



**CALIFORNIA**  
HEALTH BENEFITS REVIEW PROGRAM

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**Implementation of Assembly Bill  
1996: University of California  
Analysis of Legislation Mandating  
Health Care Benefits and Services**

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A Report to the Governor and Legislature from  
The University of California

December 22, 2005

CHBRP 06-01



**Implementation of Assembly Bill 1996:  
University of California Analysis of  
Legislation Mandating Health Care  
Benefits and Services**

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## EXECUTIVE SUMMARY

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On September 22, 2002 Governor Davis signed Assembly Bill 1996 (Statutes of 2002, Chapter 795) This bill “requested the University of California to assess legislation proposing mandated health care benefits to be provided by health care service plans and health insurers, and to prepare a written analysis in accordance with specified criteria.”

This report is submitted by the University of California in compliance with California Health and Safety Code, Section 127664, which requests the University to submit a report to the Governor and the Legislature no later than January 1, 2006, regarding the implementation of Chapter 7, Part 2 of Division 107 of the Health & Safety Code (AB 1996). This report provides background information regarding the context in which AB 1996 was passed, the objectives and provisions of AB 1996, the establishment of the California Health Benefits Review Program (CHBRP) at the University of California, and the processes, systems, and methods CHBRP has implemented to meet the intent of AB 1996.

### Context of AB 1996

- AB 1996 was enacted to provide the California Legislature with an objective analytical tool to evaluate an increasing number of complex bills proposing mandates of specific health-insurance benefits.
- The State requested University of California (UC) to evaluate legislatively-proposed health-insurance mandates because it believed UC would provide impartial, thorough, science-based analysis of these bills. According to the August 6, 2002 Senate Insurance Committee analysis, AB 1996 author Thomson believed that by providing medical, economic and actuarial expertise and current, accurate data and information to the Governor and the Legislature, UC would facilitate more informed policy-making with regard to proposed health-benefit mandates.

### AB 1996: Objectives and Provisions

The key provisions of AB 1996 require that:

- UC analyze all legislation proposing a mandated health-insurance benefit or service, and that these analyses be prepared with relevant data on the legislation’s public health, medical, and financial impacts, as defined.
- Analyses be submitted within a specified 60-day timeframe to provide the relevant legislative policy committees with timely information to inform their deliberations.
- Support for UC to conduct these analyses be provided through a non-General Fund source, specifically, fees levied by the Department of Managed Health care and The Department of Insurance on health care service plans and health insurers, respectively, the total annual amount of which would not exceed \$2 million.
- Legislative requests to UC pursuant to AB 1996 be made by the appropriate policy or fiscal committees which the legislative leadership has designated as the Senate Banking, Finance & Insurance Committee and the Assembly Health Committee.
- UC develop and implement conflict-of-interest provisions to prohibit participation in the analyses by a person with a material financial conflict of interest.
- UC use a certified actuary or other person with relevant knowledge and expertise to determine the financial impact of a given bill.
- UC post every analysis on the Internet and make them available to the public on request.

## **Establishment of CHBRP under UC**

The University established the California Health Benefits Review Program (CHBRP) to implement the provisions of AB 1996. Although CHBRP is administered by UC, it functions independently from UC's institutional policy and program interests in responding to the Legislature's requests for analyses. To ensure expertise and objectivity, the implementation process entails:

- identifying appropriate research expertise vis-à-vis a statewide faculty task force, drawing upon faculty from UC's Schools of Medicine and Public Health, as well as from the University of Southern California, Loma Linda University School of Medicine, and Stanford University;
- establishing a National Advisory Council (NAC) of experts from outside the state, including providers, purchasers, consumers, health-policy experts, and health plans;
- recruiting and hiring professional analytic and administrative staff;
- designing a transparent and timely review process;
- developing an appropriate conflict-of-interest policy;
- retaining Milliman to provide independent actuarial services;
- retaining librarians and content experts to support the review of relevant scientific literature;
- developing standardized methods for gathering data necessary to analyze the medical effectiveness, public health, and financial impacts of each proposed mandate;
- developing methods for analyzing the various impacts of each proposed mandate:
  - The Medical Effectiveness Team at UCSF developed a process for conducting literature searches and a hierarchical method of analyzing the literature to report on whether and to what extent a particular mandate will result in changes in relevant patient outcomes.
  - The Cost Team at UCLA, along with actuaries at Milliman, designed methods to determine baseline coverage, utilization, and costs and a model to project impacts of a particular benefit mandate.
  - Using the findings of the Cost and Medical Effectiveness Teams, the Public Health Impact Team at UC Berkeley assesses the overall change in health outcomes in the affected population, using the estimates of changes in utilization resulting from the mandate combined with the rates of effectiveness of intervention derived from the medical-effectiveness literature review. In addition, the Public Health Impact Team estimates the extent to which the proposed benefit or service reduces premature death and the economic loss associated with disease or condition.
- developing a standard report format; and
- creating a user-friendly Web site, <http://www.chbrp.org/index.html>, to disseminate CHBRP reports.

## **Outcomes and products**

- By January 2006, CHBRP issued 22 completed reports analyzing proposed benefit mandates, plus two analyses of amended bills, and four formal follow-up letters to the Legislature clarifying or providing further explanation of completed analysis or amended version of bills.
- All of the 22 analyses requested of CHBRP were completed within the 60-day timeframe or were designated specifically as two-year bills for which an extended submission date was permitted by the Legislature.<sup>1</sup> Table 5 provides a complete list of these analyses. The four follow-up letters and two analyses of amended bills were completed within an abbreviated timeframe in order to

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<sup>1</sup> This exception occurred in CHBRP's initial year of operation when the first analyses were requested before staff had been hired and analyses procedures established.

provide useful information to the Legislature in time for hearings on the relevant bills.

- Of the seven mandate bills introduced during 2003 and analyzed by CHBRP, five were reintroduced in the second year of the two-year session. Two were not acted upon by the legislature in the first year of the session.
  - Of the five mandate bills that were reintroduced in the 2004, one was amended to pertain to another subject matter, and one did not pass out of the second house. Of the three that passed out of the legislature, two were vetoed by the Governor and one was enacted into law. One new mandate bill, introduced in 2004, was vetoed by the Governor.
  - Of the ten mandate bills introduced in 2005 and analyzed by CHBRP, seven did not move out of the legislature, either because the bill author decided to amend the bill to pertain to another subject matter, the legislation became a 2-year bill, or it was held in an appropriations suspense file. Of the three passed by the legislature, two were vetoed by the Governor and one was enacted into law.
- CHBRP staff provide oral testimony at policy committee hearings to answer questions regarding their analyses. Prior to the hearings, CHBRP staff provide any necessary assistance and clarifications requested by legislators and legislative staff regarding CHBRP's analyses. CHBRP staff and faculty provide ongoing consultation to legislative and state regulatory agency staff regarding CHBRP's analyses, and to consider the potential implications of various amendments under legislative consideration.
  - CHBRP strives to build and improve its methods, the transparency of its processes, and capacity to respond to the state legislature. This has been done by
    - meeting with stakeholders such as health plans and advocates to allow for input on specific bills and provide information on analytic methods;
    - meeting with legislative and agency staff on how to improve the readability, transparency and usefulness of the reports;
    - conducting public forums where CHBRP faculty and staff provided briefings on CHBRP's methods to the public, legislative and agency personnel, health advocates and stakeholders;
    - obtaining input from CHBRP's National Advisory Council to continuously improve the analyses and reports;
    - updating data sources and methods to reflect the most current available data and analytic approaches that can be feasibly implemented within a 60-day timeframe;
    - conducting an internal review of operations at the administrative and campus level to ensure adequate capacity to respond to the workload and deadline pressure during the first quarter of each calendar year; and
    - implementing quality improvement measures for the reports that were produced in 2005 and those expected to be produced in 2006.
  - Since its inception, the California Health Benefits Review Program has been administered by the University of California at a cost well within the \$2 million maximum annual allocation provided under AB 1996 by (non-General Fund, non-UC budgeted) funds derived from an assessment of health-insurance plans regulated by the Department of Insurance and the Department of Managed Health Care.

## INTRODUCTION

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On September 22, 2002, Governor Davis signed Assembly Bill 1996 (Statutes of 2002, Chapter 795) This bill “requested the University of California to assess legislation proposing mandated health care benefits to be provided by health care service plans and health insurers, and to prepare a written analysis in accordance with specified criteria.<sup>2</sup>”

This report is submitted by the University of California in compliance with *California Health and Safety Code*, Section 127664, which requests the University to submit a report to the Governor and the Legislature no later than January 1, 2006, regarding the implementation of Chapter 7, Part 2, of Division 107 of the Health & Safety Code (AB 1996).

The report summarizes the national and state context of AB 1996, the objectives and provisions of AB 1996, important elements of the University’s implementation, analyses requested and provided, refinements of the process, resources and budget issues, challenges for the program, and a discussion about the environment for benefit mandates over the next few years.

### **The National and State Context of AB 1996**

By 2001, state-mandated health-benefit laws were proliferating in states across the nation. In California, more than 40 mandated benefits were enacted into state law by the close of that year, and more than 14 health-benefit mandate bills were introduced in the 2002 legislative session. Policymakers generally viewed mandated benefits as desirable to provide adequate coverage for a maximum number of subscribers, and sought to implement mandated benefits without increasing premiums and thereby potentially reducing coverage rates. However, concerns arose regarding cost containment, increasing opt-outs by small employers, and whether well-intended mandates actually served their intended purposes. In response, 16 states addressed benefits mandate review legislation in 2001–2002.

### **California’s Legislative Response**

Legislative concern in California regarding the impact of health-benefits mandates was manifested in two bills introduced in the 2002 legislative session, both requiring an assessment of the effects of health-benefits legislation: AB 1801 and AB 1996.

AB 1801 (Pacheco) would have created a commission to study and report to the Legislature and the Department of Finance on: (1) the cost impact on the private sector, the Public Employees’ Retirement System, other retirement systems funded by the state or by a local government, Medi-Cal, and the Healthy Families program, resulting from proposed legislation affecting a health care service plan; (2) the impact of proposed legislation on persons in this state without health care coverage; and (3) public policies affecting health care costs and access to health care coverage in California.

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<sup>2</sup> See [Appendix 1](#) for complete text of AB 1996 (2002).



Under AB 1801, this commission was to be composed of five members, three of whom were to be appointed by the Governor. Some viewed an evaluative commission of political appointees as being vulnerable to partisan influence and potential bias. A coalition of employers, for example, opposed the bill based on the political nature of appointments, advocated for a “majority of members with backgrounds that include economics, actuarial, employers benefit specialists, insurers, health-maintenance organizations (HMOs), as well as a consumer and/or labor representative.”<sup>3</sup> Other features of the bill ran into opposition as well, such as the lack of a cap on study costs and lack of an automatic termination provision.

After consideration, the Assembly Health Committee decided to use an alternative legislative vehicle, AB 1996 (Thomson), which, on May 2, 2002, was amended to include some of the features of AB 1801, plus a broader scope of analysis that included the social, medical, and financial impacts of proposed mandated health care benefits. This version of the bill sought to create a potentially less-partisan commission. Although a majority of members were still appointed by the Governor, the membership was expanded to include representation from different stakeholder groups. The commission was given the authority to hire analytical staff and levy fees on health care service plans and insurers to provide funding for the enterprise.

Subsequent amendments to the bill located the commission within the Department of Managed Health Care, continued to expand its membership, and specified its role as independent, nonpartisan, and advisory.

In response to concerns regarding partisanship and cost, an amended version of AB 1996 (August 5, 2002) requested the University of California (UC) to administer the proposed program to provide objective analysis. This version of the bill required the UC to adopt conflict-of-interest provisions to prohibit a person from participating in any analysis in which that person has a material financial interest, capped study costs at \$2 million annually, and imposed a “sunset” provision.

According to the August 6, 2002, Senate Insurance Committee analysis, AB 1996 author Thomson believed that UC would be able to establish an independent, nonpartisan mechanism to analyze the clinical efficacy and cost effectiveness of legislative proposals for expanded health care benefits, and that by providing medical, economic, and actuarial expertise and current, accurate data and information to the Governor and the Legislature, UC would facilitate more-informed policy making with regard to legislation proposing mandated health benefits to be provided by health care service plans and health insurers. AB 1996 was chaptered into law on September 22, 2002.

## **AB 1996: Objectives and Provisions**

The preamble to AB 1996 describes the Legislature’s intent and objectives:

*The Legislature finds that there is an increasing number of proposals that mandate that certain health benefits be provided by health care service plans and health insurers as components of individual and group contracts. The Legislature further finds that many of these would potentially result in better health outcomes that would be in the public interest. However, the Legislature also recognizes that mandated benefits may*

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<sup>3</sup> Correspondence between Employers Health Care Coalition of Los Angeles and Assembly Appropriations Committee, May 10, 2002.

*contribute to the cost and affordability of health-insurance premiums. Therefore, it is the intent of the Legislature that the University of California conduct a systematic review of proposed mandated or mandatorily-offered health-benefit mandates. This review will assist the Legislature in determining whether mandating a particular coverage is in the public interest.*

Unlike the majority of other states' mandates programs, the California mandate-review law requires assessing the medical effectiveness and public-health impact *in addition* to the cost impact of a proposed mandate evaluation.<sup>4</sup> This requirement reflects the Legislature's own review process, which conducts separate policy and fiscal hearings on legislation. In addition, AB 1996 specified a timeframe—60 days—so that the relevant policy committees would have the California Health Benefits Review Program (CHBRP) analysis in time for deliberations. Finally, the Legislature intended the analyses to be unbiased, without conflicts of interest, and based on experts' review of the standards of care and reliable evidence and data sources.

To meet the intent of the Legislature, the following provisions were specified in AB 1996:

- 1) A “mandated benefit or service” is defined as “a proposed statute that requires a managed health care plan and/or health insurer” to (a) permit a person insured or covered under the policy or contract to obtain health care treatment or services from a particular type of health care provider, (b) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition, or (c) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.
- 2) All legislation proposing a “mandated benefit or service” is to be analyzed by UC and a written analysis is to be prepared with relevant data on the legislation's public health, medical, and financial impacts, as defined.
- 3) Support for UC to conduct these analyses is to be provided through a non-General Fund source, specifically fees levied by the Department of Managed Health Care and the Department of Insurance on health-service plans and health insurers, respectively, the total annual amount of which shall not exceed \$2 million.
- 4) Legislative requests to UC pursuant to AB 1996 shall be made by an appropriate policy or fiscal committee chairperson or legislative leadership. (This task has been delegated to the Chair of the Senate Banking, Finance and Insurance Committee and the Chair of the Assembly Health Committee.)
- 5) UC is to submit analyses of proposed health-insurance mandate bills to the appropriate policy or fiscal committee not later than 60 days after receiving a request from the Legislature.
- 6) UC is to develop and implement conflict-of-interest provisions to prohibit participation in the analyses by a person with a material financial conflict of interest, including a person who has a consulting or other agreement with an entity that would be affected by the legislation.
- 7) UC is to use a certified actuary or other person with relevant knowledge and expertise to determine the financial impact of a given bill.
- 8) UC is to post all analyses on the Internet and make them available to the public on request.
- 9) UC was to analyze any of 10 specified benefit mandates, if proposed at the start of the 2003 legislative session.

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<sup>4</sup> See *State Mandated Benefit Review Laws* in [Appendix 20](#) for a paper in a forthcoming issue of *Health Services Research* which examines the characteristics of state laws that have established mandate review evaluation programs in the U.S.

- 10) UC is to provide the Governor and Legislature with a report on the implementation of AB 1996 by January 1, 2006. The established “sunset date” for the program is January 1, 2007, unless a later enacted statute extends or repeals that date.

Pursuant to the enactment of AB 1996, UC established the California Health Benefits Review Program (CHBRP). Although CHBRP is administered by UC, it is designed to act as an independent program to respond objectively to the Legislature's requests for analyses. To ensure expertise and objectivity, the implementation process entailed:

- 1) identifying appropriate research expertise vis-à-vis a statewide faculty task force;
- 2) establishing a national advisory council;
- 3) recruiting and hiring professional analytic and administrative staff;
- 4) designing a transparent and timely review process;
- 5) developing an appropriate conflict-of-interest policy;
- 6) retaining an actuary;
- 7) retaining librarians and content experts to support the literature review;
- 8) obtaining data from health plans for the cost-impact analysis;
- 9) obtaining information from consumer groups and other stakeholders;
- 10) developing standardized methods for conducting literature reviews and medical-effectiveness analyses;
- 11) developing standardized methods for coverage, utilization, and cost-impact analyses;
- 12) developing standardized methods for public-health impact analyses;
- 13) creating a user-friendly Web site to disseminate CHBRP reports; and
- 14) evaluating CHBRP's products/processes/policies to ensure CHBRP is continually meeting the provisions of AB 1996.

### **Identifying Appropriate Research Expertise: Faculty Task Force**

UC's Division of Health Affairs solicited the deans of California's public and private medical schools and schools of public health for nominations of state experts to constitute a Faculty Task Force.<sup>5</sup> From these nominees, researchers were selected from the University of California at San Francisco (UCSF), UC Berkeley, and the University of California at Los Angeles (UCLA) to serve as vice chairs and to coordinate the three statutorily-required components of each insurance-mandate evaluation (medical effectiveness, financial impact, and public-health impact analyses). Researchers from UC campuses at Davis, Irvine, and San Diego and from the University of Southern California, Loma Linda University, and Stanford University were also selected to ensure participation of all accredited medical-school campuses in California. The Faculty Task Force's expertise reflects the evaluation criteria set forth in AB 1996—the inclusion of experts in health-services research and health policy, public health, economics, political science, and clinical medicine. Details on how each vice-chair's research faculty and staff have developed methods and established processes to fulfill the requirement of AB 1996 are described in detail below.

### **Establishing a National Advisory Council**

UC recruited a National Advisory Council (NAC) of experts from outside the state of California who were selected to provide balanced representation among groups with an interest in health-insurance benefit mandates. Recommendations for members of the NAC were suggested by the

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<sup>5</sup> See [Appendix 2](#), CHBRP Faculty Task Force Membership List.

CHBRP Director, Vice President of Health Affairs, and members of the Faculty Task Force and ratified by the Faculty Task Force. The NAC is composed of opinion leaders from key constituencies, including providers, purchasers, consumers, health-policy experts, and health plans.<sup>6</sup> The NAC reviews CHBRP's draft bill analyses for accuracy, balance, clarity, and responsiveness to the Legislature's request before the reports are transmitted to the Legislature.<sup>7</sup> The NAC meets annually. In addition to the annual meeting and review of individual draft reports, individual NAC members have provided advice to CHBRP staff on particular issues as they arise. During the 60-day time period, NAC reviews occur within five days of the last two weeks. Since the NAC was first organized, members have completed a total of 97 reviews. The NAC is an advisory body rather than a governance board.

### **Recruiting and Hiring Professional Analytic and Administrative Staff**

UC hired a professional analytic staff to manage the review process to ensure that reports are produced within a 60-day time period, to support the Faculty Task Force and the NAC, and to serve as a liaison with the Legislature. CHBRP staff consists of a director, four analysts, and an administrative assistant.<sup>8</sup> Administration and management of CHBRP resides in the system-wide University of California Office of the President (UCOP) within the Office of the Vice President for Health Affairs.

### **Contracting with an Actuarial Firm**

UC retained Milliman (formerly Milliman USA) after a competitive bidding process to meet the AB 1996 requirement to include actuarial analysis in the financial-impact analysis on premiums. Milliman's senior actuaries are closely involved in developing the methodological approach for each analysis. In addition, they conduct actuarial analysis on premium impacts, support the Cost Team at UCLA in analyzing coverage, cost, and utilization impacts, and support the Public Health Impact Team at UC Berkeley by providing utilization data analyses for specific populations when available. Milliman's access to proprietary aggregate claims data enables CHBRP to conduct premium impact analysis for the various market segments. (Information on data sources used in cost analyses is available in [Appendix 11](#).)

### **Retaining Librarians and Content Experts to Support the Literature Review**

The UCSF Medical Effectiveness Team and CHBRP staff addressed the need for resource-intense systematic literature review to be completed within the first three weeks of the analysis process. UCSF and CHBRP staff (1) developed a process to retain a content expert—an individual who has specialized clinical expertise pertaining to the benefit or service addressed by the proposed mandate—and (2) developed a process for retaining the services of medical librarians. Content experts were retained to (1) identify key literature, (2) assist the Medical Effectiveness Team in proposing literature search terms to be used by the medical librarian, (3) draw upon their clinical

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<sup>6</sup> See [Appendix 4](#), National Advisory Council Membership List,

<sup>7</sup> See [Appendix 3](#), NAC Review Criteria and Guidelines

<sup>8</sup> See [Appendix 5](#), CHBRP staff list

experience and knowledge of current standards of care to provide input on current and expected physician practice patterns, and (4) help identify and review the diagnostic and procedural codes associated with the mandated benefit or services. It is important to note that content experts were screened for conflicts of interest. More than one content expert was retained for an analysis in cases where expertise in more than one specialty or discipline was required (e.g., AB 1185 [2005] Chiropractic Services. See [Appendix 7](#), CHBRP Process and Policy for Selecting Content Experts).

Librarians with Masters in Library and Information Science from the UCSF Library and Center for Knowledge Management (primarily) and the UC San Diego Biological and Medical Center Libraries work with the Medical Effectiveness Team and the content expert within a four- to five-day period to (1) develop search strategies specific to the mandate, (2) conduct the literature search given inclusion/exclusion criteria developed by the Medical Effectiveness Team, (3) forward relevant abstracts of peer-reviewed literature to the Medical Effectiveness Team for researchers' review and selection, and (4) assist with any additional searches if needed and with obtaining interlibrary loans.

### **Developing a Conflict-of-Interest Policy**

UC conducts a review of all CHBRP analytic participants' potential conflicts of interest at the point of affiliation with CHBRP. To systematically review potential conflicts, and to comply with the AB 1996 requirements,<sup>9</sup>UC developed a Conflict-of-Interest reporting form for the NAC and a separate form for use by all others (faculty and staff) who contribute to CHBRP analyses.<sup>10</sup> These forms were 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 UC and CHBRP are grateful to the NAS for extending its permission to use the NAS form.)

It is essential that the work of the participants in CHBRP activities not be compromised by any material conflict of interest. All who participate in the development of CHBRP's analyses are required to complete and submit a disclosure form and to update it annually or whenever compelled to do so by a change of circumstance, (e.g., a new investment, equity interest, change of employment, or the specific nature of a given item of legislation for review). The completed forms are recorded and reviewed by UC Health Affairs staff, who monitor potential conflicts and, as appropriate, request recusals where actual or perceived conflicts of interest arise in relation to a given bill.

Faculty Task Force members are encouraged to publish their research results in peer-reviewed journals; however, they are expected to avoid legislative testimony or lobbying related to the findings of CHBRP studies while serving on the Task Force.

Recusals are noted in CHBRP's bill analyses. In the last two years, a subset of CHBRP faculty recused themselves from seven separate analyses, due to potential conflicts of interest. In these

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<sup>9</sup> Health and Safety Code section 127663 requires UC to develop and implement conflict-of-interest provisions to prohibit a person from participating in an 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 that would be affected by the mandate benefit proposal

<sup>10</sup> See [Appendix 8](#), CHBRP Conflict-of-Interest Policies, General Disclosure Form and NAC Disclosure Form

cases, other CHBRP researchers, including other faculty from the Task Force, have stepped in to conduct the relevant analysis.

As mentioned, potential content experts are screened for conflicts of interest before they are selected to work on a particular analysis. Examples of questions initially used to screen content experts are:

1. Do you have any financial interest in the proposed mandated benefit? Examples of financial conflicts:
  - Investments in pharmaceutical companies or medical device manufacturers;
  - relations with a drug company with products related to the mandate; or
  - receipt of research funding.
  
2. Do you have any interest from an insurance perspective in the proposed mandated benefit? Examples:
  - Have you acted as an expert witness? If so, for one or both sides?
  - Are you a member of a task force that has voted on the benefit being mandated?
  - Have you testified or taken a public position on the mandate?
  
3. Could your existing research create a perception of bias as it pertains to the proposed mandate? Such a perception might arise if a content expert authored research that included recommendations that are substantially similar to or directly oppose the proposed mandate.<sup>11</sup>

## **Obtaining Data from Health Plans**

CHBRP must obtain accurate coverage data from health plans and insurers to conduct the cost impact analyses according to the provisions of AB 1996. Coverage data enable CHBRP to (1) appropriately reflect existing (baseline) coverage, (2) obtain information on utilization controls (e.g., referrals requirements) if relevant to the mandate, and (3) obtain such information by market segment (e.g., large-group HMO and small-group preferred provider organization [PPO]). CHBRP worked with the California Association of Health Plans and the Association of California Life and Health Insurance Companies to obtain contact information from the largest health plans and insurers in the state (together representing approximately 75% of covered lives in California).<sup>12</sup> CHBRP works with each of these health plan representatives to ensure that bill-specific surveys are completed for CHBRP researchers to use in the cost impact analysis (see below).

## **Obtaining Information from Consumer Groups and Other Stakeholders**

CHBRP developed a process to obtain information from interested parties for bills under analysis. “Interested parties” are defined by CHBRP as any member of the public, including bill sponsors, disease-specific organizations, consumer advocate organizations, or health plans. CHBRP announces a new legislative request on its Web site and via its email listserv. Any interested party may request that he or she be added to the listserv. All interested parties who

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<sup>11</sup> See [Appendix 7](#) for details on the protocol for content expert identification, screening, and selection.

<sup>12</sup> [http://www.cattaneostroud.com/2005HMO\\_Study/table\\_3b.pdf](http://www.cattaneostroud.com/2005HMO_Study/table_3b.pdf) accessed on November 17, 2005

believe they have scientific evidence relevant to CHBRP's analysis of proposed health insurance benefit mandates are encouraged to provide that information to CHBRP's staff. In order for CHBRP to meet its statutory 60-day deadline to complete its analyses, CHBRP requests interested parties to submit information within the first 14 days of the review cycle. Information can be submitted via email, fax, or mail. CHBRP has received information through this public notification process on five completed analyses.

Once CHBRP receives the information submitted by the public, it is disseminated to the analytic team at each campus and to the actuary. The respective teams (Medical Effectiveness, Cost, and Public Health Impact) review the information to determine whether the evidence submitted is relevant to the analysis and meets the standard of rigor for inclusion. If the information is relevant and does meet the inclusion criteria, the teams will decide how to incorporate the information into the analyses. All information that has been submitted is listed in an appendix in the relevant analysis.

CHBRP also works cooperatively with the bill authors' staff to obtain any evidence or information submitted by bill sponsors. For example, Assemblymember Koretz's staff sent to CHBRP articles and citations provided by proponents of AB 228, a bill mandating that health plans cover transplantation services for HIV-positive patients. At the request of Assemblymember Koretz's office, CHBRP reviewed medical journal abstracts supplied by the California Chiropractic Association, sponsors of AB 1185, a bill that would mandate coverage of chiropractic services. Assemblymember Liu's staff sent CHBRP information submitted by proponents of AB 213, a bill mandating coverage for the treatment of lymphedema.

## **Designing a Transparent and Timely Review Process**

In order to address the evaluation criteria specified in AB 1996 (see Table 1) in a timely, transparent manner, CHBRP developed a 60-day timeline that details which activities occur on what day.<sup>13</sup> The 60-day clock is initiated upon receipt of a request from the Senate Committee on Banking, Finance and Insurance or the Assembly Committee on Health.

During the first two weeks, the program is to:

- review any potential conflicts of interest and establish recusals;
- identify the analytic teams from the Task Force, CHBRP staff, and the actuarial firm;
- work with legislative staff (including bill authors and committee staff) to clarify bill language and intent;
- conduct a mandate-specific health plan survey on coverage;
- develop literature search strategies for the medical effectiveness analysis and conduct the literature review;
- identify the appropriate codes for claims and utilization analysis;
- contact other state mandate-review programs to obtain completed analyses or share knowledge; and
- post on the Web site and send out to the listserv an announcement regarding the new request with information on how interested parties can submit information for CHBRP's consideration.

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<sup>13</sup> See [Appendix 9](#), the 60-Day Timeline of the Analytical Process



During the following three weeks the program is to:

- review any information submitted by interested parties;
- complete the medical effectiveness analysis;
- develop an analytic approach to the cost impact analysis;
- review and compile available information on gender, racial, and relevant population impacts;
- review and compile available information on the economic burden of the disease or illness the mandate attempts to address; and
- draft all three sections and compile any additional information that may be warranted (e.g., a special section on implementation or additional background material).

During the following two weeks the program is to:

- complete the first draft of the fully integrated report including appendices, tables, and executive summary;
- ensure internal review by Vice Chairs and designated internal peer reviewers; and
- revise as necessary.

During the final one-and-a-half weeks the program is to:

- ensure that a subcommittee of the NAC conducts a review of the analysis;
- make necessary revisions;
- edit, finalize, and produce the report for electronic publishing; and
- submit the report to the Legislature, email to listserv and post it on the Web site.

**TABLE 1: AB 1996 Criteria for Evaluation**

- (1) **Public health impacts**, including, but not limited to, all of the following:
- (A) The impact on the health of the community, including the reduction of communicable disease and the benefits of prevention such as those provided by childhood immunizations and prenatal care.
  - (B) The impact on the health of the community, including diseases and conditions where gender and racial disparities in outcomes are established in peer-reviewed scientific and medical literature.
  - (C) The extent to which the proposed service reduces premature death and the economic loss associated with disease.
- (2) **Medical impacts**, including, but not limited to, all of the following:
- (A) The extent to which the benefit or service is generally recognized by the medical community as being effective in the screening, diagnosis, or treatment of a condition or disease, as demonstrated by a review of scientific and peer-reviewed medical literature.
  - (B) The extent to which the benefit or service is generally available and utilized by treating physicians.
  - (C) The contribution of the benefit or service to the health status of the population, including the results of any research demonstrating the efficacy of the benefit or service compared to alternatives, including not providing the benefit or service.
  - (D) The extent to which the proposed services do not diminish or eliminate access to currently available health care services.
- (3) **Financial impacts**, including, but not limited to, all of the following:
- (A) The extent to which the coverage will increase or decrease the benefit or cost of the service.
  - (B) The extent to which the coverage will increase the utilization of the benefit or service, or will be a substitute for, or affect the cost of, alternative services.
  - (C) The extent to which the coverage will increase or decrease the administrative expenses of health care service plans and health insurers, and the premium, and expenses of subscribers, enrollees, and policyholders.
  - (D) The impact of this coverage on the total cost of health care.
  - (E) The potential cost or savings to the private sector, including the impact on small employers as defined in paragraph (1) of subdivision (l) of Section 1357, the Public Employees' Retirement System, other retirement systems funded by the state or by a local government, individuals purchasing individual health insurance, and publicly-funded state health insurance programs, including the Medi-Cal program and the Healthy Families Program.
  - (F) The extent to which costs resulting from lack of coverage are shifted to other payers, including both public and private entities.
  - (G) The extent to which the proposed benefit or service does not diminish or eliminate access to currently available health care services.
  - (H) The extent to which the benefit or service is generally utilized by a significant portion of the population.
  - (I) The extent to which health care coverage for the benefit or service is already generally available.
  - (J) The level of public demand for health care coverage for the benefit or service, including the level of interest of collective-bargaining agents in negotiating privately for inclusion of this coverage in group contracts, and the extent to which the mandated benefit or service is covered by self-funded employer groups.
  - (K) In assessing and preparing a written analysis of the financial impact of a mandated benefit pursuant to this paragraph, the Legislature requests the University of California to use a certified actuary or other person with relevant knowledge and expertise to determine the financial impact.

## Developing Standardized Methods for Literature Reviews and Medical Effectiveness Analyses

AB 1996 requires CHBRP to address in its medical impact analysis:

*“...the extent to which the benefit or service is generally recognized by the medical community as being effective in the screening, diagnosis, or treatment of a condition or disease, as demonstrated by a review of scientific and peer-reviewed medical literature.”*

*“The extent to which the benefit or service is generally available and utilized by treating physicians.”*

*“The contribution of the benefit or service to the health status of the population, including the results of any research demonstrating the efficacy of the benefit or service compared to alternatives, including not providing the benefit or service.”<sup>14</sup>*

To ensure that the medical impact analysis appropriately synthesizes and analyzes the existing body of scientific evidence as it pertains to the effectiveness of a proposed service or benefit, the Medical Effectiveness Team at UCSF has developed a process for conducting literature searches and a method for analyzing the literature to report on whether and to what extent a particular mandate will result in changes in relevant patient outcomes. This process and method are summarized below, but for further details, please see [Appendix 10](#) for a description of the general approach to the medical effectiveness analysis and for a description of the step-by-step process.

### ***Conducting the literature search***

When CHBRP receives a request to analyze bills from the California Legislature, the Medical Effectiveness Team works with the content expert and the librarian to identify appropriate search terms and launch a literature review. This includes ensuring that the scope of the literature is well defined and reflects not only the language/intent of the proposed mandate, but also the agreed-upon scope of the CHBRP analysis. The Medical Effectiveness Team identifies the type of intervention(s) mandated in the bill and the literature needed to address key issues in the bill (i.e., is the intervention a screening, diagnostic, or monitoring test, a procedure, a device, or a treatment?) and the health outcomes of interest for the proposed intervention(s) (i.e., improved limb function, better self-management of a chronic illness, or slowing of disease progression?). Key issues may also include changes in provider management of illness or injury that may result from the intervention being studied.

Screening, diagnostic, monitoring and treatment interventions require different search strategies and analytic approaches. For example, a treatment is typically designed to cure a disease or to improve function. Designing trials to determine how well the treatment works may be relatively straightforward and literature may be available to directly assess effectiveness. On the other hand, a screening test might indicate an increased risk of a disease. This may lead to recommendations for one or more types of preventive interventions. The interventions may vary in their effectiveness, and the disease, which may or may not occur even though a screening test is positive, may be treated in various ways. Extended periods of time would be necessary to assess each of these links. Testing and treatment options are continually changing over time, and studies that directly address the effectiveness questions raised in a bill are not always be available. In such cases, an effectiveness

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<sup>14</sup> Health & Safety Code, Section 127660, subdivision (a) (2) (A)-(C).

assessment of an intervention must be built upon information available for various parts of the “evidence chain.” This may influence how the medical effectiveness analysis is undertaken. These considerations are taken into account when determining the scope of the literature search. In addition, because CHBRP is governed by a 60-day time period, the literature search is limited by certain criteria, which are discussed below.

***Medical effectiveness analysis methods***

In general, Medical Effectiveness Team faculty and staff adhere to the following hierarchy of evidence, both in conducting the literature search and in analyzing the literature. In other words, certain types of articles or studies are given more “weight” because they are more comprehensive and their research designs are more rigorous. The following are listed in order from most rigorous to least:

1. meta-analyses—The Medical Effectiveness Team relies on meta-analyses, particularly those included in the Cochrane Library, as the principal source of evidence for the review. This is because researchers who have undertaken the meta-analyses typically have had the time and opportunity to examine in some detail the methods of the studies and have excluded studies with less rigorous methods. The remainder of the literature review is focused on systematic reviews and primary studies published after the studies included in the meta-analyses;
2. systematic reviews—particularly those performed by authoritative organizations, such as the U.S. Department of Health and Human Services’ Agency for Healthcare Research and Quality, U.S. Preventive Services Task Force, and Evidence-Based Practice Teams or other government agencies (e.g., National Institutes of Health, Centers for Disease Control and Prevention, Center for Medicare & Medicaid Services);
3. evidence-based guidelines;
4. individual randomized controlled trials;
5. observational studies;
6. case-control studies; and
7. clinical/practice guidelines based on consensus or opinion, rather than on evidence.

A summary of the literature is provided in a standard appendix (Appendix B) of each CHBRP report (see Table 2 below for an example).

**Table 2:** Summary of Published Studies on Effectiveness of Pediatric Asthma Self-Management and Training Interventions

<b>Citation</b>	<b>Type of Trial</b>	<b>Intervention vs. Comparison Group</b>	<b>Population Studied</b>	<b>Location</b>
Huss et al., 2003	OS	Education and computer-based instructional asthma game vs. education alone	Inner-city children	Baltimore, MD
Krishna et al., 2003	RCT	Internet-enabled, interactive multimedia asthma education and conventional education, management (with action plan) vs. conventional education and management (with action plan)	Children who visited a pediatric pulmonary clinic	St. Louis, MO

OS, observational study; RCT, randomized controlled trial.

Once the literature is reviewed and studies ranked for each outcome measure, the Medical Effectiveness Team assesses what the literature shows about the evidence of effectiveness of the proposed service or benefit on the health outcome measured. In making this assessment for each outcome measure, the Medical Effectiveness Team faculty and staff and the content expert consider the number of studies (as well as their sample size, quality, and relevance to the California population) included in any meta-analyses as well as the same issues in regard to other relevant studies. Evidence for each outcome is “graded” as falling into one of the following categories:

1. Favorable (statistically significant effect): Findings are uniformly favorable and many or all are statistically significant.
2. Pattern toward favorable (but not statistically significant): Findings are generally favorable, but there may be none that are statistically significant.
3. Ambiguous/mixed evidence: Some findings are significantly favorable and some findings with sufficient statistical power show no effect.
4. Pattern toward no effect/weak evidence: Studies generally find no effect, but this may be due to a lack of statistical power.
5. No effect: Studies have sufficient statistical power to assess effects and generally find no effect on the outcomes examined.
6. Unfavorable: No findings show a statistically significant benefit and some show significant harms.
7. Insufficient evidence to make a “call”: There are very few relevant findings, making it difficult to discern a pattern. (Note that this is different than #5 in which there is sufficient information to conclude that an intervention has no effect.)

In some cases, the literature is robust enough to provide quantifiable evidence for specific outcomes. For studies with quantifiable outcomes (e.g., decrease in number of school days absent, decrease in hospitalizations or length of hospital stay, or decrease in emergency department visits), the Medical Effectiveness Team creates a table that includes all studies that measure that specific outcome and presents the results of studies (including the Team’s assessment of studies of outcomes based on the weight of the evidence). Table 3 shows the effect of an asthma education self-management program on the mean number of school day absences for children with asthma. In this example, the “grade” for the evidence of effectiveness for this intervention in terms of school absences is “favorable” in the following sample table. The overall effect, based on seven published U.S. trials included in a meta-analysis and one additional trial from 2003, is an estimated 44% reduction in the mean number of school days absent.

<b>Table 3: Summary of Evidence of Effectiveness by Health Outcome School Day Absences (Mean days)—Favorable</b>		
<b>Trial</b>	<b>Results</b>	<b>Categorization of Results (Significance, Direction)</b>
Meta-analysis (16 trials)	SMD -0.14 [-0.23, -0.04]	Sig, fav
Estimated impact from U.S trials (7 trials included in meta-analysis)	44% reduction This reduction is calculated as the weighted average of the relevant studies (7 in the meta-analysis and 1 additional trial in 2003).	Sig, fav

<b>Table 3: Summary of Evidence of Effectiveness by Health Outcome School Day Absences (Mean days)—Favorable</b>		
<b>Trial</b>	<b>Results</b>	<b>Categorization of Results (Significance, Direction)</b>
Krishna et al., 2003	Intervention pre 7.9 → post 1.4, control pre 6.4 → post 5.4	Sig, fav
*Fireman et al., 1981	Mean intervention post 0.5, control post 4.6	Sig, fav
*Christiansen et al., 1997	Mean intervention post 2.39, control post 2.98	NS, fav
*Persaud et al., 1996	Intervention post 6.4, control post 7.6	NS, fav
*Wilson et al., 1996	Sick days in 1 month: intervention pre 1.0 → post 0.8, control pre 0.7 → post 1.4	NS, fav
*Perrin et al., 1992	Number/month: intervention pre 0.73 → post 0.24, control pre 0.14 → post 0.22	NS, fav
*Evans et al., 1987	Absences/year: intervention pre 21.3 → post 19.4, control pre 20.8 → post 19.7	NS, fav
*Rubin, 1986	Intervention pre 13.0 → post 14.1, control pre 17.0 → post 18.6	NS, fav

\* Included in meta-analysis.

Key: fav, favorable; NS, not significant; sig, significant; SMD, standardized mean difference.

### **Developing Standardized Methods for Coverage, Utilization, and Cost Impact Analyses**

In AB 1996, California legislators identified two major sets of financial information that they were interested in understanding regarding proposed health benefits mandates: (1) current coverage, utilization and cost, and (2) projected changes in coverage, utilization and costs after the implementation of a mandate.

The specific information regarding current coverage requested by the California Legislature for each mandate includes:

- existing coverage of the service in the current insurance market;
- current utilization and cost of providing a benefit;
- public demand for coverage among self-insured plans; and
- current costs borne by insurers.

The specific information regarding post-mandate effects requested by the Legislature includes:

- changes in utilization;
- changes in the per unit cost of providing the service;
- administrative costs;
- impact on total health care costs;
- costs or savings for different types of insurers; and
- impact on access and availability of services.

### ***Public Demand***

Based on criteria specified under AB 1996, CHBRP is to report on the “level of public demand for health care coverage for the benefit or service, including the level of interest of collective bargaining agents in negotiating privately for inclusion of this [mandated benefit] coverage in

group contracts and the extent to which” self-insured plans currently have coverage for the proposed mandate as a method to gauge public demand for that mandate.

To determine the collective bargaining agents’ level of interest in negotiating privately for inclusion of this mandated benefit coverage in group contracts, CHBRP queries the California Labor Federation and the Service Employees International Union (SEIU), California State Council. Based on conversations with these large collective bargaining agents, unions do not generally include benefit-by-benefit provisions during the negotiations of their health insurance policies. Instead, they tend to negotiate on benefit “packages” with broad parameters (e.g. premium levels, cost-sharing arrangements, and coverage for dependants). In order to determine whether any local unions engage in negotiations for any particular benefit mandate, they would need to be surveyed individually.<sup>15</sup>

To determine the “extent to which the mandated benefit or service is covered by self-funded employer groups,” CHBRP queries the largest public self-funded employer group, the California Public Employees’ Retirement System (CalPERS) regarding existing coverage of the proposed mandate. CalPERS benefit coverage is reported in each CHBRP bill analysis.

### ***California Cost and Coverage Model***

To respond to AB 1996 cost and coverage evaluation provisions, the UCLA Cost Team and actuaries from Milliman developed the California Cost and Coverage Model. This model addresses each of these baseline and post-mandate financial impacts, with the exception of public demand for expanding coverage, which is addressed through discussion with unions and California Public Employees’ Retirement System (CalPERS) to determine the breadth of support for each proposed mandate, and the impacts of mandates on access and availability, which require assumptions about whether there are serious supply constraints that might affect the cost or availability of a service if demand substantially increased in response to a mandate.

The California Cost and Coverage Model (see [Appendix 11](#)) is primarily an actuarial forecasting model. Such models are particularly appropriate when substantial behavioral changes in response to mandates are likely to be limited in the short run. To the extent that mandates have a small impact on health insurance premiums and overall health care expenditures, behavioral changes do not need to be modeled and an actuarial forecast should produce a reliable approximation of a mandate’s financial impact.

**Definition of terms.** “Cost” is defined as the aggregate expenditures, or prices paid, for health care services—not as the costs incurred by the providers of health care. The rationale for this definition of “cost” is that legislators are ultimately interested in evaluating the financial impact of mandates on each of the major payers for health care services in the state.

The following elements of cost are included in the model:

- insurance premiums;
- member cost sharing;
- total cost of covered benefits;
- costs paid by patients who have insurance for mandated services not currently covered by insurance; and

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<sup>15</sup> Communication with SEIU and California Labor Federation on February 8, 2005

- total expenditures for health insurance and uncovered mandated benefits.

“Utilization” is defined as the frequency or volume of use of a mandated service. Utilization is the product of the number of health plan members who use the mandated service and the average number of mandated services they use per calendar period.

“Coverage” is defined as the extent to which the mandated services are covered by insurance—either through a health care service plan (an HMO) or a health insurance policy.

**Data sources.** To estimate current levels of coverage, utilization, and expenditures for the mandated benefit(s), CHBRP constructed a baseline Cost and Coverage Model using data from three primary sources: (1) the 2003 California Health Interview Survey (CHIS), (2) the 2004 California Health Care Foundation/Health Research and Education Trust (CHCF/HRET) California Employer Health Benefits Survey, and (3) the Milliman Health Cost Guidelines. Actual enrollment data from state agencies providing coverage to individuals who lack coverage from private sources are used to validate the CHIS estimates of those enrolled in Medi-Cal and Healthy Families programs.

#### Coverage and demographic data sources.

The 2003 CHIS is used to identify the demographic characteristics and estimate the insurance coverage of the population in the state. The CHIS is a random telephone survey of over 44,000 households conducted in multiple languages by the UCLA Center for Health Policy Research. This survey allows CHBRP to estimate the number of people with individual insurance coverage and the number with employer-sponsored insurance coverage.

To obtain estimates of the percentage of employees by size of firm and type of health plan, CHBRP used the 2004 California Health Care Foundation/Health Research and Educational Trust (CHCF/HRET) survey of California employers. Collected annually since 2000, these data provide estimates of numbers of employees working in such firms and their types of coverage, based on a representative sample of California’s employers. Coverage categories include conventional fee-for-service (FFS), preferred provider organizations (PPOs), point-of-service (POS) plans, and health maintenance organizations (HMOs). Furthermore, the CHCF/HRET survey also provides information on whether each health plan is self-insured or underwritten.

The model includes four plan types (HMO, POS, PPO, and FFS) and three categories of private purchasers (large group, small group, and individual) to represent typical insured plan benefits in California. Specifically, the privately-insured market was divided into large-group (51 or more employees), small-group (two to 50 employees), and individual coverage, because each of these markets is subject to different regulations and market forces. Since POS plans are similar in type and regulatory requirements as HMOs, POS enrollees are combined with HMO enrollees to form the “HMO” category. Since the number of enrollees in FFS plans is small, the FFS enrollees are combined with PPOs to form the “non-HMO” category. The model thus produces estimates for each market segment (HMO and non-HMO plans for large and small employers and for those enrolled in the individual market). In addition, the model captures those covered under CalPERS



(HMO), Medi-Cal (Managed Care), and Healthy Families.<sup>16</sup> The final estimates for California’s population divided by market segments are shown in Table 4.

To determine baseline coverage for a mandated benefit, CHBRP conducts an ad hoc survey of the seven largest California health plans and insurers—Aetna, Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare. Enrollment and coverage estimates from these insurers vary across assessments because some mandates are limited to Knox-Keene licensed plans (HMOs) or to policies regulated under the California Insurance Code. Coverage for CalPERS, Medi-Cal Managed Care, and Healthy Families is usually publicly available through the Department of Health Services (DHS), Managed Risk Medical Insurance Board (MRMIB), and CalPERS Web sites.

#### Utilization and expenditure data sources.

The utilization and expenditure data for the California Cost and Coverage Model are drawn primarily from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by actuaries in many of the major health plans in the United States. The guidelines provide a flexible but consistent basis for estimating health care costs for a wide variety of commercial health insurance plans. The HCGs are used nationwide and by several California HMOs and insurance companies, including at least five of the largest plans. It is likely that these organizations would use the HCGs, among other tools, to determine the initial premium impact of any new mandate. Thus, in addition to producing accurate estimates of the costs of a mandate, the HCG-based values should also be good estimates of the premium impact as estimated by the HMOs and insurance companies.

Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. In particular, the data come from health insurance companies, “Blues” plans, HMOs, self-funded employers, and from private data vendors. The data are mostly from loosely-managed health care plans, such as traditional indemnity-style plans and PPO plans. The HCGs are also based on data commonly used by health services researchers.

All the baseline analyses performed by Milliman start with PPOs in the large-group market, then make adjustments to the baseline data to account for differences by type of insurance, size of market, and geographic location. The process of applying adjustments to arrive at estimates of baseline utilization and expenditures in each of the market segments, and the process of estimating changes in utilization due to mandates, are both described in the detailed model description, *The California Cost and Coverage Model: An Analytic Tool for Examining the Financial Impacts of Benefit Mandates* (see [Appendix 11](#))<sup>17</sup>

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<sup>16</sup> MRMIP, Access for Infants and Mothers, and other public programs are included in the “Other Public Programs, non-Medi-Cal, Medicare” category.

<sup>17</sup> In 2005, CHBRP undertook an extensive revision to the Cost Model by updating the population estimates to appropriately model for impacts to the CalPERS, Medi-Cal, and Healthy Families. In addition, CHBRP decided to present two categories of plans (HMO/POS vs PPO/FFS) in 2005. Because *The California Cost and Coverage Model: An Analytic Tool for Examining the Financial Impacts of Benefit Mandates* was written in 2004, it does not reflect these changes. However, it discusses CHBRP’s general approach to modeling the cost impact to the privately-insured market.

