumstances not addressed above that might reasonably be construed by others as affecting your judgment in matters within the assigned task of the committee or other activity in which you have been invited to participate, and therefore might constitute an actual or potential source of bias, please describe them briefly.

PART II—CONFLICT-OF-INTEREST DISCLOSURE

Instructions: When the State of California requests the University of California's assistance in convening scientific advisory committees, such as the California Health Benefits Review Program, (CHBRP) or asks UC for recommendations of scientific experts to produce reports, such as CHBRP's evaluations of health insurance mandates, for the purpose of providing expert advice intended to be used by the State in formulating state laws or regulations, it is essential that the work of the participants in such activities not be compromised by any significant conflict of interest.

For this purpose, the term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.

Except for those situations in which UC and/or the government agency requesting UC's and CHBRP's assistance determines that a conflict of interest is unavoidable and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a UC-convened scientific advisory committee, such as CHBRP, or serve as a UC- or CHBRP-recommended expert evaluator when the report(s) developed by such service are intended to be used by the State as part of the official process for developing government laws or regulations, if the individual has a conflict of interest that is relevant to the functions to be performed.

The term "conflict of interest" means something more than individual bias. There must be an *interest*, ordinarily financial, that could be directly affected by the work of CHBRP or the UC- or CHBRP-recommended expert evaluator.

Conflict of interest requirements are *objective* and *prophylactic*. They are not an assessment of one's actual behavior or character, one's ability to act objectively despite the conflicting interest, or one's relative insensitivity to particular dollar amounts of specific assets because of one's personal wealth. Conflict–of– interest requirements are objective standards designed to eliminate certain specific, potentially compromising situations from arising, and thereby to protect the individual, the other members of the committee, the institution, and the public interest. The individual, the committee, and the institution should not be placed in a situation where others could reasonably question, and perhaps discount or dismiss, the work of the committee simply because of the existence of conflicting interests.

The term "conflict of interest" applies only to *current interests*. It does not apply to past interests that have expired, no longer exist, and cannot reasonably affect current behavior. Nor does it apply to possible interests that may arise in the future but do not currently exist, because such future interests are inherently speculative and uncertain. For example, a pending formal or informal application for a particular job is a current interest, but the mere possibility that one might apply for such a job in the future is **not** a current interest.

The term "conflict of interest" applies not only to the personal interests of the individual but also to the *interests of others* with whom the individual has substantial common financial interests if

these interests are relevant to the functions to be performed. Thus, in assessing an individual's potential conflicts of interest, consideration must be given not only to the interests of the individual but also to the interests of the individual's spouse and dependent children, the individual's employer, the individual's business partners, and others with whom the individual has substantial common financial interests.

Consideration must also be given to the interests of those for whom one is acting in a fiduciary or similar capacity (e.g., being an officer or director of a corporation, whether profit or nonprofit, or serving as a trustee).

This disclosure form is used for members of CHBRP, an entity that UC has convened at the request of the state, and for CHBRP-recommended experts whose reports and/or advice are to be provided to a state agency or to the Legislature for official use to evaluate proposed health insurance benefit mandates legislation. For such activities, the focus of the conflict-of-interest inquiry is on the identification and assessment of any interests that may be directly affected by the use of such reports in the regulatory process.

For example, if CHBRP or the CHBRP-recommended expert evaluator were conducting a study of a proposed health insurance benefit mandate requiring coverage for a particular medical technology, the focus of the conflict–of interest–inquiry would be on the identification and assessment of any interests that would be directly affected by that regulatory process if the report were to provide the basis for regulatory action or inaction. The concern is that if an individual (or others with whom the individual has substantial common financial interests) has specific interests that could be directly affected by the regulatory process, the individual's objectivity could be impaired.

Such interests could include an individual's significant stock holdings in a potentially affected medical technology company or being an officer, director, or employee of the company. Serving as a consultant to the company could constitute such an interest if the consulting relationship with the company could be directly affected or is directly related to the subject matter of the regulatory process.

An individual's other possible interests might include, for example, relevant patents and other forms of intellectual property, serving as an expert witness in litigation directly related to the subject matter of the regulatory process, or receiving research funding from a party that would be directly affected by the regulatory process if the research funding could be directly affected or is directly related to the subject matter of the regulatory process and the right to independently conduct and publish the results of this research is limited by the sponsor. Consideration would also need to be given to the interests of others with whom the individual has substantial common financial interests—particularly spouses, employers, clients, and business or research partners.

Questions: The following questions are designed to elicit information from you concerning possible conflicts of interest that may be relevant to the function(s) you have been asked to serve in regard to CHBRP's evaluation of proposed health insurance mandates.

1. <u>EMPLOYMENT</u>. (a) If the reports resulting from CHBRP's health insurance benefit mandate evaluations were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports:

(i) if you are employed or self-employed, could your current employment or self- employment (or the current employment or self-employment of your spouse, registered domestic partner, or dependent children) be directly affected?

YES NO NOT APPLICABLE If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(ii) to the best of your knowledge, could any financial interests of your (or your spouse's or dependent children's) employer or, if self- employed, your (or your spouse's or dependent children's) clients and/or business partners be directly affected?

YES NO NOT APPLICABLE

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(iii) if you are an officer, director or trustee of any corporation or other legal entity, could the financial interests of that corporation or legal entity be directly affected?

YES NO NOT APPLICABLE

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(iv) if you are a consultant (whether full-time or part-time), could there be a direct effect on any of your current consulting or advisory relationships?