**Table 4. Insurance Coverage of Californians by Market Segment, 2005**

<b>Uninsured Market Segment</b>					
	<b>Ages (years)</b>				<b>Total</b>
	0–17				<b>672,000</b>
	18–64				<b>4,226,000</b>
	65+				<b>21,000</b>
<b>Publicly-Funded Market Segment</b>					
	<b>Ages (years)</b>	<b>HMO<sup>1</sup></b>	<b>Non-HMO<sup>2</sup></b>	<b>Total</b>	
Healthy Families	0–17	63,000	114,000	<b>577,000</b>	
Healthy Families	18–64 <sup>3</sup>	31,000	3,000	<b>35,000</b>	
Medicare, non-Medi-Cal	18–64	91,000	76,000	<b>167,000</b>	
Medicare	65+	796,000	2,020,000	<b>2,806,000</b>	
CalPERS	0–17	210,000	64,000	<b>274,000</b>	
CalPERS	18–64	585,000	179,000	<b>764,000</b>	
Medi-Cal	All ages			<b>5,877,000</b>	
Other public (non-Medi-Cal/ Medicare)	0–17			<b>133,000</b>	
Other public (non-Medi-Cal/ Medicare)	18–64			<b>382,000</b>	
Other public (non-Medi-Cal/ Medicare)	65+			<b>179,000</b>	
<b>Privately-Insured Market Segment</b>					
	<b>Ages (years)</b>	<b>HMO<sup>1</sup></b>	<b>Non-HMO<sup>2</sup></b>	<b>Total</b>	
<i>Individually-purchased</i>					
Individually purchased	0–17	23,000	245,000 <sup>3</sup>	<b>468,000</b>	
Individually purchased	18–64	665,000	820,000	<b>1,485,000</b>	
<i>Employment-based</i>					
Small group (non CalPERS) <sup>5</sup>	0–17	524,000	397,000	<b>921,000</b>	
Small group (non CalPERS) <sup>5</sup>	18–64	1,575,000	1,152,000	<b>2,727,000</b>	
Self-insured <sup>6</sup>	0–17	153,000	55,000	<b>209,000</b>	
Self-insured <sup>6</sup>	18–64	448,000	160,000	<b>609,000</b>	
Underwritten <sup>6</sup>	0–17	595,000	118,000	<b>713,000</b>	
Underwritten <sup>6</sup>	18–64	1,778,000	341,000	<b>2,118,000</b>	
Large group (non-CalPERS) <sup>5</sup>	0–17	2,634,000	1,332,000	<b>3,966,000</b>	
Large group (non-CalPERS) <sup>5</sup>	18–64	6,001,000	3,406,000	<b>9,407,000</b>	
Self-insured <sup>6</sup>	0–17	366,000	293,000	<b>658,000</b>	
Self-insured <sup>6</sup>	18–64	869,000	749,000	<b>1,618,000</b>	
Underwritten <sup>6</sup>	0–17	3,173,000	134,000	<b>3,307,000</b>	
Underwritten <sup>6</sup>	18–64	7,447,000	343,000	<b>7,790,000</b>	
<b>California's Total Population</b>				<b>35,086,000</b>	

Sources: 2003 California Health Interview Survey (CHIS), 2004 California Health Care Foundation/Health Research and Education Trust (CHCF/HRET) Survey of California Employers.

<sup>1</sup> "HMO" includes HMO and POS enrollees.

<sup>2</sup> Non-HMO" includes PPOs and FFS enrollees.

<sup>3</sup> Healthy Families 18–64-year-old category only includes those who are aged 18 years and less because those over 18 are not eligible.

<sup>4</sup> CHIS data only distinguishes individuals with HMO coverage from those with non-HMO coverage.

<sup>5</sup> Estimates of workers in HMOs, PPOs, POS, and FFS are obtained by multiplying the percentages of workers in each plan type from HRET 2004 data and CHIS population estimate of workers.

<sup>6</sup> Estimates of workers in HMOs, PPOs, POS, and FFS who are in self-insured plans are obtained by multiplying the percentages of self-insured workers in each plan type from HRET 2004 data and CHIS 2003 population estimate of workers.

## Developing Standardized Methods for Public Health Impact Analyses

AB 1996 requires a written analysis of the public health impact of legislation that proposes a mandated benefit or service, including, but not limited to, the following:

*The impact on the health of the community, including the reduction of communicable disease and the benefits of prevention such as those provided by childhood immunizations and prenatal care.*

*The impact on the health of the community, including diseases and conditions where gender and racial disparities in outcomes are established in peer-reviewed scientific and medical literature.*

*The extent to which the proposed service reduces premature death and the economic loss associated with disease.<sup>18</sup>*

Researchers from the Public Health Impact Team at UC Berkeley identified data sources and developed the specific methods to evaluate proposed mandates based on the above-specified criteria.

### ***Health outcomes and data sources***

Prior to collection of baseline public health data, the CHBRP analysis team meets to determine and define the relevant health outcomes related to the proposed mandate. For each defined health outcome, baseline data on the incidence and prevalence and health services utilization rates of associated conditions are collected. There are four primary datasets that are used to conduct the public health impact analysis: CHIS, the California Behavioral Risk Factor Survey (BRFS), the CDC WONDER database, and the claims database maintained by Milliman.

### ***Data elements and analysis***

Four types of data are needed to conduct the public health impact analysis. First, estimates of baseline health status and health care utilization rates of relevant services are collected. Baseline health status data include, but are not limited to, rates of disease, morbidity, mortality, premature death, disability, health behaviors, and other risk factors stratified by age, gender, race, and ethnicity. Measures of relevant baseline health care utilization in the affected population are obtained and may include rates of physician visits, emergency department visits, and inpatient admissions, length of stay, and prescription drug. Utilization measures may also be stratified by age, gender, condition, and type of health insurance. The specific services for which utilization rates are needed vary by benefit mandate.

Second, the change in coverage suggested by the proposed legislation is estimated. This includes estimates of the number of insured Californians who are presently covered for the proposed benefit and the number who would be newly covered if the mandate were enacted. Coverage rates are derived from surveys of employers and health plans regarding current coverage for the specific mandate benefits. The affected population will vary by mandate and may be defined by gender, age, condition, and type of health insurance coverage.

Third, measures of utilization impacts are estimated for insured Californians who are presently covered for the proposed benefit and those who will be newly covered for the benefit, after the mandate. For persons newly covered by the mandate, an assumption is made about their

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<sup>18</sup> Health & Safety Code, Section 127660, subdivision (a) (1).

utilization of the new benefit based on current use of those with existing coverage, as well as use of similar kinds of services by the affected population. Expert opinion and a literature review guide the assumptions regarding expected changes in utilization for people who are currently covered.

Finally, based on the findings from the literature review on medical effectiveness, estimates are made on the impact of new utilization of the mandated benefit on specific health outcomes in the affected population (e.g., the effect of asthma self-management training on the reduction of hospitalizations). The literature review may include meta-analyses and randomized controlled trials providing information on the effectiveness of the proposed benefit or service on specific health outcomes. The Public Health Impact Team compiles the results to produce an overall mean estimate that can be used to calculate the predicted health effects of the benefit mandate. This final step in the analysis assesses the overall change in health outcomes in the affected population, using the estimates of changes in utilization resulting from the mandate combined with the rates of effectiveness of intervention derived from the medical effectiveness literature review. For each specific health outcome reviewed in the literature for which baseline health outcomes data are available, the estimated impact on each health outcome is applied to the affected population to determine the overall change in outcomes resulting from the mandate. In addition, the Public Health Impact Team estimates the extent to which the proposed benefit or service reduces premature death and the economic loss associated with disease and includes expected effects by gender and race/ethnicity whenever data are available.<sup>19</sup>

### **Disseminating CHBRP Reports**

The CHBRP Web site, <http://www.chbrp.org>, provides full access to all CHBRP reports and the legislation analyzed in the reports, as required by AB 1996. The Web site also announces new requests from the Legislature and provides instructions on how interested parties can provide CHBRP with evidence they believe should be considered in its analyses. Reference documents describing CHBRP's processes and methods are also available. Individuals associated with CHBRP's work are also listed, including CHBRP's staff ([Appendix 5](#)), Task Force members ([Appendix 2](#)), and NAC members ([Appendix 4](#)). Finally, the Web site serves as the forum for making announcements. For example, a public informational session for legislative staff held in Sacramento on January 24, 2005, was announced on the Web site.

CHBRP also maintains a listserv as an additional venue for disseminating information. Any member of the public interested in receiving email notices from CHBRP may join the listserv by means of an online sign-up process. Currently there are approximately 100 individuals who have signed up to receive such notices, including legislative staff, consumer and interest groups, health plan representatives, and state government agency employees from other states.

### **Evaluating CHBRP's Products to Ensure Compliance with Provisions of AB 1996**

UC continually evaluates the products, processes, and policies of CHBRP to ensure that the program is in compliance with the requirements of AB 1996.

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<sup>19</sup> For additional details on the public health impact methods for analyses, see [Appendix 12](#).

For example, UC reviews the conflict-of-interest form on an annual basis to ensure that it reflects the most up-to-date standards from a national and scientific perspective. All CHBRP-related personnel update their disclosures on an annual basis using the revised forms. UC also ensures that the CHBRP reports make no recommendations to the Legislature as to the adoption of a particular bill. In addition, CHBRP reports are not to use language that may imply bias for or against the proposed mandate. Every effort is made to ensure that statements that appear to be pure judgments—not grounded in evidence, expertise, or sound methods—are excluded from the final reports.

#### ***Discussions with legislative staff during summer/fall of 2004***

During the summer and fall of 2004, CHBRP staff met with legislative staff from the Senate Insurance Committee (now Banking, Finance and Insurance), the Assembly Health Committee, the Senate Health Committee, the Senate Republican Caucus, the Assembly Republican Caucus, the Senate Appropriations Committee, and the Assembly Appropriations Committee to obtain feedback on the first round of reports and determine ways CHBRP could improve the transparency of the review process and methods, responsiveness to bill analysis requests, and the completeness and readability of the reports.

Legislative staff stressed the limited period of time they have to digest the “heavy” reports CHBRP provides. They felt that it was important to have key information—including important caveats—in the executive summary. In addition, they expressed some frustration at having to hunt for the cost impact tables at the end of the reports. In response to these comments, CHBRP revamped the executive summary to include the salient bullet points to each analysis and a summary table of coverage, utilization, and cost impacts.

Because mandate bills would generally apply to CalPERS, Medi-Cal, and MRMIB, legislative staff stated that it would be important for CHBRP reports to explicitly state the cost impact to these programs. The Appropriations Committees were most interested in this information since it would be part of the legislative analyses their staff prepare for members during the hearings. In light of this, CHBRP worked with CalPERS to obtain baseline enrollment and premium information for its HMO product lines (self-insured products are exempt from mandates). CHBRP also worked with the DHS to clarify which data sources to use and to obtain baseline, state-wide, payment rate information for Medi-Cal Managed Care. MRMIB also worked with CHBRP to provide baseline enrollment, premium and benefit information for Healthy Families, Access for Infants and Mothers (AIM), and Major Risk Medical Insurance Program (MRMIP). CHBRP has established cooperative, working relationships with each of these organizations and agencies.

#### ***Discussions with legislative staff, agencies, Governor’s office in summer/fall of 2005***

CHBRP conducted another round of meetings in Sacramento during the summer and fall of 2005. CHBRP staff met with the staff from the Senate Banking, Finance and Insurance Committee, the Assembly Health Committee, the Senate Health Committee, the Senate Republican Caucus, the Assembly Republican Caucus, the Senate Appropriations Committee, the Assembly Appropriations Committee, the Senate President Pro Tem, the Department of Managed Health Care (DMHC), the California Department of Insurance (CDI), DHS (including Medi-Cal staff and DHS leadership), MRMIB, CalPERS, and the Governor’s Office to update knowledge of stakeholders’ experience with CHBRP processes and reports. In addition, CHBRP held discussions with other stakeholders, including individual health plans and insurers, the California Association of Health Plans, and consumer advocates.

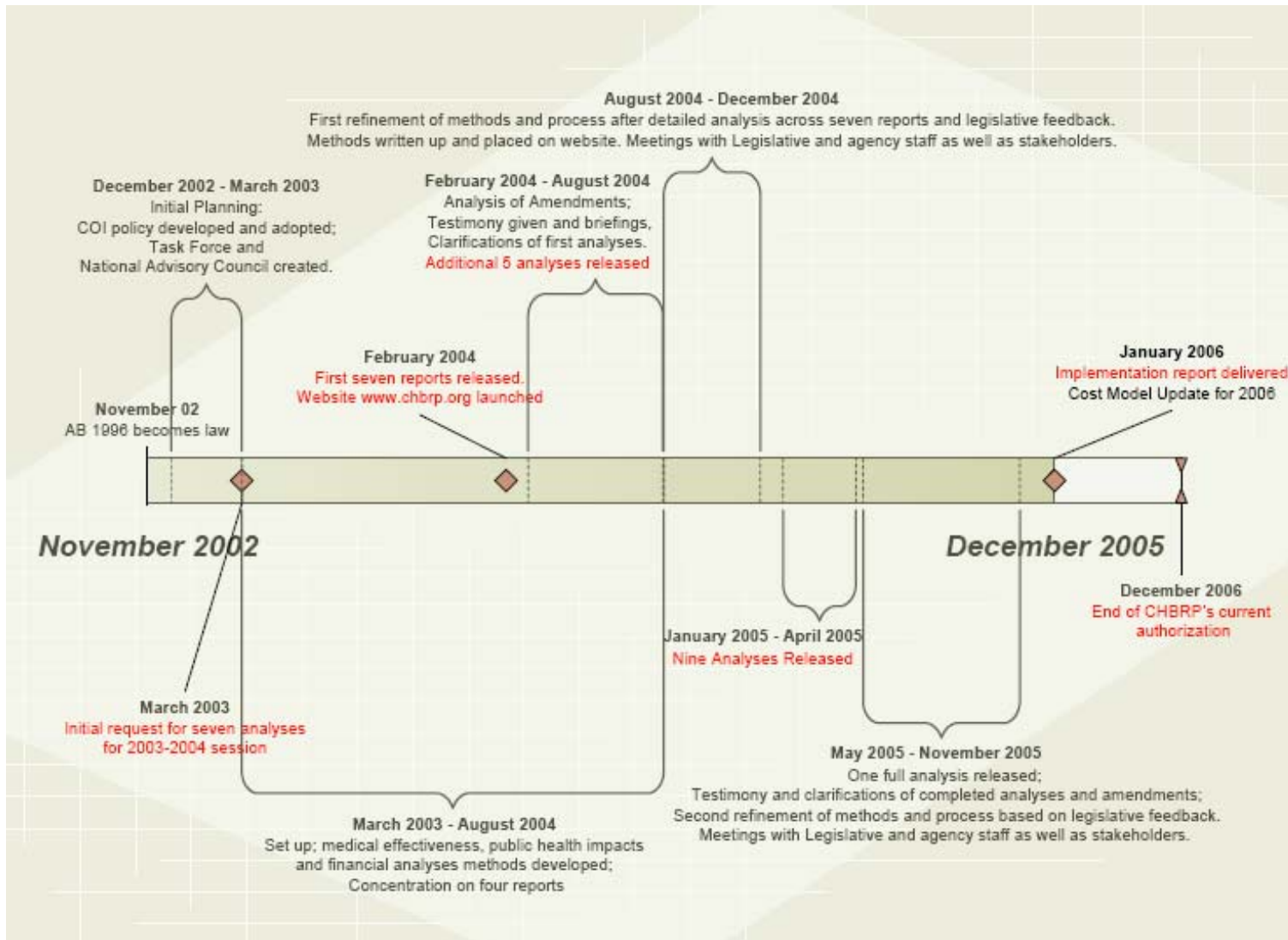
Legislative staff all reported that they utilize the CHBRP analyses, generally find the information they need in the analyses, and find the reports responsive, comprehensive, and useful. Staff also stated that the CHBRP reports provide the essential technical information the Legislature needs to deliberate the complex policy arena of health insurance benefit mandates. In previous years, staff stated that they were completely dependent on information provided to them by advocates, health plans and insurers, and interest groups. Now, as a result of CHBRP reports, they report having an improved perspective of the current status of health care coverage, and the potential impacts of the proposed mandate.

Other key messages relayed by staff:

- Legislative/executive agency staff rely heavily on CHBRP reports to write analyses for hearings or during gubernatorial review of bills that have passed the Legislature.
- The executive summaries of the CHBRP reports are the key sections used in staff analyses.
- CHBRP reports are an important tool to help answer legislators' questions.
- Staff discuss reports with stakeholders, such as the health plans, and the sponsor.
- While staff understood that some analytic questions are outside the scope of AB 1996, they would still like to have a better sense of (1) longer-term impacts of certain bills, especially those that might be preventive in nature, and (2) the impact on the uninsured, even if the impact was negligible.
- Staff stressed the importance of transparency in the analyses, for example, to express in executive summaries how utilization assumptions are derived, since they are the basis of the premium and fiscal impact estimates.
- Generally, CHBRP reports are trusted due to use of neutral language. This helps to avoid the appearance of bias in reporting results.
- It would be helpful if CHBRP consents to continue to deal with amendments on a case-by-case basis. Staff agreed that, in cases in which it was not possible to conduct an analysis of an amendment in time for the next hearing, a letter describing the analytic issues would be useful.

In order to be responsive to legislative needs while maintaining a rigorous analytic process that can feasibly be conducted within a 60-day timeframe, CHBRP is considering various approaches for the upcoming 2006 legislative year (discussed in further detail in the next section).

**Figure 1: University of California's Timeline for Implementing the Provisions of AB 1996 2002–2005**



**FULFILLING THE LEGISLATIVE INTENT: SYSTEMATIC REVIEWS OF PROPOSED BENEFIT MANDATES**

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By January 2006, CHBRP will have issued 22 completed reports analyzing proposed benefit mandates, two analyses of amended bills, and four formal follow-up letters to the Legislature clarifying or providing further explanation of completed analysis or amended version of bills.

All of the 22 analyses requested of CHBRP were completed within the 60-day timeframe or were designated specifically as two-year bills for which an extended submission date was permitted.<sup>17</sup> Table 5 provides a complete list of these analyses. The four follow-up letters and two analyses of amended bills were completed within the 60-day timeframe in order to provide useful information to legislative staff in time for the relevant hearings.<sup>20</sup> In addition, CHBRP also began the analysis of SB 1843 (Karnette, 2004), a bill that would have mandated health plans and insurers cover inpatient care for newborns as specified. The analysis was terminated per the direction of legislative staff since Senator Karnette decided to withdraw the bill from further consideration.

**Table 5: CHBRP Completed Analyses, 2004–2005**

<b>2005</b>				
<b>Analyzed Legislation</b>	<b>Author</b>	<b>Topic</b>	<b>Completed Analyses</b>	<b>Outcome</b>
SB 576	Ortiz	Tobacco Cessation Services	8/22/05	Vetoed by Governor
AB 1185	Koretz	Chiropractic Services	7/5/05	2 yr. bill
SB 913	Simitian	Medication therapies; Rheumatic Diseases	4/16/05	2 yr. bill: Placed on Appropriations Suspense File
SB 749	Speier	Pervasive Developmental Disorders/Autism	4/16/05	2 yr. bill
SB 572	Perata	Mental Health Benefits	4/16/05	2 yr. bill
SB 415	Alquist	Prescription Drugs: Alzheimer's Disease	4/16/05	Gutted/amended
SB 573	Romero	Elimination of Intoxication Exclusion	4/7/05	Vetoed by Governor
AB 228	Koretz	Transplantation Services: Human Immunodeficiency Virus	4/7/05	Enacted
AB 213	Liu	Lymphedema	4/7/05	2 yr. bill
AB 8	Cohn	Mastectomies and Lymph Node Dissections	3/7/05	Gutted/amended

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<sup>20</sup> This exception occurred in CHBRP's initial year of operation when the first analyses were requested before staff had been hired and analyses procedures established.



**Table 5: CHBRP Completed Analyses, 2004–2005 (continued)**

2004				
Analyzed Legislation	Author	Topic	Completed Analyses	Final Disposition of Legislation
SB 1157	Romero	Elimination of intoxication exclusion	4/27/04	Vetoed by Governor
SB 1158	Scott	Hearing Aids	4/19/04	Vetoed by Governor
AB 1927	Cohn	Vision Services	4/16/04	Gutted/ amended
AB 2185	Frommer	Asthma Management	4/14/04	Enacted
SB 1555	Speier	Maternity Services	4/1/04	Vetoed by Governor
SB 897	Speier	Maternity Services	2/9/04	Reintroduced as SB 1555
SB 174	Scott, Koretz, and Wiggins	Hearing Aids for Children	2/9/04	Reintroduced as SB 1158
SB 101/1192**	Chesbro	Substance Disorder Treatment	2/9/04	SB 101 was reintroduced as SB 1192. SB 1192 failed to be reported out of the Assembly Health Committee
AB 1549	Frommer, Chan, and Laird	Childhood Asthma	2/9/04	Reintroduced as SB 2185
AB 1084	Maddox	Access to Vision Providers	2/9/04	Reintroduced as AB 1927
AB 547	Liu	Ovarian Cancer Screening*	2/9/04	Gutted/amended
AB 438	Lieber	Osteoporosis Screening	2/9/04	Died pursuant to Art. IV, Sec. 10(c) of the Constitution

### Impartial Analyses to Help the Legislature and Governor Evaluate Mandate Bills

CHBRP strives to provide the Legislature with a standardized, impartial framework to discuss the complex policy arena of health insurance mandates. CHBRP analyses explicitly report on (1) the medical effectiveness of a proposed mandated benefit or service in terms of clinical outcomes, (2) the projected cost impacts of the mandate in terms of per member per month premiums and total expenditures, (3) the estimated public health impacts in terms of the population and by public health outcomes, and (4) data limitations and caveats. In its first two full years of implementation, CHBRP reports documented the medical, public health, and financial impact of 22 bills (and in some cases, related amendments). In the 22 analyses completed by December 2005, CHBRP documented \$424 million in total costs and \$28 million in potential savings for proposed analyzed mandates. A review of the medical effectiveness analyses indicated a “pattern toward favorable” or “favorable” associated with eleven mandates. A review of the public health impacts analyses indicated favorable impacts (including increased utilization of services associated with favorable outcomes) for eight mandates. CHBRP’s systematic means of evaluating the cost impacts, public health impacts, and medical effectiveness of proposed health benefit mandates is summarized in Table 6 below.

Of these reports, a few proposals pertain to services already widely covered (e.g., transplantation for persons with HIV infection or intoxication exclusion—treatment services for health problems incurred while intoxicated with alcohol or drugs). That a proposed mandated service may already be widely available is an important factor for the Legislature to consider; for example, if a particular benefit is underutilized or not accessed by those who need them, other barriers, besides coverage, may exist in the health care delivery system.

In addition to providing a basic framework for the Legislature and Governor to consider the *impacts* of a particular mandate bill, CHBRP analyses also contribute to the evaluation process by explicitly defining the *scope* of a mandate bill. For example, in order for CHBRP to proceed with an analysis, the researchers must define the clinical terms and explicitly state which services are considered “bundled” into the mandate benefit. If a mandate bill changes the delivery of a certain service by defining standards of care or restricting utilization controls, CHBRP researchers make every effort to indicate whether and how such delivery changes will alter practice patterns or utilization.

TABLE 6: Summary of the Estimated Impact of Mandate Bill Analyzed by CHBRP in 2004 and 2005					
Bills Analyzed	Medical Effectiveness of a Mandated Service or Treatment	Estimated Utilization Impact of Mandate	Estimated Cost Impact in Terms of Total Health care Expenditures <sup>1</sup>	Estimated Cost Impact in Terms of % Premium Changes by Payer <sup>2</sup>	Estimated Public Health Impact
<b>2005</b>					
<b>SB 576 (Ortiz) Tobacco Cessation Services</b>	Counseling interventions, brief advice from physicians and clinical staff, and FDA-approved pharmacotherapy are effective treatments for tobacco cessation, as measured by abstinence or quit rates	+10% (from 10%–11%)	\$89.4 million including \$19.5 million in total savings (+15%)	Private: Employers (0.18%) Individuals w/group Insurance (0.18%) Individuals w/individual coverage (0.42%)  Public: CalPERS (0.09%) Medi-Cal (0.9%) HFP (0.02%)  Members' out-of-pocket expenditures <sup>3</sup> Copayment: (-0.07%) Direct payment: (-100%)	Short-term savings of \$7.9 million from reduced use of ambulatory services; short-term health outcomes: reduction in low-birth-weight deliveries (n = 58) and acute myocardial infarction (n = 146). Long-term outcomes, not quantified, include a reduction in morbidity and mortality, improved health status, decreased work absenteeism, and lower rate of utilization of medical services.

Bills Analyzed	Medical Effectiveness of a Mandated Service or Treatment	Estimated Utilization Impact of Mandate	Estimated Cost Impact in Terms of Total Health care Expenditures <sup>1</sup>	Estimated Cost Impact in Terms of % Premium Changes by Payer <sup>2</sup>	Estimated Public Health Impact
<b>AB 1185 (Koretz) Chiropractic Services</b>	Evidence indicates a pattern toward favorable outcomes for chiropractic services with respect to pain relief, objective clinical signs, such as physical exams and adverse events, and functional status, such as decrease in disability and reduction in sick leave. However, state of literature is not sufficient to draw definitive conclusions.	+28%	\$71.6 million (+12%)	Private: Employers (0.15%) Individuals w/group Insurance. (0.19%) Individuals w/individual coverage (0.26%)  Public: CalPERS (0.24%) Medi-Cal (0%) HFP (0.23%)  Members' out-of-pocket expenditures <sup>3</sup> Copayment: (0.75%) Direct payment (-100%)	Possible increase in health status as suggested by effectiveness literature, possible decrease of economic loss associated with musculoskeletal conditions, such as back pain.
<b>SB 913 (Simitian) Medication Therapies: Rheumatic Diseases</b>	The mandate would prohibit designating a preferred drug among the FDA-approved drug therapies for rheumatic diseases.  Biological response modifiers are effective at improving patient outcomes; however, there are no head-to-head trials to provide evidence of comparative effectiveness.	0.0%	\$11.5 million (0.02%)	Private: Employers: (0.02%) Individuals w/group insurance (0.02%) Individuals w/individual coverage (0.03%)  Public: CalPERS (0.02%) MediCal (0.03%) HFP (0.01%)  Members' out-of-pocket expenditures: (0.02%)	No impact on public health because bill would have no impact on utilization of biological response modifiers.

Bills Analyzed	Medical Effectiveness of a Mandated Service or Treatment	Estimated Utilization Impact of Mandate	Estimated Cost Impact in Terms of Total Health care Expenditures <sup>1</sup>	Estimated Cost Impact in Terms of % Premium Changes by Payer <sup>2</sup>	Estimated Public Health Impact
<b>SB 749 (Speier) Diagnostic Protocol for Pervasive Developmental Disorders/Autism</b>	<p>The mandate would require coverage of a specific process for diagnosing autism.</p> <p>There are no data evaluating the effectiveness of the mandated process to diagnose autism. Based on available literature, processes specified by the bill would increase accuracy of diagnosis, lower average age of diagnosis, and decrease time between first referral and diagnosis</p>	10.0%	\$1.3 million (0.002%)	<p>Private: Employers: (0.002%) Individuals w/group Ins. (0.002%) Individuals w/individual coverage (0.003%)</p> <p>Public: CalPERS (0.002%) MediCal (0.008%) HFP (0.0227%)</p> <p>Members' out-of-pocket expenditures:<sup>3</sup> (0.002%)</p>	If improved testing results in earlier diagnosis and effective treatment, then intervention would improve functioning of those affected and reduce economic loss associated with reduced productivity. Unable to quantify public health outcomes since no quantifiable evidence was presented in the limited literature.
<b>SB 572 (Perata) Mental Health Benefits</b>	<p>Insufficient evidence to evaluate the effect of health insurance parity on mental health outcomes.</p> <p>The mandate would require coverage for diagnosis and treatment of mental illnesses under the same terms as other medical conditions.</p>	<p>Inpatient days/1,000 members (-2.4%) Outpatient days/1,000 members (+8.5%)</p>	\$118.6 million (0.21%)	<p>Private; Employers: 0.32% Individuals w/group insurance (0.29%) Individuals w/individual (0.42%)</p> <p>Public: CalPERS (0.07%) Medi-Cal (0.0%) HFP (0.10%)</p> <p>Members' out-of-pocket expenditures: (-0.99%)</p>	The scope of potential outcomes includes reduced suicides, reduced inpatient psychiatric care, reduced symptomatic distress, improved quality of life, health improvements for co-morbid conditions, and other social outcomes. Any improvements in outcomes resulting from SB 572 are dependent on changes in access to care, utilization of care, and the appropriateness and effectiveness of that care or treatment.

Bills Analyzed	Medical Effectiveness of a Mandated Service or Treatment	Estimated Utilization Impact of Mandate	Estimated Cost Impact in Terms of Total Health care Expenditures <sup>1</sup>	Estimated Cost Impact in Terms of % Premium Changes by Payer <sup>2</sup>	Estimated Public Health Impact
<b>SB 415 (Alquist) Prescription Drugs: Alzheimer's Disease</b>	All the FDA-approved medications for the treatment of Alzheimer's disease (including cholinesterase inhibitors) have some favorable effect on most of the outcomes analyzed.	No change	No change	No change	No impact: Most major health plans that cover outpatient prescription drugs already cover at least one FDA-approved medication for the treatment of Alzheimer's disease.
<b>SB 573 (Romero) Elimination of Intoxication Exclusion</b>	There is no published data about the medical effects of prohibiting disability insurers from excluding coverage of losses sustained while insured individuals are intoxicated or under the influence of controlled substances.	No change	No change	Insurers in California stated they do not utilize the provision to exclude based on intoxication, therefore no change is projected.	No impact: No evidence insurers are denying medical claims for alcohol- or controlled substance-related injuries.
<b>AB 228 (Koretz) Transplantation Services: HIV</b>	For those who undergo transplant surgery, HIV-positive patients have similar outcomes (e.g. survival rates) as those who are HIV-negative.	No change	No change	No change	No impact: The bill would not increase the number of organ transplants to HIV+ persons due to inherent supply constraints.

Bills Analyzed	Medical Effectiveness of a Mandated Service or Treatment	Estimated Utilization Impact of Mandate	Estimated Cost Impact in Terms of Total Health care Expenditures <sup>1</sup>	Estimated Cost Impact in Terms of % Premium Changes by Payer <sup>2</sup>	Estimated Public Health Impact
<b>AB 213 (Liu) Coverage for Lymphedema</b>	There is a lack of consensus on clinical definition of lymphedema, as well as on the standards of care for its treatment. However, based on available evidence, manual lymphatic drainage was found to reduce the volume of lymphedema and pain and discomfort levels. Compression therapy was found to an effective treatment for lymphedema.	1.48% per patient	\$213,855 (0.0003%)	Private: Employers: (0.003%) Individuals w/group insurance (0.0003%) Individuals w/individual coverage (0.0005%)  Public: CalPERS (0.003%) MediCal (0.0008%) HFP (0.0006%)  Members' out-of-pocket expenditures: <sup>3</sup> (0.0003%)	Favorable public health outcomes for specific treatments but inconclusive on the overall impact of the mandate.
<b>AB 8 (Cohn) Mastectomies and Lymph Node Dissections</b>	There are no published studies that provide evidence of a difference in patient health outcomes for mastectomy or axillary lymph node dissection based on length of hospital stay.	9.5% increase in inpatient admissions for mastectomy and lymph node dissection; -3.0% decrease in outpatient surgery for mastectomy and lymph node dissection; 10% increase in inpatient days for mastectomy and lymph node dissection.	\$960,000 (0.002%)	Less than 0.001%	No impact: There is no evidence that length of stay will have an impact on population's health.

Bills Analyzed	Medical Effectiveness of a Mandated Service or Treatment	Estimated Utilization Impact of Mandate	Estimated Cost Impact in Terms of Total Health care Expenditures <sup>1</sup>	Estimated Cost Impact in Terms of % Premium Changes by Payer <sup>2</sup>	Estimated Public Health Impact
<b>2004</b>					
<b>SB 1157 (Romero) Elimination of Intoxication Exclusion</b>	SB 1157 is identical to SB 573 in terms of language relevant to health insurers; the impacts are identical. SB 573 updated this earlier analysis by reviewing the literature of any new studies and soliciting new information from interested parties. The findings are the same.	See SB 573	See SB 573	See SB 573	See SB 573
<b>SB 1158 (Scott) Hearing Aids for Children [coverage once every 36 months]</b>	Evidence shows that the treatment of hearing loss with hearing aids is clinically effective.	4%	\$.8 million (0.02%)	Varies by market segment, 0.03% to 0.06%, with the greatest impact being on the small-group HMO market.	Societal savings in terms of reducing lost productivity and costs to the educational and health care systems.
<b>AB 1927 (Cohn) Vision Care Providers</b>	There is a lack of reliable information regarding the quality-of-care differentials associated with optometrists vs. ophthalmologists and other physicians.	No change	No change	No change	Lack of reliable information on quality-of-care differentials and public demand for access so that public health impacts are inconclusive.
<b>AB 2185 (Frommer) Asthma Management (self-management and training, as well as medical devices)</b>	Self-management and training programs are effective. Effectiveness of medical devices is inconclusive.	See AB 1549	\$180,000 (0.007%) includes offset of 0.002% for reduced ER and hospitalization utilization.	Varies by market segment, ranging from 0.006% in HMO large group and 0.009% in small-group and individual market.	Public health impact includes a reduction in: school absences (166,000 fewer missed days per year); restricted-activity days (6,200 fewer children would report their physical activity is limited due to asthma); ER visits (360 fewer visits); and hospitalizations (115 fewer hospitalizations).



Bills Analyzed	Medical Effectiveness of a Mandated Service or Treatment	Estimated Utilization Impact of Mandate	Estimated Cost Impact in Terms of Total Health care Expenditures <sup>1</sup>	Estimated Cost Impact in Terms of % Premium Changes by Payer <sup>2</sup>	Estimated Public Health Impact
<b>SB 1555 (Speier)- Maternity Coverage for CDI-regulated insurance carriers only</b>	Identical to SB 897	No change	\$400,000 (0.01%)	Virtually all the impact would be concentrated in the individual insurance market (10% increase). Total expenditures for privately insured small and large firms would increase by less than 0.01%. Total costs in the group market, for both small and large firms, are estimated to increase by less than 0.01%.	Identical to SB 897
<b>SB 897 (Speier)- Maternity Coverage for DMHC- and CDI- regulated products</b>	There is a lack of data on the effectiveness of the <i>package</i> of maternity services mandated by SB 897. Evidence indicates that individual elements of maternity services, such as screening for specific conditions, are effective in avoiding perinatal complications, mortality, and other poor birth outcomes.	No change	\$440,000 (0.01%)	See SB 1555	This mandate is not likely to impact the health of the community through the benefits of prenatal care, because 97.6% of the insured target population is already covered for prenatal care.
<b>SB 174 (Scott, Koretz, Wiggins) Hearing Aids for Children (coverage once every 12 months)</b>	Evidence shows that the treatment of hearing loss with hearing aids is clinically effective.	4%	\$1 million (0.03%)	Varies by market segment, ranging from 0.05%–0.09%, with greatest impact on small-group HMO market.	Effective early intervention in hearing loss can save society costs in terms of reducing lost productivity and costs to the educational and health care systems.

Bills Analyzed	Medical Effectiveness of a Mandated Service or Treatment	Estimated Utilization Impact of Mandate	Estimated Cost Impact in Terms of Total Health care Expenditures <sup>1</sup>	Estimated Cost Impact in Terms of % Premium Changes by Payer <sup>2</sup>	Estimated Public Health Impact
<b>SB 101/1192 (Chesbro) Parity of Coverage for Substance Abuse Treatment with coverage of medical care</b>	Substance abuse treatment is effective in reducing dependency; however, effectiveness of treatment type and setting varies depending on several factors, such as severity of the patient's addiction.	Increases in utilization for substance abuse treatment will vary based on plan type, with HMOs having smaller increases (2% for outpatient services) than those with loosely-managed arrangements (30% for outpatient services).	\$6.8 million (0.01%–0.3%)	Insurance premiums would be expected to increase by a range of 0.1% to 0.4%, depending on the market segment.	Effective treatment has been shown to reduce medical costs, improve care for individuals with health problems unrelated to their dependence, and reduce the health risks of the general population.
<b>AB 1549 (Frommer, Chan, and Laird) Childhood Asthma Management (OTC drugs, prescription medication, associated pediatric outpatient self-management training &amp; education)</b>	Asthma programs have had favorable effects on a variety of health outcomes for children with symptomatic asthma.	4% for asthmatic children enrolled in HMO and POS plans; 10% increase in asthma self-management training and education; use of OTC drugs for pediatric asthma increase by 10%.	\$420,000 (0.02%). Savings associated with reduced emergency room and hospital utilization is estimated to offset total expenditures by .002%. (approx. 10% of increase is offset by savings)	Mandate will have a small impact on commercial HMO and POS costs.	These estimates represent an upper bound: Public health impacts include a reduction in: school absences (180,000 fewer missed days per year), restricted-activity days (6,800 fewer children would report their physical activity is limited due to asthma) ER visits (400 fewer), and hospitalizations (130 fewer).

<b>Bills Analyzed</b>	<b>Medical Effectiveness of a Mandated Service or Treatment</b>	<b>Estimated Utilization Impact of Mandate</b>	<b>Estimated Cost Impact in Terms of Total Health care Expenditures<sup>1</sup></b>	<b>Estimated Cost Impact in Terms of % Premium Changes by Payer<sup>2</sup></b>	<b>Estimated Public Health Impact</b>
<b>AB 1084 (Maddox) Vision Care Providers</b>	There is a lack of reliable information regarding the quality-of-care differentials associated with optometrists vs. ophthalmologists and other physicians.	No change	No change	No change	Lack of reliable information on quality-of-care differentials and public demand for access so that public health impacts are inconclusive.
<b>AB 547 (Liu) Ovarian Cancer Screening</b>	The clinical benefits of screening are currently unknown; there is insufficient evidence to support screening's benefit, and insufficient evidence to support there is no benefit.	Possible increase of 14% for women aged 18 to 64 years; and 24% increase for women aged 50 to 64 years.	\$68 million (0.18%)	The impact of the mandate is estimated to range from 0.11% to 0.23% for different categories of employment-based insurance. Public insurers are exempt from the mandate and thus are not affected.	The current state of medical knowledge is that ovarian cancer screening is associated with uncertain benefits and known harms (e.g., anxiety of false-positive results, costs of screening and evaluations, risks of complications from surgical evaluations).
<b>AB 438 (Lieber) Osteoporosis Screening</b>	Of the studies reviewed, there were none that directly assessed whether osteoporosis screening is effective in reducing fractures.	22% increase for privately-insured women between 50 and 64 years	\$52 million (0.14%)	Total estimated would increase by less than 1% for all privately-insured individuals.	The public health impact of a mandate to provide coverage for osteoporosis screening would be relatively small. The number of women aged 50–64 years needed to screen to prevent one fracture is large, approximately 700.

<sup>1</sup> Total expenditures include total premiums and out-of-pocket spending for co-payments and non-covered benefits.

<sup>2</sup> Percentages differ from those in published reports due to rounding to second decimal.

<sup>3</sup> Members' out-of-pocket expenditures refer to privately-insured members' out-of-pocket expenditures, co-payments and direct payments for services not covered under the benefit.

AB 1996 required nonpartisan and independent analysis of health insurance mandate bills. Thus, CHBRP developed a process to ensure that biases in its findings are minimized or eliminated. These checks include systematically reviewing conflicts of interest of faculty and staff and content experts (as discussed above in Developing a Conflict-of-Interest Policy sections);<sup>21</sup> uniformly applying transparent, standardized methods for all analyses (e.g., literature review methods, medical effectiveness analysis methods, cost impact analysis methods, and public health impact analysis methods); and creating venues to obtain input from stakeholders and any interested party.

The NAC review enhances this ability of CHBRP to produce balanced, impartial analyses by providing feedback on early draft analyses from different stakeholder groups. For each analysis, CHBRP staff selects a subcommittee—generally five members—of the NAC membership to serve as the reviewers. On a rotating basis, these members are selected to represent a balanced set of perspectives, including consumers, providers, employers/purchasers, health plans, industry, and experts. NAC reviewers provide input when a particular draft explanation, method, or underlying assumption may be perceived as leading to biased results. In addition, the NAC members' input enhances the overall quality of the product by (1) reviewing and providing comments on the methods, assumptions, and data sources used in the analyses, (2) identifying sections that warrant further explanation, clarification, or citation, and (3) noting text that may need to be reworded to be more accessible to a lay audience.

### **A Resource Outside of California**

CHBRP has received attention and has become a resource outside of California. For example, Washington State's Sunrise Review Process has cited CHBRP's analysis of SB 174 (Scott) in its own analysis of a state bill that would mandate the coverage of hearing aids for children.<sup>22</sup> In Alberta, Canada, the provincial government is replicating parts of CHBRP's model by establishing a government-academic partnership that will allow officials to assess the medical effectiveness and associated potential cost of a new benefit or technology being considered for coverage by their publicly-funded health program.

CHBRP staff has worked to establish relationships with mandate evaluation programs in other states, and contacts such programs when a new analysis is underway. Other states have piggybacked on the communication channels CHBRP has established (e.g., using a common listserv) to contact one another and share learning and completed mandate reports.

Independent of their work with CHBRP, members of the Faculty Task Force have attended conferences to share with fellow researchers and health policy experts methods they have developed. Faculty are expected to publish related work in a special edition of *Health Services Research* in June, 2006 (see [Appendix 20](#)). Such additional work, independent of CHBRP funding, helps to disseminate sound analytical methods to other states and analytic or academic bodies. In addition, by subjecting the methods to scrutiny by peers in the policy and academic communities, CHBRP stands to benefit over the longer term by constant quality improvement in analytic methods.

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<sup>21</sup> See [Appendix 8](#).

<sup>22</sup> From [http://www.doh.wa.gov/hsqa/sunrise/2005/Hearing\\_Aid\\_Final\\_Rpt.doc](http://www.doh.wa.gov/hsqa/sunrise/2005/Hearing_Aid_Final_Rpt.doc), accessed December 7, 2005

## **Challenges Inherent to the CHBRP Analytic Process**

The overarching challenge is delivering a scientific, rigorous, high-quality analysis within the 60-day timeframe required by statute. This inherent challenge was apparent at the startup of the program and continues to present challenges for (1) identifying mandate bills in time for CHBRP analysis, (2) clarifying bill language and legislative intent to produce responsive, useful analyses for the Legislature, (3) appropriate planning to support the expected workload, (4) obtaining coverage data from health plans, and (5) responding to legislative queries or follow-up analysis requests for amendments.

### ***Start-up***

During the initial months following the passage of AB 1996, UCOP considered various structural options for building the program. One was to fully staff the program in-house and contract directly with an actuarial firm. In terms of initial setup and future coordination, that approach would have been the simplest option. However, upon further consideration and discussions with faculty from various campuses, UC decided to implement a hybrid model in which the administration and some analytic work would occur at UCOP, but the bulk of the writing and analysis would fall to the designated campuses. This model was the more desirable approach from UCOP's perspective because (1) faculty, junior faculty, and graduate students could derive benefits in terms of collaborative research opportunities, (2) the quality of the CHBRP reports would be enhanced by an internal peer-review process, and (3) the quality of the CHBRP reports would be enhanced by using faculty who are experts in their field.

CHBRP faculty and staff at the various campuses, librarians, and the contracting actuarial firm have expressed a desire to continue to work on CHBRP analyses and be affiliated with the program. Faculty confirm having derived satisfaction in serving the public interest and contributing their research and knowledge to the policy-making process. As mentioned, the program also provides a way in which junior faculty and graduate students can collaborate with senior faculty and explore various topics within the health policy and health services research discipline.

### ***Identifying mandate bills***

During 2003–2004, mandate bills were not necessarily identified by the Legislature early in the session since members were not yet familiar with the CHBRP process and the newly-adopted requirements to have mandate bills go through the analytic process in time for the policy committee hearings. As a result, the mandate bills were not readily referred to CHBRP. As a consequence, some bills were referred to CHBRP with less time to produce a report before the policy hearing deadline.

Since that first session, CHBRP has worked with the Assembly Health and the Senate Banking, Finance and Insurance Committees to improve the bill identification process. The Assembly Health Committee sent a memorandum out to all Assembly members discussing the CHBRP process and the requirement for an analysis. The Senate Banking, Finance and Insurance Committee did the same on the Senate side. In January 2005, CHBRP also conducted a public information workshop in Sacramento targeting legislative staff to educate them about CHBRP methods and process.

UC has worked independently to track legislation to identify potential mandate bills. The second year of each two-year legislative session (upcoming, 2006) presents additional challenges due to an accelerated hearing calendar. Approximately 30 days are allotted from the point of bill introduction to the time it must pass out of the policy committees in the house of origin. To address this issue

and provide the CHBRP the statutory 60-day time period, CHBRP entered discussions in the fall of 2005 with the Senate Banking, Insurance and Finance and the Assembly Health Committees to propose the adoption of a rule waiver. The hoped-for rule waiver would allow policy committees to hear mandate bills within a schedule that would permit the statutory 60-day period to run before the special policy hearing date. CHBRP is open to considering any other options to ensure adequate time for analysis.

### ***Bill language and legislative intent***

Legislative language in mandate proposals is sometimes vague and difficult to interpret. It is important for CHBRP to correctly interpret a bill since the interpretation could alter the scope of an analysis or the accuracy of impact estimates. Examples of questions that might not be addressed by bill language include: (1) does the mandate apply to all insurance markets (e.g., small group or individual), (2) does the mandate apply to all populations (adults and children), and (3) does the mandate restrict utilization management or impact physician referral requirements?

CHBRP's general approach has been to interpret the bill language referring only to the bill as written. For example, regulatory staff from the DMHC have told CHBRP that they would only refer to secondary sources for legislative intent if the law was not clear on its face or ambiguous.

As a general practice, CHBRP routinely conducts an interview with the bill author's staff upon receipt of each bill request. While this interview may supplement CHBRP's understanding of the legislative intent of the bill and populations to be covered, the author interview does not necessarily provide sufficient information to model the effect of the mandate's implementation. For example, in AB 1185, a bill proposing coverage for chiropractic services, the question of who would deliver chiropractic services and how they would be delivered was not addressed. CHBRP staff entered into a series of discussions with the author and sponsor, which allowed the analysis to be built on the assumption that services would likely be provided according to the current benefit structure, that is, by chiropractic networks under contract with Knox-Keene licensed plans and health insurers.

One disadvantage of relying exclusively on these informal conversations was that it created the expectation on the part of the bill author and sponsor that assumptions for the analysis could be revised without consequence. In fact, these assumptions drive the analyses from Day 1—from the literature search terms to the development of utilization assumptions to developing the health-plan coverage survey. When language is not clarified from the start, valuable time is lost from the limited analytic period.

As a remedy, CHBRP staff have developed a protocol that allows CHBRP to clarify language so that faculty and staff can proceed with an analysis while keeping lines of communication open with the bill author and committee staff. CHBRP will continue to seek immediate clarification by bill authors of all ambiguous provisions of the bill relevant to the analysis. The new protocol however, formalizes in a written document CHBRP's interpretation of unclear language and will clarify the scope of analysis and questions to be addressed in the analysis. This clarification will be developed, when possible in conjunction with the bill author (and potentially committee staff) and transmitted no later than Day 4 after receipt of the bill request. (See [Appendix 13](#) for details on the *Clarification of Bill Language and Legislative Intent*.) By adopting this protocol in the first stages of CHBRP's analysis, the final report will be more valuable and accurate.

CHBRP will host a second information briefing during the winter of 2006, which will be open to the public, but targeted to legislative staff. This briefing session on CHBRP processes will also provide an opportunity to listen to legislative members' and staff's general concerns regarding ways to confirm that the assumptions used for CHBRP analysis are consistent with the author's intent.

### ***Workload***

CHBRP must have sufficient capacity to do multiple (e.g., eight or more) analyses on simultaneous 60-day timelines. CHBRP faculty and staff must produce multiple drafts on multiple bills in a very compressed timeframe. Because the process is protocol-driven, there are no shortcuts to produce an abbreviated analysis.

The number of bills referred to CHBRP is difficult to predict, so underestimating the amount of scalability that will be needed and over-preparing for expansion are both problems that can arise in a development process. In the first years of operation, CHBRP relied on short-term contracts with a variety of individuals and institutions to allow for flexibility in workload until CHBRP amassed enough experience to better estimate its resource needs. In fall 2005, CHBRP developed a plan to build capacity to manage and conduct multiple, simultaneous analyses during the September 2005–June 2006 cycle. Staff needs were anticipated assuming a total of 10–12 analyses and four to six simultaneous analyses.

CHBRP will rely on additional personnel at the campus level and at UC in order to have resources “at the ready.” For example, the Vice Chairs have each hired additional staff with graduate-level training and experience to work on CHBRP analyses during the first quarter of the year. The actuarial firm has made a commitment for a senior actuary to conduct internal peer review and provide analytic services if needed. The literature search process, conducted almost entirely at the UCSF campus during the first years, will involve libraries at other campuses to distribute the workload and increase capacity. Librarians from Health Science libraries at the UC Davis, UC Irvine, and UC San Diego campuses have been recruited and trained to conduct searches for CHBRP. UCSF Library is also investigating options for obtaining literature search assistance “on demand” to initiate literature searches without waiting for a medical librarian to become available.

When the Legislature is not in session, CHBRP undertakes several projects to improve the quality and transparency of its process and products. In the fall of 2004, for example, CHBRP staff conducted a national survey to identify those states which conduct reviews of benefit mandates and the attributes of those evaluations. As a result of this effort, CHBRP has become a clearinghouse for insurance benefit mandate review organizations nationally.

As discussed, during the summer and fall months of both 2004 and 2005, CHBRP conducted numerous interviews with legislative staff and state agency personnel to obtain feedback on the CHBRP process and products. In addition, recommendations from these discussions were presented to the NAC at their annual meetings. Feedback and advice from the NAC are also taken into account to improve the data sources, substance and presentation of the analyses.

In the fall and winter of 2005, CHBRP staff also implemented and trained faculty on a new software application that will allow multiple parties to review, edit, and share documents. These improvements have helped CHBRP to operate more efficiently and, as a result, enhance our ability to be responsive to legislative requests.

CHBRP updates its Cost and Coverage Model annually, during the fourth quarter of the calendar year. The Cost Team supplies updated CHIS and CHCF/HRET data, as described in the California Cost and Coverage Model section (see Appendix 11). In addition, CHBRP incorporates updates and validates the model based on information collected from health plans and the insured. Specifically, CHBRP staff request each major commercial health plan to complete a questionnaire to obtain baseline enrollment data that would serve as a basis for all analyses. Other improvements included adding a question on high-deductible plans designed to reflect the trend by purchasers toward these products. Lastly, CHBRP validates the CHIS estimates of those enrolled in managed care plans covered under Medi-Cal and MRMIB programs by comparing enrollment figures provided directly by these agencies.

### ***Responsiveness to deliberations of policy committee***

CHBRP has received informal requests from committee staff to revisit an analysis after the final report has been issued and the 60-day deadline has passed, based on an amendment the committee or author may seek during or after the report has been heard in the policy committee. CHBRP determines whether to revise an analysis on a case-by-case basis depending on the resources available and scope of the amendment. Although CHBRP attempts to remain responsive to the Legislature, the program has sought to avoid analyzing “hypothetical bills.” As CHBRP gains more experience with the resources required for analysis of amendments, the goal is to develop a clearer understanding with the Legislature as to which circumstances allow for analyzing amended bills, particularly during those times when full 60-day analyses are in progress.

### ***Consistent and accurate data on current coverage***

To determine baseline coverage for a mandated benefit, CHBRP conducts ad hoc surveys of the seven health insurers that provide coverage for the majority of Californians who are privately insured: Aetna, Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare. In the first years of implementation, health plans’ responsiveness and reliability of the data they provided data varied. Part of the problem has been the short turnaround time afforded the health plans to respond to the survey.

In order to make the process more efficient, CHBRP solicited baseline data from the health plans in fall 2005. The data request was designed to piggyback on the plans’ reporting requirement to DMHC. This gives plans an opportunity to reconcile the enrollment figures with those reported to regulators, thereby enhancing the reliability of the data and making reporting to CHBRP less onerous to the health plans. Valid baseline enrollment data used across all analyses should make the ad hoc survey process less burdensome on the health plans since summary data will be on file with CHBRP. In response to a request by legislative staff, CHBRP will also identify those plans that do not respond to the survey on individual health mandates. Regulators have agreed to encourage health plans/insurers to complete the surveys on time.

Finally, in response to health plan concerns regarding the use of proprietary data, CHBRP has also instituted a policy to destroy proprietary information submitted by the health plans within 30 days of submitting a completed analysis to the legislature. (See [Appendix 14](#)).



### ***Proposed refinements to the analysis***

CHBRP protocols place high standards on the research on which the program is willing to rely, in part because more rigorous, comprehensive literature (e.g., meta-analysis of large randomized controlled trials) are more reliable. Although legislative staff see the value of this, they are often in the position of recommending a decision to members based on limited data or anecdotal evidence. In these cases, legislative staff requested that CHBRP seek ways to present “less rigorous” data that may still meet a threshold for inclusion. One example is to seek ways to report on longer-term (greater than one year) cost and public health impacts. Currently, analyses limit impact assessment to one year because there is greater uncertainty in predicting impacts over a longer time span. Also, almost all employer group coverage and actuarial analyses focus pricing projections on a one-year horizon. Legislative staff felt there was merit to CHBRP making some projections, with qualifications, to guide the discussion of what happens in the “out years.”

Legislative staff also desired to correlate the impact of premium price on the uninsured. Currently, CHBRP refrains from quantifying this impact, if it is less than one percent of an increase in premiums, recognizing the many factors that impact price and participation in the marketplace. Nevertheless, legislative staff felt there was value in providing an estimate (even if it were negligible) since they are often presented with estimates from various sources.

Other issues were raised by the Legislature looking for CHBRP to conduct more decision-support research. For example, the legislative staff requested that CHBRP provide information on scope of practice bills. Specifically, CHBRP was asked to look at mandates that amend the Business and Professions Code to identify whether scope of practice was based on quality differentials by profession or solely as a result of political negotiation. Since these types of bills are currently outside the scope of AB 1996, CHBRP does not have the authority to conduct such evaluations.

Agency staff suggested that future proposed legislation may call for the repeal of existing mandates. Staff stated that a CHBRP analysis would be necessary to determine whether the mandate is considered medically effective, whether there would be any projected savings to the health care market, and what impacts a repeal of a mandate may have on the public health.

### ***Applicability of the medical literature***

CHBRP’s Medical Effectiveness Team has encountered three specific challenges in addition to the general challenges described above. First, some mandate bills address topics for which few well-designed studies have been completed, such as transplantation services for persons with HIV (AB 228). In such cases, the Medical Effectiveness Team must rely on studies that do not adequately control for potential confounders (i.e., factors other than the intervention that might explain the results) and which lack statistical power (i.e., do not have sample sizes that are large enough to detect statistically significant differences between the intervention and comparison groups).

Second, some mandate bills include multiple interventions or services. Examples include AB 213 (treatment of lymphedema) and AB 1185 (chiropractic services). Many studies focus on a single intervention or service, and their findings are not applicable to all of the interventions or services proposed in a bill. Studies that examine multiple services often do not compare the same bundle of interventions or services, which limits the Medical Effectiveness Team’s ability to generalize findings across studies. The interventions or services studied also may not perfectly match the interventions or services proposed in a bill. In addition, some studies compare the delivery of different services by different types of health professionals (e.g., chiropractors and physical therapists). When reviewing

these studies, the Medical Effectiveness Team cannot ascertain whether findings are due to the service provided or the type of health professional who provided it.

Third, some bills address parity in coverage for treatment of a disease or condition rather than coverage of specific services. The mental health parity bill (SB 572) is a good example of this type of bill. Such bills are difficult to analyze because they implicitly assume that parity in coverage will improve access to services which will, in turn, increase use of appropriate and effective services and thus improve health outcomes. The available medical literature often does not enable the Medical Effectiveness Team to make these causal links. In the case of the mental health parity bill (SB 572), studies of the effects of implementation of parity coverage at the state and federal level are currently being conducted, but few studies had been published at the time the bill was introduced.

In each of these cases, CHBRP reports on both what the literature is able to convey and its limitations. To the extent possible, CHBRP also provides supplemental explanatory sections when the traditional medical effectiveness analytic framework does not lend itself to the particular bill. For example, CHBRP's analysis of SB 572 provided a section on the effects of implementation and what studies were being conducted on the effects of California's previously enacted mental health parity law.

## FUTURE DIRECTIONS IN THE NATIONAL AND STATE CONTEXT

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CHBRP will continue to respond to requests that fall within the scope of its authority and will continue to work to provide policy-relevant analysis. The analyses CHBRP may conduct in the future depend on the extent to which the Legislature will continue to use mandates as policy tools to address both perceived and actual access problems, and whether the Legislature expands or contracts the scope and nature of legislation subject to CHBRP analysis.

### Other States' Mandated Benefit Review Laws and Programs

As previously mentioned, other states have mandate evaluation programs. As of 2004, 29 states have established a formal health benefits review process or have enacted a law requiring evaluations of benefits mandates.<sup>23</sup> ([See Appendix 15.](#))

AB 1996 is the only legislation that places the evaluation requirements squarely on a university. More than half of the mandated benefit review laws place the responsibility on a government entity such as the state's insurance commissioner or the legislative analyst office. Eight have required existing or newly formed commissions or task forces to take up the responsibility. Six place responsibility, solely or in part, on the sponsor or proponent of the particular mandate legislation.

Most states' review processes focus on a review of the financial impact of legislative proposals. This includes the fiscal impacts to publicly-funded programs and the financial impact to the health insurance market in terms of health care premiums. Of those that conduct financial impact analysis on the privately-insured market all use an actuarial analysis—either contracting with a firm or using in-house actuaries to conduct the premium analysis.

The mandate benefit review laws of 12 states include “medical efficacy” as a criteria for evaluation. Discussions with these states reveal that the method of conducting medical efficacy literature reviews varies from state to state—while some conduct their own literature review and analysis (or directly contract the work out), others primarily rely on information submitted to them through a public submission process. Based on the information provided to CHBRP by these states as of 2004, none have developed an explicit “hierarchical” method of analyzing the literature for drawing conclusions on medical effectiveness.

While virtually all states' mandate reviews include “social impacts” (e.g., impacts on utilization, coverage, and access), only six include public health impacts as an explicit criterion for evaluation. As of 2004, based on the information provided to CHBRP by these states, none attempt to link the medical outcomes with the coverage and utilization rate estimates to arrive at quantifiable public health impacts—for example the reduction in the number of school days missed as a result of coverage for pediatric asthma treatment. This type of evaluation is a difficult undertaking, and CHBRP analyses can only provide these estimates when the medical outcomes literature provides quantifiable estimates and when population-based data sources are available.

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<sup>23</sup> These include states that have a formal mandate evaluation process in place. As of 2004, about 27 of these have a process in place as a result of legislation. Information for this section is derived from results of a telephone survey of all states, conducted during the summer and fall of 2004 by CHBRP staff (See [Appendix 15](#)). It also reflects evaluations of mandated benefit review laws conducted by researchers at UC Berkeley as of September 2004 (See *State Mandated Benefit Review Laws* in [Appendix 20](#)).

## Potential Future Mandates

AB 1996 defines a “mandate” in the following terms:

*...a “mandated benefit or service” means a proposed statute that requires a health care service plan or a health insurer, or both, to do any of the following:*

- (1) Permit a person insured or covered under the policy or contract to obtain health care treatment or services from a particular type of health care provider.*
- (2) Offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition.*
- (3) Offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.*

To date, CHBRP has not received any requests to analyze a bill that mandates *offering* of a particular service or benefit. Virtually all of the mandate bills have mandated *coverage* of a benefit or service. Three bills have focused on preventative services—screenings for osteoporosis and for ovarian cancer, and tobacco cessation treatment. Two bills that CHBRP has analyzed mandated health plans to allow access to specific provider types for services permitted within their scope of practice—optometrists and chiropractors.

### ***Prescription drugs***

Sometimes a mandate bill may not fit neatly into what is typically considered a “mandate.” Prescription drug mandates are an example of mandates that are highly specific. These mandates attempt to carve out specific drugs that may already be required under the broader umbrella of “medical necessity” as defined under the Knox-Keene Act and the regulations currently being promulgated by the DMHC.<sup>24</sup> It is possible that the Legislature may be interested in bringing forth such legislative proposals in future years, because prescription drugs are the fastest-growing component of health care costs and because many drug manufacturers use direct-to-consumer advertising to stimulate demand for new and more expensive drug products. In response to rising costs, health plans have developed formularies or contracted out to pharmacy benefit management companies for formulary management. In the same way that state mandate benefits were in part a reaction to managed care, there may be an analogous increase in drug-specific mandate bills in reaction to increased pharmacy management.

In the 2005–2006 Legislative Session, CHBRP received two drug bills (SB 415 and SB 913) that mandated access to specific drugs. Discussions during the committee hearing revealed some uncertainty around the current benefit structure with respect to the gatekeeper functions of health plans: the role of prior authorization, step therapy, formulary design, and contractual arrangements with drug manufacturers, which overlay the determination of medical necessity by a primary care physician. For future drug bills, CHBRP will need to provide a context for prescription drug benefit bills that reveals the layering of health care decisions and that provides legislators with sufficient information to determine whether their bills’ language actually targets the issue they intended to address.

### ***“Consumer-driven” plans***

CHBRP recognizes the trend toward product development with greater cost-sharing by the enrollee or subscriber. High-deductible policies have become more common. In addition, there is an array of

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<sup>24</sup> <http://wps.dmhc.ca.gov/regulations/docs/regs/6/1105641312767.pdf> accessed on December 14, 2005

alternatives for individuals and employers that aim to increase cost sharing by individuals: health savings accounts, health reimbursement arrangements, and association health plans. Anticipating mandate bills in response to this trend, CHBRP has modified its carrier survey of the health plans with the highest enrollment in California to obtain baseline information on the number of individuals covered through these insurance vehicles. This will allow CHBRP to more accurately assess who bears the cost of proposed benefit mandates, and help anticipate evaluation of any mandate bills that attempt to “level the playing field” among insurance products.

## APPENDICES

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The California Health Benefits Review Program is administered by the Division of Health Affairs at the University of California Office of the President, under Wyatt R. Hume, Acting Provost and Vice President for Health Affairs. Jeffrey Hall is the Acting CHBRP Director and Director, Legislation and Policy.

Additional free copies of this and other CHBRP bill analyses and publications may be obtained by visiting the CHBRP Web site at [www.chbrp.org](http://www.chbrp.org).



## **Appendix 1: Assembly Bill 1996**

*On September 22, 2002 Governor Davis signed Assembly Bill 1996 (Statutes of 2002, Chapter 795) This bill “requested the University of California to assess legislation proposing mandated health care benefits to be provided by health care service plans and health insurers, and to prepare a written analysis in accordance with specified criteria.”*

*AB 1996 was enacted to provide the California Legislature with an objective analytical tool to evaluate rapidly increasing numbers of complex bills proposing mandates of specific health insurance benefits. The State requested the University of California (UC) to evaluate legislatively-proposed health insurance mandates because it believed UC would provide impartial, thorough, science-based analysis of these bills.*

*According to the August 6, 2002 Senate Insurance Committee analysis, AB 1996 author Thomson believed that by providing medical, economic and actuarial expertise and current, accurate data and information to the Governor and the Legislature, UC would facilitate more informed policy-making with regard to proposed health benefit mandates.*





## Assembly Bill No. 1996

### CHAPTER 795

An act to add and repeal Chapter 7 (commencing with Section 127660) of Part 2 of Division 107 of the Health and Safety Code, relating to health care.

[Approved by Governor September 22, 2002. Filed with Secretary of State September 22, 2002.]

#### LEGISLATIVE COUNSEL'S DIGEST

AB 1996, Thomson. University of California: analysis of legislation mandating health care benefits and services.

Existing law regulates the provision of health care benefits by a health care service plan and by a health insurer.

This bill would request the University of California to assess legislation proposing mandated health care benefits to be provided by health care service plans and health insurers, and to prepare a written analysis in accordance with specified criteria.

This bill would request the University of California to develop and implement conflict-of-interest provisions that would prohibit a person from participating in any analysis in which he or she knows or has reason to know he or she has a material financial interest.

This bill would provide funding for the University of California's work from fees imposed upon health care service plans and health insurers, which would not exceed a total of \$2,000,000. The fees would be deposited in the Health Care Benefits Fund, which would be created by the bill. Initial startup funding would be loaned to the Health Care Benefits Fund from the Managed Care Fund and the Insurance Fund.

This bill would request the University of California to submit a report to the Governor and the Legislature by January 1, 2006, on the implementation of the bill's provisions.

The bill's provisions would remain in effect until January 1, 2007.

*The people of the State of California do enact as follows:*

SECTION 1. The intent of the Legislature in enacting this act is:

(a) To promote the public interest to assure that all residents of this state have reasonable access to quality health care.

(b) To analyze the clinical efficacy and cost-effectiveness of legislative proposals for expanded health care benefits using clear criteria for evaluating each proposal.



(c) To facilitate the provision of quality, cost-effective health services by providing current, accurate data and information to the Governor and the Legislature for the purpose of determining health-related programs and policies in connection with proposed legislation.

(d) That the University of California publish a written analysis of the clinical efficacy and cost-effectiveness of each legislative proposal, including supporting expert data.

(e) The Legislature finds that there is an increasing number of proposals that mandate that certain health benefits be provided by health care service plans and health insurers as components of individual and group contracts. The Legislature further finds that many of these would potentially result in better health outcomes that would be in the public interest. However, the Legislature also recognizes that mandated benefits may contribute to the cost and affordability of health insurance premiums. Therefore, it is the intent of the Legislature that the University of California conduct a systematic review of proposed mandated or mandatorily offered health benefit mandates. This review will assist the Legislature in determining whether mandating a particular coverage is in the public interest.

SEC. 2. Chapter 7 (commencing with Section 127660) is added to Part 2 of Division 107 of the Health and Safety Code, to read:

CHAPTER 7. UNIVERSITY OF CALIFORNIA ASSESSMENT ON  
LEGISLATION PROPOSING MANDATED BENEFITS OR SERVICES

127660. (a) The Legislature hereby requests the University of California to assess legislation proposing a mandated benefit or service, as defined in subdivision (d), and to prepare a written analysis with relevant data on the following:

(1) Public health impacts, including, but not limited to, all of the following:

(A) The impact on the health of the community, including the reduction of communicable disease and the benefits of prevention such as those provided by childhood immunizations and prenatal care.

(B) The impact on the health of the community, including diseases and conditions where gender and racial disparities in outcomes are established in peer-reviewed scientific and medical literature.

(C) The extent to which the proposed service reduces premature death and the economic loss associated with disease.

(2) Medical impacts, including, but not limited to, all of the following:

(A) The extent to which the benefit or service is generally recognized by the medical community as being effective in the screening, diagnosis,



or treatment of a condition or disease, as demonstrated by a review of scientific and peer reviewed medical literature.

(B) The extent to which the benefit or service is generally available and utilized by treating physicians.

(C) The contribution of the benefit or service to the health status of the population, including the results of any research demonstrating the efficacy of the benefit or service compared to alternatives, including not providing the benefit or service.

(D) The extent to which the proposed services do not diminish or eliminate access to currently available health care services.

(3) Financial impacts, including, but not limited to, all of the following:

(A) The extent to which the coverage will increase or decrease the benefit or cost of the service.

(B) The extent to which the coverage will increase the utilization of the benefit or service, or will be a substitute for, or affect the cost of, alternative services.

(C) The extent to which the coverage will increase or decrease the administrative expenses of health care service plans and health insurers and the premium and expenses of subscribers, enrollees, and policyholders.

(D) The impact of this coverage on the total cost of health care.

(E) The potential cost or savings to the private sector, including the impact on small employers as defined in paragraph (1) of subdivision (l) of Section 1357, the Public Employees' Retirement System, other retirement systems funded by the state or by a local government, individuals purchasing individual health insurance, and publicly funded state health insurance programs, including the Medi-Cal program and the Healthy Families Program.

(F) The extent to which costs resulting from lack of coverage are shifted to other payers, including both public and private entities.

(G) The extent to which the proposed benefit or service does not diminish or eliminate access to currently available health care services.

(H) The extent to which the benefit or service is generally utilized by a significant portion of the population.

(I) The extent to which health care coverage for the benefit or service is already generally available.

(J) The level of public demand for health care coverage for the benefit or service, including the level of interest of collective bargaining agents in negotiating privately for inclusion of this coverage in group contracts, and the extent to which the mandated benefit or service is covered by self-funded employer groups.



(K) In assessing and preparing a written analysis of the financial impact of a mandated benefit pursuant to this paragraph, the Legislature requests the University of California to use a certified actuary or other person with relevant knowledge and expertise to determine the financial impact.

(b) The Legislature requests that the University of California provide every analysis to the appropriate policy and fiscal committees of the Legislature not later than 60 days after receiving a request made pursuant to Section 127661. In addition, the Legislature requests that the university post every analysis on the Internet and make every analysis available to the public upon request.

(c) The Legislature requests that the University of California first analyze any of the following benefit mandates proposed in the 2001–02 Legislative Session, if introduced or proposed to be introduced at the start of the 2003–04 Legislative Session, and a request for an analysis is made by the author or the relevant policy committee chair:

- (1) Bone marrow testing for prospective donors.
- (2) Infertility treatment.
- (3) Specified ovarian cancer screening and diagnostic tests.
- (4) Medically necessary prescription drugs.
- (5) Wigs for patients who have undergone chemotherapy.
- (6) Bone mineral density testing for osteoporosis.
- (7) Hearing aids.
- (8) Hyperbaric oxygen therapy for an acute or chronic brain condition.
- (9) Substance-related disorders.
- (10) Genetic disease tests for certain populations.

(d) As used in this section, “mandated benefit or service” means a proposed statute that requires a health care service plan or a health insurer, or both, to do any of the following:

- (1) Permit a person insured or covered under the policy or contract to obtain health care treatment or services from a particular type of health care provider.
- (2) Offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition.
- (3) Offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

127661. A request pursuant to this chapter may be made by an appropriate policy or fiscal committee chairperson, the Speaker of the Assembly, or the President pro Tempore of the Senate, who shall forward the introduced bill to the University of California for assessment.



127662. (a) In order to effectively support the University of California and its work in implementing this chapter, there is hereby established in the State Treasury, the Health Care Benefits Fund. The university's work in providing the bill analyses shall be supported from the fund.

(b) For fiscal years 2002–03 to 2005–06, inclusive, each health care service plan, except a specialized health care service plan, and each health insurer, as defined in Section 106 of the Insurance Code, shall be assessed an annual fee in an amount determined through regulation. The amount of the fee shall be determined by the Department of Managed Health Care and the Department of Insurance in consultation with the university and shall be limited to the amount necessary to fund the actual and necessary expenses of the university and its work in implementing this chapter. The total annual assessment on health care service plans and health insurers shall not exceed two million dollars (\$2,000,000).

(c) The Department of Managed Health Care and the Department of Insurance, in coordination with the university, shall assess the health care service plans and health insurers, respectively, for the costs required to fund the university's activities pursuant to subdivision (b).

(1) Health care service plans shall be notified of the assessment on or before June 15 of each year with the annual assessment notice issued pursuant to Section 1356. The assessment pursuant to this section is separate and independent of the assessments in Section 1356.

(2) Health insurers shall be noticed of the assessment in accordance with the notice for the annual assessment or quarterly premium tax revenues.

(3) The assessed fees required pursuant to subdivision (b) shall be paid on an annual basis no later than August 1 of each year. The Department of Managed Health Care and the Department of Insurance shall forward the assessed fees to the Controller for deposit in the Health Care Benefits Fund immediately following their receipt.

(4) "Health insurance," as used in this subdivision, does not include Medicare supplement, vision-only, dental-only, or CHAMPUS supplement insurance, or hospital indemnity, accident-only, or specified disease insurance that does not pay benefits on a fixed benefit, cash payment only basis.

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.



127664. The Legislature requests the University of California to submit a report to the Governor and the Legislature no later than January 1, 2006, regarding the implementation of this chapter. Initial startup funding for the university shall be loaned to the Health Care Benefits Fund from the Managed Care Fund created pursuant to Section 1341.4 and the Insurance Fund created pursuant to Section 12975.8 of the Insurance Code. The Health Care Benefits Fund shall reimburse the Managed Care Fund and the Insurance Fund by September 30, 2003, from the 2003–04 fiscal year assessments received under subdivision (b) of Section 127662. The annual fee for the 2002–03 fiscal year shall be collected at the time the 2003–04 fiscal year assessments are made.

127665. This chapter shall remain in effect until January 1, 2007, and shall be repealed as of that date, unless a later enacted statute that becomes operative on or before January 1, 2007, deletes or extends that date.





## Appendix 2: Faculty Task Force Membership List

### Task Force Members

**Helen Halpin, PhD** *Vice Chair, Public Health Impact*, University of California, Berkeley

**Gerald Kominski, PhD** *Vice Chair, Cost Impact*, University of California, Los Angeles

**Ed Yelin, PhD** *Vice Chair, Medical Effectiveness*, University of California, San Francisco

**Wayne Dysinger, MD, MPH**  
Loma Linda Medical Center

**Theodore Ganiats, MD**, University of California, San Diego

**Sheldon Greenfield, MD**, University of California, Irvine

**Richard Kravitz, MD**, University of California, Davis

**Thomas MaCurdy, PhD**  
Stanford University

**Thomas Valente, PhD**, University of Southern California

### Task Force Contributors

**Wade Aubry, MD**,  
University of California, San Francisco

**Yali Bair, PhD**,  
University of California, Davis

**Nicole Bellows, MHSA**,  
University of California, Berkeley

**Meghan Cameron, MPH**,  
University of California, Los Angeles

**Janet Coffman, MA, MPP**,  
University of California, San Francisco

**Patricia Franks, BA**,  
University of California, San Francisco

**Miriam Laugesen, PhD**  
University of California, Los Angeles

**Noelle Lee, BA**  
University of California, San Francisco

**Harold Luft, PhD**  
University of California, San Francisco

**Witney McKiernan, RN**  
University of California, San Francisco

**Sara McMenamin, PhD**  
University of California, Berkeley

**Nadereh Pourat, PhD**  
University of California, Los Angeles





### **Appendix 3: NAC Review Criteria and Guidelines**

A National Advisory Council (NAC) reviews CHBRP's analyses for quality and objectivity before analyses are transmitted to the Legislature. This document provides the criteria and guidelines used for these reviews.

*Purpose of the review:* To help assure the accuracy, responsiveness, completeness, and clarity of CHBRP analyses of proposed health insurance benefit mandates undertaken for the California legislature.

*Structure of bill analyses:* The bill analyses are structured around specific issues mentioned in AB 1996, CHBRP's authorizing legislation, which asks the University of California to address the medical impacts of mandated services, as well as the estimated financial and public health impacts, of each bill. When a particular piece of legislation would mandate something other than the coverage of services (e.g., access to certain types of providers), CHBRP may decide to modify the structure of the written report and provide the Legislature with other information it deems more relevant to the bill's potential impacts.

*Audience:* CHBRP's primary audience is the California State Legislature and each report is submitted to the committee that requested it (either the Assembly Committee on Health or the Senate Committee on Insurance) as well as to the author(s) of the legislation analyzed. Other members and committees of the Legislature, as well as California state government agencies such as the Office of the Governor, the Departments of Managed Health Care and Insurance, and the California Public Employees Retirement System (CalPERS), may also be interested in CHBRP analyses. AB 1996 further requires CHBRP to make its written analyses available to the public on its website, [www.chbrp.org](http://www.chbrp.org). There may be additional interest in CHBRP reports both in California and nationally.

*Review Criteria:* CHBRP asks National Advisory Council reviewers to comment on the extent to which the report meets the criteria of: 1) accuracy and objectivity, 2) responsiveness to the legislative request, 3) completeness, and 4) clarity of presentation using the specific questions on the review form as a guide to the extent they are helpful.



**National Advisory Council Review of CHBRP Draft Bill Analysis**

**Date:** \_\_\_\_\_

**Reviewer Name:** \_\_\_\_\_

**Bill Number or Name of Draft Report:** \_\_\_\_\_

Using as much space as you need, please comment in the boxes below on the extent to which the draft report meets each of the following criteria using the specific questions as a guide to the extent they are helpful. There is space at the bottom of the form for other general comments or mention of specific parts of the text about which you have comments. When possible please indicate whether your comment might fall into the following categories: 1) suggestions; 2) issues or items that you identify that you want to make sure the authors are aware of or are considering; 3) serious concerns that must be addressed.

**Accuracy and Objectivity:**

- Are conclusions adequately supported with objective evidence?
  - Does the analysis adequately discuss situations for which evidence does not exist and discuss the implications of this lack of evidence?
  - Does the analysis avoid perceptions of bias, for instance, by noting when cited studies are conducted by interested parties or by properly framing findings that may have resulted from biased research or reporting?
  - Are potentially politically-sensitive issues handled appropriately, using neutral language?
- \_\_\_\_\_

**Responsiveness:**

- Are the analyses, findings and conclusions relevant to the bill in question?
- \_\_\_\_\_
- \_\_\_\_\_

**Completeness:**

- Does the analysis adequately address each of the issues of medical, financial, and public health impacts specified in AB 1996? If not, does the text or appendices offer an explanation? ([Click here for a list of the issues requested of each of the CHBRP analyses in AP 1996](#))
  - To the best of your knowledge, does the report exclude any high-quality evidence that would alter the findings or conclusions of the report?
- 
- 

**Clarity:**

- Does the executive summary concisely and clearly summarize the findings described in the analysis?
  - Are the findings clearly and concisely stated in understandable language?
  - Is supporting evidence described in sufficient detail?
  - Upon first mention, are technical terms defined appropriately for an interested lay audience?
  - Is the organization of the report easy to follow and appropriate for the topic?
- 
- 

**Other Comments:**

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## Appendix 4: National Advisory Council Membership List

**Susan Dentzer**

Health Correspondent  
NewsHour with Jim Lehrer, PBS  
Alexandria, VA  
*Chair*

**John Bertko, FSA, MAAA**

Vice President and Chief Actuary  
Humana Inc.  
Flagstaff, Arizona

**Deborah Chollet, PhD**

Senior Fellow  
Mathematica Policy Research  
Washington, DC

**Michael Connelly, JD**

President and CEO  
Catholic Healthcare Partners  
Cincinnati, OH

**Maureen Cotter, ASA**

Founder and Owner  
Maureen Cotter & Associates, Inc.  
Dearborn, MI

**Patricia Danzon, PhD**

Celia Z. Moh Professor  
The Wharton School, University of Pennsylvania  
Philadelphia, PA

**Joe Ditre, JD**

Executive Director  
Consumers for Affordable Health Care  
Augusta, ME

**Jack Ebeler, MPA**

President and CEO  
Alliance of Community Health Plans  
Washington, DC

**Allen D. Feezor**

Chief Planning Officer  
University Health System of Eastern Carolina  
Greenville, NC

**Charles "Chip" Kahn, MPH**

President and CEO  
Federation of American Hospitals  
Washington, DC

**Lauren LeRoy, PhD**

President and CEO  
Grantmakers In Health  
Washington, DC

**Trudy Lieberman**

Health Policy Editor  
Consumers Union  
Yonkers, NY

**Devidas Menon, PhD, MHSA**

Executive Director and CEO  
Institute of Health Economics  
Edmonton, AB

**Marilyn Moon, PhD**

Vice President and Director, Health Program  
American Institutes for Research  
Silver Spring, MD

**Michael Pollard, JD, MPH**

Consultant, Federal Policy and Regulation  
Medco Health Solutions  
Washington, DC

**Karen Pollitz, MPP**

Project Director  
Georgetown University Health Policy Institute  
Washington, DC

**Christopher Queram**

President and Chief Executive Officer  
Wisconsin Collaborative for Healthcare Quality  
Madison, WI

**Richard Roberts, MD, JD**

Professor of Family Medicine  
University of Wisconsin-Madison  
Madison, WI

**Frank Samuel, LLB**

Science and Technology Advisor  
Governor's Office, State of Ohio  
Columbus, OH

**Roberto Tapia-Conyer, MD, MPH, MSc**

Senior Professor  
National University of Mexico  
Cuahtémoc, Mexico

**Prentiss Taylor, MD**

Vice President, Medical Affairs  
Amerigroup  
Chicago, IL

**Reed V. Tuckson, MD**

Senior Vice President  
United Health Care  
Minnetonka, MN

**Judith Wagner, PhD**

Scholar-in-Residence  
Institute of Medicine  
Washington, DC

**Dale Whitney**

Corporate Health and Welfare Manager  
UPS Corporation  
Atlanta, GA

**Ronald A. Williams**

President  
Aetna, Inc.  
Hartford, CT



## Appendix 5: CHBRP Staff List

**Jeffrey R. Hall, JD**  
Acting Director – CHBRP  
510-287-3876  
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**Susan Philip, MPP**  
Assistant Director  
510-287-3877  
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**Cynthia Robinson, MPP**  
Principal Analyst  
510-987-9177  
cynthia.robinson@chbrp.org

**Sachin Kumar, BA**  
Research Analyst  
510-987-0259  
sachin.kumar@chbrp.org

**Christina Davis**  
Administrative Assistant  
510-287-3878  
christina.davis@chbrp.org

Mailing Address:

California Health Benefits Review Program  
University of California Office of the President  
Division of Health Affairs  
1111 Franklin St. - 11th Floor  
Oakland, CA 94607-5200  
Fax: 510-987-9715  
CHBRP mainline: 510-287-3876



## **Appendix 6: CHBRP Actuaries**

AB 1996 requires the University of California to use a certified actuary or other person with relevant knowledge and expertise to determine the financial impact.

CHBRP has retained Milliman, Inc. to serve this function. The actuarial firm has made a commitment for a senior actuary to conduct internal peer review and provide analytic services if needed.

Senior consulting actuaries on CHBRP projects are:

Jay C. Ripps, FSA, MAAA.  
650 California Street, 17th Floor  
San Francisco, CA 94108-2702

Robert G. Cosway, FSA, MAAA  
La Jolla Centre II  
9255 Towne Centre Drive, Suite 900  
San Diego, CA 92121-3042

Information on Milliman is available at <http://www.milliman.com>

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Jay Ripps, FSA, MAAA of Milliman recused himself from contributing to all CHBRP analyses beginning March 1, 2005. His recusal is valid through his duration as acting chief actuary at Blue Shield of California.



## Appendix 7: CHBRP's Process and Policy for Selecting Content Experts

This document clarifies the process, and serves as guidelines by which CHBRP identifies, screens, and selects content experts for each bill analysis.

This process should be undertaken as early as possible—preferably one week before the Legislature's request for CHBRP bill analysis. If that is not possible, then this process should occur during days 0-4 of the 60-day time period.

Not all bill analyses require the use of a content expert. For example, for a bill that may have a small number of providers (e.g. transplant centers that conduct surgeries for HIV+ patients), the need for a content expert might be filled by conducting a survey of those providers, making use of in-house expertise (e.g. within Milliman) or a combination of the above. This determination will be made on a case-by-case basis.

### I. Criteria for Selecting the Content Expert

1. In general, content experts need clinical and/or health services research experience in order to:
  - Advise the medical effectiveness team and other members of the analytic team on:
    - Key literature to facilitate literature review and analysis to determine whether mandated benefit/service/treatment is clinically effective (e.g., state of the art research, research specific to California, summary of evidence on effectiveness)
    - Search criteria for literature review (e.g., medical conditions and outcomes) to assure that the team is using the appropriate search terms to identify key articles
    - Research in progress that could affect the final conclusions of the effectiveness analysis
    - Clinical care management, controversies in practice, and knowledge of specialty society positions and guidelines.
  - Advise cost and public health team on:
    - Incidence and prevalence rates of medical condition (s) addressed by the mandate
    - Bundle of services utilized, and the associated CPT codes, ICD-9 codes, pharmaceuticals, and devices
    - Will those newly covered by the mandate be likely to change utilization?
    - How would the mandate change physician practice patterns?
    - Will utilization of mandated benefit/service produce offsets in current or future utilization? In other words, does mandated benefit/service replace old interventions or become add-ons, complements, or substitute? Is there an associated time-horizon for those cost offsets (i.e. how long would it take for the health care system to realize the cost of those savings—one year, 5 years, etc.)
2. Content experts need to be interested in and willing to work in what may be a controversial area. CHBRP reports are sometimes used in an adversarial context. We need to treat both sides of an issue in a balanced and fair manner in CHBRP reports.



3. Are they clearly identified with one side or another? It does not necessarily disqualify them but we may want to get someone identified with the other side.
  - How comfortable would they be if they were criticized by advocates on one side or another?
4. Content experts need to be available for consultation during the timeframe that they are needed by CHBRP.
5. Content experts must not have a financial, business, or professional conflict of interest (See section below for Conflict-of-Interest Screening Questions)

## **II. Process for Identifying Potential Content Experts**

CHBRP staff will initiate the search for content experts by taking the following steps:

1. Query full Faculty Task Force for recommendations (UC faculty have first priority as content expert, followed by person with California experience)
2. Query other UC research centers (e.g., Public Health Institute)
3. Query Milliman for suggestions
4. Identify NIH grant recipients on subject area
5. Work with Librarian to search for most frequent and/or most recent authors of articles on subject
6. Solicit help from state and national specialty societies
7. Solicit recommendations from candidates who are not available.

## **III. Process for Screening Potential Content Experts' Qualifications, Interests, Availability**

1. Initial Screening: CHBRP staff will conduct initial screening of content experts based on:
  - Clinical and/or health services research experience
  - Strengths and weaknesses of potential expert and how/whether best to use him/her. For example, if he/she would not be a good clinical expert but may be knowledgeable about insurance, access, and the health services research as it relates to the mandate, we may consider him/her as a potential reviewer
  - Interest and willingness to work in a potentially controversial area
  - Availability in general but particularly during the first 3 or 4 days after CHBRP request and for review of draft report
  - Potential Conflicts-of-interest (see following section).
2. Staff will follow-up with fax/e-mail if a written explanation is requested by content expert's assistant.
3. CHBRP staff may interview several potential content experts.
4. CHBRP staff will forward CVs and pertinent information about potential content experts to medical effectiveness, public health, and cost teams for consideration.
5. Once a potential content expert is identified and CHBRP teams agree that the content expert meets criteria, staff will forward these following questions to the content expert:
  - What medical condition(s) related to this mandated benefit, service, treatment have highest prevalence?
  - What is your view of the clinical effectiveness of this mandated benefit, service, treatment for this condition(s)?
  - Are there alternatives that are already generally covered services?

- What key literature will help facilitate literature review and analysis document evidence of the effectiveness of the mandated benefit/service/treatment (e.g., state of the art research, research in progress, research specific to California)?
- What research in progress could affect the final conclusions of the effectiveness analysis?
- What is clinical care management?
- What are controversies in practice?
- What are specialty society positions and guidelines?
- What are search criteria for literature review (e.g., conditions and outcomes) and search terms?
- What are the incidence and prevalence rates of the medical condition addressed by the mandate? What is the population used in the denominator to calculate these rates (entire population, women ages 50+, etc.)?
- Who are current users of care for the medical condition addressed by the mandate (e.g., women ages 50+)? What bundle of services do they utilize, and the associated CPT codes, ICD-9 codes, pharmaceuticals, devices., etc.?
- Who will be newly covered by the mandate? Specifically, how will utilization change as a result of the mandate? Will there be more users (change in utilization rates per 1000), a different mix of services among current users (change in intensity of care per user), or both?
- Will utilization of the mandated benefit produce offsets in current or future utilization?

#### IV. Process for Screening Potential Content Experts' Potential Conflicts of Interest

These questions are designed to prod the potential content expert to think of and flag potential conflicts of interest (COI) before they undergo the formal written COI review process. CHBRP staff will bring any issues that could potentially prohibit an individual from participating as an expert (but are not obvious grounds for recusal) to the Legislative Director's (or the designee's) attention immediately.

1. Do you have any financial interest in the proposed mandated benefit?
  - Examples of financial conflicts: investments in pharmaceutical companies or medical device manufacturers; relations with drug company with products related to mandate, research funding or own investments related to this mandate?
2. Do you have an interest from an insurance perspective in the proposed mandated benefit?
  - Examples: Have they acted as expert witness, if so, for one or both sides? Member of a task force that has voted on benefit being mandated, testified or taken a public position on mandate?
3. Could your existing research create a perception of bias as it pertains to the proposed mandate?
  - This might arise if a content expert authored research that included recommendations that are substantially similar to or directly oppose the proposed mandate. We would not want to place a content expert in the position of having to objectively evaluate their own research. This is to limit the possibility that outside observers could perceive that our experts may have a documentable, pre-existing bias that the outcome of the CHBRP review be consistent with their own research finding and prior recommendations. Since they are a content expert, it is likely that their name will come up in literature search; however, their work would need to be evaluated to determine whether there is potential for bias.

**V. Selecting the Content Expert**

1. If the content expert candidate indicates his/her ability, interest, willingness, availability to answer questions, then CHBRP staff will provide a COI form to complete and sign.
2. The content expert candidate completes the COI form and forwards it to CHBRP staff.
3. The COI application is reviewed.
4. CHBRP staff notifies the content expert candidate and the CHBRP analytic teams of COI status.



## **Appendix 8: 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.*

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

AB 1996, 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 COI form completion process:**

- When a new CHBRP staff or faculty is hired or designated to work on CHBRP analyses, the CHBRP Assistant Director is to send 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 analyses-specific work. However, the lead analyst should also feel free to send the request letter/form but just notify the CHBRP Assistant Director so there is no accidental duplication. In addition, the lead analyst and/or the lead from the CHBRP Effectiveness Team should initially screen the potential content expert by querying him/her about any potential conflicts of interest. (See Section: Initial Screening Questions for Potential Content Experts.)
- The CHBRP Assistant, the OHA Legislative Director, the CHBRP Director and the lead CHBRP analyst (if specific to a bill) should be carbon copied on the COI request email.

**General Submission Process:**

- When a new or revised COI form is submitted, original goes to the CHBRP Assistant, who will provide it to the CHBRP Assistant Director for an initial review and make a copy for the OHA Legislative Director. The CHBRP Assistant Director is to flag any potential issues for the OHA Legislative Director to facilitate review.
- Electronic versions of completed COI forms will be saved on the X drive at: CHBRP\Administration\Conflict of Interest\Completed Forms. Folder will have protected access.
- The OHA Legislative Director will update the database with the new information and send to CHBRP staff.
- The OHA Legislative Director will contact the person to clarify any questions, if necessary.
- The CHBRP Assistant Director will review the database to keep abreast of any potential conflicts of interest.

*Information to track in database:*

- Name
- CHBRP function
- CHBRP mandates reviewed
- Dates: signed, OHA Legislative Director review, other review (e.g., Task Force)
- Present employer
- Bias/potential conflict reported/comments

*Ongoing Review of potential conflicts– Reviewing and Tracking*

- When a new analysis is requested, as part of the initial 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 email providing information about the conflict. Both potential conflicts and recusals from a specific bill analysis should be documented in the file. The OHA Legislative Director will send an email to CHBRP staff (and sometimes the 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 Assistant Director and the CHBRP Assistant 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.

If individuals have not submitted a form despite repeated follow up by the CHBRP Assistant Director and/or the CHBRP Assistant, then the CHBRP Director will send a letter to those who have not completed their COI forms. The OHA Legislative Director has written a formal letter to the CHBRP Director, explaining that this is a serious problem; the CHBRP Director will then write to those whose forms are outstanding, using the OHA Legislative Director's letter as leverage (same as letter sent to certain Task Force and NAC Members for the 2004-2005 update period).

*Annual Updates of COI forms*

The first round of COI forms covered the time period 9/1/03-8/31/04 (they say they cover the period through 12/31/04).

The 2<sup>nd</sup> updates requested covered the period 9/1/04-8/31/05.

The third update will cover the period 9/1/05- 12/31/06. The update will occur as follows:

- 1) The Legislative Director will review the 2005 form and work with CHBRP staff to determine whether updates need to be made. As part of that review, it will be determined whether a "short form" for use with content experts can or should be developed. Forms should be finalized by August 1, 2005.
- 2) The CHBRP Assistant and Assistant Director will work together to complete an update request to all CHBRP affiliated faculty and staff during the first week of August.
  - o If the information that was submitted the previous year is the same, individuals will have the option as using form that was developed last year. This allowed individuals to check a box that stated "same as last year" and return it with their signature page.

- CHBRP Assistant will send out via US Mail to faculty, UCOP staff and NAC members by the end of 2005 and include a copy of last year's form, so that they can assess whether anything has changed.
- 3) Faculty and UCOP staff will be requested to return all COI forms by December 31, 2005.

### **Initial Screen Questions for Potential Content Experts:**

These questions serve as a guide for conversation between the designated faculty on the Effectiveness Team (or sometimes the CHBRP lead analyst) and an individual being considered to serve as a content expert. They are designed to get the potential content expert to think of and flag potential conflicts of interest before they undergo through the formal written COI review process. The CHBRP lead analyst should bring any issues that could potentially prohibit an individual from participating as an expert (but are not obvious grounds for recusal) to the Legislative Director's attention immediately.

- 1) Do you have any financial interest in the proposed mandated benefit?
  - Examples of financial conflicts: investments in pharmaceutical companies or medical device manufacturers
- 2) Do you have an interest from an insurance perspective in the proposed mandated benefit?
  - Examples: Have they acted as expert witness, if so, for one or both sides? Member of a task force that has voted on benefit being mandated, testified or taken a public position on mandate?
- 3) Could your existing research create a perception of bias as it pertains to the proposed mandate?
  - This might arise if a content expert authored research that included recommendations that are substantially similar to or directly oppose the proposed mandate. This is to limit the possibility that outside observers could perceive that our experts may have a documentable, pre-existing bias that the outcome of the CHBRP review be consistent with their own research finding and prior recommendations.

**University of California (UC)  
Form for Obtaining Background Information and Conflict of Interest Disclosure for  
Activities Related to the California Health Benefits Mandate Review Program<sup>1</sup>**

NAME: \_\_\_\_\_

TELEPHONE: \_\_\_\_\_

ADDRESS: \_\_\_\_\_  
\_\_\_\_\_

E-MAIL ADDRESS: \_\_\_\_\_

CURRENT  
EMPLOYER: \_\_\_\_\_

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 SEPTEMBER 1, 2004 AND ENDING DECEMBER 15, 2005.

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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.**

If some or all of the requested information is contained in a previously submitted copy of this form, you may revise and resubmit your previously submitted form, including additional responses or comments below as necessary and supplemented by a copy of your curriculum vitae.

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

**IF YOUR INFORMATION HAS NOT CHANGED SINCE YOU LAST SUBMITTED A CONFLICT OF INTEREST DISCLOSURE FORM TO CHBRP, PLEASE SEE THE SIMPLIFIED SUBMISSION INSTRUCTIONS ON THE LAST PAGE OF THIS DOCUMENT.**

**PART I -- BACKGROUND INFORMATION**

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<sup>1</sup> 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.**



## Instructions

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

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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. EMPLOYMENT. (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 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 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 \$10,000 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).**

2. INVESTMENT INTERESTS. 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 either at less than \$10,000 or at less than a 5% equity interest, 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 necessary).**

3. PROPERTY INTERESTS. 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. RESEARCH FUNDING AND OTHER INTERESTS. (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, or

**YES**  **NO**  **NOT APPLICABLE**

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

(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?

**YES**       **NO**       **NOT APPLICABLE**

**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:

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**IF YOUR CONFLICT OF INTEREST DISCLOSURE INFORMATION HAS NOT  
CHANGED SINCE YOU LAST SUBMITTED THIS FORM:**

Check this box, sign and date your signature below to affirm that ALL of the information requested in this *Form for Obtaining Background Information and Conflict of Interest Disclosure for Activities Related to the California Health Benefits Mandate Review Program* is in the form you submitted previously on \_\_\_\_\_ .

[Date previous form submitted]

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*During your period of service, **September 1, 2005 through December 15, 2006**, 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.*

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SIGNATURE

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DATE

Reviewed by: \_\_\_\_\_

Responsible California Health  
Benefits Review Program Administrator

---

DATE

**University of California (UC)**  
**Form for Obtaining Background Information and Conflict of Interest Disclosure for**  
**National Advisory Committee Members' Activities**  
**Related to the California Health Benefits Mandate Review Program<sup>2</sup>**

NAME: \_\_\_\_\_

TELEPHONE: \_\_\_\_\_ E-MAIL ADDRESS: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CURRENT  
EMPLOYER: \_\_\_\_\_

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 SEPTEMBER 1, 2004 AND ENDING AUGUST 31, 2005.

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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.**

If some or all of the requested information is contained in a previously submitted copy of this form, you may revise and resubmit your previously submitted form, including additional responses or comments below as necessary and supplemented by a copy of your curriculum vitae.

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

IF YOUR INFORMATION HAS NOT CHANGED SINCE YOU LAST SUBMITTED A CONFLICT OF INTEREST DISCLOSURE FORM TO CHBRP, please see the instructions on the last page of this document.

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<sup>2</sup> 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.**

## **PART I -- BACKGROUND INFORMATION**

### **Instructions**

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**

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 recommending 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.**

We anticipate that most, if not all, members of the National Advisory Committee (NAC) of CHBRP will report potential conflicts of interest because the NAC membership is comprised explicitly to include advice from a balanced group of interested and expert stakeholders. UC and/or the California government agency requesting UC's and CHBRP's assistance has determined that conflicts of interest are unavoidable for National Advisory Committee members and will not, in most cases, disqualify them from participating on the Committee. In affirmation of NAC's advisory, non-decision making role in the CHBRP process, all CHBRP reports will contain the disclaimer: "*CHBRP appreciates and is grateful for the valuable assistance and thoughtful critiques provided by the National Advisory Committee members. The National Advisory Committee does not, however, necessarily approve, disapprove, or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.*" Nevertheless, National Advisory Committee members must publicly disclose those conflicts of interest.

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, UC, or the National Advisory Committee member.