___YES ___NO ___NOT APPLICABLE

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(v) regardless of the potential effect on the consulting relationship, do you have any current or continuing consulting relationships (including, for example, commercial and professional consulting and service arrangements, scientific and technical advisory board memberships,

serving as an expert witness in litigation, or providing services in exchange for honorariums and travel expense reimbursements, but excluding consulting relationships for which you received less than \$5,000 in fees, honorariums, reimbursements or other compensation) that are directly related to the subject matter of the possible government regulatory action or inaction?

YES NO NOT APPLICABLE If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(b) If you are or have ever been a government employee (either civilian or military), to the best of your knowledge are there any federal or state conflict of interest restrictions that may be applicable to your service in connection with your activities on behalf of CHBRP?

YES NO NOT APPLICABLE If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(c) If you are a government employee, are you currently employed by a state or federal agency that is sponsoring proposed health insurance benefit mandates? If you are not a government employee, are you an employee of any other sponsor (e.g., advocacy group, private foundation, etc.) of proposed health insurance benefit mandates?

YES NO NOT APPLICABLE If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

<u>2. INVESTMENT INTERESTS</u>. Taking into account stocks, bonds, and other financial instruments and investments including partnerships - excluding broadly diversified mutual funds and any investment or financial interest valued at less than \$5,000, but including any equity interest in non-publicly traded entity - if the reports resulting from CHBRP's health insurance benefit mandate evaluations were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports –

(a) Do you or your spouse or dependent children own directly or indirectly (e.g., through a trust or an individual account in a pension or profit-sharing plan) any stocks, bonds or other financial instruments or investments that could be affected, either directly or by a direct effect on the business enterprise or activities underlying the investments?

YES NO NOT APPLICABLE

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(b) Do you have any other significant financial investments or interests such as commercial business interests (e.g., sole proprietorships), investment interests (e.g., stock options), or personal investment relationships (e.g., involving parents or grandchildren) that could be affected, either directly or by a direct effect on the business enterprise or activities underlying the investments?

YES NO NOT APPLICABLE If "Yes," briefly describe the circumstances here (continuing on the last page of the form if

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

3. <u>PROPERTY INTERESTS</u>. Taking into account real estate and other tangible property interests, as well as intellectual property (patents, copyrights, etc.) interests, if the reports resulting from CHBRP's health insurance benefit mandate evaluations were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports –

(a) Do you or your spouse or dependent children own directly or indirectly any such property interests that could be directly affected?

___YES ___NO ___NOT APPLICABLE

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(b) To the best of your knowledge, do any others with whom you have substantial common financial interests (e.g., employer, business partners, etc.) own directly or indirectly any such property interests that could be directly affected?

___YES ___NO ___NOT APPLICABLE

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

4. <u>RESEARCH FUNDING AND OTHER INTERESTS</u>. (a) Taking into account your research funding (including gifts, if used for research, grants and contracts) and other research support (e.g., equipment, facilities, industry partnerships, research assistants and other research personnel, etc.), if the reports resulting from CHBRP's health insurance benefit mandate

evaluations were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports –

(i) could the research funding and support for you or your close research colleagues and collaborators be directly affected, <u>or</u>

(ii) if you have any research agreements for current or continuing research funding (including gifts, grants and contracts) or support from any party whose financial interests could be directly affected, and such funding or support is directly related to the subject matter of the regulatory process, do such agreements significantly limit your ability to independently conduct and publish the results of your research (other than for reasonable delays in publication, as defined by UC policy or, if you are not UC faculty, 30 days, in order to file patent applications)?

YES _____NO ____NOT APPLICABLE If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(b) Is the central purpose of CHBRP's health insurance benefit mandate evaluations for which this disclosure form is being prepared a critical review and evaluation of your own work or that of your employer?

YES NO NOT APPLICABLE If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(c) Do you have any existing professional obligations (e.g., as an officer of a scientific or engineering society) that effectively require you to publicly defend a previously established position on an issue that is relevant to the functions to be performed in CHBRP's health insurance benefit mandate evaluations?

YES _____NO ____NOT APPLICABLE If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(d) To the best of your knowledge, will your participation in CHBRP's health insurance benefit mandate evaluations enable you to obtain access to a competitor's or potential competitor's confidential proprietary information?

YES NO NOT APPLICABLE

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(e) Could your participation in CHBRP's health insurance benefit mandate evaluations create a specific financial or commercial competitive advantage for you or others with whom you have substantial common financial interests?

YES NO NOT APPLICABLE

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(f) If the CHBRP health insurance benefit mandate evaluations for which this form is being prepared involve reviews of specific applications and proposals for contract, grant, fellowship, etc. awards to be made by sponsors, do you or others with whom you have substantial common financial interests, or a familial or substantial professional relationship, have an interest in receiving or being considered for awards that are currently the subject of the reviews that are being conducted?

<u>YES</u><u>NO</u><u>NOT APPLICABLE</u> If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(g) If CHBRP's health insurance benefit mandate evaluations for which this form is being prepared involve developing requests for proposals, work statements, and/or specifications, etc., are you interested in seeking an award under the program for which the committee on which you have been invited to serve is developing the request for proposals, work statement, and/or specifications, or, are you employed in any capacity by, or do you have a financial interest in or other economic relationship with, any person or organization that to the best of your knowledge is interested in seeking an award under this program?

___YES ___NO ___NOT APPLICABLE

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

FURTHER EXPLANATION OF "YES" RESPONSES:

During your period of service, **January 1, 2013 through December 31, 2013,** for which the preceding disclosures apply, any changes in the information reported, or any new information that needs to be reported, must be reported promptly by written or electronic communication to the responsible CHBRP administrator.

SIGNATURE

DATE

PRINT NAME

Reviewed by Name/Title:

Responsible California Health Benefits Review Program Administrator DATE