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's National Advisory Committee, an entity that UC has convened at the request of the state whose advice is to be provided to CHBRP and ultimately 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.

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. The following questions are designed to elicit information from you concerning possible conflicts of interest that are relevant to the functions of the CHBRP National Advisory Committee upon which you have been asked to serve.

1. EMPLOYMENT. (a) If the reports resulting from 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 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 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 \$10,000 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 this CHBRP activity?

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).**

2. INVESTMENT INTERESTS. 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 either at less than \$10,000 or at less than a 5% equity interest, 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 necessary).**

3. PROPERTY INTERESTS. 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. RESEARCH FUNDING AND OTHER INTERESTS.

(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, **or**

(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 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 CHBRP's health insurance mandate reviews?

YES     NO     NOT APPLICABLE

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

(g) If the 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:

---

**IF YOUR CONFLICT OF INTEREST DISCLOSURE INFORMATION HAS NOT  
CHANGED SINCE YOU LAST SUBMITTED THIS FORM:**

Check this box, sign and date your signature below to affirm that ALL of the information requested in this *Form for Obtaining Background Information and Conflict of Interest Disclosure for Activities Related to the California Health Benefits Mandate Review Program* is in the form you submitted previously on \_\_\_\_\_.

[Date previous form submitted]

---

*During your period of service, **September 1, 2004 through August 31, 2005**, 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. When you are requested to review draft evaluation of a specific mandate, CHBRP will send you a reminder notice to review your previously-submitted Disclosure Form and to report any additional information that may be relevant to the specific mandate evaluation that you have been asked to review.*

\_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
DATE

Reviewed by: \_\_\_\_\_

Responsible California Health Benefits  
Review Program Administrator

\_\_\_\_\_  
DATE



## Appendix 9: 60-day Timeline of the Analytical Process

AB 1996 requires the CHBRP to provide the Legislature with its analysis within 60 days of having received a request from the referring committee. To meet this deadline, a timeline was developed to coordinate the various analytical processes. Below is an abbreviated version of the CHBRP 60-day timeline that describes in broad terms the steps taken to produce a report.

Assigned Personnel	Day 0-3
<b>CHBRP Staff</b>	<ol style="list-style-type: none"> <li>1. Work with faculty to identify and screen content expert per protocol.</li> <li>2. Convene conference call so that all potential faculty/staff recusals can be identified.</li> <li>3. Post analysis request on web site (including solicitation for information from interested parties by Day 19).</li> <li>4. Work with faculty and bill author's office to clarify intent of the bill in writing.</li> </ol>
<b>Task Force Members (including Vice Chairs)</b>	<ol style="list-style-type: none"> <li>1. Establish lead faculty for analysis.</li> <li>2. Select peer faculty Reviewer.</li> <li>3. Discuss bill and issues specific to the analysis, including content expert selection.</li> <li>4. Identify areas of draft bill warranting clarification from bill author's office.</li> <li>5. Discuss conflicts and potential recusals.</li> </ol>
<b>Cost Team/Actuaries</b>	<ol style="list-style-type: none"> <li>1. Discuss with internal faculty/staff any potential conflicts so recusals can be identified and executed.</li> <li>2. Confer with clinical (and potentially health services research) content expert and others on call regarding scope, strategy and search terms for cost literature review.</li> <li>3. Provide effectiveness team with any mandate-specific questions to add as part of literature review/effectiveness analysis.</li> </ol>
<b>Effectiveness Team</b>	<ol style="list-style-type: none"> <li>1. Work with faculty-staff leads to contact content expert and conduct initial (verbal) conflict-of-interest (COI) screening and complete COI form.</li> <li>2. Discuss with internal faculty/staff any potential conflicts so recusals can be identified.</li> <li>3. Begin to identify search terms.</li> <li>4. Consult with clinical/content expert, provide librarians with essential bibliography and determine scope of search, search terms and strategies for librarians.</li> <li>5. Develop a diagram of likely effects of the mandate (e.g., increase in use of treatment vs. increased screening, true and false positives, possible treatment, etc.).</li> </ol>
<b>Public Health Team</b>	<ol style="list-style-type: none"> <li>1. Discuss with internal faculty/staff any potential conflicts so recusals can be identified.</li> <li>2. Confer with clinical content expert and others on call about scope, strategy and search terms for public health literature review.</li> <li>3. Provide questions to the effectiveness team regarding literature needed for PH analysis (e.g. prevalence, incidence, racial disparities).</li> </ol>
<b>Librarians</b>	Conduct literature search iteratively under direction of effectiveness team with input from content expert (Days 0-4)

Assigned Personnel	Day 4-6
<b>CHBRP Staff</b>	<ol style="list-style-type: none"> <li>1. Prepare and send statement of legislative intent of bill to all teams.</li> <li>2. Consult with faculty lead, effectiveness team, content expert, cost team, public health team, and actuaries on health plan coverage questionnaire.</li> </ol>
<b>Task Force Members (including Vice Chairs)</b>	<ol style="list-style-type: none"> <li>1. Review and comment on HP questionnaire.</li> <li>2. Suggest any non-NAC external reviewers if special bill that requires specific types of reviewers.</li> </ol>
<b>Cost Team/Actuaries</b>	<p>► <b>Launch cost literature search.</b></p> <ol style="list-style-type: none"> <li>1. Conduct cost literature review (Days 4-7).</li> <li>2. Review and comment on HP questionnaire.</li> </ol>
<b>Effectiveness Team</b>	<p>► <b>Essential bibliography due.</b></p> <ol style="list-style-type: none"> <li>1. Provide UCSF librarians with essential bibliography (key, seminal research).</li> <li>2. Identify types of services and outcomes to be examined.</li> <li>3. Join content expert to review search results and provide feedback to librarian on any needed additions/modifications.</li> </ol>
<b>Public Health Team</b>	<p>► <b>Launch public health literature search.</b> Conduct public health impact literature review (Days 4-7).</p>
<b>Librarians</b>	

Assigned Personnel	Day 7-10
<b>CHBRP Staff</b>	<ol style="list-style-type: none"> <li>1. Send coverage survey to health plans.</li> <li>2. Contact NAC reviewers.</li> <li>3. Collect coverage information from in-house EOCs and send to cost team/actuaries.</li> <li>4. Compile coverage information for CalPERS, Healthy Families, and Medi-Cal Managed Care.</li> <li>5. Contact SEIU and Cal Federation of Labor to assess public demand.</li> </ol>
<b>Task Force Members (including Vice Chairs)</b>	Review coverage information sent by CHBRP team from EOCs and on public programs
<b>Cost Team/Actuaries</b>	<ol style="list-style-type: none"> <li>1. Decide on strategy for projecting new utilization.</li> <li>2. Review coverage information sent by CHBRP team from private EOCs and contracts/provider manuals on public programs.</li> <li>3. Participate in conference call with Health plans/CHBRP staff to answer questions regarding health plan survey.</li> </ol>
<b>Effectiveness Team</b>	<ol style="list-style-type: none"> <li>1. Join clinical content expert to identify articles they want to read in full text.</li> <li>2. Report on search and key literature.</li> <li>3. Continue to collect, review and synthesize literature for medical impacts (Days 10-13).</li> </ol>
<b>Public Health Team</b>	<ol style="list-style-type: none"> <li>1. Collect baseline data (e.g. prevalence, incidence, racial disparities, etc.) (Days 10-14).</li> <li>2. Provide Actuaries information on how data should be cut to meet PH's needs for analysis.</li> </ol>
<b>Librarians</b>	<p>► <b>Refined bibliography due.</b></p> <ol style="list-style-type: none"> <li>1. Provide effectiveness team, content expert with refined bibliography.</li> <li>2. Provide PH teams and Cost teams abstracts per request (e.g. cost effectiveness analysis articles; prevalence, incidence).</li> <li>3. Conduct any additional searching requested.</li> </ol>

<b>Assigned Personnel</b>	<b>Day 11-14</b>
<b>CHBRP Staff</b>	<p>► <b>Health plan coverage data due.</b></p> <ol style="list-style-type: none"> <li>1. Contact any health plan that has not yet provided coverage data.</li> <li>2. Synthesize health plan data and forward to faculty.</li> <li>3. Ensure all proprietary information is masked.</li> </ol>
<b>Task Force Members (including Vice Chairs)</b>	Review health plan responses to survey questionnaire.
<b>Cost Team/Actuaries</b>	<p>► <b>Provide utilization data.</b></p> <ol style="list-style-type: none"> <li>1. Review health plan survey responses and let CHBRP staff know if there any gaps in responses that need to followed up on.</li> <li>2. Revised/Final proposal for actuarial work estimate due.</li> <li>3. Provide public health team with coverage impacts based on health plan responses and review of the cost literature.</li> </ol>
<b>Effectiveness Team</b>	Prepare draft medical impact tables of key findings including info needed by cost and public health teams.
<b>Public Health Team</b>	Prepare draft public health tables with baseline information.

<b>Assigned Personnel</b>	<b>Day 15-20</b>
<b>CHBRP Staff</b>	<ol style="list-style-type: none"> <li>1. Review information submitted by interested parties and highlight any that would need to be considered by any team(s) in particular.</li> <li>2. Review PH and Cost tables from Actuaries-- provide comments/ questions.</li> </ol>
<b>Task Force Members (including Vice Chairs)</b>	<ol style="list-style-type: none"> <li>1. Review information submitted by interested parties and highlight any that would need to be considered by any team(s) in particular.</li> <li>2. Review and comment on draft introduction/background.</li> <li>3. Review PH and Cost tables from Actuaries-- provide comments/ questions.</li> </ol>
<b>Cost Team/Actuaries</b>	<ol style="list-style-type: none"> <li>1. Review information submitted by interested parties.</li> <li>2. Draft cost tables due from actuaries to cost team/CHBRP staff/faculty.</li> <li>3. Draft tables/data pulls due to PH team/CHBRP staff/faculty.</li> <li>4. Cost team compiles information from cost literature (e.g. offsets, substitution effects, shifts to other programs).</li> <li>5. Draft cost section with place holders for final cost tables and final cost estimates.</li> </ol>
<b>Effectiveness Team</b>	Review information submitted by interested parties
<b>Public Health Team</b>	<ol style="list-style-type: none"> <li>1. Review information submitted by interested parties.</li> <li>2. Public health team decides parameters for public health impact estimate (e.g. outcome measures).</li> <li>3. Review the PH Data pull tables and consult with actuaries on proposed revisions.</li> </ol>



Assigned Personnel	Day 21-25
<b>CHBRP Staff</b>	<ol style="list-style-type: none"> <li>1. Review and comment on Draft effectiveness section.</li> <li>2. Check for consistency with Cost Tables -- send comments to effectiveness team.</li> </ol>
<b>Task Force Members (including Vice Chairs)</b>	<ol style="list-style-type: none"> <li>1. Review and comment on Draft effectiveness section.</li> <li>2. Check for consistency with Cost Tables--provide comment to staff lead to compile.</li> </ol>
<b>Cost Team/Actuaries</b>	<ol style="list-style-type: none"> <li>1. FINAL cost tables due from actuaries to cost team/CHBRP staff/faculty.</li> <li>2. FINAL tables/data pulls due to PH team/CHBRP staff/faculty.</li> <li>3. 1st Draft cost section due.</li> <li>4. Draft cost section circulated by COB.</li> </ol>
<b>Effectiveness Team</b>	<ol style="list-style-type: none"> <li>1. <b>1st Draft effectiveness section due.</b></li> <li>2. Draft effectiveness section circulated by COB to Friday task force call participants.</li> </ol>
<b>Public Health Team</b>	<ol style="list-style-type: none"> <li>1. Write draft of public health impact section (Days 21-25).</li> <li>2. 1st Draft PH section due. Draft PH section circulated by COB.</li> </ol>

Assigned Personnel	Day 26-31
<b>CHBRP Staff</b>	<ol style="list-style-type: none"> <li>1. Check for consistency and content between cost tables and text, and underlying assumptions.</li> <li>2. Check for consistency among effectiveness sections, PH and cost sections.</li> <li>3. Prepare full integrated draft with executive summary and introduction.</li> </ol>
<b>Task Force Members (including Vice Chairs)</b>	<ol style="list-style-type: none"> <li>1. Check for consistency and content between cost tables and text, and underlying assumptions.</li> <li>2. Check for consistency among effectiveness sections, PH and cost sections.</li> </ol>
<b>Cost Team/Actuaries</b>	▶ <b>Revised cost section due to CHBRP staff by COB.</b>
<b>Effectiveness Team</b>	▶ <b>Revised effectiveness section due to CHBRP staff by COB.</b>
<b>Public Health Team</b>	▶ <b>Revised public health section due to CHBRP staff by COB.</b>

Assigned Personnel	Day 32-40
<b>CHBRP Staff</b>	<p>▶ <b>Full Draft Due.</b></p> <ol style="list-style-type: none"> <li>1. SEND to content expert, full task force, peer faculty reviewer by COB.</li> <li>2. Revise based on comments from FTF, content expert, cost team/actuaries.</li> </ol>
<b>Task Force Members (including Vice Chairs)</b>	▶ <b>Review and send comments to CHBRP staff to compile on integrated draft report--use consistency checklist.</b>
<b>Cost Team/Actuaries</b>	▶ <b>Review and send comments to CHBRP staff to compile on integrated draft report--use consistency checklist.</b>
<b>Effectiveness Team</b>	Revise based on comments from FTF, content expert
<b>Public Health Team</b>	Revise based on comments from FTF, content expert
<b>Librarians</b>	Revise based on comments from FTF, content expert

<b>Assigned Personnel</b>	<b>Day 41-45</b>
CHBRP Staff, All teams	<ul style="list-style-type: none"> <li>▶ Revised full draft sent to NAC, Editor and any other external expert reviewer by COB.</li> <li>▶ Send NAC review version to faculty lead and analytic team.</li> <li>▶ Editor's review is concurrent with NAC review, with a final proofread by the editor on Day 50.</li> </ul>
<b>Assigned Personnel</b>	<b>Day 46-49</b>
CHBRP Staff	<ol style="list-style-type: none"> <li>1. Comments received by NAC, Editor, designated faculty task force members, other external reviewers by COB.</li> <li>2. Forward comments to faculty lead, Vice Chairs, teams, and actuaries.</li> </ol>
Task Force Members (including Vice Chairs)	Faculty lead to review NAC and Editor comments and work with teams to ensure all comments are addressed.
Cost Team/Actuaries	<ul style="list-style-type: none"> <li>▶ Final revised cost section due.</li> <li>1. Work with CHBRP staff and faculty to revise in response to reflect NAC and editor comments.</li> <li>2. Send final revised section to CHBRP staff by Day 49.</li> </ul>
Effectiveness Team	<ul style="list-style-type: none"> <li>▶ Final revised cost section due.</li> <li>1. Work with CHBRP staff and faculty to revise in response to reflect NAC and editor comments.</li> <li>2. Send final revised section to CHBRP staff by Day 49.</li> </ul>
Public Health Team	<ul style="list-style-type: none"> <li>▶ Final revised cost section due.</li> <li>1. Work with CHBRP staff and faculty to revise in response to reflect NAC and editor comments.</li> <li>2. Send final revised section to CHBRP staff by Day 49.</li> </ul>
<b>Assigned Personnel</b>	<b>Day 50-54</b>
CHBRP Staff	<ol style="list-style-type: none"> <li>1. Report Editing, Layout and Production.</li> <li>2. Send draft to Editor for final proofread.</li> <li>3. CHBRP staff sends draft to faculty lead and Vice Chairs with editor's final proofread comments.</li> </ol>
Task Force Members (including Vice Chairs)	▶ Review and sign-off on revised, edited report or specify remaining changes.
<b>Assigned Personnel</b>	<b>Day 55-59</b>
CHBRP Staff, All teams	<ol style="list-style-type: none"> <li>1. Revisions to incorporate final Vice Chair changes, if necessary.</li> <li>2. Provide final version to VP of Health Affairs.</li> <li>3. Final formatting and proofing and any changes in response to VP's review.</li> </ol>
<b>DAY #</b>	<b>Day 60</b>
CHBRP Staff	<ul style="list-style-type: none"> <li>▶ Final report sent to State Legislature.</li> <li>1. Electronic version of report (.PDF format) transmitted to bill authors, task force and other report contributors, to requesting committees by e-mail, and posted on web site.</li> <li>2. CHBRP mailing list notified.</li> </ul>



## **Appendix 10: Evaluating Medical Effectiveness for the California Health Benefits Review Program**

This appendix contains two documents:

- 1) *Evaluating Medical Effectiveness for the California Health Benefits Review Program*: This paper summarizes the methods used in CHBRP's medical effectiveness analysis. This paper is to be published in a forthcoming issue of *Health Services Research*. Dissemination of this preliminary version is intended to provide the California Legislature and other interested parties with detailed descriptions of the methods used by the California Health Benefits Review Program in its reports. Please do not cite or reproduce for any other purpose without consent of the authors and written notification of the California Health Benefits Review Program.
- 2) *Details of CHBRP's Approach to Evaluating Medical Effectiveness, September 2005*: This document lays out the step-by-step approach to conducting a medical literature review and conducting a medical effectiveness analysis for CHBRP reports.



HSR-04-0301

Evaluating Medical Effectiveness for the California Health Benefits Review Program

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## **Abstract**

An important aspect of the mandate assessments requested by the California legislature is a review of the scientific and medical literature on the medical effectiveness of the proposed health insurance benefit mandate. Although such a review bears many similarities to effectiveness reviews that might be undertaken for publication as research studies, several important differences arise from the requirements of the California legislation.

Our reviews are intended to assist the legislators in deciding whether to support a specific mandate to modify health insurance benefits in a particular way. Thus, our assessments focus on how the scientific literature bears on the proposed mandate, which may involve a complicated chain of potential effects leading from altered coverage to ultimate impact on health. Evidence may be available for only some of the links in the chain. Furthermore, not all the evidence may be directly applicable to the diverse population of California or the subpopulation affected by the mandate.

The mandate reviews, including the medical effectiveness analyses, may be used in a potentially contentious decision-making setting. The legislative calendar requires that they need to be timely, yet they must be as valid, credible, and based on the best information available as possible. The focus on applicability also implies the need for informed, technical decisions concerning the relevance of the articles for the report, and these decisions need to be made as transparent as possible. These goals and constraints yield an approach that differs somewhat from an investigator-initiated review of the literature.

## **Introduction**

Under the provisions of Assembly Bill 1996 (*California Health and Safety Code* Section 127660 *et seq.*), the State Legislature may ask the University of California to *assess legislation proposing mandated health care benefits to be provided by health care service plans and health insurers, and to prepare a written analysis* [of its medical, financial, and public health impacts] *in accordance with specified criteria* (California Health and Safety Code). Furthermore, the legislation requires an assessment of the “[m]edical impacts, including, but not limited to...[t]he extent to which the benefit or service is generally recognized by the medical community as being effective in the screening diagnosis, or treatment of a condition or disease, as demonstrated by a review of the scientific and peer reviewed medical literature.” This overall effort, known as the California Health Benefits Review Program (CHBRP), uses staff and a task force of faculty experts at various public and private universities in California to summarize the scientific evidence in an objective manner without offering recommendations, deferring such policy-making decisions to the State Legislature (cite other papers in journal).

Drawing on their experiences during the first two years of CHBRP (Table 1), the authors describe in this paper the approach taken in the medical effectiveness analysis that forms one part of each proposed mandate review (California Health Benefits Review Program). (The other parts are utilization, cost, and coverage impacts and public health impact.) The CHBRP medical effectiveness review process, conducted by a team of physicians, health services researchers, and staff, differs from that of an investigator-initiated review because it seeks an assessment in the context of a specific proposed mandate. The review cannot narrow its focus simply because high quality evidence is not

available. Rather, it requires as broad an assessment as is needed to address the mandate, with objective and defensible decisions about the relevance and quality of the available literature. Compounding the difficulty in making such decisions is that the review must be completed in sixty days.

### **Medical Effectiveness Reviews in the Context of the CHBRP Rationale**

State coverage mandates for screening and/or treatment vary widely. This has historically stemmed, at least in part, from differing amounts of pressure from people and organizations concerned about particular diseases as well as differences in the evidence presented for and against coverage (Holtzman). The CHBRP analyses are intended to offer the legislature unbiased, evidence-based information to assist in making its decisions. The legislature is often inundated with arguments by advocacy groups or special interests that may benefit from or be threatened by the mandate. Given this potentially contentious setting, the reviews must be as complete, transparent, and evidence-based as possible.

Some argue that coverage mandates are unnecessary—if a new medical intervention is beneficial and worth more than its cost, health plans will eventually cover the service, passing the cost on through premiums. Even if the scientific evidence were clear, however, mandates might arguably be needed because: (1) medical knowledge accumulates slowly and assessing it is expensive, so insurers may lag in their assessments or not undertake them because of the public good nature of the assessment: (2) some interventions may provide health benefits to people other than those insured (externalities) and thus be undervalued in the private market: (3) it is impossible for insurers to differentially price policies at the level of detail that would allow consumers to



make tradeoffs between less expensive but less effective interventions and more effective but higher cost ones: (4) mandates might also be designed to address market failures, such as the incentive for insurers to avoid covering beneficial but expensive services needed by a small number of people in the hope they will choose to enroll in other plans. Mandates might also be intended to eliminate or create bargaining advantages for certain groups of providers, drugs, or devices such that insurers have to offer them even if other comparable alternatives are available.

In addition to the politically sensitive issues of assessing such benefits and costs, the potentially relevant data themselves may not be clear-cut. Therefore, the reviews are likely to be controversial. In describing our approach to a CHBRP medical effectiveness review, this paper addresses three types of challenges/issues: (1) the types of evidence that should be examined, and in particular, the tension between efficacy vs. effectiveness: (2) issues arising from the fact that some mandates focus on expanding coverage for an intervention without an immediate effect; (3) issues arising from attempting to be responsive to legislative needs.

### **Effectiveness versus Efficacy in a CHBRP Mandate Review**

Medical effectiveness is defined as the benefit achieved when services are rendered under ordinary circumstances by average physicians for typical patients (D'Agostino and Kwan 1995). This is in contrast to efficacy, which is defined as how well the intervention works in the research setting, or under ideal circumstances. The CHBRP analysis focuses on evidence in the peer-reviewed scientific literature of effectiveness.

The scientific literature considers double-blind, randomized controlled trials (RCT) to be the “gold standard” for clinical decision-making purposes. The design of a RCT limits the possibility that unforeseen characteristics might influence the outcome of interest (Victora, Habicht, and Bryce 2004) (MacLehose et al. 2000). When both RCTs and non-experimental studies of the effectiveness of an intervention are available, the latter often show larger estimates of effectiveness (MacLehose et al. 2000). Similarly, clinical trials with inadequately concealed random allocation show estimates of effect that are 40% larger than those of trials with well-concealed random allocation (Kunz and Oxman 1998). Thus, there is a general preference for the more tightly controlled study designs.

Numerous studies have also shown that the quality of published studies varies and that one can usually reach more valid and reliable assessments of a given question by systematically reviewing all the relevant literature, grading each study for its adherence to experimental guidelines, and then summarizing the results, preferably based on the well-conducted studies, using specific statistical methods. The Cochrane Collaboration sponsors a growing library of such meta-analyses. CHBRP effectiveness reviews therefore use a hierarchy of evidence that values meta-analyses of multiple RCTs most highly (see Table 2). Systematic reviews meet many of the same criteria but typically do not have summary measures of effect, usually because the various studies do not provide comparable metrics. In theory, RCTs (as well as meta-analyses and systematic reviews) can focus on either efficacy or effectiveness. If the treatment is provided under ideal conditions, such as in a teaching hospital with rigid adherence to protocol, it would be an efficacy trial. If the intervention is administered under usual practice conditions in the

community with variable implementation and adherence by clinicians and patients it would be an effectiveness trial.

The problem for CHBRP reviews arises from the fact that tight control of subjects, randomization (and thus the need for full informed consent) and blindedness of researchers and subjects becomes increasingly difficult as one moves from efficacy to effectiveness studies. Furthermore, the costs of a trial skyrocket as the interventions become less standardized—a key aspect of effectiveness trials, the presence of confounding factors more common, and the length of time to assess outcomes greater. Even when RCTs focus on drugs or interventions in community settings, the patient population is often carefully selected for those most likely to benefit, avoiding both unnecessary risk and “statistical noise” associated with patients having potential confounding risk factors (D'Agostino and Kwan 1995; Dieppe et al. 2004). Well-done RCTs thus may provide data with a high degree of internal validity, but such studies often do not have the desired high external validity or generalizability (Black 1996; D'Agostino and Kwan 1995; Victora, Habicht, and Bryce 2004). Yet, a key intent of the mandate reviews is to address the issue of generalizability.

For example, AB 438 dealt with osteoporosis screening in healthy women between the ages of 50 and 64. The medical effectiveness team found evidence with respect to the effectiveness of screening in older or high risk women, but very little evidence from RCTs to support screening and treatment of this younger population. More importantly, none of the evidence directly addressed whether screening actually reduced the prevalence or hip fractures or their sequelae. Instead, the evidence from some trials showed that screening could identify women with low bone density, while

other studies indicated that low bone density was associated with increased risk of fracture. Yet other studies indicated that some interventions could reduce the rate at which bone mass was lost. Thus, the likely benefits of increased rates of screening depend on a long chain of causation, only parts of which might be assessed. (See Figure 1).

More commonly, RCTs might not be fully applicable in the review of proposed health care mandates, because new interventions are often tested only in subjects without comorbidities that may complicate the trial. For example, a RCT of a new non-steroidal anti-inflammatory agent conducted solely on younger populations does not provide us with the information we need about potential adverse drug events in elderly populations that have elevated incidences of co-morbidities (D'Agostino and Kwan, 1995; Dieppe et al., 2004). Unless a health care mandate is directed solely at services for a particular subgroup, such as the childhood asthma mandate (AB 1549) or the maternity services mandates (SB 897 and SB 1555), the CHBRP medical effectiveness team must consider the impact of a proposed health care mandate on all Californians regardless of age, ethnicity, or socio-economic status.

If well-done meta-analyses are not available, the team gives preference to systematic reviews and then to evidence-based guidelines, again supplementing these as needed with RCTs published since the last review or guideline. Uncontrolled observational studies, case-controlled studies, and clinical or practice guidelines based on consensus or opinion would, ideally, carry the least weight. Because of the time constraints for the mandate reviews, the CHBRP team cannot undertake formal meta-

analyses, but if no relevant meta-analyses or systematic reviews are available, less formal approaches may be used.

While a clear hierarchy of evidence such as in Table 2 is desirable, it is often necessary to make tradeoffs between evidence drawn from studies higher on the methodological hierarchy and evidence that may be more relevant to the question at hand, but from less tightly controlled or rigorous sources. Excluding data from non-randomized studies biases the evidence base in favor of interventions that are more easily evaluated with RCTs but may not necessarily be more effective (Des Jarlais, Lyles, and Crepaz, 2004). The CHBRP team must consider evidence in the context of reasonableness and feasibility. Having chosen to be somewhat more flexible rules in an attempt to offer more useful assessments to the legislature, all decisions by the team must be clearly delineated and included in the report to avoid the appearance of arbitrariness.

### **Complexities of the *Real World* of a Mandate Review**

A second level of complexity arises from the fact that the CHBRP team is assessing a proposed health insurance mandate, rather than a specific clinical intervention. This creates several problems affecting CHBRP reviews. Mandates are written to become law and as such cannot have the type of specificity one would like for a scientific study. For example, a mandate might be written to cover all appropriate devices for the care of patients with asthma, rather than the devices made by a specific manufacturer that are the subject of published trials. Furthermore, the medical benefits, as well as the costs and savings associated with the intervention may not occur immediately, nor be clearly attributable to the mandate.

The goal of the CHBRP analysis, beginning with the medical effectiveness report, is not to merely present the results of RCTs, but also to examine the potentially far-reaching effects of adopting the intervention under consideration. Figure 1 illustrates this with a flow chart depicting steps involved with the set of mandates addressing *screening tests*, such as the osteoporosis screening or the ovarian cancer screening mandates. The effectiveness literature typically deals with questions *within* the box seen in the figure, that is, the sensitivity and specificity of the test. Outside the box are issues related to the willingness of patients to request the test, and physicians to offer it, and the implications of treatment. While relevant to a CHBRP mandate analysis, they are not typically addressed in the empirical literature.

The passage of a mandate means only that insurance companies must cover the appropriate costs consistent with their usual policies. Passage does not mandate that physicians or patients avail themselves of services covered. Using the example of screening tests for ovarian cancer (a blood test, a sonogram or both), either a physician would first have to offer the test and the patient accept it, or the patient would have to convince the physician to order it. In the event of a positive test, a patient would then have to agree to a complete diagnostic workup that includes surgery, which has its own set of additional complications. While there will often be published studies of treatment effectiveness (separate from the screening studies), there are unlikely to be any studies of the implications for patients treated unnecessarily (the false positives), falsely reassured (false negatives), or correctly reassured (the true negatives). Although such outcomes issues are not typically the focus of a RCT, all relevant scenarios must be considered during a CHBRP medical effectiveness review.

Some mandates include a broad mix of services, such as a collection of educational programs for patients with asthma or a package of services provided as part of prenatal care. The analysis of the osteoporosis screening mandate also involved a review of exercise programs and drug treatment for the prevention of osteoporosis. The causal pathways for such interventions may involve multiple behavioral steps that are difficult to specify and measure (Victora, C. G., J. P. Habicht, and J. Bryce 2004). Even if there is solid evidence on various links in the chain, few studies will have examined the entire chain, much less in a double-blinded randomized controlled manner. Studies will almost never exist that examine every combination of the components of such interventions to determine which ones are crucial.

In some instances data are absent due to ethical considerations. Senate Bill (SB)-897 would have mandated that insurance companies provide a minimum combination of maternity and neonatal services in all health plans. (The intent of the mandate was to preclude some insurers from offering plans attractive only to people not planning on becoming pregnant.). The CHBRP team found some published evidence on the effectiveness of different components of the packages, but none on the whole “package” of prenatal care because it would be unethical to deny prenatal care to pregnant women in order to test the effectiveness of more than specific aspects of care in a trial. Fortunately, the debate over this bill focused not on whether prenatal care was beneficial, but whether the insurance market should be segmented by such benefit exclusions.

In undertaking a review of medical effectiveness, one must first ask which outcome measures will be used. The team typically analyzes all appropriate outcome measures for which literature is available. For example, AB 1549, Childhood Asthma

Management, required coverage of over-the-counter and prescription asthma medications and associated pediatric asthma outpatient self-management training and education. The medical effectiveness team examined the impact of the interventions on such outcomes as the number of days with asthma symptoms (or the number of symptom-free days), asthma symptom scores, the number of exacerbations of disease, the forced expiratory flow rate (FEV) (a measure of lung function), coping scores, knowledge scores (child and caregiver), activity restriction, emergency room utilization, use of medications, and quality of life measures, among other measures. Analysis of all known outcome variables was important, because some interventions had positive, albeit insignificant, effects on some outcomes but significant positive effects on other outcomes. If only selected outcomes were included, the medical effectiveness report could have been criticized as being biased.

Such comprehensiveness, however, requires the team to provide guidance to the Legislature in comparing the various outcome variables, especially if some are favorable and others are not. This ranges from explanations of the physiologic measures, such as the FEV, to discussing whether an intervention should be “better than” or just “not worse than” the alternative. For example, AB 228, the Transplantation HIV mandate, focused on coverage for transplants for patients who were HIV positive (HIV+). Advances in highly active antiretroviral therapy (HAART) since 1996 have made transplantation a viable possibility for many HIV+ patients. For most outcome variables, including patient survival, graft survival, and measurements of viral activity, HIV+ transplant patients enjoyed outcomes comparable to that of HIV negative (HIV-) patients. In this instance, the appropriate “test” was not whether being HIV+ resulted in better transplant outcomes,



but rather whether it was still associated with much worse outcomes. Among HIV+ liver transplant patients, however, those who suffered from hepatitis C tended to fare worse than other patients undergoing liver transplantation. The team felt it necessary to clarify that HIV- liver transplant patients with hepatitis C also had poorer outcomes than HIV- patients without hepatitis C. Hepatitis C thus appeared to be the biggest impediment to survival following a liver transplant, not HIV status.

Whenever possible, the medical effectiveness team looks at the language of the mandate itself as a guide for determining the outcomes of interest. However, for a multitude of reasons such as ethics, expense, or feasibility, data relevant to the outcomes of interest are not always available from RCTs or even observational studies or guidelines. A review therefore often involves analyses of less meaningful short-term endpoints, such as results of bone density scans, rather than more consequential endpoints such as the number of fractures prevented.

In conducting a mandate analysis, the medical effectiveness team tabulates the various studies informing the analysis by outcome measure, listing the number of patients in each study. Ideally, one would incorporate data on the size of the trial as weights in estimating the proportionate effect attributable to the intervention. This, however, is often not possible. In the case of AB-228, *Transplantation Services: HIV*, the effectiveness team had to rely on case reports, case series, and observational studies, mostly from the small number of centers in the United States and Europe performing transplants on HIV+ patients. Every few years, the authors would re-publish their cases in new, peer-reviewed articles, adding new patients to their series along with up-to-date information on the survival and medical courses of earlier patients. Except for the few

cases in which adequate and distinctive histories were provided, overlap with patients in earlier articles could not be determined. The team also relied on a published observational study comparing HIV+ and HIV- renal transplant patients using a national database. The patients in this database almost certainly included patients in reports from transplant centers, but this national database did not contain information on HIV status for all patients. The team decided to simply provide all information available from all peer-reviewed articles while simultaneously cautioning readers that the true number of patients was smaller than it appeared.

### **The Steps Involved in a Medical Effectiveness Mandate Review**

To some extent, even the limited approach described above faces challenges in the actual undertaking of a review. Not only is the 60 calendar-day timeline extremely tight, but multiple reviews by the team are usually underway simultaneously. This has led to a series of logistical and analytic adaptations.

**Preparing for the Medical Effectiveness Review.** The CHBRP faculty and staff have developed a protocol for conducting a medical effectiveness analysis for each proposed mandate. As seen in Figure 2, the search for a content expert begins immediately, because it is important to find an appropriate consultant without a real or perceived conflict of interest. Conflicts may be either financial or may reflect strong advocacy or research positions. In the case of AB 228, the transplantation-HIV mandate, the medical effectiveness team first considered a physician who, it turned out, had been instrumental in drafting the legislation.

The content expert is usually a physician or other health professional practicing in a field that bears on the mandate but without known biases or the appearance of biases.

For AB 213, the lymphedema mandate, for example, we identified a physical therapist trained in the specialized techniques that were addressed by the mandate. Although one of only a small number of physical therapists trained in the techniques under consideration, she was not aware of the legislation until the medical effectiveness team conferred with her about joining the team as the content expert.

The medical effectiveness review team members meet at the initiation of the literature review to characterize the scope of the search, search terms, inclusion and exclusion criteria, the databases to be used, and the relevant CPT codes (current procedural terminology codes that describe medical or psychiatric procedures performed by physicians and other health providers) needed by the cost and public health teams. They communicate closely with the other teams to reach an agreement concerning the meaning and intent of the mandate. For example, CHBRP faculty and staff concurred that the transplantation in HIV mandate should be treated as an anti-discrimination bill so the medical effectiveness team would focus on whether the outcomes of HIV+ patients undergoing transplantation were significantly worse or comparable to those of HIV- patients. If the data suggested that outcomes were similar, then excluding HIV+ patients from coverage would not be justified on the basis of medical effectiveness.

Early agreement was even more critical on the best way to analyze SB 572, a bill that would mandate that the diagnosis, treatment, and coverage of all mental health problems be on a par with those of medical illnesses. Evaluating the effectiveness of every potential intervention for each of the more than 400 distinct diagnoses included in the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV), was impossible (American Psychiatric Association). Instead, CHBRP's analysis of

SB 572 was designed to provide the California State Legislature with background information on policies and legislation in California, other states, and at the federal level that affect health insurance coverage for mental health conditions, and thus focused more broadly on what is known about the effects of “mental health parity” legislation in other settings. While clearly not the “standard model” of a CHBRP effectiveness review, it was both feasible and more relevant.

**The Literature Search and Review.** The effectiveness team next determines the extent to which the results of the literature search (conducted by a medical librarian in an organized, pre-determined, and reproducible manner) are likely to address the question underlying the proposed mandate. If necessary, the search terms and the inclusion and exclusion criteria would be broadened. The range of specificity and clarity of the mandates varies substantially. AB 228, the transplantation-HIV mandate, for example, addressed a range of specific transplantation services (solid organ, skin, cornea, and bone marrow), each of which required searches. AB 213, the lymphedema mandate, sought to mandate the *standard of care* for lymphedema patients, but a literature search did not reveal a clearly defined *standard of care*. The medical effectiveness team pointed this out and thus reported on all types of treatments, including specialized physical therapy and pharmaceutical agents legally available in the United States.

There might not be sufficient available literature to analyze some mandates as written. AB 8, the mastectomy mandate, would require health plans to allow breast cancer patients to remain in the hospital for 48 hours following a mastectomy and 24 hours following an axillary lymph node dissection (surgical removal of lymph nodes in the armpit). Most of the recent literature concerning length of stay following surgery for

breast cancer in the United States consisted of analyses of outpatient mastectomy programs, rather than the lengths specified in the bill. The CHBRP team instead used recent observational studies contrasting outpatient mastectomies involving stays of less than 24 hours with inpatient mastectomies involving hospital stays of 24 hours.

In contrast, for SB 576, which concerns health care coverage of tobacco cessation services, the targeted literature search resulted in 168 references, including 9 meta-analyses. The medical effectiveness team reviewed the meta-analyses, many of which were published in the Cochrane library and were updated as recently as 2004, as well as the recommendations and conclusions of 2 evidence-based reviews. On the basis of meta-analyses and systemic reviews alone, the medical effectiveness team was able to review the effectiveness of counseling, brief advice, and pharmacotherapy on tobacco cessation.

At least two faculty and/or staff members of the effectiveness team review the abstract for each article found during the literature search to determine its eligibility for inclusion in the study database. The primary reason for exclusion at this stage is that the study was not conducted on a population relevant to the California population. The inclusion and exclusion criteria for articles differ for each review and become a part of the report. In general, the medical effectiveness team restricts the literature search to studies in English. For some outcome measures, such as physiological effects, results from non-United States-based populations may be relevant. For other outcomes, e.g., school absence days for children with asthma, the differences in expectations between U.S. and other settings may be so great that the reviews would be limited to U.S.-based populations. Although the medical effectiveness team strives in the analysis to adhere to

the preferred hierarchy of articles as shown in Table 2, observational studies, case-control studies, and even practice guidelines based on consensus or opinion are retained in the study data base pending review of the more scientifically rigorous articles.

Although abstracts may not adequately reflect all the results in the full article, some decisions to exclude a manuscript are initially made on that basis. While abstracts may emphasize outcomes with positive rather than negative findings, we expect that few articles with empirical findings would fail to mention those findings in the abstract. We therefore feel reasonably comfortable in excluding articles whose abstracts do not indicate empirical findings. Once the full-text article is retrieved, the effectiveness review team reapplies the initial inclusion and exclusion criteria to ensure the relevance of the study to the proposed mandate. These decisions are based on whether the studies meet inclusion or exclusion criteria, without regard for the conclusions of the study.

**Analyzing the literature.** The review of the articles obtained is guided by the following questions: 1) Are the results applicable to the diverse population of California? 2) Does the intervention have a statistically significant effect? 3) Does the intervention have a clinically meaningful effect? 4) Does the article concern effectiveness as opposed to efficacy? If articles not applicable to the California population are included in meta-analyses or systematic reviews, the team attempts to determine whether their inclusion alters the overall findings of the published reviews (e.g., all the non-applicable studies show a benefit and the evidence from the remaining studies are equivocal). As an example, if all the studies showing the value of parent training in asthma management were undertaken among highly educated, ethnically homogeneous populations in the upper Midwest and that the effectiveness was greatest during the winter, then such

findings would be of limited relevance in California. Although the medical effectiveness team anticipated when CHBRP first became operational that studies would sometimes be excluded due to lack of relevancy to the population of California, no study conducted in the United States has yet to be excluded for this reason.

The full-text article is sometimes not retrieved quickly enough to meet CHBRP deadlines, forcing the team to rely on the published abstract. The abstract may omit information allowing assessment of the relevance to the particular CHBRP review or the comparability of the study participants to the population in California that would be affected by the mandate. The team keeps a log of articles that appear relevant but for which full text was not available in time for inclusion in the draft report. Those arriving after this date, but during the time period when a report is under review, are evaluated to see if they would alter the assessment in a substantive way, and if so, they are included.

### **Summarizing the Evidence and Preparation of the Medical Effectiveness Report**

The effectiveness team reviews the results of meta-analyses and other studies for each outcome measure. Not all studies, however, are equally relevant. Judgment sometimes needs to be exercised to “downweight” studies because they are old relative to current medical practice, or of limited applicability to the mandate situation, or of less rigorous methodology. Such decisions are made by the group and documented with the rationale for downweighting or exclusion. Within this framework, two types of summary measures are useful. One reflects the consistency of findings across studies with respect to the measure, the other is a weighted average of the effect.

Based on the weight of the evidence available in terms of relevance, sample size, and methods used, the team assigns a “grade” for each outcome (Table 3). This is neither

a simple “vote counting” with every study counting equally, nor a simple weighted average that assumes all studies are of comparable value except for sample size. The report should present the reader with a sense of the patterns of findings and also provide a sense of the magnitude of the differences among studies. The effectiveness review team first looks for consistency of findings across studies. The same overall (weighted mean) effect may be generated by a situation in which all the studies indicate a benefit vs. another in which some show no effect, or even harm, but one large study shows a substantial beneficial effect. The former may be more convincing, if only because it does not rely so heavily on a single study, and there is no contrary evidence to be raised by advocates. Large sample observational studies, especially if there is concern about non-comparability of groups, should not automatically overwhelm small, well-controlled studies. Contrariwise, tightly controlled studies that deal more with efficacy should not automatically overshadow observational studies addressing effectiveness. In discussing the pattern of results, the team takes into account statistical significance, sample size, and relevance, as well as the direction of the effect. A large number of statistically insignificant studies with small samples, but a totally consistent direction of effect can nonetheless be convincing.

If the conclusions of several published meta-analyses differ substantively, the review team will try to determine why. The discrepancies in conclusions might be explained by differences in the inclusion or exclusion criteria for the various meta-analyses or the RCTs comprising them, or some published meta-analyses may use less rigorous criteria. Alternatively, the screening procedure or therapy may have improved



over time and be reflected in the later analyses. In such cases, the team may decide not to weight the data from some studies as much as others.

For studies with quantifiable outcomes, the team summarizes the specific outcome of interest, for example, the reduced number of emergency room visits following an asthma management program. The team begins the process by tabulating all the studies measuring the specific outcome of interest along with the reported results. They also take into account the relevance and power to detect statistical significant findings of the study. The team also considers the plausibility of the findings and the overall patterns of evidence. Such judgments and the rationale for them are recorded in the final report or its appendices.

Because samples and populations often differ across studies, calculations to determine the overall effectiveness of an intervention begin with a determination of the proportionate effect attributable to the intervention. Studies with more subjects typically have a greater effect on the statistical significance of the outcome and, therefore, are weighted more heavily in estimating the overall effect of the intervention. The studies with the highest and lowest outcome effects demarcate the range of effects observed. (Occasionally implausible extreme values may be omitted, and this is noted.)

The effectiveness report provides the groundwork for the public health and cost impact analyses components of Assembly Bill 1996. In some cases, the effectiveness review points to issues that should be addressed in other sections. For example, expanding coverage to a new population might generate a widespread acceptance of the intervention and, therefore, increase usage rates among people who are already covered. This scenario would increase the impact on health outcomes of the proposed mandate.

On the other hand, the impact on health outcomes is likely to be small if a screening intervention would be covered by a mandate but treatments are not readily available or are not covered, or if the mandated screening intervention is widely available and used. On the other hand, if the cost and utilization team estimates that coverage would lead to a broad expansion in the indications for use that would lead to the intervention being applied to people for whom there is less evidence of a benefit, that would affect the effectiveness assessment.

## **Conclusions**

The medical effectiveness analysis is a fundamental component of each mandate review undertaken by the California Health Benefits Review Program. The implications of the effectiveness assessment directly affect the public health impact estimates. Some of the effectiveness estimates are incorporated directly in the utilization analyses.

To some extent, the foundation of the effectiveness review builds on the logical steps from mandated coverage to having an impact on individuals, specifying the scope of the procedures and interventions to be examined and the outcomes to be assessed. The scientific literature is searched for evidence, preferably well-performed meta-analyses, plus those RCTs published after the last available meta-analysis. At the same time, the team members recognize the value of non-randomized studies and guidelines in informing public policy.

If there is little or no evidence that an intervention is effective, the arguments in favor of mandating its coverage are weaker. On the other hand, multiple well-performed meta-analyses comprised of randomized controlled trials, all suggesting that the intervention is beneficial, provide strong evidence in support of the clinical impact of the

intervention. It is important, however, to distinguish the situation in which there are many large, well-powered, studies, none (or few) of which indicate the intervention is effective, from (a) the case in which few studies of effectiveness have been done, or (b) they are all of very small size. In the first instance one can say that researchers have looked, but have been unable to find an effect, in the latter two situations, one must say that the research is not available to reach a conclusion. Conveying these distinctions to legislators, rather than to researchers or reviewers, can be a challenge.

The mandate proposals that are the most difficult to assess are those in which the available evidence is not related directly to the mandate and the medical effectiveness team has to use its scientific expertise and judgment in as unbiased a manner as possible to present evidence with supporting rationale. The goal is to create, using a reasoned approach and in a brief period of time, a document with transparent methods, findings, conclusions and rationale that can withstand critical scrutiny. This may involve occasional judgments that deviate from strict adherence to rigid protocols, but such deviations are sometimes necessary to provide legislators with useful assessments. The CHBRP goal is to provide valid and timely information to a political process. Offering precise or delayed answers to questions more narrow than the mandates we are asked to review would not achieve that goal. Whether the public will think it worth the effort to bring research-based evaluations to the political arena will have to be determined by evaluations over a period of time.

**Table 1. California Health Benefits Review Program Analyses (2004-2005)**

Analyzed Legislation	Topic	Completed Analyses
AB 438	Osteoporosis Screening	2/9/04
AB 547	Ovarian Cancer Screening*	2/9/04
AB 1084	Access to Vision Providers	2/9/04
AB 1549	Childhood Asthma	2/9/04
SB 101/1192**	Substance Disorder Treatment	2/9/04
SB 174	Hearing Aids for Children	2/9/04
SB 897	Maternity Services	2/9/04
SB 1555	Maternity Services	4/1/04
AB 2185	Asthma Management	4/14/04
AB 1927	Vision Services	4/16/04
SB 1158	Hearing Aids	4/19/05
SB 1157	Elimination of intoxication exclusion	4/27/04
AB 8	Mastectomies and Lymph Node Dissections	3/7/05
AB 213	Lymphedema	4/7/05
AB 228	Transplantation Services: Human Immunodeficiency Virus	4/7/05
SB 573	Elimination of Intoxication Exclusion	4/7/05
SB 415	Prescription Drugs: Alzheimer's Disease	4/16/05
SB 572	Mental Health Benefits	4/16/05
SB 576	Tobacco Cessation Services	4/16/05
SB 749	Pervasive Developmental Disorders/Autism	4/16/05
SB 913	Medication therapies; Rheumatic Diseases	4/16/05

\* Subsequent to a request from the California Assembly Committee on Health to analyze AB 547, the bill was amended and no longer concerns ovarian cancer screening. The version of the bill analyzed and included here was the legislation's original language.

\*\* Subsequent to a request from the California Senate Insurance Committee to analyze SB 101, the bill was reintroduced as SB 1192 using the same language.

**Table 2: Preferred Hierarchy of Articles used in the Effectiveness Review\***

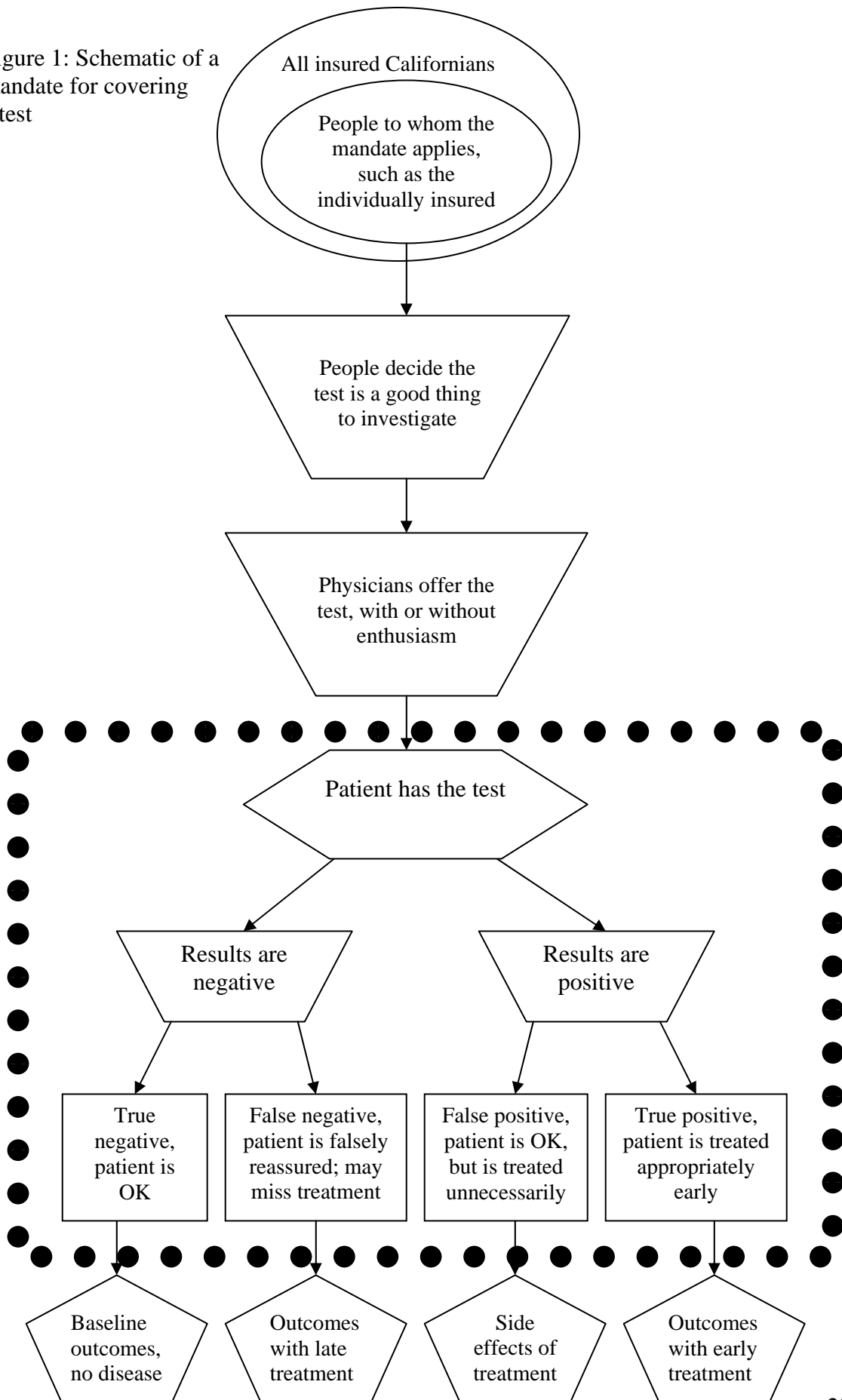
Study/Publication Type	Study/ Publication Relates to Efficacy	Study/Publication Relates to Effectiveness
1. Meta- analyses <sup>§</sup>	+	
2. Systematic reviews <sup>¶</sup>	+	
	(especially when part of a meta-analysis)	
3. Evidence-based guidelines		+
4. Individual randomized clinical trials	+	
	(unless it is an effectiveness trial)	
5. Observational studies		+
6. Case-control studies		+
7. Clinical/practice guidelines based on consensus or opinion, rather than on evidence		+

\* Note: Exceptions to the hierarchy may occur, depending on the methodology used in each study. Studies or reviews critically based on evidence are given more weight.

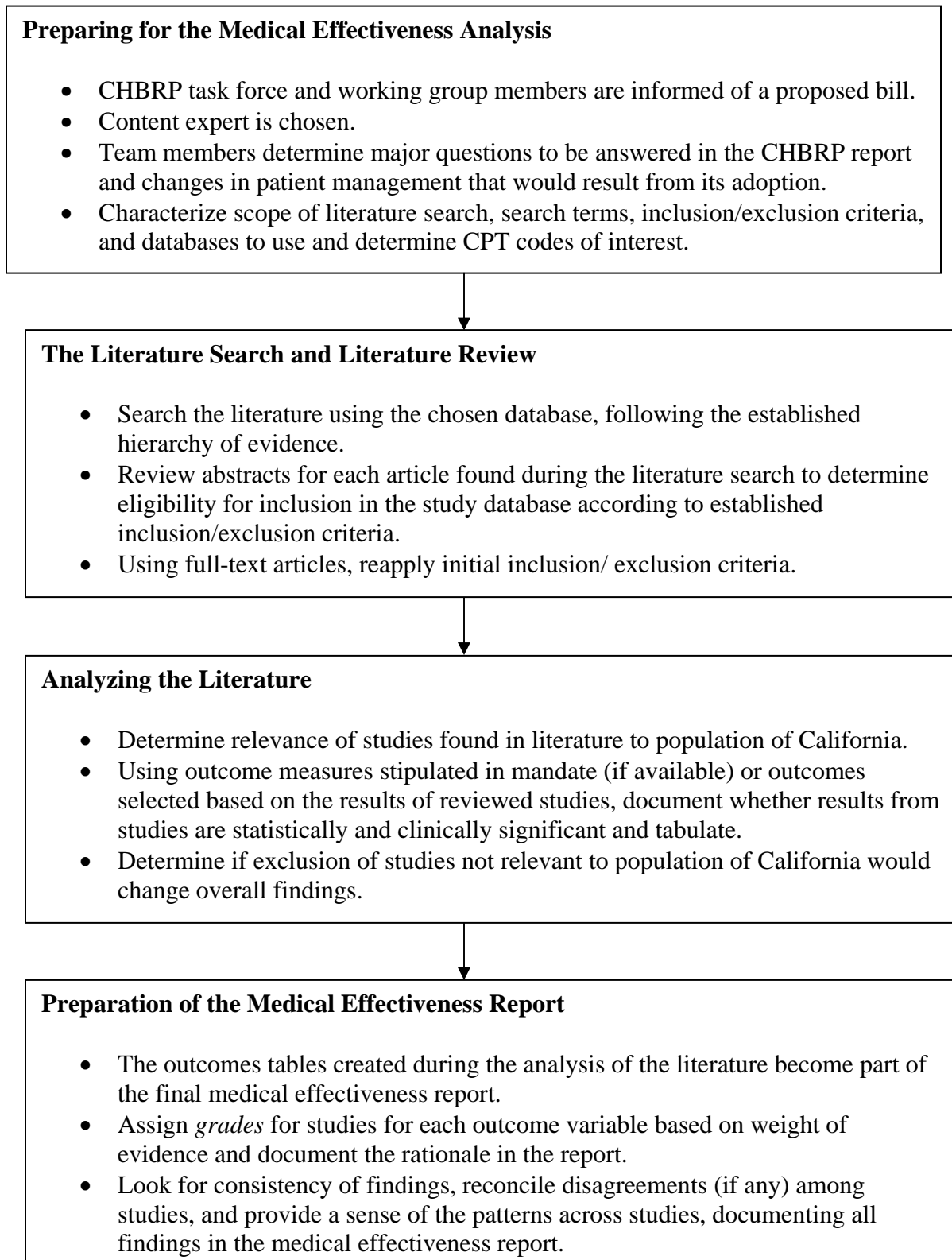
<sup>§</sup> particularly those included in the Cochrane library

<sup>¶</sup> particularly those performed by authoritative organizations such as the Agency for Healthcare Research and Quality, US Preventive Services Task Force, Evidence-based Practice Centers, National Institutes of Health, and Center for Disease Control

Figure 1: Schematic of a mandate for covering a test



**Figure 2: Steps in a CHBRP Medical Effectiveness Analysis**



**Table 3: Grading System for the Evidence for each Outcome Measure**

Favorable (statistically significant effect)	Findings are uniformly favorable, many or all are statistically significant
Pattern/trend towards favorable (but not statistically significant)	Findings are generally favorable, but there may be none that are statistically significant
Ambiguous/mixed evidence	Some significantly favorable, and some significantly unfavorable findings
Pattern towards no effect/weak evidence	Studies generally find no effect, but this may be due to a lack of statistical power
Unfavorable	Statistical evidence of no effect in literature with sufficient statistical power to make this assessment
Insufficient evidence to make a “call”	Very few relevant findings, so that it is difficult to discern a pattern



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# Details of CHBRP's Approach to Evaluating Medical Effectiveness

## September 2005

CHBRP reports include three types of information about proposed health insurance benefit mandates: (1) the medical effectiveness of services included in the legislation, (2) the cost impacts of the bill, and (3) the bill's public health impacts. This document lays out, in detail, the process and methods used by CHBRP in providing the first of these types of information—medical effectiveness.

### **I. First Steps in Evaluating Medical Effectiveness: Preparing to Conduct the Literature Search**

- A. California Health Benefits Review Program (CHBRP) receives request to analyze bills from the California State Legislature and then informs faculty and staff who will work on the analysis.
- B. The CHBRP team working on the analysis of a particular bill reviews the bill, and the Medical Effectiveness Team is directed to begin its review and analysis. Librarians also review the bill to prepare for the literature review.
- C. The Medical Effectiveness Team, with assistance from the other members of the CHBRP analysis team, identifies a content expert for the bill. This expert is usually a clinician in a relevant specialty who is knowledgeable about clinical controversies associated with the proposed mandate. The content expert is also usually familiar with clinical epidemiology or health services research in general or evidence-based medicine in particular. The proposed content expert must be able to devote the necessary effort in the short time frame required for the review.
- D. The content expert reviews the bill. The clinical expert assists Medical Effectiveness Team faculty and staff in clarifying the meaning of the terms used in the proposed mandate. For example, in reviewing the literature pertaining to the analysis of Assembly Bill 1549 (2003) (AB 1549), Childhood Asthma Management, the clinical expert explained what pulmonologists mean by “treatment action plans” and the differences between types of action plans—peak flow–based versus symptom-based.
- E. The Medical Effectiveness Team, in consultation with the University of California, San Francisco (UCSF) librarian and clinical expert, defines the scope of the literature search.
  1. The Medical Effectiveness Team identifies the type of intervention(s) in the bill and the literature needed to address key issues in the bill (i.e., Is the intervention a screening, diagnostic, or monitoring test, a procedure, or a treatment?). Key issues may also include changes in patient management resulting from the intervention being studied.

2. In some instances, the bill may be broad and must be assessed in pieces. For example, analysis pertaining to Senate Bill 101 (2003) (i.e., parity coverage for substance-related disorders) would ideally examine treatments for addictions included in the bill's mandate (e.g., alcohol, nicotine, cocaine).
  3. Screening, diagnostic, monitoring, and treatment interventions require different approaches. For example, a treatment is typically designed to cure a disease or to improve function, and designing trials of how well the treatment works may be relatively straightforward, so literature may be available to directly assess effectiveness. On the other hand, a screening test might indicate an increased risk of a disease. This may lead to recommendations for one or more types of preventive interventions. The interventions may vary in their effectiveness, and the disease, which may or may not occur even given a positive screening result, may be treated in various ways. Extended time periods would be necessary to assess each of these links. Testing and treatment options are continually changing over time, and studies that directly address the effectiveness questions that are being asked will not always be available. Thus, an effectiveness assessment of an intervention will have to be built upon information available for various parts of the "evidence chain." This may influence how the medical effectiveness analysis is undertaken.
- F. The Medical Effectiveness Team, with input from other CHBRP team members, the UCSF librarian, and the clinical expert, determines the inclusion and exclusion criteria for the literature search.
1. The Medical Effectiveness Team identifies the types of studies that are appropriate for the type of intervention. For example, if the mandate is about osteoporosis treatment, then studies of primary prevention of osteoporosis would be excluded.
  2. The Medical Effectiveness Team uses the following inclusion/exclusion criteria, with input from the librarian:
    - a. Include only abstracts in English.
    - b. Limit the literature search to U.S. studies for utilization and cost studies. For example, international studies of osteoporosis screening were included in the CHBRP analysis (of AB 438 (2003), Osteoporosis Screening) because of an interest in physiological effects. However, when the outcome is behavioral or likely to depend on specific aspects of the U.S. health care system, as in the CHBRP analysis of educational interventions for childhood asthma, the literature search would include only U.S. studies, because of uncertainties in the content of what is deemed "usual care" in international settings.

- c. Limit the search to the population affected by the proposed mandate. For example, for the CHBRP analysis of AB 1549, Childhood Asthma Management, “children” were defined as individuals aged 0 to 18 years, and studies of subjects older than 18 years were excluded.
  - d. Identify types of articles to search for in the following descending order of usefulness for effectiveness reviews: meta-analyses, systematic reviews, evidence-based guidelines, and primary studies. This hierarchy of evidence reflects ideal circumstances. In some instances, meta-analyses of randomized controlled trials (RCTs) may be available only for very narrowly defined aspects of the intervention, while a few primary studies might address the full scope of the question at hand. The rigor of the former must be balanced against the relevance of the latter.
  - e. Limit the search to the past 20 years. The CHBRP research team may shorten this time period, if there is a large body of literature on the topic and/or there have been dramatic increases or decreases in the prevalence of the problem or rapid advances in treatment.
3. The Medical Effectiveness Team and librarian search the following databases:
- a. The Cochrane Library and MEDLINE (PubMed).
  - b. CINAHL, Web of Science, and PsychINFO, if relevant.
  - c. EMBASE (this database contains mostly international studies, and it may not be searched if there is sufficient literature from U.S. sources).

## **II. Conducting the Literature Search**

- A. The Medical Effectiveness Team, the clinical expert, and the UCSF librarian meet to define the scope of the search, search terms, inclusion and exclusion criteria, and the databases to be used.
- B. The librarian conducts the search, contacting the clinical expert with questions as they arise, and returns the final search results in EndNote. (See Section [III, Retrieving the Articles](#), below.)
- C. A Medical Effectiveness Team staff member records all search terms and MeSH headings.
- D. The Medical Effectiveness Team and the clinical expert assess the extent to which the results of the literature search address the questions and issues underlying the proposed mandate. If the initial literature search returns few results, search criteria may be reexamined, and the librarian will run additional or modified searches, or a

Medical Effectiveness Team staff member will search and select articles from the reference lists of articles already retrieved.

- E. The Medical Effectiveness Team provides a list of relevant services and Current Procedural Terminology (CPT), diagnosis-related group (DRG), and *International Statistical Classification of Diseases (ICD-9)* codes to other team members. These codes ensure that the Medical Effectiveness, Public Health, and Cost Impact Teams are performing analyses on identical clinical entities. The Medical Effectiveness Team also shares relevant literature with the Public Health and Cost Impact teams, when applicable.

### **III. Retrieving the Articles**

- A. At least two Medical Effectiveness Team faculty and staff members review the abstract for each article retrieved to determine its eligibility for inclusion in the study database.
  - 1. The Medical Effectiveness Team reviews all abstracts returned by the search before retrieving full-text articles.<sup>1</sup> The criteria for excluding articles from the full-text set may include: (1) duplicate studies, or (2) study subjects irrelevant to the California population to be affected by the mandate.
  - 2. Once the full-text article is retrieved, the Medical Effectiveness Team reapplies the initial inclusion/exclusion criteria to ensure the study is relevant to the proposed mandate.
- B. The Medical Effectiveness Team retrieves full-text articles available on the Internet via University of California library Web sites. If an article is unavailable online, a Medical Effectiveness Team staff member makes a document request from the library. Library staff scan documents unavailable electronically and post them on a password-protected Web site or send the documents to staff requesting the articles.
- C. For articles not available at a University of California campus, the Medical Effectiveness Team requests an article from an online journal or uses a commercial document delivery service.
- D. There may be instances in which the full-text article cannot be retrieved quickly enough to meet the timeline of CHBRP reviews. (The timeline dictates a date by which all articles need to be available for inclusion in the initial assessments.) In those instances, the Medical Effectiveness Team relies on the published abstract. It is important to acknowledge that reliance on an abstract may omit information relevant to a CHBRP review, including some of a study's results and information with which to evaluate how comparable the study population is to California's population. The Medical Effectiveness Team keeps a log of articles that appear relevant, but for which

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<sup>1</sup> This approach risks excluding a useful article based on its abstract. Accepting this risk is necessary, given the short time frame for the report. However, articles tend to overstate, rather than understate, their findings.

full text was not available in time for inclusion in the draft report. If articles arrive after the draft report date, they will be examined while the report is being under review to determine whether they articles would alter the assessment in a substantive way.

#### **IV. Reviewing the Articles**

- A. In general, Medical Effectiveness Team faculty and staff adhere to the following hierarchy of analysis:
1. Meta-analyses—particularly those included in the Cochrane Library
  2. Systematic reviews—particularly those performed by authoritative organizations, such as the Agency for Healthcare Research and Quality, U.S. Preventive Services Task Force and Evidence-Based Practice Teams or other government agencies (e.g., National Institutes of Health, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services)
  3. Evidence-based guidelines
  4. Individual RCTs
  5. Observational studies
  6. Case-control studies
  7. Clinical/practice guidelines based on consensus or opinion, rather than on evidence
- B. The Medical Effectiveness Team reviews published meta-analyses for consistency. If there are several published meta-analyses that yield substantively different results, Medical Effectiveness Team faculty and staff determine possible explanations (e.g., meta-analyses vary in their inclusion/exclusion criteria, or one or more may not meet criteria for rigor in conducting a meta-analysis). This may lead to “down weighting” some results. The rationale for this “down weighting” is discussed in the mandate analysis.
- C. The Medical Effectiveness Team relies on meta-analyses as the principal source of evidence for the review. This is because researchers who have undertaken the meta-analyses typically have had the time and opportunity to examine the methods of the underlying studies in some detail and exclude those studies with less credible results.
- If published meta-analyses are available, the Medical Effectiveness Team generally uses the meta-analyses as the principal source of information for the review and then limits the focus of the remainder of the literature review to systematic reviews and primary studies published after reports included in the meta-analyses. For example, if the meta-analysis was published in June 2001 and included studies up to December 1, 2000, the Medical Effectiveness Team focuses the search on primary studies published on or after December 1, 2000.
- D. If no applicable meta-analyses are available, the Medical Effectiveness Team proceeds down the hierarchy of articles.

- E. Adherence to the hierarchy of study designs may not be possible or advisable in all cases. For example, if a mandate proposes coverage of a new screening test and there are meta-analyses of the sensitivity and specificity of the test, but only well-designed and executed observational studies of how the test affects practice and clinical outcomes, the meta-analyses cannot fully substitute for observational studies.
- F. The Medical Effectiveness Team makes the initial assessment of the medical effectiveness of the proposed mandate based on available meta-analyses.
1. Effectiveness team faculty and staff then review subsequent literature to ascertain whether there is reason to question the initial assessment of the proposed mandate from the results of the literature search. The review of the subsequent literature is guided by the following questions: (1) Does the intervention have a statistically significant effect? (2) Does the intervention have a clinically meaningful effect? (3) Are the results applicable to the diverse California population? Studies that are not applicable to the California population are excluded from the review.
  2. For each study published after the meta-analysis, the Medical Effectiveness Team records whether the results for each outcome selected for analysis are statistically significant. Regardless of statistical significance, relevant results are noted for each outcome in the study. In selecting outcomes for analysis, outcomes defined in the language of the proposed mandate are addressed. If no specific outcomes are outlined in the bill, the clinical expert and Medical Effectiveness Team select patient-oriented health outcomes based on the results of reviewed studies. Thus, there is a preference for health outcomes, such as school days absent due to illness, rather than a physiological measure or test result (for example, the lung function measure of forced expiratory volume in one second—FEV1).
  3. The Medical Effectiveness Team will generally not have the time to undertake a detailed review of the methods and quality of individual studies in the same manner that a meta-analysis team can.
  4. Table 1 is an example of the way the Medical Effectiveness Team records information from each study included in the literature search.



**Table 1.** Summary of Published Studies on Effectiveness of Pediatric Asthma Self-Management and Training Interventions (Invented Examples)

<b>Citation</b>	<b>Type of Trial</b>	<b>Intervention vs. Comparison Group</b>	<b>Population Studied</b>	<b>Location</b>
Huss et al., 2003	OS	Education and computer-based instructional asthma game vs. education alone	Inner-city children	Baltimore, MD
Krishna et al., 2003	RCT	Internet-enabled, interactive multimedia asthma education and conventional education, management (with action plan) vs. conventional education and management (with action plan)	Children who visited a pediatric pulmonary clinic	St. Louis, MO
*LeBaron et al., 1985	RCT	Education vs. usual care	Low- to middle-income and higher patients at private pediatric allergy practices	San Antonio, TX

\* Indicates trial was included in the meta-analysis (Wolf et al., 2003).

Key: OS=observational study; RCT=randomized clinical trial

## **E. Making a Qualitative “Call” on the Literature**

- A. In a conference call or group meeting, the Medical Effectiveness Team faculty and staff and the clinical expert review the results of relevant studies for each outcome measure and decide collectively, based on the weight of the evidence available, on the effectiveness of the intervention in various dimensions.
- B. In making a “call” for each outcome measure, the Medical Effectiveness Team faculty and staff and the clinical expert consider the number of studies (as well as their sample size, quality, and relevance to the California population) included in any meta-analyses as well as the same issues in regard to other relevant studies.
- C. As a group, the faculty, staff, and clinical expert determine if any studies should be excluded from the review because of methodological issues or lack of relevance to the proposed mandate and then assign a “grade” for the weight of the evidence across studies for each outcome.
- D. To “grade” the evidence for each outcome measure, the Medical Effectiveness Team uses a grading system<sup>1</sup> with the following categories:

<sup>1</sup> The foregoing system was adapted from the system used by the U.S. Preventive Services Task Force, available at <http://www.ahcpr.gov/clinic/3rduspstf/ratings.htm>. The medical effectiveness team also considered guidelines from the Centers for Medicare & Medicaid Services, (available at <http://www.cms.hhs.gov/mcac/8b1-i9.asp>) and guidelines from the Blue Cross and Blue Shield Association (available at <http://www.bcbs.com/tec/teccriteria.html>).

<sup>2</sup> In this instance, the word “trend” may be used synonymously with “pattern.”

1. Favorable (statistically significant effect): Findings are uniformly favorable, and many or all are statistically significant.
  2. Pattern<sup>2</sup> toward favorable (but not statistically significant): Findings are generally favorable, but there may be none that are statistically significant.
  3. Ambiguous/mixed evidence: Some findings are significantly favorable, and some findings with sufficient statistical power show no effect.
  4. Pattern toward no effect/weak evidence: Studies generally find no effect, but this may be due to a lack of statistical power.
  5. No effect: There is statistical evidence of no clinical effect in the literature with sufficient statistical power to make this assessment.
  6. Unfavorable: No findings show a statistically significant benefit, and some show significant harms.
  7. Insufficient evidence to make a “call”: There are very few relevant findings, so it is difficult to discern a pattern.
- E. In a situation in which an intervention “should” have a beneficial effect, one would like to find evidence in categories 1 or 2. Results in category 3 indicate that the evidence is mixed, and that there is sufficient statistical power so that studies showing no effect could have detected an effect if one were present. It may be the case that the intervention works for some people, or in some situations, or in some circumstances, but not in others. Results in category 5 indicate, with a fair degree of certainty, that the intervention does not work, and results in category 6 indicate that the intervention is probably harmful. The difference between categories 4 and 7 is that in the former category there are typically quite a few studies, usually with insufficient statistical power to rule out an effect. In the latter category, there may be just a few studies with highly divergent results.

## **F. Summarizing the Quantifiable Evidence for Specific Outcomes**

- A. For studies with definite and quantifiable outcomes (e.g., school days absent, hospitalizations, and emergency department visits due to asthma), the Medical Effectiveness Team creates a table that includes all studies that measure that specific outcome and presents the results of those outcomes (including the Team’s “call” for that outcome based on the weight of the evidence). Table 2 shows the effect of an asthma educational self-management program on the mean number of school day absences for children with asthma. The “call” for the evidence of effectiveness for this intervention in terms of school absences is “favorable.” The overall effect, based on seven published U.S. trials included in a meta-analysis and one additional trial from 2003, is an estimated 44% reduction in the mean number of school days absent.

**Table 2. Summary of Evidence of Effectiveness by Health Outcome  
School Day Absences (mean days)—favorable**

<b>Trial</b>	<b>Results</b>	<b>Categorization of Results (Significance, Direction)</b>
Meta-analysis (16 trials)	SMD -0.14 [-0.23, -0.04]	Sig, fav
Estimated impact from U.S trials (7 trials included in meta-analysis)	44% reduction This reduction is calculated as the weighted average of the relevant studies (7 in the meta-analysis and 1 additional trial in 2003). <a href="#">See Table 5.</a>	Sig, fav
Krishna et al., 2003	Intervention pre 7.9 → post 1.4, control pre 6.4 → post 5.4	Sig, fav
*Fireman et al., 1981	Mean intervention post 0.5, control post 4.6	Sig, fav
*Christiansen et al., 1997	Mean intervention post 2.39, control post 2.98	NS, fav
*Persaud et al., 1996	Intervention post 6.4, control post 7.6	NS, fav
*Wilson et al., 1996	Sick days in 1 month: intervention pre 1.0 → post 0.8, control pre 0.7 → post 1.4	NS, fav
*Perrin et al., 1992	Number/month: intervention pre 0.73 → post 0.24, control pre 0.14 → post 0.22	NS, fav
*Evans et al., 1987	Absences/year: intervention pre 21.3 → post 19.4, control pre 20.8 → post 19.7	NS, fav
*Rubin 1986	Intervention pre 13.0 → post 14.1, control pre 17.0 → post 18.6	NS, fav

\* Included in meta-analysis.

Key: fav=favorable; NS=not significant; pre=preintervention; post=postintervention; Sig=significant; SMD=standard mean difference.

**B. The Medical Effectiveness Team calculates the overall effectiveness from multiple studies.**

1. Many meta-analyses (particularly those included in the Cochrane Library) report their results as the standardized mean difference (SMD), which is a unitless measure.
2. To obtain values in natural units, such as number of physician visits, the Medical Effectiveness Team reviews data from the original published studies. The protocol for calculating the effectiveness of an intervention from multiple studies appears below, Section VI. C.
3. In undertaking such calculations, the Medical Effectiveness faculty and staff take into account the plausibility of the findings and the overall pattern of the evidence, especially when not all studies have been independently assessed in a high-quality meta-analysis. That is, simple weighted averages may yield misleading results if one or more studies (perhaps with a poor design or unrepresentative patient population) have extreme results. Put another way, it would be confusing to readers if Medical Effectiveness Team faculty and staff, after due consideration, determined that the overall weight of the

evidence was equivocal, yet the weighted average of studies, some of which may be of poor quality, showed a substantial difference in the outcome measure. Whenever such judgments are made, the CHBRP medical effectiveness analysis will convey the rationales for those judgments.

C. The Medical Effectiveness Team uses the following protocol to calculate the overall effectiveness of an intervention.

1. If the available study does not give an overall “adjusted” measure of the effect of an intervention that takes into account the fact that the experimental and control groups may differ somewhat, even if they were formed by randomization, an overall measure is estimated.
2. To develop this estimate, the proportionate effect attributable to the intervention is calculated and then applied to the overall population (control plus experimental) in the study.
3. Raw data from the original published studies are inserted into a spreadsheet. (A sample calculation for the Krishna study in Table 2 is shown below, in Table 3.) This study examines the effect of an educational self-management intervention on the number of days children with asthma were absent from school.
4. Baseline data, if available, and postintervention data for this study are noted below in Table 3. In this instance, the intervention group had a somewhat higher rate of school absence days (7.90) during baseline than did the control group (6.40). The difference for the intervention group (-6.50) equals postintervention data (1.40) minus baseline data (7.90).
5. Baseline data for intervention and control groups (7.15) are averaged. (Implicitly, this is assuming the two groups are the same, reflecting randomization, and the observed differences are due to chance variation.) If the study gave the numbers of cases in each group, those are used as weights. If not, they are assumed to be of equal size.

**Table 3.** Calculating the Overall Effectiveness of an Intervention: Proportionate Reduction in School Day Absences

<b>Trial</b>		<b>Intervention Group</b>	<b>Control Group</b>	<b>Average</b>
Krishna et al., 2003	Baseline	7.90	6.40	7.15
	Postintervention	1.40	5.40	
	Difference	-6.50	-1.00	
	% difference	-82.3%	-15.6%	
	expected difference	-5.88	-1.12	
	expected savings in days absent			-4.77
	expected days absent in control group			6.03
	proportionate reduction in days absent in intervention			<b>-79.0%</b>

- The % difference (-82.3) = difference (-6.50)/baseline (7.90). This is the observed percentage reduction in the intervention group.
- Expected difference (-5.88) = % difference (-82.3) (the percentage reduction in the intervention group) times the baseline average for the total group (7.15).
- Expected savings in days absent (-4.77) = intervention expected difference (-5.88) – control expected difference (-1.12)
- Expected days absent in control group (6.03) = baseline average (7.15) + control expected difference (-1.12). A comparable figure is calculated with the observed percentage reduction in the control group times the overall baseline rate.
- Proportionate reduction in days absent in intervention (-79.0%) = expected savings in days absent (-4.77) / expected days absent in control group (6.03)

6. The last calculation compares intervention and control groups. Thus, even if the intervention group experiences a reduction in days absent, if the control group shows a greater reduction than the intervention group, it appears as if the intervention group has increased in the number of absent days.

For studies that publish only postintervention data, the proportionate reduction = (control – intervention)/control (see Table 4).

**Table 4. Calculating Proportionate Reduction in School Day Absences with Postintervention Results Only**

Trial		Intervention Group	Control Group	
Fireman et al., 1981	Postintervention	0.5	4.6	<b>-89.1%</b>

7. Next, a weighted average calculation is made to find the overall proportionate reduction in days absent for the intervention groups. Studies with more subjects have a greater effect on the outcome.

**Table 5. Calculating the Weighted Average to Find the Overall Proportionate Reduction in School Days Absent**

Trial	Total*	% Reduction	(Weighted)
Krishna et al., 2003	228	-79.0%	-25.5
Fireman et al., 1981	26	-89.1%	-3.3
Christiansen et al., 1997	42	-19.8%	-1.2
Persaud et al., 1996	36	-15.8%	-0.8
Wilson et al., 1996	59	-60.0%	-5.0
Perrin et al., 1992	56	-79.1%	-6.3
Evans, et al., 1987	204	-3.8%	-1.1
Rubin 1986	54	-5.2%	-0.4
Total	705		<b>*-43.6%</b>

\*Weighted average rounded to 44% in Table 2.

Key: N=number of subjects in each study

8. The low and the high values of the estimates are highlighted to derive a point estimate and a range.



**Appendix 11: The California Cost and Coverage Model: Analyses of the Financial Impacts of Benefit Mandates for the California Legislature**

This paper summarizes the methods used in CHBRP's cost impact analysis.

This paper is to be published in a forthcoming issue of *Health Services Research*. Dissemination of this preliminary version is intended to provide the California Legislature and other interested parties with detailed descriptions of the methods used by the California Health Benefits Review Program in its reports. Please do not cite or reproduce for any other purpose without consent of the authors and written notification of the California Health Benefits Review Program.

Since this paper was written in 2004, CHBRP has updated its methods to model for impacts on publicly-funded programs. However, this paper still serves as a current reflection of CHBRP's approach to analyzing impacts on the privately-insured market.



# **The California Cost and Coverage Model: Analyses of the Financial Impacts of Benefit Mandates for the California Legislature**

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## **ABSTRACT**

**Objective.** To produce cost estimates of proposed health insurance benefit mandates for the California legislature.

**Data Sources.** 2001 California Health Interview Survey, 2002 Kaiser Family Foundation/Health Research and Education Trust (KFF/HRET) California Employer Health Benefits Survey, Milliman Health Cost Guidelines, and ad hoc surveys of large health plans.

**Study Design.** We developed an actuarial model to estimate short-term (one-year) changes in utilization and total health care expenditures, including insurance premiums and out-of-pocket expenditures, if insurance mandates were enacted. This model includes baseline estimates of current coverage and total current expenditures for each proposed mandate.

**Principal Findings.** Analysis of seven legislative proposals indicated one-year increases in total health care expenditures among the insured population in California ranging from 0.006% to 0.200%. Even when proposed mandates were expected to reach a large target group, either utilization or cost was sufficiently low to keep total cost increases minimal.

**Conclusions.** Our ability to develop a California-specific model to estimate the impacts of proposed mandates in a timely fashion provided California legislators during the 2004 legislative session with more-detailed coverage and cost information than is generally available to legislative bodies.

**Key Words.** Insurance mandates; health care expenditures; utilization and cost impacts; evidence-based policy analysis.

## **THE CALIFORNIA COST AND COVERAGE MODEL**

The California Health Benefits Review Program (CHBRP) is charged by the California legislature with estimating the medical effectiveness, public health, and cost implications of proposed health benefit mandates. Cost implications include factors such as the effect on premiums and out-of-pocket and administrative costs, the effect on the number of uninsured individuals and access to health care services, and effects on the provision of health insurance by different types of employers. In response to this legislation, we developed a California Cost and Coverage Model to estimate the financial impacts of proposed health insurance mandates. This article explains the general methods and employed in developing this model, and presents results from the application of this model during the 2004 legislative session, as well as an example of how the model was used to produce estimates for osteoporosis screening. The model was used to produce financial impacts of specific mandates reported elsewhere in this volume.

### **ESTIMATING THE FINANCIAL EFFECTS OF HEALTH INSURANCE MANDATES IN CALIFORNIA**

The California Cost and Coverage model serves as a unique example of a model developed in a timely and transparent manner. It was constructed and validated by researchers and UCLA and staff at Milliman, with input from the larger CHBRP project team, during a six-month period during the second half of 2003 in time to analyze legislative initiatives requested by the legislature starting in December 2003 that were then considered during the first half of 2004. Our ability to develop a California-specific model to estimate the impacts of proposed mandates in such a timely fashion provided California legislators during the 2004 legislative session with more-detailed, specific coverage and cost information than was previously available

to legislative bodies. The model was updated at the end of the 2004 calendar year for analysis of bills during the 2005 legislative session.

In the legislation that created the California Health Benefits Review Program (CHBRP), California legislators identified two major types of financial effects they were interested in understanding regarding proposed mandates, summarized in Table 1: (1) the present coverage of the benefit and existing utilization and costs, and (2) projected changes in utilization and costs following a mandate.

The specific baseline information requested by the legislature for each mandate includes: the current utilization and cost of providing a benefit (A1); existing coverage of the service in the current insurance market (A2); public demand for expanding coverage (A3); and the current costs borne by insurers (A4). The specific post-mandate information requested by the legislature includes: utilization changes (B1); changes in the per-unit cost of providing the service (B2); administrative costs (B3); impact on total health care costs (B4); the costs or savings for different types of insurers (B5); and the impact on access and availability of services (B6).

The California Cost and Coverage Model has been used by CHBRP to address each of these baseline and post-mandate financial impacts with the exception of items A3 and B6. The public demand for expanding coverage (A3) is addressed by CHBRP through interviews with key stakeholders (insurers, unions, consumer advocates, employers, and legislative staff) to determine the breadth of support for each proposed mandate.

The impacts of mandates on access and availability (B6) require assumptions about whether there are serious supply constraints that might affect the cost or availability of a service if demand substantially increased in response to a mandate. Making these estimates is complicated by the limited existing literature on the actual costs or economic impact of

expanding the range of benefits provided by insurers. Only a small number of studies have been conducted. One study by the General Accounting Office suggests the most common effect of mandates is to increase overall costs and to reduce coverage (United States General Accounting Office 1996). A similar result was found in a review of studies of the cost effects of mandates (Jensen and Morrissey 1999). In both these studies, however, the effect of mandates on premiums was quite large, generally more than a few percentage points.

To date, none of the mandates reviewed by CHBRP have suggested that demand for the service would far exceed the ability of providers to supply the service. In the event that CHBRP reviews a mandate that could result in excess demand, at least in the short-term, these supply constraints can be factored into the per-unit costs of delivering the service (B2) or into the projected changes in utilization rates (B1), or both.

**Table 1.** Utilization, Cost, and Coverage Issues Mandated for Examination Under AB 1996

A. Baseline Utilization, Costs, and Coverage
A1. What are the current utilization levels and costs of the mandated benefit?
A2. How widespread is the current coverage of the mandated benefit?
A3. How much public demand is there for expanding the coverage of this service?
A4. What are the current costs borne by payers (both public and private entities) in the absence of the mandated benefit?
B. Projected Changes in Utilization, Costs, and Coverage
B1. How will utilization change as a result of the mandate?
B2. How will changes in coverage required by the mandate affect the cost of the affected services?
B3. To what extent does the mandate affect administrative and other expenses?
B4. What will be the impact of the mandate on total health care costs?
B5. What costs or savings for each category of insurer are expected to result from the mandate?
B6. How will the mandate impact access and health service availability?

The California Cost and Coverage Model is primarily an actuarial forecasting model. Such models are particularly appropriate when substantial behavioral changes in response to

mandates are likely to be limited in the short run. For example, a mandate requiring osteoporosis screening for all insured women ages 50-64 is unlikely to have an impact on the decision of employers to offer insurance, the rate of take-up of insurance by employees, or employer decisions about who is eligible for insurance in their firms, because the overall financial impact of such mandatory screening is likely to be small. Therefore, to the extent that our actuarially forecasted impact of a mandate has a small impact on health insurance premiums and overall health care expenditures (relative to large annual increases in premiums driven by overall utilization and price increases), behavioral changes do not need to be modeled and an actuarial forecast should produce a reliable approximation of a mandate's marginal impact on employers and employees. In cases where large marginal impacts are estimated, we need to account for possible changes in employer and employee behavior, as discussed below.

### **Previous Research on the Effect of Benefit Mandates**

Economists have generally focused more attention on what are known as individual or employer-based mandates (see, for example, (Gruber 1994; Summers 1989)). Such mandates are requirements on individuals and firms to purchase insurance but usually are not concerned with particular benefit packages. Although policy-makers refer loosely to mandates, broadly speaking, the kinds of mandates CHBRP examines usually are *benefit* mandates that require health insurers to cover specific services, in contrast to *insurance* mandates that require employers to provide insurance coverage to uninsured employees. There is a well-developed literature on mental health parity, which is effectively an expansion of benefits. With a few exceptions ((Jensen, and Morrisey 1999); (Gabel, and Jensen 1989); (United States General Accounting Office 1996)), however, the literature on estimating the effects of benefit mandates is not as well developed as other areas of health economics and health services research.

Although these studies cite evidence that benefit mandates can increase the marginal cost of insurance premiums substantially (for example, more than 1 percent), most of these mandates involve packages of services that are fairly comprehensive. In contrast, as shown below, the mandates evaluated in California to date have focused on very specific services that are often relatively low-cost on a per-unit basis.

## **METHODS**

### **Data Sources**

To estimate current levels of coverage, utilization, and expenditures for the mandated services, we constructed a baseline cost and coverage model using data from three primary data sources: (1) the 2001 California Health Interview Survey (CHIS); (2) the 2002 Kaiser Family Foundation/Health Research and Education Trust (KFF/HRET) California Employer Health Benefits Survey; and (3) the Milliman Health Cost Guidelines. In addition, we conducted ad hoc surveys of the largest health plans in California for each proposed mandate to determine the baseline (i.e., pre-mandate) percentage of total members currently covered for the mandated benefit. A detailed description of the model is presented elsewhere (Kominski et al, 2004).

### **Population Affected by Insurance Mandates in California**

#### Baseline Population with Insurance Coverage

The 2001 California Health Interview Survey (CHIS 2001) is used to identify the demographic characteristics and estimate the insurance coverage of the population in the state. To obtain estimates of the percentage of employees by size of firm and type of health plan, we used the 2002 Kaiser Family Foundation/Health Research and Educational Trust (KFF/HRET) survey of California employers. These data provide estimates of numbers of employees working in such firms and their types of coverage, based on a representative sample of California's

employers. Coverage categories include conventional fee-for-service (FFS), Preferred Provider Organizations (PPOs), Point-of-Service plans (POS), and Health Maintenance Organizations (HMOs). Furthermore, the KFF/HRET survey also provides information on whether each health plan is self-insured or underwritten. The latter two data elements were used to complement the CHIS data, since CHIS does not provide details on PPO, POS, or self-insured coverage.

We divided the insured market into four different types of health plans (HMO, PPO, POS, and FFS) and three market segments (large group, small group, and individual) to represent typical insured plan benefits in California. Specifically, the commercial market was divided into large-group (51 or more employees), small-group (2 to 50 employees), and individual coverage, because each of these markets is subject to different regulations and market forces. The baseline model generally excludes people covered by Medicare, since states do not have authority for mandating benefits under the Medicare program.

Table 2 shows the distribution of California's population by health plan and market segment based on these data. Most mandates affect only those with private insurance who are not employed in self-insured firms. For 2004, we estimate that 16.261 million Californians were potentially affected by such mandates. For mandates that affect only Knox-Keene licensed plans in California (i.e., HMOs), we estimate that 9.817 million Californians were potentially affected by such mandates in 2004.

**Table 2. Insurance Coverage of Californians, 2004**

		HMO	PPO	POS	FFS	Total
<b>Medi-Cal</b>	All ages					4,864,000
<b>Healthy Families</b>	0-17					458,000
<b>Medicare, non-Medi-Cal</b>	65+					2,619,000
<b>Other public, non-Medi-Cal</b>	0-64					389,000
<b>Other public coverage, non-Medi-Cal elderly</b>	65+					122,000
<b>Uninsured</b>	All ages					4,616,000

<b>Individually purchased</b>	0-64	748,000		854,000 <sup>1</sup>		1,602,000
<b>Employment based</b>						
Small group <sup>2</sup>						
Self-insured <sup>3</sup>	0-64	109,000	69,000	50,000	3,000	231,000
Underwritten <sup>3</sup>	0-64	2,630,000	1,247,000	877,000	45,000	4,799,000
Large group <sup>2</sup>						
Self-insured <sup>3</sup>	0-64	714,000	2,451,000	303,000	23,000	3,491,000
Underwritten <sup>3</sup>	0-64	6,439,000	1,739,000	1,621,000	61,000	9,860,000
<b>California's Total Population</b>						33,051,000

Notes:

Sources: 2001 California Health Interview Survey, 2002 Kaiser Family Foundation/Health Research and Education Trust Survey of California Employers.

<sup>1</sup> CHIS data only distinguishes individuals with HMO coverage from those with non-HMO coverage.

<sup>2</sup> Estimates of workers in HMOs, PPOs, FFS, and POS are obtained by multiplying the percentages of workers in each plan type from CA HRET 2002 data and CHIS population estimate of workers.

<sup>3</sup> Estimates of workers in HMOs, PPOs, FFS, and POS who are in self-insured plans are obtained by multiplying the percentages self-insured workers in each plan type from HRET 2002 data and CHIS population estimate of workers. Estimates are then inflated to account for the proportion of children covered (29.11%).

### Population with Insurance, but Not Currently Covered by the Proposed Mandate

We estimate the proportion of the insured population currently not covered by the proposed mandate by conducting ad hoc surveys of the largest health plans in the state. We ask them to provide us with estimates of the number and percentage of their members who currently do not have coverage for the proposed mandate, by market segment and by firm size.

### **Baseline Premium Data**

We obtain baseline data on insurance premiums for the large and small group insurance directly from the 2002 Kaiser Family Foundation/Health Research and Education Trust (KFF/HRET) California Employer Health Benefits Survey. For the individual market, we obtain estimates from Milliman.



## **Costs versus Expenditures**

Because of the presence of insurance, it is important to identify the cost to whom – i.e., insurer, employer, employee, patient, or society in general. As defined in the California Cost and Coverage Model, cost represents the aggregate expenditures, or the prices paid, for health care services – not the costs incurred by the providers of health care. The rationale for this definition of cost is that legislators are ultimately interested in evaluating the financial impact of mandates on each of the major payers for health care services in the state.

The elements of cost included in the model are: (1) insurance premiums; (2) member cost-sharing; (3) cost of services currently not covered, i.e., the amount paid by users of services proposed by the mandate but not currently covered by insurance; and (4) total expenditures, i.e., the sum of amounts paid for insurance plus the amounts paid for such services not covered by insurance.

## **Baseline Utilization of and Expenditures for Mandated Services**

The baseline utilization and expenditure data for the California Cost and Coverage Model are drawn primarily from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by actuaries in many of the major health plans in the United States. The HCGs are licensed and used nationwide and by several California HMOs and insurance companies, including at least five of the largest plans. It is likely that these organizations would use the HCGs, among other tools, to determine the initial premium impact of any new mandate. Thus, in addition to producing what we believe are accurate estimates of the costs of a mandate, the HCG-based values should also be good estimates of the premium impact as estimated by the HMOs and insurance companies.

Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. In particular, the data come from health insurance companies, Blue Cross/Blue Shield plans, HMOs, self-funded employers, and from private data vendors from throughout the U.S. The data are mostly from loosely managed healthcare plans, such as traditional indemnity style plans and PPO plans. The HCGs are also based on data commonly used by health services researchers. Specific examples of these data sets include:

- Nationwide commercial claims data for approximately 4 million members, purchased from a commercial vendor (MEDSTAT);
- Claims data from Milliman clients who agree to use of their blinded data for research, consisting of about 3 million members;
- All commercial inpatient claims from 24 states that release this information, including data on all hospital discharges in California. These data are purchased directly from the states, but are also available through the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project (HCUP).

Because most of data used by Milliman to develop the HCGs represent “loosely” managed care from throughout the U.S., all the baseline analyses performed by Milliman start with PPOs in the large-group market, then make adjustments to these baseline data to account for differences by type of insurance, size of market, and geographic location. This process is described in more detail elsewhere (Kominski et al, 2004).

### **Estimating the Impact of a Proposed Mandates**

We estimate the impact of proposed mandates in the following general manner. We start with baseline premiums and out-of-pocket expenditures in 2005 obtained from the 2002 KFF/HRET survey and Milliman HCGs trended forward to account for changes in utilization

and unit costs since 2002. These estimates are average per capita expenditures within each of the market segments (large-group, small-group, individual) and insurance plan types (HMO, PPO, POS, FFS), and are multiplied by the population estimates obtained from CHIS and KFF/HRET in each market segment/insurance plan category to obtain total baseline expenditures.

We then develop baseline estimates of utilization within each category using Milliman's HCGs, or other published sources of data identified in the course of the literature review conducted for each analysis.

In general, mandated benefits fall into one of the three general categories of benefits expansion, in which the mandate benefit is:

1. already covered for a portion of the insured population, so the mandate is expanding existing coverage to a broader population;
2. currently available but only as a non-covered (i.e., non-insured) service, so the mandate is expanding coverage to a service that is currently paid out-of-pocket;
3. newly available service, so the mandate is expanding coverage for a service not previously available.

In the first two cases, existing Milliman HCGs and other data can be used to establish baseline utilization rates, whereas there is no baseline utilization in the third case. Changes in utilization resulting from the mandate can be estimated using claims data in the first case, but in all three cases, previously published studies or "educated guesses" may be necessary to estimate how utilization levels will change in the post-mandate period. During the 2004 legislative session, all of the proposed mandates fell into the first category above; namely, benefits that were already available to some portion of the insured population. As a result, we were able to obtain reliable estimates of baseline utilization from existing claims data.

The key assumption in estimating the impact of a proposed mandate is determining how much utilization will change. For proposed mandates such as osteoporosis (discussed in more detail below) and ovarian cancer screening, we developed estimates of baseline utilization from claims data for women who are currently treated for these conditions, and then made assumptions about the increased use of screening based on utilization rates of screening mammography and Pap smears.

### **Forecasting Longer-Term Effects**

Although legislators may expect savings in health care costs from mandates of preventive services, due to the reduction in the need for other services, the short-term effect on premiums is usually an increase. Accordingly, our model generally projects increased insurance premiums based on actuarial assumptions. Immediate and long-term cost savings as a result of mandates are not modeled or estimated because of the inherent difficulty in forecasting reductions in future costs accurately, even though some mandated services may result in longer-term savings to the health care system.

### **Modeling Dynamic Responses in the Private Market for Health Insurance**

The decision to offer insurance by employers is a function of worker demand, labor market conditions, and establishments' costs (price) of coverage along with firm level characteristics, competition in the market, and the size of other firms in the market (Hadley, and Reschovsky 2002). Firm size is the most commonly measured factor determining whether firms offer insurance. In 1998, ninety-four percent of establishments with 100+ employees offered health insurance (Bureau of Census 2002) whereas only 66 percent of firms with 10-24 employees offered insurance. Moreover, the size of the firm affects the number of insurance plans employees are offered (Moran, Chernew, and Hirth 2001).

Employees also have the choice of taking coverage if offered by the employer. If the out-of-pocket premium cost is too high, some eligible workers will forgo coverage, and the employees who forgo coverage are likely to be those who anticipate not benefiting as much from health insurance, such as those who are younger or in better health. If such “low-cost enrollees” drop out of the employer’s covered pool, the premium for the remaining enrollees is likely to further increase (aside from the effects of the mandate per se). This selective disenrollment (i.e., adverse selection) may eventually lead the employer to drop coverage entirely. Under conditions of increased premiums, mandates may impact access to health care (Table 1, B6). Depending on the magnitude of the premium increase, the number of employers offering insurance in the group market may go down, or employers may absorb the premium increase. If employers no longer offer insurance, employees face several choices. Employees may become uninsured, may switch to spousal coverage if available, they may enroll in a public insurance program if eligible, or may buy individual coverage. Individuals already purchasing insurance may drop coverage altogether if they cannot afford the new premium.

The impact on public programs is mainly observed in the low-income population. This population is most affected by price changes and is more likely to be eligible for income-tested benefits. In general, low-income individuals tend not to buy insurance even at very low prices (Chernew, Frick, and McLaughlin 1997). The loss of private coverage and increase in public insurance participation is considered as a crowd-out effect. There is some controversy about how large crowd-out effects are. However, in general, employees who are eligible for public insurance take up employer-provided insurance less frequently (Cutler, and Gruber 1996).

The Lewin Group has developed estimates as part of its Health Benefits Simulation Model that incorporate both these effects, and find that the overall average elasticity of demand

for insurance is  $-0.34$  (Lewin Group 2002). This elasticity varies from  $-0.55$  for individuals with \$10,000 annual income to  $-0.09$  for individuals with annual income of \$100,000. For mandates that have a large impact on premiums, relative to average annual increases in California health insurance premiums, our analyses include discussion of the possible impacts on the number of Californians who might become uninsured in response to premium price increases, based on Lewin's estimated elasticity. Only two bills analyzed during the 2004 legislative session (Senate Bill 897, maternity benefits, and the follow-up companion bill, SB 1555) resulted in large premium increases for those without coverage for the proposed mandated benefit. Our analyses of those bills used Lewin's elasticity of demand for insurance to estimate the potential increase in the number of uninsured due to estimated premium increases.

Finally, we assume that marginal cost changes estimated in our analyses get passed on directly to employers and thus to employees.

## **RESULTS**

During the 2004 legislative session, we used the California Cost and Coverage Model to analyze the cost and coverage impacts of nine bills introduced into the California legislature. These bills included mandates adding osteoporosis screening, ovarian cancer screening, pre-natal and maternity services, substance abuse treatment (including smoking cessation), asthma self-management training and supplies, and hearing aids for children.

Table 3 provides the results of the model for one particular mandate – osteoporosis screening – and for one of the plan types affected by the mandate (large group HMO). Similar analysis is done for each plan type, and the effect on the entire state is based on the aggregate values. This proposed mandate would have affected women ages 50-64. Currently, no health plans in California provide general screening benefits for osteoporosis, but women at high risk

are eligible for screening and treatment, both of which are covered by most plans. Based on data from the Milliman HCGs, we estimated that at baseline, 11 percent of women ages 50-64 are high risk, and thus eligible for screening, and that 8 percent of women ages 50-64 are actually using osteoporosis screening services, at a cost of \$173 per screening. Post mandate, we estimated that screening rates would increase from 8 to 30 percent. This assumption was based on the two-year rates for mammography in California of 72-76 percent reported by the Pacific Business Group on Health. Taking the mid-point of this range, 74 percent, implies a 37-percent annual rate of osteoporosis screening. We reduced this rate to 30 percent to reflect the fact that osteoporosis screening was likely to be used less often relative to mammography during the first years of the benefit.

We estimated that the annual increase in screening rates of 22 percentage points due to the mandate would produce about a 0.95-percent increase in newly diagnosed osteoporosis, based on an incidence rate of 4.33 percent ( $0.22 * 0.0433 = 0.0095$ ), and that roughly two-thirds of these newly diagnosed cases would seek treatment at an annual cost of \$1300, including the cost of an office visit and prescriptions. Finally, we assumed that 0.13 percent of those newly diagnosed with osteoporosis would avoid hip or vertebral fractures, and thus would produce a savings on average of \$19,000 by avoiding hospitalization. Therefore, the net increase in premiums of \$0.33 shown in Table 3 represents the net impact of increased utilization, increased treatment costs for newly diagnosed cases, and savings related to reduced hospitalizations.

**Table 3. Summary Table of Cost Impacts of Proposed Mandate for Osteoporosis Screening of Women Ages 50-64, 2004**

	<b>Baseline (Pre-Mandate)</b>	<b>Post Mandate</b>	<b>Mandate Impact</b>	<b>Annual Expenditure Impact</b>
<b>Insurance Market</b>	Large Group			
<b>Type of Insurance</b>	HMO			
<b>Insured Population in Market Segment</b>	6,439,000	6,439,000		
<b>Insured Women Ages 50-64 in Market Segment</b>	542,000	542,000		
<b>Portion of Insured Women with Screening Benefit</b>	11%*	100%		
<b>Portion of Insured Women Ages 50-64 Who Are Screened for Osteoporosis</b>	8%*	30%		
<b>A. Insured Premiums</b>				
Average Portion of Premium Paid by Employer	\$169.13	\$169.38	\$0.25	\$19,680,000
Average Portion of Premium Paid by Employee	\$48.87	\$48.94	\$0.07	\$5,640,000
Total Premium	\$218.00	\$218.32	\$0.33	\$25,320,000
<b>B. Covered Benefits Paid by Member (deductibles, copays, etc)</b>				
	\$7.72	\$7.73	\$0.01	\$840,000
<b>C. Total Cost of Covered Benefits</b>	\$225.72	\$226.05	\$0.34	\$26,160,000
<b>D. Benefits Not Covered</b>	\$0.00	\$0.00	\$0.00	\$0
<b>E. Total Expenditures per Member</b>	\$225.72	\$226.05	\$0.34	\$26,160,000
<b>Percent Increase in Premiums</b>			0.15%	
<b>Percent Increase in Expenditures</b>			0.15%	

\* At baseline, women at high risk for osteoporosis have coverage for screening and treatment, but general screening for the entire female population ages 50-64 is not a covered benefit.

Note: Dollars may not add precisely due to rounding error.

Table 4 summarizes the major cost and coverage impacts of these proposed mandates, including a revised maternity benefits bill that was introduced subsequent to our original analysis. In general, the mandates analyzed during the 2004 legislative session would have produced small increases in total health expenditures according to our estimates; ranging 0.006 to 0.020 percent of total health expenditures among insured Californians. The small impact of these mandates is primarily attributable to the fact the proposed benefits were relatively inexpensive on a per-unit basis (osteoporosis screening, ovarian cancer screening, hearing aids for children, and childhood asthma self-management) or would be used by a relatively small percentage of the insured population (substance disorder treatment and maternity services).



In every case except maternity services, the proposed mandate would have a small impact on the insurance premiums. In the case of maternity services, we estimated a 13% premium increase on average among the 44,000 individuals (male and female) ages 25-39 who currently purchase individual policies, because premiums are typically age-related, but do not differ by gender. Based on Lewin's estimated elasticity of demand for insurance, we predicted that a 13-percent increase in premiums among this age 25-39 group would produce a 3.4-percent increase in the uninsured – about 1,900 additional uninsured Californians, of whom about 12 percent would be eligible for Medi-Cal.

## **DISCUSSION**

The California Cost and Coverage Model is based on a widely used actuarial model of national Health Cost Guidelines developed by Milliman augmented with two California-specific data bases that represent “gold standards” for understanding the distribution of California's population by insurance status (CHIS) and the level of premiums paid by California employers and employees (KFF/HRET). The existence of these databases provided us with the ability to develop a California-specific model to estimate the impacts of proposed mandates in a very timely fashion.

In general, the legislature responded very favorably to the detail provided in our financial impact analysis, and given the “bottom-line” orientation of most legislators, focused considerably on our estimates of the impact on health insurance premiums and total health expenditures, including out-of-pocket expenditures. One minor criticism of our financial analyses was that the major assumptions and impacts were not presented in a standardized manner across reports. We responded to this feedback by developing standardized templates for

**Table 4. Summary of Cost and Coverage Impacts of Legislative Bills Analyzed Using the Cost and Coverage Model During the 2004 Legislative Session**

<b>Assembly or Senate Bill Number</b>	<b>Proposed Benefit Mandate</b>	<b>Insured Members Targeted by Proposed Mandate</b>	<b>Total Targeted Insured Population (millions)</b>	<b>Insured Members Without Coverage Prior to Mandate (millions)</b>	<b>Utilization Rate Prior to Mandate</b>	<b>Utilization Rate After Mandate</b>	<b>Total Insured Members Affected by Mandate (millions)</b>
AB 438	Osteoporosis Screening	Women 50-64	1.777	1.580	11.00%	30.00%	16.261
AB 547	Ovarian Cancer Screening	Women 18-64	5.890	5.540	6.00%	22.00%	16.261
SB 101	Substance Disorder Treatment	Members 0-64	16.261	16.261	**	**	16.261
SB 174	Hearing Aids for Children	Members 0-17*	4.408	1.630	63.00%	65.00%	15.513
SB 897	Maternity Services	Members 0-64	0.375	0.375	1.34%	1.34%	16.261
SB 1555	Maternity Services	Non-HMO Members 0-64	0.292	0.292	1.34%	1.34%	6.444
AB 2185	Childhood Asthma Self-Management	HMO Members 0-17	3.495	0.377	54.00%	64.00%	16.261

\* Does not apply to children covered by individual policies and enrolled in HMOs.

\*\* Multiple services are affected by mandate, so a single utilization rate does not apply.

Source: Analyses of individual bills conducted by the California Health Benefits Review Program. Individual reports are available at <http://www.chbrp.org/analyses.html>

summarizing the impacts of proposed mandates on coverage, utilization, per-unit costs, and total expenditures. These standardized templates have been used for analyses we have been conducting during the current 2005 legislative session.

## **CONCLUSIONS**

The California Cost and Coverage Model represents a comprehensive effort to develop a model by actuaries and health services researchers to estimate the effects of health insurance benefit mandates for different types of insurers and for different employer firm sizes. The goals of this model are to provide accurate and timely estimates of health insurance benefit mandates to legislatures, and to make those estimates as transparent as possible. Based on feedback we have received from the legislature and from health plans, we have met these goals. As more states become interested in evaluating the financial impacts of mandates, actuarial models such as the one described here can be developed in a timely manner so that researchers and stakeholders can assess the quality of the data and assumptions used to estimate the impacts of benefit mandates.

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**Appendix 12: Assessing the Public Health Impact of State Health Benefit Mandates**

This paper summarizes the methods used in CHBRP's public health impact analysis.

This paper is to be published in a forthcoming issue of *Health Services Research*. Dissemination of this preliminary version is intended to provide the California Legislature and other interested parties with detailed descriptions of the methods used by the California Health Benefits Review Program in its reports. Please do not cite or reproduce for any other purpose without consent of the authors and written notification of the California Health Benefits Review Program.





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**Assessing the Public Health Impact of State Health Benefit Mandates**

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## INTRODUCTION

In the early 1990's, when the US was considering comprehensive health care reform legislation under the Clinton Administration, public health professionals rallied to demand that the public's health be a key consideration in the redesign of the system (APHA, 1993; Partnership for Prevention, 1993; Schauffler et al., 1994; Warner and Warner, 1993). The issues and concerns of the public health community ranged from securing adequate resources to performing basic public health functions, to collecting more comprehensive data to monitor changes in the public's health, to obtaining comprehensive coverage for preventive care to promote the public's health. The common refrain at the time was, "Where is the health in health care reform?" (Fielding and Halfon, 1994).

Concerns about access and the costs of care dominated the public policy debates leaving little room for questions about the effectiveness or quality of care and little to no discussion of how the proposed reforms might affect the health of the American people. While public health advocates were successful in getting many of their proposed reforms into the health care reform bills that were considered on the floor of the US Senate and House of Representatives in 1994, ultimately no comprehensive health care reform legislation was enacted (Schauffler, 1997). Since this time, very little attention has been given to questions of how proposed health care reforms might affect the health of the population at the state or national level.

The enactment of state mandated benefit review laws has provided an opportunity to integrate measures of public health impacts into health care reforms. Unfortunately, few states have included comprehensive requirements to assess the impact of state benefit mandates on the public's health. Of the 26 states that require reviews of mandated benefit legislation, 25 require an assessment of the cost impact, 12 require an assessment of the medical efficacy, and only 6

have language requiring an assessment of the public health impact (Bellows, et al., 2006). Table 1 presents the specific requirements of these six states to address public health impacts in preparing a mandated benefit review -- additional requirements to address cost and medical efficacy are not discussed in this paper. In reference to public health impacts, the Minnesota law states that the review must include the “public health impacts” of the proposed mandate, but gives no further information as to how these impacts should be defined (Minnesota Statutes, Chapter 62J, Section 26). Three of the other states (Maine, Massachusetts, and Washington) are similarly vague, requiring that the review examine the impact on the “health status” of the population (Maine Revised Statutes, Title 24A, Chapter 33, Section 2752; General Laws of Massachusetts, Title 1, Chapter 3, Section 38C; Revised Code of Washington, Title 48, Chapter 48.47, Sections 005-900). Hawaii requires that the review include the impact of the mandate on “morbidity, mortality, or quality of care” (Hawaii Revised Statutes, Chapter 23, Sections 51-52). A review of the completed reviews produced by these states revealed that none of them produced a public health impact analysis that attempted to translate medical efficacy into population-based outcomes.

The level of detail required for the public health impact analysis in California’s statute, AB 1996, is much more comprehensive compared to the five approaches mentioned above. AB 1996 specifies that these reports include an analysis of the public health impacts of proposed health benefit mandates including a) the impact on the health of the community, including the reduction of communicable disease and the benefits of prevention such as those provided by childhood immunizations and prenatal care, b) the impact on the health of the community, including diseases and conditions where gender and racial disparities in outcomes are established in peer-reviewed scientific and medical literature, and c) the extent to which the proposed service

reduces premature death and the economic loss associated with disease. As shown in Table 1, only the reviews conducted in California have attempted to quantify the public health impacts as part of their standard MBR process.

The goal of this paper is to describe the methods used by the California Health Benefits Review Program (CHBRP) in conducting the public health impact analysis. This will serve as a guide for other states interested in incorporating a public health impact analysis into their state mandated benefit review process. This will include a discussion of data sources, required data elements, and the methods used to quantify the impact of a mandated health benefit on: overall public health, on gender and racial disparities in health outcomes, on premature death, and on the economic loss associated with disease. In addition this paper will identify the limitations of the public health impact analysis conducted by the CHBRP program. Finally, we will conclude with a discussion of the role that a public health impact analysis can play in the health policy-making process and political debate.

## **METHODS**

AB 1996 did not specify the methods by which any of the three analyses (cost, medical effectiveness, or public health) are to be conducted, instead relying on the researchers in the University of California schools of medicine and public health to develop the appropriate methods. After conducting the first 12 reviews in 2004, the public health team drafted a template based on this experience to be used as a starting point for all of the public health impact analyses. The four components of the public health impact section of the reviews (baseline health outcomes, impact on overall community health, impact on community health where gender and

racial disparities exist, reduction of premature death and the economic loss associated with disease) are described in detail below.

### **Present Baseline Health Outcomes**

This first section of the public health impact analysis, “Present Baseline Health Outcomes,” describes 1) the baseline prevalence and incidence of the disease and related conditions, 2) the health outcomes related to the disease or condition such as morbidity, mortality, disability, and quality of life, and 3) the health care utilization related to the disease or condition such as physician visits, hospital visits, emergency department visits, and pharmaceutical use.

A three-tiered hierarchy is used to prioritize sources of incidence and prevalence data: Tier 1-state maintained registry (i.e., census of all persons with the disease of interest), Tier 2-California-specific estimates from population-based surveys, and Tier 3-national estimates from population-based surveys (where Tier 1 is the most preferred). State-level registries are the preferred source for prevalence and incidence data since they represent the entire population of persons with a disease or condition in the state. Unfortunately, statewide registries are limited to a small number of diseases and conditions. Of the CHBRP reviews conducted in 2004 and 2005, there have been two in which state-maintained registry data have been used to estimate the incidence and prevalence of diseases: Autism Diagnosis (SB 749) and Ovarian Cancer Screening (AB 547). Autism data was obtained from regional center intake files that were used as a proxy for a registry of persons with autism in California (CHBRP, 2005a). To estimate the rates of ovarian cancer in California, the California Cancer Registry data on the prevalence and incidence of specific cancers diagnosed in California each year was used (CHBRP, 2004a).

Once it has been determined that no state-level registry exists, California-specific estimates from population-based surveys (Tier 2 data) are explored. The main source of California-specific estimates of health conditions and illnesses is the California Health Interview Survey (CHIS).<sup>1</sup> The CHIS is conducted every two years by the UCLA Center for Health Policy Research and it includes questions addressing the health status, health-related behaviors, insurance coverage, access to health care, and use of health care services of California children, adolescents, and adults. In 2001 and 2003, data were collected from approximately 55,000 randomly selected households in California. Data from CHIS can be stratified by gender, age, race and ethnicity. To the extent that CHIS does not cover a specific health outcome of interest the annual California Behavioral Risk Factor Survey (BRFS) is used.<sup>2</sup> The BRFS dataset is much smaller (based on approximately 4,000 randomly selected adults), but it contains more specific information regarding health-related behaviors that directly relate to disease and injury. BRFS data can be stratified by gender, age, race and ethnicity. The California BRFS is conducted annually by the Survey Research Group (SRG) under the California Department of Health Services Cancer Surveillance Section. When data on a specific illness or disease are not available in either the CHIS or BRFS datasets, literature reviews are conducted to find California-specific incidence and prevalence data in peer-reviewed journals.

National data are used for conditions or illnesses where no California-specific data exist. Datasets maintained by the National Center for Health Statistics such as the National Health Interview Survey, National Health and Nutrition Examination Survey, and National Vital Statistics System are consulted for applicable data. In addition, the CDC website is searched for potential sources of data, as are websites of national associations affiliated with the disease or

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<sup>1</sup> Data can be found at [www.askchis.com](http://www.askchis.com)

<sup>2</sup> Data can be found at [www.surveymethods.com](http://www.surveymethods.com)

condition of interest. Literature searches are also conducted to find studies of national incidence and prevalence rates published in peer-reviewed journals.

The section of the CHBRP report on baseline health outcomes also presents data on health outcomes associated with the disease such as morbidity and mortality. In consultation with the medical effectiveness team and a clinical expert, a list of relevant health outcomes for each disease is developed. Morbidity data are searched using the same procedure outlined above for incidence and prevalence data. Data on mortality rates are available through the WONDER database query system, maintained by the Centers for Disease Control and Prevention (CDC).<sup>3</sup> This database contains mortality data from all death certificates filed in the United States for the years 1979 through 2002. Annual data on the number of deaths and death rates are available by underlying cause of death and can be stratified by state, age, race, and gender.

In addition to baseline data on disease-specific morbidity and mortality, health care utilization data are also presented. Health care utilization data such as rates of physician visits, emergency department visits, inpatient admissions and length of stay, and prescription drug use stratified by age, gender, condition and type of health insurance are obtained from the Milliman USA Health Cost Guidelines database.<sup>4</sup> Most of these data are from traditional indemnity-style plans and PPO plans. Adjustments to account for differences in California by type of insurance, market size, and geographic location are made by Milliman USA, a national actuarial firm. In addition, the CHBRP model adjusts for differences in member demographics, regional physician and hospital practice patterns, and managed care effects specific to the California health care system. Details on the methodology used to make these adjustments can be found elsewhere in this issue (Kominski et al., 2006).

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<sup>3</sup> Data is located at <http://wonder.cdc.gov>

<sup>4</sup> More information of the Milliman USA Health Cost Guideline database can be found at [http://www.millimanusa.com/tools\\_products/health\\_cost.aspx](http://www.millimanusa.com/tools_products/health_cost.aspx).

## **Impact of the Proposed Mandate on Public Health**

The four data elements needed to conduct the public health impact analysis on the overall impact on the health of the community are: baseline health status, coverage impacts of the mandate, utilization impacts of the mandate, and the medical impact of the benefit. Once these four pieces of data have been collected, the overall impact on the health of the community can be calculated using the steps outlined below. We illustrate these steps using the CHBRP analyses of Assembly Bill 438 (AB 438) on osteoporosis screening and Senate Bill 576 (SB 576) on tobacco cessation services as examples (CHBRP, 2004b; CHBRP 2005b).

Coverage Impacts: The first step in the analysis is to obtain the coverage impacts from the team working on the cost section of the report. To determine the coverage impacts, the population that will be directly affected by the mandate, including those who are currently covered for the benefit and the number of Californians who will be newly covered for the benefit as a result of the mandate, are identified. The affected population may vary as a function of age, gender, prevalence of the targeted condition, and type of health insurance coverage that will be subject to the mandate, as specified in the bill. For example, legislation could apply only to enrollees in HMOs, those with all forms of private health insurance, or all covered lives in the state including those with Medicaid and Healthy Families. For each proposed benefit mandate these factors will vary. More information regarding the methods used to derive the coverage impacts can be found elsewhere in this issue (Kominski et al., 2006).

Utilization Impacts: The second step in this analysis is to calculate the number of people who will utilize the benefit as a result of the mandate. The cost team estimates the utilization impacts separately for insured Californians who are presently covered for the proposed benefit



and those who will be newly covered for the benefit, post-mandate. For persons newly covered by the mandate, an assumption is made about their utilization of the new benefit based on current use for those with existing coverage, as well as use of similar kinds of services for the affected population (more information regarding the methods used to derive utilization impacts can be found in Kominski et al. in this issue). For persons with current coverage of the benefit, an estimate is made regarding any potential for this utilization to change as a result of the mandate. The total number of new persons expected to utilize a benefit post-mandate is calculated as follows: [# newly covered\*change in utilization rate] + [# previously covered\*change in utilization rate]. This accounts for two factors: one, that there could be some baseline utilization rate in the population without coverage at baseline that was paid for out-of-pocket and two, that as a result of the passing of the mandate, changes in utilization could also occur in the population with current coverage.

Health Impacts: The third and final step in this analysis is to assess the overall change in health outcomes in the affected population using the estimates of changes in utilization combined with the rates of effectiveness derived from the medical impact literature review. Based on the findings from the literature review on medical effectiveness, estimates are made on the impact of utilization of the benefit on health outcomes by the medical effectiveness team. The results for each health outcome are compiled to produce an overall mean estimate that can be used to calculate the health effects of the benefit mandate. The methods used to conduct the literature search are presented in a separate paper in this issue (Luft et al., 2006). For each specific health outcome reviewed in the literature for which there is baseline data available and a mean effect calculated, the estimated impact on each health outcome is applied to the population of new utilizers to determine the overall change in outcomes resulting from the mandate.

*Example 1: Impact of Osteoporosis Screening Mandate on the Reduction of Hip Fractures*

Assembly Bill 438, introduced in 2004, mandated coverage for “osteoporosis screening” in postmenopausal women in California between the ages of 50 and 64 years in public and private insurance plans regulated by the Department of Insurance and Department of Managed Care. The steps taken to calculate the public health impact of this mandate one year after implementation are shown using one health outcome of osteoporosis, hip fractures.

Step 1 - Calculate the Coverage Impacts: The target population under the proposed osteoporosis screening mandate (AB 438) is women ages 50-64 with private health insurance (n = 1.8 million). To calculate the number of newly covered individuals, the number of women in this target population was multiplied by the percentage of privately insured women ages 50-64 who currently lack coverage for the proposed benefit or treatment (89%). This results in 1.6 million women newly covered for screening under this mandate.

Step 2 - Calculate the Utilization Impacts: Based on the utilization data provided in the cost impact section, it was assumed that 30% of the newly covered women (1.6 million) would be screened for osteoporosis within the first year of implementation, for a total of 480,000 women (CHBRP, 2004b). We also assumed that there would be no increase in the utilization rate for women with current coverage for osteoporosis screening. Thus, we estimated that a total of 480,000 privately insured women ages 50-64 would be newly screened for osteoporosis in the first year of passage of the benefit mandate.

Step 3 - Calculate the Health Impacts: The review of the literature assessing the medical effectiveness of osteoporosis screening for women ages 50-64 found that for every 3,750 women screened, one hip fracture was prevented. Therefore, we estimated that osteoporosis screening in

the newly covered population of 480,000 women would prevent approximately 128 hip fractures (480,000/3,750) among women ages 50-64 with private health insurance in California in the first year after passage of the mandate.

*Example 2: Impact of Smoking Cessation Mandate on the Reduction of Low Birthweight Births*

Senate Bill 576, introduced in 2005, mandated coverage for tobacco cessation services in public and private insurance plans regulated by the Department of Insurance and Department of Managed Care in California including smoking cessation counseling and all FDA-approved smoking cessation pharmacotherapies. The steps taken to calculate the public health impact of this mandate are shown using one health outcome of tobacco use, low birthweight births.

Step 1 - Calculate the Coverage Impacts: It is estimated that there are 40,000 pregnant smokers with health insurance coverage in California and that 30% (12,000) of these would gain coverage for smoking cessation benefits as a result of the mandate.

Step 2 - Calculate the Utilization Impacts: Based on research published in tobacco control literature it was assumed that pregnant smokers without coverage had quit rates of 14% and that this rate would increase to 22% with coverage for smoking cessation treatments – for a difference of 8%. This means that in the population of 12,000 pregnant smokers who would gain coverage for smoking cessation treatments, an additional 1,000 (12,000 \* 8%) would quit as a result of the mandate.

Step 3 - Calculate Public Health Impacts using Medical Impacts: The review of the literature assessing the medical effectiveness of quitting smoking on low birthweight births found that among non-smokers the rate of low-birth weight births was 6% compared to 12%

among smokers (a difference of 6%). Thus, we estimate there will be approximately 60 fewer low birthweight babies (1,000\*6%) in the first year after passage of the mandate.

### **Impact on Community Health Where Gender and Racial Disparities Exist**

The overall impact on the health of the community with respect to gender or racial disparities of the proposed benefit mandate is also addressed in the public health impact analysis. The first step is to conduct a literature search to determine if the proposed mandate covers a health condition for which gender and racial disparities in outcomes are known to exist. In order to quantify the effect of the proposed mandate on gender and racial disparities the following information is needed: 1) baseline incidence or prevalence of the condition by gender and race, 2) coverage impacts by gender and race, 3) utilization impacts by gender and race, and 4) medical impacts by gender and race. Once it has been established that there is a gender or racial disparity in health outcomes and the four pieces of information mentioned above have been collected, the impact on community health can be calculated using the same steps as outlined previously for osteoporosis screening and smoking cessation services. In most cases it is not possible to obtain all four pieces of information and thus we were not able to present the impact on gender or racial disparities in a quantitative way in analyses conducted in 2004 and 2005.

For reviews where it is not possible to calculate the impact on gender and racial disparities, qualitative information is presented instead. For example, in the CHBRP review of SB 749, autism screening, it was found that there is evidence that Blacks were more likely to have a diagnosis of autism compared to Whites. In addition, evidence was found that indicated that Blacks are diagnosed and treated for autism later compared to Whites. Therefore the review concluded that to the extent that the mandate results in earlier diagnosis and treatment for autism,

this could reduce the disparities between Whites and Blacks in outcomes associated with later diagnosis and treatment (CHBRP, 2005a).

### **Reduction of Premature Death and the Economic Loss Associated with Disease**

The extent to which the proposed service reduces premature death and the economic loss associated with disease is also addressed in the public health impact analysis. In order to quantify the reduction in premature death the following information is needed: 1) baseline mortality data on the disease or condition of interest, 2) coverage impacts of the mandate, 3) utilization impacts of the mandate, and 4) medical impacts of the mandate where mortality is a relevant health outcome. In order to carry out a calculation of the mortality impact the following must be true: 1) mortality must be a relevant health outcome, 2) the mandate would increase coverage or utilization of the benefit, and 3) the mortality impact of the benefit has been established in the medical effectiveness literature. In the case where it is determined that premature death is a relevant health outcome, mortality data are reviewed to determine the baseline magnitude of the problem. In addition, to the extent that reduced mortality is a health outcome reported in the medical effectiveness literature, an impact of the mandate on premature death is conducted using the methodology described above. It has not yet been possible, in the 22 reviews that have been conducted in 2004 and 2005, to quantify the reduction of premature death. In each case the report contains an explanation of why a mortality impact was not calculated.

In order to present an estimate of the economic loss associated with disease, a literature review on the societal costs of illness is conducted. This is separate from the cost analysis, which calculates the direct cost of expanding coverage. Due to the time constraints of the

CHBRP analysis (60 days), it is not possible for the CHBRP team to quantify the indirect costs of disease for each mandate. In lieu of this, a literature review on lost productivity, absenteeism, and quality of life is conducted. In cases where the indirect cost of illness has been estimated for California, these data are presented in the report, if not, national data are presented. Where data on the economic loss associated with a disease have not been published, this is noted in the report.

In order to carry out a calculation of the reduction of the economic loss associated with disease the following must be true: 1) the mandate would increase coverage or utilization of the benefit, and 2) the economic loss associated with disease has been calculated either in California or nationally. It has not yet been possible, in the 22 reviews that have been conducted in 2004 and 2005, to quantify the reduction in economic loss associated with disease, aside from mandates where we conclude that there would be no reduction in the economic loss associated with disease due to the mandate not impacting coverage or utilization. For example in the analysis of Assembly Bill 228, which mandated coverage for organ transplants to HIV+ patients, we concluded that the bill would not result in an increase in the number of organ transplants to HIV+ persons (CHBRP 2005c). Therefore, although there was evidence that end-stage organ disease is associated with significant economic loss through lost productivity, CHBRP concluded that AB 228 would not reduce these economic losses.

## **LIMITATIONS**

It is not always possible to present the required information to satisfy each of the elements of the public health impact analysis as mandated by AB 1996. In instances where there is insufficient evidence, i.e. the evidence in the literature is conflicting or is not robust, this is

noted in the review. In cases where no research has been published on a particular area (gender racial disparities, economic loss, etc.) this is also noted in the review. Common limitations to each of the sections in the public health impact analysis (public health impact, impact on gender and racial disparities, and economic loss and premature death associated with the disease) are noted below.

Additionally, it is not always possible to quantify the overall impact on the health of the community due to methodological limitations of the medical effectiveness literature. These limitations include a lack of consensus within the literature on the clinical definition of the disease, lack of standards of care for treatment, inconsistent inclusion or exclusion criteria across studies, and inconsistency in the measurements of outcomes across studies. Without a quantification of the overall impact of a certain treatment or service, it is impossible to translate the impact of the treatment or service in terms of the health of the community.

In addition, the extent to which the effects of the benefit or treatment that are observed in the literature can be translated to the real world is another limitation to the calculation of the impact on the health of the community. Most of the estimated rates of medical effectiveness used in the public health impact analysis are based on the results of randomized clinical trials, where the populations participating in these trials are rarely broadly representative of the underlying populations with a specific condition. Furthermore, the study population has voluntarily elected to participate in the study and have agreed to receive the treatment. Finally, study participants are often limited to the patients receiving care in a few treatment centers or limited to a specific geographic region, and all of the treating physicians are asked to follow a standardized protocol for delivering treatment. Thus, the treatment in the trials is provided in a

relatively controlled environment that does not necessarily represent the way care is usually provided in the community.

Another limitation is the lack of information on differences in treatment or outcomes of a disease by race and ethnicity.. While baseline health outcome measures in California can be reported by race and ethnicity, it is rarely possible to translate the health effects that result from utilization of mandated services into population health impacts by race and ethnicity, without knowing how health care utilization, treatment practices, and medical efficacy rates vary by race and ethnicity. However, all baseline health data, where there are differences in health outcomes by race and ethnicity in California, are included in the reports prepared for the legislature. As a result, the existing disparities are presented, even if the extent to which the disparities may be reduced as a result of the mandate cannot be assessed.

Finally, it is not always possible to present an analysis of the economic loss associated with disease. It is beyond the scope of the analysis, with a 60-day timeframe, to conduct an analysis of lost productivity and other measures of economic loss of a disease not directly related to treatment. Instead we rely on previously published studies of lost productivity or other measures of economic loss associated with disease. In cases where there has been no previous research estimating the economic loss associated with a particular disease, we are unable to report this information in the review.

## **DISCUSSION**

The findings from the public health impact analysis are presented in each CHBRP report as summarized key findings in the executive summary as well as in one of the three main sections of the report (medical effectiveness, cost, and public health impacts). In addition, public



health impact data and estimates are presented in tabular form at the end of each report. While the findings of the public health impact analyses of benefit mandate bills have not generated any controversy in the political debate and policy discussion over any of the 22 health benefit mandates review laws completed by CHBRP as of August 2005, the public health findings are often referred to in the legislative hearings on the bills, particularly on the part of public health advocates and consumer groups. In fact, even groups who routinely oppose all mandate bills on principle, such as the Association of California Life and Health Insurance Companies and the California Chamber of Commerce, often bow to the potential benefits of the mandated treatment or service on the affected population. In addition, the public health impacts are also often included in the bill analyses prepared by legislative staff, sometimes with entire sections of the CHBRP reports quoted in the analysis.

The only debate that has arisen from these estimates relates to the fact that projected impacts are only made for one year following the bill. Public health groups, in particular, have expressed concern that many health outcomes are not realized after only one year, specifically for many preventive services, where the health benefits are often long term. An effort will be made in future analyses to express in qualitative terms, what the long-term health benefits associated with a mandate might be.

One issue that has been a challenge for the CHBRP analyses is how to present outcomes in such a way that does not make them appear too precise without confusing legislators and their staff. From an academic perspective, the point estimates as presented in the reports have the appearance of precision, when they are simply estimates around which there is a great deal of uncertainty. In a scientific report, one would report that uncertainty in the form of a confidence interval that illustrates the range of findings that are likely not to have occurred by chance.

However, most legislators do not understand the underlying statistical analyses and how to interpret confidence intervals. Policy makers prefer point estimates, and will most likely disregard any confidence intervals presented in the report. To compensate for this, numbers presented in the public health section have been rounded so that they do not appear too precise.

To conclude, the approach that California has adopted to review proposed health benefit mandates represents a leap forward in its consideration of the impact of such mandates on the health of the population. The approach is unique in its specific requirement to address public health impacts as well as the attempt to quantify these impacts by the CHBRP team. Even though there are limitations to the analysis in this regard, the reports that are submitted to the legislature on each bill do highlight the need for these kind of data for a more effective policy-making process. While limitations in the availability of public health and health services data constrain our ability to conduct the analyses, the work being done in California is important in its intent and objectives. Requiring the assessment of public health effects of health benefit mandates suggests that the California legislature, through its enactment of AB 1996, has adopted health improvement as an explicit goal for California's health care system. The requirement to make available this information to the state government has the potential ultimately to increase the availability of health insurance products in California that will maximize public health.

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## TABLES

Table 1: Specific Language Used in Mandate Benefit Review Laws in States where Public Health Impact is Addressed.

State	Reference	Specific Language Regarding Public Health Impacts	Quantify PH Impact in Review
CA	California Law. Health and Safety Code 127660-127665.	1.) the impact on the health of the community, including the reduction of communicable disease and the benefits of prevention such as those provided by childhood immunizations and prenatal care, 2.) the impact on the health of the community, including diseases and conditions where gender and racial disparities in outcomes are established in peer-reviewed scientific and medical literature, and 3.) the extent to which the proposed service reduces premature death and the economic loss associated with disease.	Yes
HI	Hawaii Revised Statutes. Chapter 23, Sections 51-52	(1)The social impact (including). (H) The impact of providing coverage for the treatment or service (such as morbidity, mortality, quality of care, change in practice patterns, provider competition, or related items).	No
ME	Maine Revised Statutes. Title 24A, Chapter 33, Section 2752.	C. The medical efficacy of mandating the benefit, including: (1) The contribution of the benefit to the quality of patient care and the health status of the population...	No
MA	Massachusetts General Laws of Massachusetts. Title 1, Chapter 3, Section 38C.	(2) the medical efficacy of mandating the benefit, including the impact of the benefit to the quality of patient care and the health status of the population ...	No
MN	Minnesota Statutes. Chapter 62J, Section 26.	The evaluation must include... public health, economic, and fiscal impacts of the proposed mandate.	No reviews have been conducted.
WA	Revised Code of Washington. Title 48, Chapter 48.47, Sections 005-900.	(C) Evidence of health care service efficacy: (iii) To what extent will the mandated benefit enhance the general health status of the state residents?	No

Note: These are only portions of the codes that refer specifically to either the public health impacts or health status of the population. This does not imply anything on the remaining requirements of a review such as cost or medical efficacy impacts.

**Table 2: Calculated Public Health Impact of Osteoporosis Legislation on Hip Fractures**

Calculated One Year Post-Mandate	
Target population: Privately insured women ages 50-64	1.8 million
Newly Covered (89% of target pop not currently covered)	1.6 million
Rate of screening among newly covered	30%
Newly screened (#)	480,000
Number of Hip Fractures prevented (1 Prevented/3750 Screened)	128

Source: California Health Benefits Review Program. Analysis of Assembly Bill 438: Osteoporosis Screening. A report to the 2003-2004 California Legislature, February 2004.

**Table 3: Calculated Public Health Impact of Smoking Legislation on Low Birthweight Births**

Calculated One Year Post-Mandate	
Target population: Insured pregnant smokers	40,000
Pregnant smokers newly covered for smoking cessation (30%)	12,000
Difference in Quit Rates between insured and uninsured	22%-14% = 8%
New Quitters = difference in quit rates * newly covered	1000
Number of Low Birthweight (LBW) Births prevented = [Smoker LBW Rate (12%) -Non-Smoker LBW Rate (6%) ]* Number of New Quitters (1000)	60

Source: California Health Benefits Review Program. Analysis of Senate Bill 576: Tobacco Cessation Services. A report to the 2005-2006 California Legislature, April 2005.



## Appendix 13: Clarification of Bill Language and Legislative Intent

CHBRP staff met with key committee and legislative staff to obtain feedback on reports and process improvement. CHBRP and committee staff discussed the challenges of obtaining clarification on ambiguous bill language to ensure consistency with the bill author's intent. We agreed to the following:

- CHBRP staff should continue to have direct conversations with bill author's staff and, when referred by the bill author's staff, the bill's sponsor to clarify ambiguous bill language and legislative intent.
- Committee staff should be involved in discussions, especially at the point of agreement or if they can help in facilitating, furthering discussions with bill author's staff.
- Based on bill language and discussions with bill author's staff, it is reasonable to send in writing CHBRP's analytic decisions so that the analysis can proceed.
- Along those lines, it is important to discuss whether there will be foreseeable amendments that the CHBRP analysis can take into account.
- CHBRP is to determine when to proceed with the analysis—Day 5 is the latest the timeline will allow.
- CHBRP will document discussions and agreements with legislative staff and bill sponsors using the following questionnaire, "Health Insurance Mandate Bill Questionnaire for Bills to be Referred to the California Health Benefits Review Program."

## Health Insurance Mandate Bill Questionnaire

### For Bills to be Referred to the *California Health Benefits Review Program*

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[Bill Number, (Author) and Introduction Date] *(Please use additional pages)*

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Date:

Prepared by:

- I. What would the proposed bill do, specifically:
- What service/benefit is it mandating?
  - Are there any limits on who can provide the service? (e.g., if the service falls within the scope of practice of multiple providers)
  - Are there any limits on the service/benefit?
  - Are there specific enrollee groups the mandate applies to? (e.g., over 65+)
  - What Code is it amending?
- II. What problem is the bill trying to address?
- III. Does the bill have sponsors? If so, who are they? (Please provide contact information)
- IV. Has this insurance mandate been proposed in previous bills? (If so, please provide Bill Number and Legislative Session)
- V. Are there related requirements already in place? If so, where in the Insurance Code or Knox-Keene are they?
- VI. Is this bill to affect the following health insurance market segments (check all that apply):
- Knox-Keene Plans (health care services plans regulated by the Department of Managed Health Care)**
    - Full Service Knox Keene Plans only (i.e., excludes specialized HMOs) (health plans regulated by DMHC)
    - All Knox Keene Plans including specialized HMOs
  - Insurance plans (health policies and plans regulated by the California Department of Insurance)**
  - Private Insurance, including:**
    - Employer-Based plans:
      - Large Group plans
      - Small Group plans
    - Individually purchased plans
  - Public Insurance, including**
    - CalPERS
    - Medi-Cal
    - Healthy Families, or other state programs (e.g., Major Risk Medical Insurance Program, Access for Infants and Mothers)
  - Others:
- VII. As far as you are aware, are there activities in other states that are similar to this proposed bill?
- VIII. Who are anticipated supporters, opponents?
- IX. Are there any plans to amend the bill? If so, can you provide information on what the amendment will be?
- X. Mandate-specific questions: [Add here]





## **Appendix 14: Health Care Service Plans' and Health Insurers' Proprietary Data Document Destruction Policy**

The California Health Benefits Review Program (CHBRP) acknowledges its responsibility to preserve information relating to litigation, audits and investigations. It is a crime to alter, cover up, falsify, or destroy any document to prevent its use in an official proceeding. Failure on the part of employees to follow this policy can result in possible civil and criminal sanctions against CHBRP, the University of California and its employees and possible disciplinary action against responsible individuals (up to and including termination of employment). Each employee has an obligation to contact the CHBRP Director of a potential or actual litigation, external audit, investigation or similar proceeding involving CHBRP that may have an impact as well on the approved records retention and document destruction schedule.

**Documents covered under this policy.** This policy covers "proprietary data," that is, all records and documents that may associate data with a specific health care service plan or health insurer, as referenced in Health and Safety Code Section 127662, that have been received by CHBRP from Health Plans in connection with CHBRP's analytical activities under Health and Safety Code Sections 127660 -127664.

**Document Destruction.** CHBRP is responsible for the ongoing process of identifying its records of proprietary data that have met a maximum retention period of 30 days after the relevant report is submitted to the legislature, and overseeing their destruction. Destruction of the proprietary data may be accomplished by shredding, burning, or sending them to the landfill.

**Electronic Documents.** Electronic documents that reveal proprietary data shall be retained as if they were paper documents. Therefore, any electronic files that contain proprietary data shall be scheduled to be destroyed by the end of the maximum retention period. Destruction of electronic documents may be accomplished by deleting proprietary data from CHBRP's electronic files. Data that has been de-identified by removing the health plan's or health insurer's name may be retained beyond the maximum retention period noted above.

**Suspending Document Destruction.** Upon any indication of an official investigation of CHBRP related to any legal proceeding or by any governmental entity, document destruction shall be suspended immediately. Destruction shall be reinstated upon conclusion of such proceeding.

**Document Retention.** CHBRP shall retain documents for the period of their immediate or current use, unless located in the following document retention schedule.

**Use of Documents.** CHBRP staff shall remove health plan or insurer identifiers prior to circulating it outside of UCOP, including CHBRP-affiliated faculty and contracted actuaries.

Effective date of policy: 12/31/05



## Appendix 15: Other States' Health Benefit Review Programs

During the summer and fall months of 2004, CHBRP staff contacted every state in the United States to determine what organizations, processes, or requirements other states had in place to evaluate health insurance benefit mandates. The following summarizes the objectives, methods, and key findings.<sup>1</sup>

### OBJECTIVES

The objective of this project is to gather and synthesize information about other states' programs that analyze health benefit mandates.<sup>2</sup>

This information is to be used for four main, primarily operational, purposes:

1. To establish ongoing relationships with similar organizations in other states.
2. To identify other states' analyses of benefit mandates.
3. To provide an overview of other states' activities to analyze health insurance benefit mandates.
4. To provide a basis for developing hypothesis about such activities that could be used in subsequent research.

### METHODS: OVERVIEW

- Use of "key informant interview" method to gather information due to:
  - Lack of published analytical literature about the activities related to mandate evaluation programs,
  - Lack of comprehensive data on all 50 states due to recent activity.
- Interview questions designed to meet 4 main objectives as outlined above.

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<sup>1</sup> The findings summarized here differ slightly from those presented in *State Mandate Review Laws* in Appendix 20, Selected Papers in a Forthcoming Issue of *Health Services Research*, due to different methods for obtaining data. *State Mandate Review Laws* examines the characteristics of state laws that have established mandate review evaluation programs in the U.S. while this document summarizes information reported by key informants in each state. Differences between laws that authorize mandate evaluation programs and the actual program implementation occur because: 1) there has not been enough time to develop a program or process in compliance with the new law; 2) the laws do not always explicitly dictate the criteria and steps for mandate evaluations. Therefore the implementation of such laws and policies are subject to interpretation and can vary from time to time (for example, with changes in administration.) 3) State governments and their various departments do not always uniformly implement laws related to mandate evaluation programs or processes even when criteria and steps for evaluations may be explicitly defined. This may occur due to several reasons, including limits on data availability, limits on staff and funding resources, or the political climate in the state.

<sup>2</sup> For the purposes of this project, a mandate is defined per the provisions of AB 1996.

- Information collected consists of 1) responses to interview questions; 2) state laws that establish processes or programs for health benefit mandate evaluations, where applicable; 3) examples of completed mandate evaluations, where applicable 4) other information voluntarily provided by state.

## **DETAILED STEPS**

### **Preparatory Work**

1. During a two week period in January 2004, CHBRP conducted limited research to identify programs or processes other states had in place to evaluate health benefits mandate. The information collected largely consisted of contact information and some general information about program processes.
2. A database was developed, including all 50 states and DC, with relevant program names and contacts where available. The information collected in January was used to initially populate the database.
3. Interview questions were designed to elicit specific information about each states' systems or processes to conduct mandate evaluations, including:
  - whether a particular state had a systematic evaluation process or formal program in place,
  - how each program came into being,
  - the institutional structure and funding mechanism of existing programs, and
  - the scope, process, report format, and dissemination methods for completed analysis.
4. Interview questions were developing by
  - discussing project with National Conference of State Legislatures and learning what information they had in-house,
  - reviewing studies conducted by GAO and the Blue Cross and Blue Shield Association, and
  - using CHBRP as a reference point to obtain comparative information.

### **Identifying Key Informants**

1. For each state, an Internet search was conducted. Search strings included: “[state name] health benefit mandate”, “[state name] health mandate study”, “[state name] health insurance mandate” and similar variations.
2. Contacted individuals with whom CHBRP staff had already established contact in January.
3. For states for with no contact information in the database, staff contacted:
  - state department/bureau of insurance (generally, first),

- chairpersons of legislative committees (on health, insurance or related matters),
- other state legislators with a record of having drafted legislation relating to benefits mandate evaluation programs or moratoria on mandates, if applicable,
- other state agencies (e.g. department of health),
- interest groups that appeared to track health insurance mandates within their state (e.g., small business associations, chambers of commerce) to see whether they knew of an existing program and which state agency or office CHBRP should contact, and/or
- other “leads” resulting from literature or web-based research, such as special commissions on health (e.g. Wyoming HealthCare Commission).

4. If the initial contact was not knowledgeable, staff pursued other sources as listed above.

For states that had no formal program or process, staff obtained information from at least two sources to verify non-existence. At least one of these sources included the staff with a legislative committee on insurance/health or the state department of insurance.

**TABLE 1: INTERVIEW QUESTIONS TO KEY INFORMANTS IN OTHER STATES:**

<b>Basic contact</b>	
1	Organization name, Contact's name, address, phone numbers, email, website
<b>History</b>	
2	How were you established (e.g. legislation? charged by Governor? charged by State Insurance Commissioner?)
3	When did the organization come into being?
4	How many studies have been completed in this time?
<b>Structural</b>	
5	What is your charge/mission/organizational goal?
6	Where does the organization fit within the state's governmental framework? (related: Is it independent?)
7	What is the primary source of funding?
8	Do you specifically document or examine potential conflicts of interests?
9	Do you have committees? If so, what type are they (i.e. having governance authority or are strictly advisory?)
<b>Analysis-specific</b>	
10	Is the trigger to perform an assessment automatic, or is it only by request? If by request, when does this have to be received?
11	Do you make recommendations? (related: Are there any constraints on reporting of findings?)
12	Do you study proposed legislation and/or passed legislation? Do you examine cumulative impacts?
13	What type of analyses do you perform (i.e. actuarial, public health, medical effectiveness, other)? a. Do you have specific criteria for assessing the effectiveness and/or a process for determining the hierarchy of evidence?
14	What are the steps involved in completing the analysis? a. What fields of expertise do you have represented on staff? Do you employ independent consultants? b. Do you use assessments performed by other groups or organizations?
15	Does your state Medicaid program have a process to assess new technologies, benefits or services for benefit determinations? If so, what is the process?
16	What is the timeframe for completing an assessment?
17	Do you put out requests for information (RFI)? To whom? (e.g. Stakeholders: health plans/insurers, consumers groups, provider community, public commentary)
18	Are you required to examine mandates effects on other state programs such as Medicaid, SCHIP, etc.? Do you examine transfer or secondary effects (e.g. private sector to Medicaid or private sector to uninsured?)
19	What is the format of your output? (e.g. reports, testimony)
20	To whom are findings released? Are they publicly available? Can you provide examples?
21	How are your impact assessments used and by whom?
22	If analyzing proposed legislation, do you track the legislation? How?
23	How do you deal with amendments and changes to legislation after the initial request?
24	What is your analysis review process? Is it sent to external parties (e.g. non-authors and/or those who do not have a direct stake in the outcome of the mandate)?

## **Interviews and information collection**

1. Interview format was a conversation where interview questions acted as conversation guides.
2. Key informants in states with any form of established program were asked the complete set of interview questions with probing questions as necessary (e.g. existing legislation, analysis that was publicly available.)
3. Those in states with no program were asked additional probing questions about other programs that may have previously existed, or proposals that were to set up mandate evaluation programs or process. Those questions necessary to confirm non-existence of a program were asked.
4. Interview responses documented in database mentioned above.
5. Key informants in all states were asked to provide relevant documentation, including but not limited to, copies of state laws establishing the mandate evaluation program as well as any samples of completed analyses. States whose studies were limited to fiscal impact of legislation on state agencies (and not financial impact on insurers) were asked follow-up questions to verify that their financial studies did not include the impact to those privately insured (non-ERISA exempt) and, when appropriate, for copies of these fiscal analyses. All hard copy files by state are maintained at CHBRP office.
6. A contact log was maintained during the key informant search phase, interview phase and validation phase.

## **Validation**

1. Responses to interview questions are currently being validated by comparing responses with other sources. For example, states that we found to have mandate evaluation program were cross-checked against Blue Cross and Blue Shield Association December 2003 listing and American Association of Health Plans (now known as America's Health Insurance Plans) 2004 listings of states with existing mandated benefit evaluation laws.
2. Responses were compared in a limited fashion, with information included on the states' web sites. This was done for states that had web sites with information on their mandate evaluation programs.
3. Completed interview questions and responses were sent via email to the key informant (and/or a co-worker or supervisor when necessary) with a request to verify our documentation of their responses. Contacts have been asked to reply with any additional corrections within one week. One week, after the deadline was passed a reminder email was sent out. After another ten days, a follow up phone call is made.

4. Follow-up contact is made with states to clarify points of confusion and discrepancies between sources or to follow up on responses that have altered dramatically from initial interview phase to validation phase without sufficient explanation.

## FINDINGS

These findings are based on validated survey questions with all 49 states plus the District of Columbia. However, KS, KT, NM, TN, WV, and WY were contacted, interviewed, sent verification but the final responses were not validated (i.e. due to non-response).

1. 26 states some form of a systematic process or program in place, defined as follows:
  - a. program/process must at least evaluate the financial impact of a mandate. This may include proposed mandates in bill form or retrospective analyses of existing mandates on private insurers and/or insured.
  - b. process must be “regular” in that 1) those who are responsible for conducting the evaluations do so per the provisions of state law (if applicable), 2) the process is automatically triggered by the nature of the legislative process (e.g., when bill is proposed; when bill gets a 2<sup>nd</sup> hearing; when it is being heard in committee with jurisdiction), or 3) the process is triggered by request of the state legislature or a state agency or 4) the process occurs at some regular interval defined by policies or law (e.g. annually, every 5 years).
2. 29 states have legislation that requires or authorizes some form of health benefit mandate evaluation or have some form of a systematic process or program in place. The majority of these states have either established a program specifically for this purpose (e.g., a commission) or assigned the duty to an existing staff. A few require the bills’ sponsors to submit an evaluation of the mandate’s probable impact as part of the analysis for legislative hearings (See Table 2 for a summary of these programs and where they are housed in each state).
3. Differences between laws that authorize mandate evaluation program or processes and the actual processes implemented occur frequently because:
  - a. The law is so new that there has not been enough time to develop a program or process in compliance with the law (as of the point of contact with CHBRP staff)
  - b. The laws do not always explicitly dictate the criteria and steps for mandate evaluations. Therefore the implementation of such laws and policies are subject to interpretation and can vary from time to time (for example, with changes in administration).
  - c. State governments and their various departments do not always uniformly implement laws related to mandate evaluation programs or processes even when criteria and steps for evaluations may be explicitly defined. This may occur due to several reasons, including limits on data availability, limits on staff and funding resources, or the political climate in the state.

- d. When the mandate evaluation law places the onus of conducting the evaluation on the sponsor of the legislation, it is difficult for any one state entity to enforce—the responsibility to enforce the law becomes diffuse.
4. The steps involved in performing the analyses vary considerably in 2 main regards:
  - a. Independent research, contracted services, information from interested parties
  - b. Nature of questions addressed
5. Nearly all programs are funded by the respective state’s general funds. California and Colorado are unique in that the programs are funded through assessing fees on health insurers.
6. 11 states are permitted or requested to make recommendations.
7. No other states appear to expressly address conflict of interest issues, however, most did not consider this question to be applicable since analyses are conducted by state employees or their contractors (and are thereby bound by state codes). Programs that are commission-based were generally designed to represent various and balanced interest of stakeholders.
8. Based on the conversations with the key informants the following are the scope of analyses they have conducted as of 2004
  - a. 26 (all) analyze cost impact: defined as analyzing impact on the private health insurance sector, as opposed to the fiscal impact on state budget
  - b. 5 analyze public health: defined as reporting on the impact of the mandate on the health of the population
  - c. 14 analyze medical effectiveness: defined broadly as reviewing and reporting on the medical literature
  - d. 13 analyze “social impact”: defined impacts on coverage and utilization levels
9. Observations on Cost:
  - a. Defined as analyzing impact on the private health insurance sector, as opposed to the fiscal impact on state budget
  - b. Many appear to analyze the total cost of the benefit versus the marginal cost of mandating the benefit
  - c. Focus of all programs
    - emphasizes on premium impacts and costs to the state.
    - Most review coverage and utilization levels (which is also sometimes called “social impact”)
10. Observations on Effectiveness:
  - a. Defined broadly as reviewing and reporting on the medical literature
  - b. Wide variation in whether/how states routinely analyze medical effectiveness.
  - c. No states report having express criteria for analyzing the literature. Note: As some contract for medical analytic services, the systematic nature of their approach is difficult to assess.



11. Observations on Public Health:
  - a. Defined broadly as reporting on the impact of the mandate on the health of the population. None appear to systematically quantify public health outcomes based on the medical literature and analysis on changes in utilization.
  - b. “Social impacts” typically include coverage and utilization criteria
  - c. Only 5 states perform public health impact analyses
12. All states performing mandates said that their records are publicly available. The manner of availability varies widely from “available on request” to access via the internet to public dissemination of findings.
13. States’ responses to questions related to the specifics of analyses were occasionally met with some uncertainty. For example, if they evaluated medical effectiveness, they were able to state that they (or their contractor) conducted a literature review but did not know if a hierarchy of evidence was created to assess effectiveness. To obtain more reliable information, examples of analyses, where available, were reviewed.

**TABLE 2: OTHER STATES' HEALTH BENEFITS REVIEW PROGRAMS:  
INSTITUTIONAL STRUCTURE**

STATE (1)	Commission (2)	Department of Insurance (3)	Legislative Services (4)	Sponsors (5)	Other State Agency (6)	University
Arizona				√		
Arkansas	√					
California						√
Colorado (7)	√			√		
Florida				√		
Georgia		√				
Hawaii (8)			√			
Indiana (9)	√	√				
Kansas					√	
Kentucky		√				
Louisiana			√			
Maine		√				
Maryland	√					
Massachusetts					√	
Minnesota					√	
Nevada (10)			√			
New Hampshire		√				
New Jersey	√					
North Carolina			√			
North Dakota			√			
Ohio			√			
Pennsylvania	√					
South Carolina	√					
Tennessee			√			
Texas		√				
Utah		√				
Virginia	√					
Washington					√	
Wisconsin		√				

(1) States listed here have a formal mandate evaluation program or process; or they have a law requiring evaluation of health insurance mandate bills by sponsors of a bill.

(2) Commission-based programs usually consist of individuals appointed by the executive branch, the legislative branch and represent different industry and consumer interests. Commissions that evaluate health insurance benefits often conduct other types of analysis related to health care programs in the state.

(3) "Department of Insurance" programs includes the "Insurance Commissioner," "Office of Insurance" or the equivalent agency in that respective state. These are housed in the executive branch of the state government.

(4) "Legislative Services" programs include those that are housed at the departments or agencies designed to support the state legislature.

(5) The requirement for conducting evaluations falls primarily on the bill sponsors. Sponsors may mean a member of the state legislature but usually mean an outside organization or association advocating for passage of the bill.

(6) "Other State Agency" programs include those that are housed at another agency under the executive branch besides the Department of Insurance

(7) Colorado has two separate laws: One creates a mandate evaluation commission that is to sunset in May 2005 and another law requires any sponsor of a legislation to provide a "social" and "financial" impact analysis of the proposal to the legislative committee with jurisdiction.

(8) Hawaii's mandate evaluation is conducted by the State Auditor, who reports to and is considered part of the legislative branch.

(9) Indiana has a "Mandate Health Benefit Task Force" whose members are appointed by the Governor and is staffed by the Insurance Commissioner

(10) Nevada's legislature passed two concurrent resolutions to study 1) the cost of existing mandates (1990) and 2) whether any existing mandates ought to be repealed (1992). Both of these were conducted by subcommittees appointed by the Legislative Commission.

Source: California Health Benefits Review Program, 2004.



## Appendix 16: Responses to Inquiries from Interested Stakeholders

This appendix contains two examples of correspondence between CHBRP and interested parties. As evidenced by these letters, submissions by interested parties typically seek to offer additional research bearing on the bill analysis, or ask for further clarification about the method used in the cost or public health impact of the bill. Submissions by interested parties are available upon request.

- **Assembly Bill 213: Lymphedema.** The first example is CHBRP correspondence with Mr. Robert Weiss, an advocate on behalf of patients with lymphedema. CHBRP's response letter illustrates the approach for weighing information provided by a stakeholder. In this case, CHBRP provides a table describing how each article was considered and why a specific article may not have met the criteria for inclusion. As illustrated, an article may fall short of the inclusion criteria for various reasons (e.g., the study design is relatively low on the hierarchy of study designs, the research is outdated, the article is published in a language other than English). This systematic way of reviewing articles is key to conducting a fair analysis of the literature within the first two weeks of the 60-day timeframe.
- **Senate Bill 913: Biological Medications for Rheumatic Disease.** The second example is CHBRP correspondence with Mr. Tom Murphy, Chair of The California Arthritis Foundation Council. CHBRP's response letter illustrates the approach taken when interested parties seek clarification of the methods for the cost or public health impact. As illustrated by the letter, CHBRP's approach is to provide information or clarification regarding the underlying assumptions, data sources and discrete steps taken to produce its estimates.



*Via email from Mr. Robert Weiss to Michael Gluck, Director, CHBRP,  
On Tue, Aug 23, 2005, at 11:01 PM, PDT, lymphactivist@aol.com*

Dear Dr. Gluck,

I noticed that the CHBRP analysis of SB 576 has been through two revisions, even though the original analysis was to have been the "final" analysis. I would like to know what is the process whereby factual omissions, incorrect statements, and other errors in a "final" analysis may be corrected. If not corrected the Health Committee members will be taking action on the basis of faulty and incorrect information.

The analysis I refer to is the "CHBRP Analysis of Assembly Bill 213 Health Care Coverage for Lymphedema" issued April 7, 2005. I would like to know the procedure for my bringing to the attention of the CHBRP corrected facts, additional analyses bearing on the bill that was not covered in the analysis, and comments on the approach taken which involved collection of incomplete data, and drawing conclusions on assumptions which are not evidence based. I submitted a detailed "before the analysis" brief with extensive evidence and data during the comment period but did not see any of my data used in the final analysis.

I am prepared to present additional comments based on the published analysis and additional data to the CHBRP in person and answer any questions the analysts may have.

Thank you for your attention.

Sincerely,  
Robert Weiss M.S.  
Lymphedema Treatment Advocate  
National Lymphedema Network

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Mr. Robert Weiss  
Lymphedema Activist  
10671 Baton Rouge Ave.  
Northridge, CA 91326  
Via email: [LymphActivist@aol.com](mailto:LymphActivist@aol.com)

September 16, 2005

Dear Mr. Weiss:

Thank you for your email inquiry of August 24, 2005 regarding the California Health Benefits Review Program's (CHBRP's) *Analysis of Assembly Bill 213: Health Care Coverage for Lymphedema*.

Your email requested:

- 1) Clarification on the process by which CHBRP undertakes revisions to make corrections to analyses already submitted to the Legislature.
- 2) Information on how CHBRP considered and used the data that you provided to us while we were conducting the analysis.

### **Process and Criteria for Revising Completed Analysis**

Per the provisions of Assembly Bill 1996 (*California Health and Safety Code*, Section 127660, et seq.), CHBRP responds to requests from the State Legislature to provide analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates within a 60-day time period. Within the statutory 60-day time period, CHBRP makes every effort to analyze the body of existing literature and available data to produce a report responsive to the analytic criteria specified in AB 1996.

Our policy on issuing revisions is that we only reissue a report if we uncover an error. Because the body of existing literature and available data is constantly evolving, we do not reissue a report when a new study is published or when new or updated data become available. Otherwise, we would be in the position of constantly reissuing reports. However, if a bill that we have analyzed in a previous legislative session is taken up again by the State Legislature and we are presented with a request for analysis, we will certainly update the literature review and analyze any new or updated data.

### **How CHBRP Considered and Used the Information You Submitted**

Within the first two weeks of obtaining a request from the State Legislature, CHBRP staff post on our Web site 1) the request letter, 2) the bill that we are requested to analyze, and 3) a solicitation to interested parties to submit information by a specified date. You provided a wealth of information, including published articles as well as your own research, and you did so in time for us to review the information during the analysis period.

The information that we receive from interested parties is subject to the *same* criteria we impose on the literature that we gather through our own internal literature search and review. While the literature review may result in several references—in the case of AB 213 over one hundred—, in CHBRP analyses we rely on a hierarchy of study designs to help us rank-order studies—from those that are most reliable, authoritative, and comprehensive to those in which research methodologists have less confidence, such as case reports and other kinds of studies in which alternative treatments are not evaluated by randomization.

In this hierarchy, formal meta-analyses of randomized clinical trials and systematic reviews of such trials are given the greatest weight, followed by evidence-based guidelines and individual randomized trials and then by such observational (non-randomized) study designs as case reports (of individual patients) or case series (of groups of patients).

In addition, due to time constraints, we only review articles that are published in English and those that have been published recently so that we are sure to be aware of changes in techniques of treatment that have occurred over time. If you are interested in learning more about our literature review and medical effectiveness analysis methods please see: *Evaluating Medical Effectiveness for the California Health Benefits Review Program* at: [http://www.chbrp.org/documents/medeffect\\_paper.pdf](http://www.chbrp.org/documents/medeffect_paper.pdf).

We have attached here, for your reference, a detailed table that shows 1) documents and citations referenced in the information you provided, 2) document type, 3) whether we reviewed the document or citation, 4) whether the document was cited in the final analysis, and 5) whether the document met our criteria for inclusion in the literature search and review. It should be noted that whenever a document you submitted met our criteria for inclusion and did not meet any of the criteria for exclusion, we included it in our analysis.

Finally, you submitted documents that included your analysis regarding the appropriateness of providing health coverage for the treatment of lymphedema. While we reviewed these materials, we are not able to rely on your analysis, since CHBRP is required to conduct our own medical effectiveness analysis. However, we certainly examined the source references you cited—a summary of how we treated those references is also included in the attached table.

Thank you again for the detailed information that you provided for our consideration in the *Analysis of Assembly Bill 213: Health Care Coverage for Lymphedema*. CHBRP values the input provided to us from all stakeholders and we will continue to make every effort to ensure that we review such input appropriately. We hope this letter answers the questions you raised. Please feel free to contact Susan Philip, Assistant Director, at 510-287-3877 or [susan.philip@chbrp.org](mailto:susan.philip@chbrp.org) if you have further comments or questions.

Sincerely,



Jeffrey Hall  
Director, Legislation and Policy  
Office of Health Affairs



**AB 213 Document Analysis**

**Documents Provided by Robert Weiss and Actions Taken by UCSF Medical Effectiveness Team with Documents**

Doc. #	Doc title	Doc type	Reviewed	Cited study in analysis	Did not meet inclusion criteria	Other comments
1	National Lymphedema Network	Brochure	yes	no	✓	
2	Cost-Efficacy of Lymphedema Treatment- Preliminary Model	Poster presentation (not peer-reviewed)	yes	no	✓	
3	Boris M, Weindorf S Lasinski B. (1997): Persistence of lymphedema reduction after complex lymphedema therapy	Peer- reviewed journal article: Case reports	yes	no (but other papers by these authors were included)	✓	
4	Campisi C, Boccardo F, Zilli A, et al (2001): The use of vein grafts in the treatment of peripheral lymphedemas: long term results	Peer reviewed journal article: Observational study	yes	no	✓	Surgical techniques not evaluated for this mandate
5	Campisi C, Boccardo F, Zilli A, et al (2001): Long-term results after lymphatic-venous anastomoses for the treatment of obstructive lymphedema	Peer-reviewed journal article: Observational study	yes	no	✓	Surgical techniques not evaluated for this mandate
6	Casley-Smith JR, Boris M, Weindorf S et al (1998): Treatment for lymphedema of the arm- the Casley-Smith method, a noninvasive method produces continued reduction (1998)	Peer-reviewed journal article: Cost-effectiveness analysis	yes	no	✓	
7	Daane S, Poltoratszy P, Rockwell WB (1998): Post-mastectomy lymphedema management: evolution of the complex decongestive therapy technique	Peer-reviewed journal article: Historical; observational study	yes	no	✓	
8	Foldi E (1996): Prevention of dermatolymphangioadenitis by combined physiotherapy of the swollen arm after treatment of breast cancer	Peer-reviewed journal article: Observational study	yes	yes		Used because no RCT of this outcome were found
9	Ko D, Lerner R, Klose G (1998): Effective treatment of lymphedema of the extremities	Peer -reviewed journal article: Observational (prospective study)	yes	no	✓	
10	Krishnamoorthy K (1999): Estimated costs of acute adenolymphangitis to patients with chronic manifestations of bancroftian filariasis in India	Peer-reviewed journal article: Cost-benefit analysis	yes	no	✓	

**AB 213 Document Analysis**

**Documents Provided by Robert Weiss and Actions Taken by UCSF Medical Effectiveness Team with Documents**

Doc. #	Doc title	Doc type	Reviewed	Cited study in analysis	Did not meet inclusion criteria	Other comments
11	Lerner, R (1998): Complete decongestive physiotherapy and the Lerner Lymphedema Services Academy of lymphatic studies (the Lerner School)	Peer-reviewed journal article: Historical/observational study	yes	no	✓	
12	Miller SR, Mondry T, Reed JS, et al., (1998): Delayed cellulitis associated with conservative therapy for breast cancer	Peer reviewed journal article: Case series	yes	no	✓	
13	O'Brian BM, Mellow CG, Khazanchi RK, et al., (1990): Long-term results after microlymphaticovenous anastomoses for the treatment of obstructive lymphedema	Peer reviewed journal article: Observational study	yes	no	✓	Surgical techniques not evaluated for this mandate
14	Reid T (1996): Treatment of lymphedema and recurrent cellulitis	Peer-reviewed journal article: Case report	yes	no	✓	
15	Cost-Efficacy of lymphedema treatment: a collection of case studies	Questionnaire and case studies provided by Mr. Weiss	yes	no	✓	
16	Fact Sheet on Lymphedema	Document provided by Mr. Weiss (not peer-reviewed)	yes	no	✓	
17	WSJ Health Journal: Efforts mount to combat lymphedema, a devastating side effect of cancer care	Newspaper article	yes	no	✓	
18	Letter written by Sadkia R.J. Thiadens, R.N.	Letter	yes	no	✓	
19	The case for lymphedema treatment legislation	Information package	yes	NA	✓	
20	Health System Burden (submitted by Mr. Weiss)	News report	yes	no	✓	
21	Chrikos TN, Russell-Jacobs A, Cantor AB et al (2002): Indirect economic effects of long-term breast cancer survival (abstract submitted by Mr. Weiss)	Peer-reviewed journal article: Cohort study (not a RCT)	yes	no	✓	
22	Lymphedema Treatment Cost-Effectiveness References (see above entries for individual references in the document)	List of references with first author's last name and year	yes	no		Insufficient information to look up references
23	Rockson SG, Miller LT, Senie R, et al (1998): Workgrop III: Diagnosis and management of lymphedema	Consensus statement	yes	yes		This paper was cited in the report but was not used for information on outcomes

**AB 213 Document Analysis**  
**Documents Provided by Robert Weiss and Actions Taken by UCSF Medical Effectiveness Team with Documents**

Doc. #	Doc title	Doc type	Reviewed	Cited study in analysis	Did not meet inclusion criteria	Other comments
24	Rationale for the provisions of the proposed state bill for lymphedema treatment	Position statement	yes	no	✓	
25	Structure for a cost-efficacy study of lymphedema treatment	Document provided by Mr. Weiss (not peer-reviewed)	yes	no	✓	
26	<b>AB-1996 Responses (see below for references cited in this document)</b>	Document provided by Mr. Weiss (not peer-reviewed but containing many peer-reviewed references)	yes	no	✓	Although this document was not cited in the analysis, many of the references were cited.
27	Andersen L, Hojris I, Erlandsen M, et al (2000): Treatment of breast-cancer related lymphedema with or without manual lymphatic drainage- a randomized study	Peer-reviewed journal article: RCT	yes	yes		
28	Asdonk J (1975): Manuelle lymphdrainage, ihre wirkungsart, indikation und kontraindikation	Peer-reviewed journal article	yes	no	✓	Not in English
29	Asdonk J (1978): Improvement of circulation by manual drainage of lymph (in French)	Peer-reviewed journal article	yes	no	✓	Not in English
30	Asdonk J (1981): Physical lymph drainage and therapy of edema in chronic venous insufficiency (in German)	Peer-reviewed journal article	yes	no	✓	Not in English
31	Asdonk J (1983): Physical lymphatic drainage and edema therapy at the Feldberg Clinic	Peer-reviewed journal article	yes	no	✓	Not in English
32	Asdonk J (1995): Effectiveness, indications and contraindications of manual lymph drainage in painful edema (in German)	Peer-reviewed journal article	yes	no	✓	Not in English
33	Asdonk J, Bartetzko-Asdonk (1980): Diagnostik und richtlinien zur physiakalischen therapie beim postmastecktomischen, chronisch-progredienten armlymphodem	Peer-reviewed journal article	yes	no	✓	Not in English

**AB 213 Document Analysis**

**Documents Provided by Robert Weiss and Actions Taken by UCSF Medical Effectiveness Team with Documents**

Doc. #	Doc title	Doc type	Reviewed	Cited study in analysis	Did not meet inclusion criteria	Other comments
34	Badger CM, Peacock, JL, Mortimer PS (2000): A randomized, controlled, parallel-group clinical trial comparing multilayer bandaging followed by hoisery versus hoisery alone in the treatment of patients with lymphedema of the limb	Peer-reviewed journal article: RCT	yes	yes		
35	Box RC, Reul-Hirche HM, Bullock-Saxton JE et al (2002): Physiotherapy after breast cancer surgery: results of a randomized controlled study to minimise lymphedema	Peer-reviewed journal article: RCT	yes	no		This study only looked at the effects of individual risk assessment and patient education
36	Brennan MJ and Weitz J (1992): Lymphedema 30 years after radical mastectomy	Peer-reviewed journal article: Case report	yes	no	✓	
37	Brennan MJ (1992): Lymphedema following the surgical treatment of breast cancer: a review of pathophysiology and treatment	Peer-reviewed journal article: Review	yes	no	✓	
38	Campisi C, Boccardo F, Zilli A et al (2002): Lymphedema secondary to breast cancer treatment	Peer-reviewed journal article	yes	no	✓	Not in English
39	Boris M, Weindorf S Lasinski B (1998): The risk of genital edema after external pump compresion for lower limb lymphedema	Peer-reviewed journal article: Observational study	yes	yes		This study was cited because there were no RCT of the same outcome
40	Casley-Smith JR (1995): Alterations of untreated lymphedema and its grades over time	Peer-reviewed journal article- Observational study	yes	no	✓	
41	Casley-Smith JR (1992): Modern treatment of lymphoedema	Peer-reviewed journal article: Observational study (not a RCT)	yes	no	✓	
42	Erickson VS, Pearson ML, Ganz PA et al (2001): Arm edema in breast cancer patients	Peer-reviewed journal article: Observational study (not a RCT)	yes	yes	✓	This study was cited because there were no RCTs of the same outcome

**AB 213 Document Analysis**

**Documents Provided by Robert Weiss and Actions Taken by UCSF Medical Effectiveness Team with Documents**

Doc. #	Doc title	Doc type	Reviewed	Cited study in analysis	Did not meet inclusion criteria	Other comments
43	Howell D, Ezzo J, Bily L(2005): The effects of complete decongestive therapy or manual lymphatic drainage alone on women with secondary lymphedema following treatment for breast cancer	Cochrane report	yes	yes		This Cochrane reivew was not yet completed at the time of the preparation of the report.
44	International Society of Lymphology, Executive Committee: The diagnosis and treatment of peripheral lymphedema (1995)	Consensus statement	yes	no		A newer document (see below) was reviewed instead
45	International Society of Lymphology, Executive Committee: The diagnosis and treatment of peripheral lymphedema (2003)	Consensus statement	yes	yes		This paper was cited in the report but was not used for information on outcomes
46	Johannson K, Lie E. Ekdahl C, Lindfeldt J et al (1998): A randomized study comparing manual lymph drainage with sequential pneumatic compression for the treatment of postoperative arm lymphedema	Peer-reviewed journal article: RCT	yes	yes		
47	Johannson K, Albertsson M, Ingvar C (1999): Effects of compression bandaging with or without manual lymph drainage treatment in patients with postoperative arm lymphedema	Peer-reviewed journal article: RCT	yes	yes		
48	Jungi WF (1981): The prevention and management of lymphedema after treatment for breast cancer	Peer-reviewed journal article: Treatment suggestions	yes	no	✓	
49	Ko DSC, Lerner R, Klose G et al (1998): Effective treatment of lymphedema of the extremities	Peer- reviewed journal article: (not a RCT)	yes	no	✓	
50	Leduc O, Leduc A, Bourgeois P, et al (1998): The physical treatment of upper limb edema	Peer-reviewed journal article (not a RCT)	yes	no	✓	
51	McNeely ML, Magee DJ, Lees AW, et al (2004): The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial	Peer-reviewed journal article: RCT	yes	yes		

AB 213 Document Analysis

Documents Provided by Robert Weiss and Actions Taken by UCSF Medical Effectiveness Team with Documents

Doc. #	Doc title	Doc type	Reviewed	Cited study in analysis	Did not meet inclusion criteria	Other comments
52	Mirola BR, Bunce IH, Chapman M (1995): Psychosocial benefits of postmastectomy lymphedema therapy	Peer-reviewed journal article: Observational study	yes	no	✓	
53	Mortimer PS (1998): The pathophysiology of lymphedema	Peer-reviewed journal article: Review of causes of lymphedema	yes	no	✓	
54	NIH NCI (2004) Website: Lymphedema PDQ® (Materials for patients): <a href="http://www.nci.nih.gov/cancertopics/pdq/supportivecare/lymphedema/patient">http://www.nci.nih.gov/cancertopics/pdq/supportivecare/lymphedema/patient</a>	NIH Patient Support Website	yes	no	✓	Information helpful in writing report
55	Ochsner A, Longacre AB, Murray SD (1940): Progressive lymphoedema associated with recurrent erysiploid infection	Peer-reviewed journal article	yes	no	✓	
56	Passik SD, McDonald MV (1998): Psychosocial aspects of upper extremity lymphedema in women treated for breast carcinoma	Peer-reviewed journal article: Review	yes	no	✓	
57	Petrak JA, Lerner R. Lymphedema, In Harris JR, Lippman ME, Morrow M et al. <u>Diseases of the Breast</u> (1996)	Book	yes	no	✓	
58	Petrak JA, Heelan MC (1998): Incidence of breast carcinoma-related lymphedema	Peer-reviewed journal article( not a RCT)	yes	no	✓	
59	Petrak JA, Senie RT, Peters M, et al (2001): Lymphedema in a cohort of breast carcinoma survivors 20 years after the diagnosis of cancer	Peer-reviewed journal article: Observational study (not a RCT)	yes	no	✓	
60	Sackett DL, Richardson WS, Rosenberg W, et al (1997): <u>Evidence-based medicine: How to practice and teach EBM</u>	Book	yes	no	✓	
61	Schneider W, Schuchhardt Ch, Vollmer A, et al (2002): Fehlerhafte Kompressionsstrumpfversorgung, Folgen und Konsequenzen [Results and consequences of lymphedema treatment based on insufficient compression stockings]	Peer-reviewed journal article	yes	no	✓	Not in English
62	Schunemann H, Willich N (1997): Lymphoedema nach Mammakarzinom [Lymphedema after breast carcinoma. A study of 5868 cases]	Peer-reviewed journal article: Observational study	yes	no	✓	Not in English

**AB 213 Document Analysis**

**Documents Provided by Robert Weiss and Actions Taken by UCSF Medical Effectiveness Team with Documents**

Doc. #	Doc title	Doc type	Reviewed	Cited study in analysis	Did not meet inclusion criteria	Other comments
63	Simons MS, Cody RL (1992): Cellulitis after axillary lymph node dissection for carcinoma of the breast (1992) Note: article found on PubMed under name of "Simon"	Peer-reviewed journal article: Review	yes	no	✓	
64	Stoberl C and Partsch H (1987): Erysipel und Lymphodem: Ei oder henne? [Erysipelas and lymphedema: egg or hen?]	Peer-reviewed journal article	yes	no	✓	Not in English
65	Swenson KK, Nissen MJ, Ceronsky et a; (2002): Comparison of side effects between sentinel lymph node and axillary lymph node dissection for breast cancer	Peer-reviewed journal article: Observational study (not a RCT)	yes	no	✓	
66	Szuba A, Achalu R, Rockson SG (2002): Decongestive lymphatic therapy for patients with breast carcinoma-associated lymphedema: a randomized, prospective study of a role for adjunctive intermittent pneumatic compression	Peer-reviewed journal article- RCT	yes	yes		
67	Szuba A, Rockson SG (1997): Lymphedema: anatomy, physiology and pathogenesis	Peer-reviewed journal article (not a RCT)	yes	no	✓	
68	Szuba A, Shin Ws, Strauss HW, et al (2003): The third circulation: radionuclide lymphoscintigraphy in the evaluation of lymphedema	Peer-reviewed journal article (not a RCT)	yes	no	✓	
69	Thiadens SRJ, Rooke TW, Cooke JP (1992): "Lymphedema" in <u>Current Management of Hypertensive and Vascular Diseases</u>	Book	no	no	✓	
70	Velanovich V, Szymanski W (1999): Quality of life of breast cancer patients with lymphedema	Peer-reviewed journal article (not a RCT)	yes	no	✓	
71	Vodder E (1936): Le drainage lymphatique, une nouvelle methode therapeutique [Lymphatic drainage, a new therapeutic procedure]	Peer-reviewed journal article (not a RCT)	yes	no	✓	Not in English
72	Vodder E (1966): Die manuelle lymphdrainage und ihre medizinischen anwendungsgebiet	Peer-reviewed journal article (not a RCT)	yes	no	✓	Not in English
73	Vodder E (1969): La methode Vodder- le drainage lymphatique manuel	Description of method	yes	no	✓	Not in English

AB 213 Document Analysis

Documents Provided by Robert Weiss and Actions Taken by UCSF Medical Effectiveness Team with Documents

Doc. #	Doc title	Doc type	Reviewed	Cited study in analysis	Did not meet inclusion criteria	Other comments
74	Warsi A, Wang PS, LaValley (2004): Self-management education programs in chronic disease: a systematic review and methodological critique of the literature	Peer-reveiwed journal article:Review (not a RCT)	yes	no	✓	
75	Williams AF, Vadgama A, Franks PJ et al (2002): A randomized controlled crossover study of manual lymphatic drainage therapy in women with breast cancer-related lymphedema	Peer-reviewed journal article :RCT	yes	yes		
	<b>References found in the article by Rockson, et al (1998) that was submitted by Mr. Weiss</b>					
76	Schunemann H, Willich N (1992): Secondary lymphedema of the arm following primary therapy of breast carcinoma	Peer-reviewed journal article: Observational study	yes	no	✓	Not in English (name of journal is in German)
77	Partsch H (1995): Assessment of abnormal lymph drainage for the diagnosis of lymphedema by isotopic lymphangiography and by indirect lymphography	Peer-reviewed journal article:Review	yes	no	✓	
78	Svensson WE, Mortimer PS, Tohno (1994): Colour Doppler demonstrates venous flow abnormalities in breast cancer patient with chronic arm swelling	Peer-reviewed journal article- Observational study	yes	no	✓	
79	Foldi E, Foldi M, Weissleder (1985): Conservative treatment of lymphedema of the limbs	Peer-reveiwed journal article: Review/discussion of treatment	yes	no	✓	
80	Casley-Smith JR, Morgan RG, Pillar NB (1998): Treatment of lymphedema of the arms and legs with 5,6 benzo-pyrone	Peer-reviewed journal article: RCT	yes	no	✓	The pharmaceutical described in this article is not approved by the FDA
81	Piller NB, Morgan RG, Casley-Smith JR (1988): A double-blind, cross-over trial of O-(beta-hydroxyethyl)-rutosides (benzo-pyrone) in the treatment of lymphoedema of the arms and legs	Peer-reviewed journal article: RCT	yes	no	✓	The pharmaceutical described in this article is not approved by the FDA



**AB 213 Document Analysis**

**Documents Provided by Robert Weiss and Actions Taken by UCSF Medical Effectiveness Team with Documents**

<b>Doc. #</b>	<b>Doc title</b>	<b>Doc type</b>	<b>Reviewed</b>	<b>Cited study in analysis</b>	<b>Did not meet inclusion criteria</b>	<b>Other comments</b>
82	Mallon BC, Ryan TJ (1994): Lymphedema and wound healing	Peer-reviewed journal article: Review	yes	no	✓	

\*Inclusion/exclusion criteria for the AB 213 literature review and analysis were: 1) articles in English; 2) articles published in peer-reviewed journals from 1998 to present; 3) articles describing a) meta-analyses of randomized clinical trials (RCTs), particularly those included in the Cochrane Library, c) systematic reviews, particularly those performed by authoritative sources (e.g., Agency for Healthcare Research and Quality, U.S. Preventive Services Task Force, and Evidence-based Practice Centers or other government agencies (e.g., NIH, CDC, CMS), evidence-based guidelines, a) individual RCTs, f) observational studies, g) case-control studies, g) clinical/ practice guidelines based on consensus or opinion, rather than on evidence



California Arthritis Foundation Council

October 28, 2005

Michael E. Gluck, Ph.D.  
Director, California Health Benefits Review Program  
University of California – Office of the President  
1111 Franklin Street 11<sup>th</sup> Floor  
Oakland, CA 94607

Dear Dr. Gluck,

As a provider of objective legislative analysis, we appreciate your responsibility of providing an accurate and honest picture to the government of the potential fiscal consequences of proposed legislation. Thank you for providing the in-depth analysis of Senate Bill 913 (Simitian). As you may know, the California Arthritis Foundation Council (CAFC) was SB 913's bill sponsor. Because of the CalPERS EPO, this legislation was held in the Senate Appropriations Committee.

I write with a few questions regarding that study about cost analysis presented within the study. We would like to better understand the basic facts, assumptions, and methodology used in estimating the CalPERS cost estimate for SB 913. In particular, we have questions as to how you arrived at your estimate of the number of beneficiaries, who might be eligible to receive biologic medications. I look forward to your reply regarding the following questions.

- How did you obtain the number of CalPERS beneficiaries who have inflammatory arthritis?
- Was this number taken from publicly available data? If so, can you point me to its source?
- Did you estimate this number based on a percentage of the group? If you did choose to estimate those numbers, what percentage of the adult and pediatric populations were assumed and on what did you base your estimates?
- How did you arrive at a number of beneficiaries with disease severe enough to require treatment with Biologic medications?
- What was the cost per individual you used in your calculations?
  
- If your cost estimate methodology was not based on actual or estimated beneficiary headcount, will you please explain the approach you used?

We appreciate the need for these objective studies when legislation is being considered in order for the government to remain cost effective in its actions. We also understand the difficulties of projecting the cost efficacy of legislation, especially with such new therapies where less data is available.

We have found some data that you might find helpful in your analysis. According to 1997 Centers for Disease Control and Prevention statistics<sup>1</sup>, the estimated total cost attributable to AORC in California is \$11.3 billion. As amended, SB 913 no longer includes the Medi-Cal pilot program, thus drastically reducing costs to the state. Your study<sup>2</sup> estimated increased costs of approximately \$2 million per year for CalPERS health programs that would have been affected by this legislation. It is our feeling that the reduction in that \$11.3 billion of disability, hospitalizations, lost productivity, and lost earnings that SB 913 would bring about by providing greater access to biologic therapies would be much greater than the \$2 million per year for CalPERS.

Moreover, results from a recent Harris Interactive survey<sup>3</sup> of more than 500 European rheumatologists found that the majority of rheumatologists sampled believe patient outcomes can be improved by trying biologic agents when patients don't respond positively to initial treatments. A separate survey of patients conducted by an Austrian national patient advocacy organization found that 70 percent of patients on biologics rate significant reductions in the amount of their pain as compared to the time of their initial diagnosis; of the patients being treated with biologics, 100 percent are satisfied with their treatment.

I hope these sources will be helpful to you. Please feel free to call me at (949) 496-0613 if you have any questions or to discuss any of these points further. I will look forward to your response.

Sincerely,



Tom Murphy, Chair  
The California Arthritis Foundation Council

cc: Jack Hailey

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<sup>1</sup> CDC. Direct and Indirect Costs of Arthritis and Other Rheumatic Conditions; United States, 1997. MMWR 52(46):1124-1127, 2003.

<sup>2</sup> UC California Health Benefits Review Program (CHBRB) analysis of BS 913 from the Senate Appropriations Committee Analysis dated 5/26/05.

<sup>3</sup> PR Newswire. Survey of European Rheumatologists Finds More Can be Done to Improve Outcomes in Patients with Rheumatoid Arthritis; Vienna, Austria; June 10, 2005.



November 18, 2005

Mr. Tom Murphy, Chair  
The California Arthritis Foundation Council  
925 L Street, Ste 1200  
Sacramento, CA 95814

Dear Mr. Murphy:

Thank you for your letter of October 28, 2005 regarding the California Health Benefits Review Program's (CHBRP's) *Analysis of Senate Bill 913: Biological Medications for Rheumatic Disease*. We appreciate your interest in our report. We hope this letter clarifies the methods used to assess the medical, financial, and public health impact of the proposed mandate. A general description of the cost model used by CHBRP to estimate financial impacts for any mandate bill is provided at: <http://www.chbrp.org/costimpactsum.html>

The questions posed in your letter are indicated in italics, below, and our response to each follows.

*How did you obtain the number of CalPERS beneficiaries who have inflammatory arthritis?*

CHBRP estimated that 0.55 percent of the privately insured population under the age of 65 are diagnosed for those conditions which the U.S. Food and Drug Administration (FDA) has approved biological drugs: rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis. This estimate was based on CHBRP's consulting actuary Milliman's national claims data for privately insured individuals with a prescription drug benefit who are receiving treatment for any of these three conditions.

For lack of data on public payors, this percentage (0.55%) was applied to estimate the CalPERS population affected by the mandate (i.e., active members in Knox-Keene licensed HMOs).

As noted in the report, "An equal rate of rheumatic disease is assumed for both private and public payors, due to lack of prevalence data for public payors." (See page 22)

*Was this number taken from publicly available data? If so, can you point me to its source?*

Milliman's national claims data is a proprietary source and therefore not publicly available. The claims data represents 7.4 million people under age 65 who are covered for health benefits by private insurance carriers.

CalPERS enrollment figures for non-self-insured plans were provided to CHBRP in January 2005. Current enrollment figures are posted on their website: <http://www.calpers.ca.gov>.

*Did you estimate this number based on a percentage of the group? If you did choose to estimate those numbers, what percentage of the adult and pediatric populations were assumed and on what did you base your estimates?*

The number was based on a percentage of the group under the age of 65. CHBRP did not develop separate estimates for the adult and pediatric population.

*How did you arrive at a number of beneficiaries with disease severe enough to require treatment with biologic medications?*

The number of CalPERS beneficiaries who would be likely to receive treatment with biologic medications was estimated to be 0.09 percent. This estimate was based on the proportion of the privately insured population under age 65 diagnosed with the three rheumatic conditions who had submitted a claim for a FDA-approved biological therapy (i.e., etanercept, adalimumab, anakinra, infliximab) as identified by Milliman's claims data.

*What was the cost per individual you used in your calculations?*

The cost per individual pre-mandate was based on the average annual prescription cost for all four biologic therapies (\$16,234). This cost includes two adjustments: (1) a discount on the wholesale price of the drugs, and (2) a fee for physician administration of the drugs to patients. (See page 23). The cost per individual post-mandate was projected to increase by 5 percent (\$17,046) due to health plans losing discounts or rebates from manufacturers because they would be unable to give one drug "preferred" status over another.

*If your cost estimate methodology was not based on actual or estimated beneficiary headcount, will you please explain the approach you used?*

The cost estimate methodology was based on the average annual prescription cost per insured that used a prescription drug benefit for a FDA-approved biological therapy.

We appreciate you sharing the statistic from the Centers for Disease Control on the total cost attributable to arthritis and other rheumatic conditions. CHBRP chose not use this statistic in our analysis because it covers all forms of arthritis, including Osteoarthritis (the most prevalent form of arthritis), for which biologic drugs are not appropriate. Also, the CDC statistic is not specific to those under age 65, the population subject to this mandate.

The references you've provided on surveys conducted in Europe on biologic agents and improved patient outcomes are consistent with CHBRP's review of the medical-effectiveness literature. CHBRP found good evidence that biologic response modifiers have been shown in randomized control trials to be effective for patients at various stages of their disease in reducing joint pain and swelling, significantly halting bone degeneration and improving quality of life.

Unlike many mandates that require coverage of a specific treatment or therapy, however, the question posed by SB 913 was what would be the impact of prohibiting a health plan or insurer from designating a preferred drug within the biologic class of drugs for the

treatment of rheumatic disease.<sup>1</sup> In its review of the medical effectiveness literature, CHBRP found there were no head-to-head trials comparing individual biologic response modifiers to one another. As such, there was no evidence that would justify choosing one biologic over another and therefore CHBRP was unable to conclude that allowing equal access to any of the four biological response modifiers would compromise patient outcomes or public health.

Please accept our best wishes as you continue your efforts to advocate on behalf of patients with arthritis.

Sincerely,



Jeffrey Hall  
Acting Director, CHBRP,  
Director, Legislation and Policy  
Office of Health Affairs,  
University of California Office of the President

cc: Jack Hailey

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<sup>1</sup> SB 913 requested that no health care service plan/health or disability insurer contracting to provide coverage for drugs shall “with respect to the biologic class of drugs for the treatment of rheumatic disease, limit access to biologic therapies by designating a preferred drug.”



## **Appendix 17: Legislative and Executive Branch Analyses Referencing CHBRP Reports**

### **AB 228 (Koretz), Transplantation Services: Human Immunodeficiency Virus**

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*ASSEMBLY COMMITTEE ON HEALTH*, Hearing April 11, 2005

#### CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM (CHBRP) REPORT

Consistent with AB 1996 (Thomson), Chapter 795, Statutes of 2002, the University of California reviewed this bill with regards to medical effectiveness, utilization, cost and coverage impacts, and public health impacts. CHBRP found:

a) **Medical Effectiveness:** Patients with HIV undergoing kidney transplantation have survival rates comparable with survival rates of patients without HIV and although HIV positive kidney transplant patients have higher rates of rejection, this complication can usually be treated and managed without requiring retransplantation. In the hepatitis C-negative (HCV) population, patient and graft survival rates after liver transplantation are similar regardless of HIV status. The available evidence concerning the survivable) of HIV positive patients with hepatitis C as the cause of liver failure after liver transplantation is mixed. Data from some centers suggest that the survival rates of liver transplant patients infected with both HIV and HCV is comparable. Data from other centers suggest that liver transplant patients with dual infections fare worse. Regardless of HIV status, the shorter post-transplant survival of HCV+ patients has also been documented. In reporting the medical effectiveness, CHBRP did make several caveats, including that only a few centers in the United States perform solid organ transplantation on HIV positive patients and that several of the reports that informed their effectiveness analysis are collaborations among transplantation centers performing transplants on HIV positive patients. Therefore, data on many of the same patients are repeated in multiple papers. In cases in which details of particular patients are provided, the same patient can be identified in different reports with a reasonable degree of certainty. However, the degree of duplicate reporting on HIV positive patients undergoing transplantation is unclear.

c) **Utilization, Cost and Coverage Impacts:** According to the health plans that responded to CHBRP's survey, all HIV positive members have coverage for transplant services. Most transplant centers in California do not accept HIV positive patients, however, because they do not currently have the protocols in place to handle surgeries for HIV positive patients and/or consider HIV status a contraindication for transplantation surgery. CHBRP was unable to determine how many, if any, HIV positive patients in California have been denied access to transplants annually. DMHC reports one case that was reviewed under the Independent Medical Review process for denied coverage of transplant surgery in 2002. In addition, conversations with the two largest regional transplant networks in California indicate no denial of services on

the basis of HIV status as far as they are aware. CHBRP therefore estimates that the number of new HIV positive transplant cases will not increase as a result of this bill. All 20,368,000 Californians enrolled in health plans or insurance policies currently have coverage for transplants and therefore this bill will not increase the number of insured individuals with coverage for transplants.

d) Public Health Impacts: Because UNOS does not keep data on patients' HIV status, it is unknown how many HIV positive Californians are currently on the waiting list for organ transplants. This bill would not result in an increase of the supply of organs (liver and kidney) or the demand for transplants by HIV positive patients. CHBRP also does not expect the distribution pattern of organ transplants to shift from HIV negative to HIV positive patients or a rapid growth in the number of transplant centers in California with protocols for HIV positive patients. CHBRP reported that African Americans have substantially higher rates of HIV/AIDS, suffer greater morbidity and mortality from HIV, and have higher prevalence rates of endstage liver disease compared with Caucasians. Available evidence indicates there would be no increase in the number of organ transplants to HIV positive persons following the mandate. Therefore, although there is evidence of gender and racial disparities with regard to HIV status and related health outcomes, they concluded that this bill will have no impact on reducing these disparities. Although evidence indicates that organ failure leads to premature death among HIV positive persons, the study found that this bill would not have an impact on mortality since it would not increase the number of organ transplants performed on this population. End-stage organ disease is also associated with significant economic loss through lost productivity, but because this bill would not increase the number of organ transplants to HIV positive persons, CHBRP concluded that it will have no impact on these economic losses.

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*ASSEMBLY COMMITTEE ON APPROPRIATIONS* Hearing, 4/27/2005

Consistent with AB 1996 (Thomson), Chapter 795, Statutes of 2002, the University of California's California Health Benefits Review Program (CHBRP) reviewed this bill with regards to medical effectiveness, utilization, cost and coverage impacts, and public health impacts.

CHBRP found that, based on publicly available California hospital claims data from 2001-2002, there were 4,206 transplants performed in the state, including 1,862 bone marrow, 1,062 kidney, 789 liver, 299 heart, 144 lung, 39 simultaneous pancreas and kidney, and 11 pancreas transplants. Of these 4,206 transplants, 11 were performed on HIV positive patients. Because California has privacy laws designed to prevent the dissemination of HIV status, CHBRP believes these estimates likely under-report the true number of transplants performed on HIV positive patients.

According to the health plans that responded to CHBRP's survey, all HIV positive members currently have coverage for transplant services. CHBRP was unable to determine how many, if any, HIV positive patients in California have been denied access to transplants annually. The DMHC reports one HIV positive case was reviewed under the experimental and investigational provisions of the state's Independent Medical Review (IMR) process for denied coverage of transplant surgery

In 2002 (the health plan's denial was overturned in IMR), but has reported no cases since then.



CHBRP indicates that conversations with the two largest regional transplant networks in California indicate no denial of services on the basis of HIV status as far as they were aware. CHBRP's conversations with two of the three transplant centers (that conducted 42 of the 44 transplants that have been reported to be conducted on HIV positive patients) also indicate that in recent years, carriers have not been denying coverage for patients deemed to be acceptable candidates.

CHBRP estimates that the number of new HIV positive transplant cases will not increase as a result of this bill as all 20,368,000 Californians enrolled in health plans or insurance policies that would be subject to AB 228 currently have coverage for transplants.

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*ASSEMBLY FLOOR Analysis, 5/3/2005*

Consistent with AB 1996 (Thomson), Chapter 795, Statutes of 2002, the University of California's California Health Benefits Review Program (CHBRP) reviewed this bill with regards to medical effectiveness, utilization, cost and coverage impacts, and public health impacts.

CHBRP found that Patients with HIV undergoing kidney transplantation have survival rates comparable with survival rates of patients without HIV and although HIV positive kidney transplant patients have higher rates of rejection, this complication can usually be treated and managed without requiring retransplantation. In the hepatitis C negative (HCV) population, patient and graft survival rates after liver transplantation are similar regardless of HIV status. The available evidence concerning the survival of HIV positive patients with hepatitis C as the cause of liver failure after liver transplantation is mixed. Data from some centers suggest that the survival rates of liver transplant patients infected with both HIV and HCV is comparable. Data from other centers suggest that liver transplant patients with dual infections fare worse. Regardless of HIV status, the shorter post-transplant survival of HCV+ patients has also been documented. In reporting the medical effectiveness, CHBRP did make several caveats, including that only a few centers in the United States perform solid organ transplantation on HIV positive patients and that several of the reports that informed their effectiveness analysis are collaborations among transplantation centers performing transplants on HIV positive patients. Therefore, data on many of the same patients are repeated in multiple papers. In cases in which details of particular patients are provided, the same patient can be identified in different reports with a reasonable degree of certainty. However, the degree of duplicate reporting on HIV positive patients undergoing transplantation is unclear.

3) According to the health plans that responded to CHBRP's survey, all HIV positive members have coverage for transplant services. Most transplant centers in California do not accept HIV positive patients, however, because they do not currently have the protocols in place to handle surgeries for HIV positive patients and/or consider HIV status a contraindication for transplantation surgery. CHBRP was unable to determine how many, if any, HIV positive patients in California have been denied access to transplants annually. DMHC reports one case that was reviewed under the Independent Medical Review process for denied coverage of transplant surgery in 2002. In addition, conversations with the two largest regional transplant networks in California indicate no denial of services on the basis of HIV status as far as they are aware. CHBRP therefore estimates that the number of new HIV positive transplant cases will

not increase as a result of this bill. All 20.368 million Californians enrolled in health plans or insurance policies currently have coverage for transplants, and therefore this bill will not increase the number of insured individuals with coverage for transplants.

4) Because UNOS does not keep data on patients' HIV status, it is unknown how many HIV positive Californians are currently on the waiting list for organ transplants. This bill would not result in an increase of the supply of organs (liver and kidney) or the demand for transplants by HIV positive patients. CHBRP also does not expect the distribution pattern of organ transplants to shift from HIV negative to HIV positive patients or a rapid growth in the number of transplant centers in California with protocols for HIV positive patients. CHBRP reported that African Americans have substantially higher rates of HIV/AIDS, suffer greater morbidity and mortality from HIV, and have higher prevalence rates of endstage liver disease compared with Caucasians. Available evidence indicates there would be no increase in the number of organ transplants to HIV positive persons following the mandate. Therefore, although there is evidence of gender and racial disparities with regard to HIV status and related health outcomes, they concluded that this bill will have no impact on reducing these disparities. Although evidence indicates that organ failure leads to premature death among HIV positive persons, the study found that this bill would not have an impact on mortality since it would not increase the number of organ transplants performed on this population. End-stage organ disease is also associated with significant economic loss through lost productivity, but because this bill would not increase the number of organ transplants to HIV positive persons, CHBRP concluded that it will have no impact on these economic losses.

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*SENATE HEALTH COMMITTEE* Analysis, 6/20/2005

California Health Benefits Review Program (CHBRP) report:

Consistent with AB 1996 (Thomson, Chapter 795, Statutes of 2002), the University of California reviewed this bill with regards to medical effectiveness, utilization, cost and coverage impacts, and public health impacts. CHBRP found:

1. Medical Effectiveness: Patients with HIV undergoing kidney transplantation have survival rates comparable with survival rates of patients without HIV, and although HIV positive kidney transplant patients have higher rates of rejection, this complication can usually be treated and managed without requiring re-transplantation. In the hepatitis C negative (HCV) population, patient and graft survival rates after liver transplantation are similar regardless of HIV status. The available evidence concerning the survival of HIV positive patients with hepatitis C as the cause of liver failure after liver transplantation is mixed. Data from some centers suggest that the survival rates of liver transplant patients infected with both HIV and HCV is comparable. Data from other centers suggest that liver transplant patients with dual infections fare worse. Regardless of HIV status, the shorter post-transplant survival of HCV-positive patients has also been documented. In reporting the medical effectiveness, CHBRP did make several caveats, including that only a few centers in the United States perform solid organ transplantation on HIV positive patients and that several of the reports that informed their effectiveness analysis are collaborations among transplantation centers performing transplants on HIV positive patients. Therefore, data on many of the same patients are repeated in multiple papers. In cases in which details of particular patients are provided, the same patient can be identified in different

reports with a reasonable degree of certainty. However, the degree of duplicate reporting on HIV positive patients undergoing transplantation is unclear.

2. Utilization, Cost and Coverage Impacts: According to the health plans that responded to CHBRP's survey, all HIV positive members have coverage for transplant services. Most transplant centers in California do not accept HIV positive patients, however, because they do not currently have the protocols in place to handle surgeries for HIV positive patients and/or consider HIV status a contraindication for transplantation surgery. CHBRP was unable to determine how many, if any, HIV positive patients in California have been denied access to transplants annually. DMHC reports one case that was reviewed under the Independent Medical Review process for denied coverage of transplant surgery in 2002. In addition, conversations with the two largest regional transplant networks in California indicate no denial of services on the basis of HIV status as far as they are aware. CHBRP therefore estimates that the number of new HIV positive transplant cases will not increase as a result of this bill. All 20,368,000 Californians enrolled in health plans or insurance policies currently have coverage for transplants and therefore this bill will not increase the number of insured individuals with coverage for transplants.

3. Public Health Impacts: Because UNOS does not keep data on patients' HIV status, it is unknown how many HIV positive Californians are currently on the waiting list for organ transplants. This bill would not result in an increase of the supply of organs (liver and kidney) or the demand for transplants by HIV positive patients. CHBRP also does not expect the distribution pattern of organ transplants to shift from HIV negative to HIV positive patients or a rapid growth in the number of transplant centers in California with protocols for HIV positive patients. CHBRP reported that African Americans have substantially higher rates of HIV/AIDS, suffer greater morbidity and mortality from HIV, and have higher prevalence rates of endstage liver disease compared with Caucasians. Available evidence indicates there would be no increase in the number of organ transplants to HIV positive persons following the mandate. Therefore, although there is evidence of gender and racial disparities with regard to HIV status and related health outcomes, they concluded that this bill will have no impact on reducing these disparities. Although evidence indicates that organ failure leads to premature death among HIV positive persons, the study found that this bill would not have an impact on mortality since it would not increase the number of organ transplants performed on this population. End-stage organ disease is also associated with significant economic loss through lost productivity, but because this bill would not increase the number of organ transplants to HIV positive persons, CHBRP concluded that it will have no impact on these economic losses.

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*SENATE COMMITTEE ON BANKING, FINANCE, AND INSURANCE Hearing, 6/28/05*

Pursuant to AB 1996 (Thomson, 2002) the California Health Benefits Review Program (CHBRP), coordinated through the University of California, analyzed AB 228 for the medical effectiveness, utilization, cost and coverage impacts, and public health impacts of the benefit that the bill proposes to mandate. A representative of CHBRP will be present at this bill's hearing to answer any questions of the committee. A brief outline of CHBRP's analysis follows:

**Medical effectiveness:** A review of evidence from observational studies and case reports indicates in part that advances in medication have made transplantation viable for HIV-positive individuals, that HIV-positive patients have survival rates comparable to patients without HIV when undergoing transplantation, and that the survival rate for patients without hepatitis C undergoing liver transplantation does not vary significantly depending on HIV status. However, CHBRP notes that transplantation experience with HIV patients is limited and that long-term outcomes are unknown. In addition, there are no randomized controlled trials on the question, and available studies are generally limited to kidney and liver transplantation, with only rare reports of other organs.

**Utilization, cost, and coverage impacts:** CHBRP "estimates that the number of new HIV-positive transplant cases will not increase as a result of AB 228." Therefore, the price of health insurance is not projected to change for any party. Although CHBRP was not able to establish how many individuals are denied coverage for transplantation because of HIV status, interviews with two major transplantation centers indicate that insurers currently are not denying enrollees coverage for these transplants based on HIV status.

**Public health impacts:** CHBRP finds that AB 228 is not expected to impact community health.

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*ASSEMBLY FLOOR Analysis, 8/24/2005*

Consistent with AB 1996 (Thomson, Chapter 795, Statutes of 2002), the University of California reviewed this bill with regards to medical effectiveness, utilization, cost and coverage impacts, and public health impacts. CHBRP found:

1. **Medical Effectiveness:** Patients with HIV undergoing kidney transplantation have survival rates comparable with survival rates of patients without HIV, and although HIV positive kidney transplant patients have higher rates of rejection, this complication can usually be treated and managed without requiring re-transplantation. In the hepatitis C negative (HCV) population, patient and graft survival rates after liver transplantation are similar regardless of HIV status. The available evidence concerning the survival of HIV positive patients with hepatitis C as the cause of liver failure after liver transplantation is mixed. Data from some centers suggest that the survival rates of liver transplant patients infected with both HIV and HCV is comparable. Data from other centers suggest that liver transplant patients with dual infections fare worse. Regardless of HIV status, the shorter post-transplant survival of HCV-positive patients has also been documented. In reporting the medical effectiveness, CHBRP did make several caveats, including that only a few centers in the United States perform solid organ transplantation on HIV positive patients and that several of the reports that informed their effectiveness analysis

are collaborations among transplantation centers performing transplants on HIV positive patients. Therefore, data on many of the same patients are repeated in multiple papers. In cases in which details of particular patients are provided, the same patient can be identified in different reports with a reasonable degree of certainty. However, the degree of duplicate reporting on HIV positive patients undergoing transplantation is unclear.

2. Utilization, Cost and Coverage Impacts: According to the health plans that responded to CHBRP's survey, all HIV positive members have coverage for transplant services. Most transplant centers in California do not accept HIV positive patients, however, because they do not currently have the protocols in place to handle surgeries for HIV positive patients and/or consider HIV status a contraindication for transplantation surgery. CHBRP was unable to determine how many, if any, HIV positive patients in California have been denied access to transplants annually. DMHC reports one case that was reviewed under the Independent Medical Review process for denied coverage of transplant surgery in 2002. In addition, conversations with the two largest regional transplant networks in California indicate no denial of services on the basis of HIV status as far as they are aware. CHBRP therefore estimates that the number of new HIV positive transplant cases will not increase as a result of this bill. All 20,368,000 Californians enrolled in health plans or insurance policies currently have coverage for transplants and therefore this bill will not increase the number of insured individuals with coverage for transplants.

3. Public Health Impacts: Because UNOS does not keep data on patients' HIV status, it is unknown how many HIV positive Californians are currently on the waiting list for organ transplants. This bill would not result in an increase of the supply of organs (liver and kidney) or the demand for transplants by HIV positive patients. CHBRP also does not expect the distribution pattern of organ transplants to shift from HIV negative to HIV positive patients or a rapid growth in the number of transplant centers in California with protocols for HIV positive patients. CHBRP reported that African Americans have substantially higher rates of HIV/AIDS, suffer greater morbidity and mortality from HIV, and have higher prevalence rates of endstage liver disease compared with Caucasians. Available evidence indicates there would be no increase in the number of organ transplants to HIV positive persons following the mandate. Therefore, although there is evidence of gender and racial disparities with regard to HIV status and related health outcomes, they concluded that this bill will have no impact on reducing these disparities. Although evidence indicates that organ failure leads to premature death among HIV positive persons, the study found that this bill would not have an impact on mortality since it would not increase the number of organ transplants performed on this population. End-stage organ disease is also associated with significant economic loss through lost productivity, but because this bill would not increase the number of organ transplants to HIV positive persons, CHBRP concluded that it will have no impact on these economic losses.

**SB 573—2005 (Romero) Elimination of Intoxication Exclusion**

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*SENATE HEALTH COMMITTEE Hearing, 4/26/2005*

University of California, California Health Benefits Review Program:

In April, 2005, the California Health Benefits Review Program, within the University of California, conducted an analysis of SB 573. The report concluded that "SB 573 would have no measurable effects on the health of the people of California. This assessment results from the lack of evidence related to the medical effectiveness of the provision's amendment to current law and the lack of evidence that the public is currently affected by the ability of health insurers to use the exclusion permitted by Section 10369.12 of the California Insurance Code."

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*SENATE COMMITTEE ON BANKING, FINANCE, AND INSURANCE Hearing, 5/2/2005*

California Health Benefits Review Program Analysis:

SB 573 is considered a health mandate bill, because it would require health insurers to cover treatment for injuries sustained under the influence of drugs or alcohol. Pursuant to AB 1996 (Thompson, Chapter 795, Statutes of 2002), this committee requested an analysis of the medical, financial, and public health impacts of SB 573 by the California Health Benefits Review Program (CHBRP). The full analysis may be found on the CHBRP website at [www.chbrp.org](http://www.chbrp.org). According to CHBRP: "It is not possible to assess the medical effectiveness of SB 573, because there is no published data about the medical effects of removing existing coverage exclusions." SB 573 does not mandate a particular health care service; instead, it prevents health insurers from failing to cover losses due to the insured being intoxicated or under the influence of a controlled substance that was not administered on the advice of a physician.

CHBRP found no evidence that insurers deny claims under the UPPL exclusion in California or in other states. Seven of the 16 in-state health insurers with the highest number of covered lives were asked whether they include the UPPL exclusion in their policies or whether they deny claims based on it, and all seven responded that they do not. CHBRP found no evidence that consumers are complaining about the exclusion, nor that medical professionals in California are less likely to perform screening and counseling because of the UPPL exclusion. For these reasons, CHBRP believes that SB 573 will have little or no effect on the health of the people of California.

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*ASSEMBLY FLOOR ANALYSIS, 6/10/2005*

Pursuant to AB 1996 (Thomson), Chapter 795, Statutes of 2002, the Senate Insurance Committee requested an analysis of the medical, financial, and public health impacts of this bill by the California Health Benefits Review Program (CHBRP). CHBRP reported that it was unable to assess the medical effectiveness of this bill because there is no published data about the medical effects of removing existing coverage exclusions. CHBRP also found no evidence that California insurers or those in other states deny claims under UPPL or that

consumers are complaining about the exclusion. CHBRP contacted seven of the 16 largest insurers in California to determine if they include these provisions in their policies and all reported that they did not include the provision or deny payment for claims based on the exclusion. CHBRP found that since insurers are not currently excluding payments based on the presence of alcohol or drugs, there would be no impact on health care utilization or costs. CHBRP uncovered no evidence that medical professionals are less likely to perform such services because of the theoretical ability of insurers to use the exclusion and, therefore, concluded that SB 573 would have little or no impact on health or public health.

## SB 576 (2005) Ortiz: Tobacco Cessation Benefit

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*SENATE COMMITTEE ON BANKING, FINANCE, AND INSURANCE Hearing, 4/21/05*

CHBRP Analysis Pursuant to AB 1996 (Thomson, 2002), this committee requested that the California Health Benefits Review Program (CHBRP) analyze SB 576 for its medical, financial, and public health impacts. The executive summary and cost-impact chart of CHBRP's report are attached to this analysis. In brief, CHBRP reports that counseling interventions, brief advice from physicians, and medications are effective treatments for tobacco cessation.

As for cost, CHBRP found that SB 576 would increase premium expenditures by private employers for group insurance by 0.179%, that it would increase premium expenditures by individuals with group insurance, CalPERS, or Healthy Families by 0.181%, and that it would increase premium expenditures for individually purchased insurance by 0.420%.

Total health expenditures is expected to increase by 0.149%, a figure that incorporates savings related to reduced out-of-pocket costs and a savings related to lower health care utilization by those who successfully quit smoking. These are short term, one year savings. CHBRP notes that "The potential long-term savings of quitting are likely to be substantial due to reductions in the rate of smoking-related illnesses?", but CHBRP considered calculations of long-terms savings to be beyond the scope of their report. Hence, these long-term savings were not estimated or available to illustrate a possible offset to costs otherwise associated with the bill.

Regarding public health impact, CHBRP reports in part that in the first year of this bill's implementation, the mandate is estimated to reduce low birth weight deliveries by approximately 58 cases and would reduce acute myocardial infarction by 146 cases.

Sponsor's response to CHBRP analysis: The California Tobacco Alliance states a number of objections to the CHBRP analysis of the utilization, cost, and coverage impacts of SB 576. First, the Alliance states that a one-year cost projection does not adequately indicate the financial benefits of a smoking cessation mandate. According to the Alliance, an actuarial analysis by Buck Consultants, Inc. shows that the overall impact of smoking cessation is actually a 6.4% reduction in total plan costs. The Alliance also states that CHBRP does not adequately calculate the number of smokers that would be covered by the mandate and underestimates the number of insured individuals who would utilize cessation benefits.

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*SENATE COMMITTEE ON BANKING, FINANCE, AND INSURANCE Hearing, 4/26/05*

California Health Benefits Review Program (CHBRP) Analysis:  
As with other health insurance mandates, the Senate Banking, Finance and Insurance Committee requested the CHBRP within the University of California to analyze SB 576 for its medical, financial, and public health impacts.

In brief, CHBRP reports that counseling interventions, brief advice from physicians, and medications are effective treatments for tobacco cessation.



As for cost, CHBRP found that SB 576 would increase premium expenditures by private employers for group insurance by 0.179 percent, that it would increase premium expenditures by individuals with group insurance by 0.181 percent, and that it would increase premium expenditures for individually purchased insurance by 0.420 percent. This amounts to an overall average increase of \$.44 per member per month.

Total health expenditures are expected to increase by 0.149 percent, a figure that incorporates plan and insurer increased expenses and savings related to reduced out-of-pocket costs and a savings related to lower health care utilization by those who successfully quit smoking. These are short term, one year savings.

CHBRP notes that "The potential long-term savings of quitting are likely to be substantial due to reductions in the rate of smoking-related illnesses?" but CHBRP considered calculations of long-term savings to be beyond the scope of their report. Hence, these long-term savings were not estimated or available to illustrate a possible offset to costs otherwise associated with the bill.

Regarding public health impact, CHBRP reports in part that in the first year of this bill's implementation, the mandate is estimated to reduce low birth weight deliveries by approximately 58 cases and would reduce acute myocardial infarction by 146 cases.

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*SENATE APPROPRIATIONS COMMITTEE* Hearing, 5/16/2005

STAFF COMMENTS:

The UC California Health Benefits Review Program (CHBRB), which was created to analyze the impact of mandated health care coverage proposals in the Legislature, prepared an analysis of this proposal prior to it being amended to allow for some minor copayments. Overall, the estimated cost of providing tobacco cessation services was approximately \$90 million or about 0.15 percent of \$60 billion in total expenditures of all health plans and insurers in the state.

The fiscal impact on state programs was estimated to be approximately \$2 million per year for CalPERS health programs and approximately \$3.7 million per year for the Medi-Cal program.

STAFF NOTES that these estimates include a short term savings of about \$8 million in the first year resulting from fewer health care costs for individuals who quit smoking. This amount would become more significant over time as fewer people smoke overall.

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*SENATE FLOOR HEARING*, 5/28/2005 and *SENATE FLOOR HEARING*, 9/2/2005  
(Comments were the same for both hearings)

As with other health insurance mandates, the Senate Banking, Finance and Insurance Committee requested the CHBRP within the University of California to analyze this bill for its medical, financial, and public health impacts. In brief, CHBRP reports that counseling interventions, brief advice from physicians, and medications are effective treatments for tobacco cessation. As for cost, CHBRP found that this bill increases premium expenditures by private employers for group insurance by 0.179 percent, that it increases premium expenditures by individuals with group

insurance by 0.181 percent, and that it would increase premium expenditures for individually purchased insurance by 0.420 percent. This amounts to an overall average increase of \$.44 per member per month.

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*ASSEMBLY HEALTH COMMITTEE Hearing, 6/27/2005*

Pursuant to AB 1996 (Thomson), Chapter 795, Statutes of 2002, the California Health Benefits Review Program (CHBRP) analyzed this bill for its medical, financial and public health impacts. CHBRP concluded research reveals that counseling interventions, brief advice from physicians and clinical staff, and FDA approved medications are effective in reducing smoking use, as measured by abstinence rates. CHBRP estimated the increased costs of this bill at \$89 million (0.149%) in the first year, including savings for lower health care use. CHBRP estimated that this bill would increase premium expenditures for private employer-sponsored group coverage by 0.179%, for Cal-PERS and Healthy Families by 0.181%, and for individually purchased coverage by 0.420%. CHBRP found that tobacco cessation services have proven effective in reducing short-term disease and the cost impacts of low birth weights and heart attack in the first year after cessation. Finally, CHBRP found that tobacco cessation services also have the potential to result in long-term public health benefits and cost savings by reducing exposure to the multiple mechanisms by which smoking causes disease, disability and death. However, the CHBRP analysis only estimated first year costs and CHBRP did not consider the potential long-term savings from quitting, but did suggest the savings are likely to be substantial.

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*ASSEMBLY HEALTH COMMITTEE Hearing, 7/12/2005*

Pursuant to AB 1996 (Thomson), Chapter 795, Statutes of 2002, the CHBRP analyzed this bill for its medical, financial and public health impacts. CHBRP estimated that this bill would affect state costs by increasing premium expenditures for CalPERS by 0.87%, (\$1.9 million), would have no effect on Medi-Cal expenditures as Medi-Cal currently covers these services, and would increase Healthy Families state expenditures by .022% (\$75,000).

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*VETO Message, 10/07/2005*  
*Governor Arnold Schwarzenegger*

. . . An independent analysis of SB 576 by the University of California's Health Benefits Review Program indicates that this bill would impose costs of \$77 million on employers, plans and individuals but only increase the utilization of the benefit by two-tenths of one percent. Additionally, while more than 55% of insured Californians already have tobacco cessation coverage; only ten percent of smokers trying to quit utilize the benefit. . .

## **SB174 Scott, Koretz, and Wiggins (2004): Hearing Aids for Children**

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*SENATE COMMITTEE ON INSURANCE, 1/15/2004*

UC Mandate Report: The debate over health benefit mandates largely revolves around two points- how well the covered treatment works and how much it costs. In order to provide for an objective analysis of this debate, the Legislature passed a law requesting the University of California (UC) to study the cost-effectiveness and clinical efficacy of every legislative proposal for mandated benefits or services (AB 1996, Thomson, statutes of 2002).

AB 1996 directed UC to focus on three main areas: public health impacts; medical impacts, including how the medical community views the effectiveness of the benefit and whether the mandate would diminish access to currently-available services; and financial impacts. UC's research is funded by fees assessed on health plans and insurers at rates set by DMHC and DOI, respectively, which are not to exceed \$2 million in total.

AB 1996 defined a "mandated benefit or service" as a proposed statute requiring a health plan or health insurer to do any of the following:

1. Permit a person insured or covered under the policy or contract to obtain health care treatment or services from a particular type of health care provider.
2. Offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition.
3. Offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

The Legislature requested that the UC reports be completed within 60-day timeframes, which would allow mandate bills to meet legislative deadlines and move forward in the year they were introduced. The Senate Insurance Committee adopted a rule stating that mandate bills would not be heard before their UC reports were completed, although the chair retained broad discretion to waive the rule if it would "preclude an otherwise eligible bill from being heard during the legislative session."

Due to a number of factors, UC will not present its full report on substance-abuse treatment until mid-February. A representative of UC will be present at this hearing to explain the absence of a report on SB 174.

## SB 1158 (Scott), 2004: Hearing Aids

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*SENATE COMMITTEE ON INSURANCE, 4/19/2004*

UC Cost-Benefit Analysis Pursuant to AB 1996 (Thompson, 2002), the University of California has submitted to the Legislature a cost-benefit analysis for each of the health insurance mandate bills before the committee at its April 21, 2004, hearing: SB 1158 (Scott); SB 1192 (Chesbro); and SB 1555 (Speier). The UC reports detail the medical effectiveness, cost, and public health impact of each health mandate bill.

The reports are coordinated by a small UC staff, which oversees a network of healthcare and health insurance experts and contracts with Milliman USA for actuarial analysis. UC gives the stakeholders who are directly affected by the legislation the opportunity to submit information but no editorial control over the reports. However, UC solicits comments on initial drafts of its analyses from a national stakeholders group, including representatives of consumers, insurers and health plans, employers and other purchasers, and hospitals and other providers.

The UC reports are the only cost-benefit analyses available to the committee for consideration. The director of UC's California Health Benefits Review Program will be available to answer questions that the committee may have about the reports. The executive summary and total cost analysis of SB 1158 have been excerpted from the full report and are attached to this analysis.

### 3. UC Results in Brief

**Medical Effectiveness:** UC finds that the use of hearing aids is medically effective in treating children for hearing loss. Estimates are that the average life span of a hearing aid in a child is two years. The devices have been shown to improve speech and language development, and early detection of hearing loss followed by intervention can improve social and emotional development. Other benefits of hearing aids for children include increased social interaction, less stress, and better social and family relationships.

**Utilization, Cost, and Coverage Impacts:** SB 1158 is projected to raise premiums by \$0.11 to \$0.20 per member per month depending on the type of insurance product. UC finds that the majority (61%) of children with hearing loss currently use hearing aids despite the fact that most private health plans and health insurers do not cover the service. Mandating coverage would increase utilization by only 4% - in part because cost (an average of \$3,000 per unit) is not currently a significant barrier to access for a number of potential reasons including the following: families may prioritize hearing aid purchases in their budgets; they may have access to charities providing hearing aids for free or at reduced prices; and health plans and health insurers may offer them discounts. Because Medi-Cal and Healthy Families provide coverage for hearing aids for children, SB 1158 should not shift any cost from the private to the public sector.

**Public Health Impacts:** SB 1158 is estimated to have a minor, though positive, effect on public health, both in terms of increasing the number of children with hearing aids and in terms of savings to the educational system. An additional 3,200 children (out of 9.2 million children state-wide) would obtain hearing aids due to SB 1158, and an indeterminate number of additional children

would be able to afford hearing aids with better technology. Identifying and treating hearing loss in children reduces the likelihood that they will be misplaced in the educational system with children who are provided special (and costly) services for mental or learning disabilities.

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*ASSEMBLY COMMITTEE ON HEALTH, 6/14/2004*

AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California (UC) assess legislation proposing a mandated benefit or service, and prepare a written analysis with relevant data on the public health, medical, and economic impact of proposed health plan and health insurance benefit mandate legislation. The CHBRP was created in response to AB 1996. CHBRP's analysis of SB 1158 indicates the following:

- a) Medical Effectiveness A literature search analysis supports the conclusion that the use of hearing aids is medically effective in treating children with hearing loss. One report showed observational and anecdotal evidence that early childhood detection and intervention of hearing impairment improves speech and language development.
- b) Utilization, Cost and Coverage Impacts Approximately 61% of children with hearing loss whom do not have coverage for hearing aids use hearing aids. The estimated average cost of a hearing aid is \$3,000 and the expected life-span of a child's hearing aid is two years. Only 10% of the large group insurance market cover hearing aids, for example, CalPERS offers a benefit of \$1,000 for every 36 months. Medi-Cal and Healthy Families cover hearing aids. Medi-Cal coverage is subject to utilization controls and Healthy Families covers hearing aids and ancillary items at no charge every 36 months. In terms of this bill's impacts on cost, the CHBRP predicts an average increase of .05% or \$0.12 per member per month, with the largest impact on the small group market. CHBRP states that the mandate in this bill would likely increase access to approximately 4% of children with hearing impairments.
- c) Public Health Impacts The CHBRP report estimates that an additional 3,200 children would obtain hearing aids with the passage of this bill, and that children who had obtained hearing aids previously are likely to obtain aids with better technology with the benefit subsidy in this bill. Additionally the report provides that qualitative studies suggest that untreated hearing impairments result in increases in lost productivity, special education needs and medical care costs.

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*ASSEMBLY COMMITTEE ON APPROPRIATIONS, 6/22/2004*

AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California (UC) to assess legislation proposing a mandated benefit or service, and prepare a written analysis with relevant data on the public health, medical, and economic impact of proposed health plan and health insurance benefit mandate legislation. UC's analysis indicates CalPERS provides a hearing aid benefit of \$1,000 for every 36 months, and Medi-Cal and Healthy Families cover hearing aids. Medi-Cal coverage is subject to utilization controls and Healthy Families covers hearing aids and ancillary items at no charge every 36 months. For the privately insured, CHBRP estimates an average premium increase of .05% or \$0.12 per member per month, with the largest impact on the small group market.

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*ASSEMBLY FLOOR ANALYSIS, 8/17/2004*

AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California (UC) assess legislation proposing a mandated benefit or service, and prepare a written analysis with relevant data on the public health, medical, and economic impact of proposed health plan and health insurance benefit mandate legislation. The CHBRP was created in response to AB 1996. The California Health Benefits Review Program's (CHBRP's) analysis of SB 1158 indicates the following:

- 1) Medical effectiveness: A literature search analysis supports the conclusion that the use of hearing aids is medically effective in treating children with hearing loss. One report showed observational and anecdotal evidence that early childhood detection and intervention of hearing impairment improves speech and language development.
- 2) Utilization, cost and coverage impacts: Approximately 61% of children with hearing loss whom do not have coverage for hearing aids use hearing aids. The estimated average cost of a hearing aid is \$3,000 and the expected life-span of a child's hearing aid is two years. Only 10% of the large group insurance market cover hearing aids, for example, the California Public Employees Retirement System offers a benefit of \$1,000 for every 36 months. Medi-Cal and Healthy Families cover hearing aids. Medi-Cal coverage is subject to utilization controls and Healthy Families covers hearing aids and ancillary items at no charge every 36 months. In terms of this bill's impacts on cost, the CHBRP predicts an average increase of .05% or \$0.12 per member per month, with the largest impact on the small group market. CHBRP states that the mandate in this bill would likely increase access to approximately 4% of children with hearing impairments.
- 3) Public health impacts. The CHBRP report estimates that an additional 3,200 children would obtain hearing aids with the passage of this bill, and that children who had obtained hearing aids previously are likely to obtain aids with better technology with the benefit subsidy in this bill. Additionally the report provides that qualitative studies suggest that untreated hearing impairments result in increases in lost productivity, special education needs and medical care costs.

## SB 1555 (Speier), 2004: Maternity Services

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*SENATE COMMITTEE ON INSURANCE Hearing, 4/19/2004*

UC Cost-Benefit Analysis: Pursuant to AB 1996 (Thompson, 2002), the University of California has submitted to the Legislature a cost-benefit analysis for each of the health insurance mandate bills before the committee at its April 21, 2004, hearing: SB 1158 (Scott); SB 1192 (Chesbro); and SB 1555 (Speier). The UC reports detail the medical effectiveness, cost, and public health impact of each health mandate bill.

The reports are coordinated by a small UC staff, which oversees a network of healthcare and health insurance experts and contracts with Milliman USA for actuarial analysis. UC gives the stakeholders who are directly affected by the legislation the opportunity to submit information but no editorial control over the reports. However, UC solicits comments on initial drafts of its analyses from a national stakeholders group, including representatives of consumers, insurers and health plans, employers and other purchasers, and hospitals and other providers.

The UC reports are the only cost-benefit analyses available to the committee for consideration. The director of UC's California Health Benefits Review Program will be available to answer questions that the committee may have about the reports. The executive summary and total cost analysis of SB 1192 have been excerpted from the full report and are attached to this analysis.

### UC Results in Brief

Medical effectiveness: UC finds that "many individual elements of both maternity and neonatal care have been demonstrated to be effective." However, limitations in the studies conducted on the full range, or "package," of maternity care prevent UC from making any firm conclusions about the medical effectiveness of the benefit package, as a whole, that is required in SB 1555. Utilization, cost, and coverage impacts: SB 1555 is estimated to increase premiums between \$0.00 and \$0.90 per member per month (PMPM), depending on the type of insurance product. In terms of total premium increases, SB 1555 is the lowest-costing health mandate bill before the committee when all markets are considered. This is because coverage for maternity care is almost universal in the group market, so its effect on total costs is small.

However, most of the cost increases from mandating coverage of maternity care occur the individual insurance market, particularly the 12% of that market that currently does not have the benefit. UC projects that the cost of individual insurance premiums could increase by an average of about 13% for individuals aged 25-39 currently without coverage for the benefits. (UC does assume that those in the individual market already covered for maternity care will see their premiums decrease slightly.) Within the 12% of the individual market currently without coverage for maternity care, premium increases could cause up to 1,900 men and women to drop coverage.

UC writes that because only 12% of those with individual health insurance have purchased policies excluding maternity coverage, it does not appear that the absence of a mandate has caused significant market segmentation, whereby low-risk individuals self-select into low-cost policies and drive up costs for high-risk insurance consumers.

On the other hand, UC notes that a recent change to the Insurance Code (SB 1411, Speier, 2002) prohibits health insurers from charging different copayments and deductibles for maternity care than they do for other types of care. Because policies with maternity care often had higher deductibles and copayments than policies excluding the benefit, UC projects that, in the absence of a mandate such as SB 1555, more plans may choose to exclude maternity coverage altogether (supporters of SB 1555 make a similar argument - see below).

Public Health Impacts: According to UC: "This mandate will not impact the health of the community through the benefits of prenatal care, because a large proportion of the insured target population is already covered for prenatal care. This legislation is also not likely to make any improvements in health outcomes such as low birth weight and pre-term births?. Finally, this legislation is not likely to substantially reduce infant mortality rates or premature death among pregnant women because of the small number of women who will be affected by the mandate."

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*ASSEMBLY COMMITTEE ON HEALTH Hearing, 6/14/2004*

HEALTH BENEFITS REVIEW PROGRAM ANALYSIS Consistent with AB 1996 (Thomson), Chapter 795, Statutes of 2002, the University of California reviewed this bill to determine its financial impact in relation to the entire private health insurance market for the working-age population. As a result, although the bill only directly affects people in DOI regulated plans, the California Health Benefits Review Program (CHBRP) reports costs and coverage changes for the entire private-insurance market and the potential impact on public payers and the number of uninsured. According CHBRP, most Californians with private insurance (98%) have coverage for prenatal care and maternity services. Statewide, an estimated 284,000 privately insured individuals do not have maternity benefits. For small firms (up to 50 employees), about 74,000 adults (1.4% of those employed in small firms that provide employee health benefits) lack coverage for maternity benefits. In large firms, about 18,000 adults (0.2% of those employed in large firms that provide employee health benefits) lack this coverage. In the market for individual coverage, approximately 12% lack maternity benefits. Total expenditures (including total premiums and out-of-pocket spending for copayments and non-covered benefits) by or on the behalf of all commercially insured individuals were estimated to increase by 0.01% as a result of the bill (or \$0.03 per member per month). Virtually all of the impact is expected to be concentrated in the individual insurance market, where total costs (including total premiums and out-of-pocket spending for copayments and non-covered benefits) were estimated to increase by 0.10%. Total costs in the group market, for both small and large firms, were estimated to increase by less than \$0.03 per member per month.

The report concluded that if the mandate contained in this bill is not enacted, more commercial insurers in the individual and group insurance markets could potentially drop maternity benefits as a cost-saving strategy to lower premiums and increase market share. The report also stated that this market segmentation could drive up the premiums for insurers who continue to offer maternity benefits, and lead to more individuals with private insurance moving to the Medi-Cal program to pay for their prenatal and delivery care.



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*ASSEMBLY COMMITTEE ON HEALTH Hearing, 6/29/2004*

Consistent with AB 1996 (Thomson), Chapter 795, Statutes of 2002, the University of California reviewed this bill to determine its financial impact in relation to the entire private health insurance market. UC's California Health Benefits Review Program (CHBRP) writes that most Californians with private insurance (98%) have coverage for prenatal care and maternity services. Statewide, an estimated 284,000 privately insured individuals do not have maternity benefits. For small firms (up to 50 employees), about 74,000 adults (1.4% of those employed in small firms that provide employee health benefits) lack coverage for maternity benefits. In large firms, about 18,000 adults (0.2% of those employed in large firms that provide employee health benefits) lack this coverage. In the market for individual coverage, approximately 12% of adults (or above 192,000 people) do not have maternity benefits.

Virtually all of the financial impact of this bill is expected to be concentrated in the individual insurance market, where total costs (including total premiums and out-of-pocket spending for copayments and non-covered benefits) are estimated to increase by 0.10%. However, in the individual market, premiums are estimated to increase by 13% among people aged 25 to 39 years who currently purchase policies without maternity benefits, although UC indicates the specific dollar increase in premium expenditures for this market segment is difficult to estimate.

The report concluded that if the mandate contained in this bill is not enacted, more commercial insurers in the individual and group insurance markets could potentially drop maternity benefits as a cost-saving strategy to lower premiums and increase market share. The report also states that this market segmentation could drive up the premiums for insurers who continue to offer maternity benefits, and lead to more individuals with private insurance moving to the Medi-Cal program to pay for their prenatal and delivery care.

*ASSEMBLY FLOOR Analysis, 7/9/2004*

Consistent with AB 1996 (Thomson), Chapter 795, Statutes of 2002, the University of California reviewed this bill to determine its financial impact in relation to the entire private health insurance market for the working-age population. As a result, although SB 1555 only directly affects people in DOI regulated plans, the California Health Benefits Review Program (CHBRP) reports costs and coverage changes for the entire private-insurance market and the potential impact on public payers and the number of uninsured. According CHBRP, most Californians with private insurance (98%) have coverage for prenatal care and maternity services. For small firms (up to 50 employees), about 74,000 adults (1.4% of those employed in small firms that provide employee health benefits) lack coverage for maternity benefits. In large firms, about 18,000 adults (0.2% of those employed in large firms that provide employee health benefits) lack this coverage. In the market for individual coverage, approximately 12% lack maternity benefits. Total expenditures (including total premiums and out-of-pocket spending for copayments and non-covered benefits) by or on the behalf of all commercially insured individuals were estimated to increase by 0.01% as a result of the bill (or \$0.03 per member per month). Virtually all of the impact is expected to be concentrated in the individual insurance market, where total costs (including total premiums and out-of-pocket spending for copayments and non-covered benefits) were estimated to increase by 0.10%. Total costs in the

group market, for both small and large firms, were estimated to increase by less than \$0.03 per member per month.

The report concluded that if the mandate contained in this bill is not enacted, more commercial insurers in the individual and group insurance markets could potentially drop maternity benefits as a cost-saving strategy to lower premiums and increase market share. The report also stated that this market segmentation could drive up the premiums for insurers who continue to offer maternity benefits, and lead to more individuals with private insurance moving to the Medi-Cal program to pay for their prenatal and delivery care.

## AB 2185 (Frommer), 2004: Asthma Management

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*ASSEMBLY COMMITTEE ON HEALTH Hearing, 4/19/2004*

Consistent with AB 1996 (Thomson), Chapter 795, Statutes of 2002, the University of California reviewed the portion of this bill that mandates coverage of asthma training and education. Through their analysis of literature, they found that self-management training and education for children with symptomatic asthma has statistically significant effects in reducing the number missed school days, the percentage of children with asthma experiencing restricted-activity days, nights of nocturnal asthma, and days of asthma symptoms. They also reported that training and education was found to have an effect on increased numbers of symptom-free days and child and caregiver knowledge about asthma and its management. Additionally, these services resulted in an estimated 26% reduction in asthma-related emergency room visits and a 30% reduction in the number of asthma-related hospitalizations.

Finally, their analysis concluded that total expenditures (including total premiums and out-of-pocket costs) would increase by 0.02% in both the large- and small-group markets and the individual market. The new costs associated with increased utilization of self-management training and education and over-the-counter drugs are estimated to increase total expenditures by .022%. However, the savings associated with reduced emergency room and hospital utilization is estimated to offset total expenditures by .002% (approximately 10% of the increase is offset by savings).

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*SENATE COMMITTEE ON INSURANCE Hearing, 6/16/2004*

Pursuant to AB 1996 (Thomson, Chapter 795, Statutes of 2002), the California Health Benefits Review Program (CHBRP) analyzed this bill for medical effectiveness, cost, and public health impacts. In brief, CHBRP found that the literature supports the effectiveness of self-management training and education programs, and it suggests that self-management interventions can reduce emergency room visits and hospitalizations by 26% and 30%, respectively. Based upon the literature, CHBRP could not determine the effectiveness of spacers, nebulizers, and peak flow meters.

As for cost, CHBRP found that nearly all children enrolled in health maintenance organizations in California have coverage for the devices and education mandated in this bill. The biggest changes in utilization would be greater use of pediatric self-management education programs (+10% for children already covered) and, again, a decrease in asthma-related emergency room visits and hospitalizations. The impact on cost (total net expenditures including total premiums and out-of-pocket costs) would be an increase of 0.007% in both the large and small group markets and the individual market. Public health benefits could include the following, CHBRP found: reduced restrictions on the physical activities of children, reduced acute episodes of childhood asthma, and increased knowledge of asthma leading to improvements in childrens' lives and the lives of their caregivers.

**AB 1549 (Frommer, Chan, Laird) 2004: Childhood Asthma**

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*ASSEMBLY COMMITTEE ON HEALTH* Hearing, 4/30/2004

A portion of this bill proposes that health care service plans provide a mandated benefit. Consistent with AB 1996 (Thompson), Chapter 795, Statutes of 2002), the author is requesting that these provisions be removed from the bill in committee so that the University of California can review the issue of requiring health plans to cover medication, devices, and training and education services.



## Appendix 18: CHBRP in the Media

This appendix includes a compilation of selected media references to CHBRP. The hyperlinks indicated were current as 12/21/05.

### Newspapers:

9/4/04 SF Chronicle (Re: SB 1555)

<http://sfgate.com/cgi-bin/article.cgi?f=/c/a/2004/09/04/BUGKG8JLUJ1.DTL>

### Broadcast News:

ABC News 10 Sacramento (Re: SB 1555)

<http://www.news10.net/storyfull1.asp?id=7865>

### On-line news:

California Healthline 9/13/04 & 9/23/04 (Re: SB 1555)

<http://www.californiahealthline.org/index.cfm?Action=dspItem&itemID=105638>

<http://californiahealthline.org/index.cfm?Action=dspItem&itemID=105869>

National Lymphedema Network (Re: AB 213)

[http://www.lymphnet.org/aboutLymphedema/legislation/legSummaries\\_April2005.htm](http://www.lymphnet.org/aboutLymphedema/legislation/legSummaries_April2005.htm)

Center for Tobacco Cessation (Re: SB 576)

<http://ctcinfo.org/enewsletter/default.asp?id=194>

### Professional Newsletters:

Northern CA Association of Insurance Underwriters Vol 13, Issue 3 March 2004

What and Who is the California Health Benefits Review Program?

[http://www.northcoastahu.org/broker\\_images/northcoastahuorg/documents/newsletter-march04.pdf](http://www.northcoastahu.org/broker_images/northcoastahuorg/documents/newsletter-march04.pdf)

American College of Physicians - Sources of Legislative Information

[http://www.acponline.org/chapters/ca/legis\\_resources.htm](http://www.acponline.org/chapters/ca/legis_resources.htm)

### Other Public Policy Development:

Washington State Dept. of Health Quality Assurance

Re: SB 1158

[http://www.wasa-shhh.org/hearingaidsunrise\\_draft\\_nov19%2020\\_2\\_.pdf](http://www.wasa-shhh.org/hearingaidsunrise_draft_nov19%2020_2_.pdf)

Healthcare Georgia Foundation Policy Report "HealthTRAK Georgia"  
cited CHBRP as example of state program to review proposed health insurance benefit  
mandates.

[http://www.ciprg.com/ul/wpg/mandated\\_hb.pdf](http://www.ciprg.com/ul/wpg/mandated_hb.pdf)

Health Affairs and California Healthcare Foundation/Health Affairs Roundtable  
Conference Summary: Setting Priorities in Medical Care Through Benefit Design And Medical  
Management

<http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.300v1/DC1?eaf>

Presentation at the American Public Health Association Conference

[http://apha.confex.com/apha/133am/techprogram/paper\\_111709.htm](http://apha.confex.com/apha/133am/techprogram/paper_111709.htm)



**Appendix 19: Existing Mandates in California Law**

Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
		Benefit/Description							
<b>Standards: Mandated Benefits</b>									
	§ 1345	Basic Health Care Services							Minimum benefits for all health care service plan contracts under the Knox-Keene Health Care Service Plan Act of 1975
	1367.06	Asthma Management	Yes			X		X	A health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2005, that covers outpatient prescription drug benefits shall include coverage for inhaler spacers when medically necessary for the management and treatment of pediatric asthma.
10123.7	1367.18	Orthotic and prosthetic devices and services	Yes			X	X		Every health care service plan, except a specialized health care service plan, that covers hospital, medical, or surgical expenses on a group basis shall offer coverage for orthotic and prosthetic devices and services under the terms and conditions that may be agreed upon between the group subscriber and the plan.
10123.141	1367.19	Special footwear for persons suffering from foot disfigurement	Yes			X	X		On and after January 1, 1991, every health care service plan, except a specialized health care service plan, that covers hospital, medical, or surgical expenses on a group basis shall offer coverage as an option for special footwear needed by persons who suffer from foot disfigurement under such terms and conditions as may be agreed upon between the group contract holder and the plan. As used in this section, foot disfigurement shall include, but not be limited to, disfigurement from cerebral palsy, arthritis, polio, spinabifida, diabetes, and foot disfigurement caused by accident or developmental disability.

Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
10123.6	§ 1367.2	Alcoholism Treatment			X		X		On and after January 1, 1990, every health care service plan that covers hospital, medical, or surgical expenses on a group basis shall offer coverage for the treatment of alcoholism under such terms and conditions as may be agreed upon between the group subscriber and the health care service plan.
	§ 1367.21	Prescription Drugs: Off Label Use				X		X	Mandate to cover "off-label" uses of FDA-approved drugs –uses other than the specific FDA-approved use – in life threatening situations and in cases of chronic and seriously debilitating conditions
	1367.22	Prescription Drugs: Coverage of Previously Covered Drugs				X		X	A health care service plan contract, issued, amended, or renewed on or after July 1, 1999, that covers prescription drug benefits shall not limit or exclude coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. Nothing in this section shall preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate for the enrollee, nor shall anything in this section be construed to prohibit generic drug substitutions as authorized by Section 4073 of the Business and Professions Code.
	§ 1367.25	Contraceptive Prescription Drugs				X		X	A health care service plan contract that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration approved prescription contraceptive methods designated by the plan. In the event the patient's participating provider, acting within his or her scope of practice, determines that none of the methods designated by the plan is medically appropriate for the patient's medical or personal history, the plan shall also provide coverage for another federal Food and Drug Administration approved, medically appropriate prescription contraceptive method prescribed by the patient's provider.



Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
10123.5	§ 1367.3	Providing comprehensive preventive care of children 17 or 18 years old			X		X		On and after January 1, 1993, every health care service plan that covers hospital, medical, or surgical expenses on a group basis shall offer benefits for the comprehensive preventive care of children. This section shall apply to children 17 and 18 years of age, except as provided in paragraph (4) of subdivision (b).
10123.55	§ 1367.35	Providing comprehensive preventive care of children 16 years or under			X			X	On and after January 1, 1993, every health care service plan that covers hospital, medical, or surgical expenses on a group basis shall provide benefits for the comprehensive preventive care of children 16 years of age or younger under terms and conditions agreed upon between the group subscriber and the plan.
N/A	§ 1367.4	Insurance coverage for blindness/partial blindness		X	X			X	No plan issuing, providing, or administering any contract of individual or group coverage providing medical, surgical, or dental expense benefits applied for and issued on or after January 1, 1986, shall refuse to cover, or refuse to continue to cover, or limit the amount, extent, or kind of coverage available to an individual, or charge a different rate for the same coverage solely because of blindness or partial blindness.
N/A	§ 1367.45	AIDS Vaccine coverage		X	X			X	Every individual or group health care service plan contract that is issued, amended, or renewed on or after January 1, 2002, that covers hospital, medical, or surgery expenses shall provide coverage for a vaccine for acquired immune deficiency syndrome (AIDS) that is approved for marketing by the federal Food and Drug Administration and that is recommended by the United States Public Health Service.
10176.61	§ 1367.51	Diabetes benefits	Yes			X		X	Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2000, and that covers hospital, medical, or surgical expenses shall include coverage for the following equipment and supplies for the management and treatment of insulin-using diabetes, non-insulin-using diabetes, and gestational diabetes as medically necessary, even if the items are available without a prescription.

Source		Benefit/Description	Population/Products Affected			Nature of Coverage		Detailed Description	
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage		Shall Cover
10123.184	§ 1367.54	Maternity benefits (Expanded Alpha Feto Protein )		X	X			X	Every group health care service plan contract that provides maternity benefits, except for a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 1999, and every individual health care service plan contract of a type and form first offered for sale on or after January 1, 1999, that provides maternity benefits, except a specialized health care service plan contract, shall provide coverage for participation in the Expanded Alpha Feto Protein (AFP) program, which is a statewide prenatal testing program administered by the State Department of Health Services.
10123.8	1367.6	Breast cancer benefits	Yes			X		X	Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2000, shall provide coverage for screening for, diagnosis of, and treatment for, breast cancer.
10123.82	1367.61	Prosthetic device benefits for Laryngectomy				X		X	Every health care service plan contract which provides for the surgical procedure known as a laryngectomy and which is issued, amended, delivered, or renewed in this state on or after January 1, 1993, shall include coverage for prosthetic devices to restore a method of speaking for the patient incident to the laryngectomy.
10123.87	1367.62	Maternity benefits: restrictions		X	X			X	No health care service plan contract that is issued, amended, renewed, or delivered on or after the effective date of the act adding this section, that provides maternity coverage, shall do any of the following: (1) Restrict benefits for inpatient hospital care to a time period less than 48 hours following a normal vaginal delivery and less than 96 hours following a delivery by caesarean section.

Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
10123.88	1367.63	Reconstructive surgery	Yes	X	X			X	Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, renewed, or delivered in this state on or after July 1, 1999, shall cover reconstructive surgery, as defined in subdivision (c), that is necessary to achieve the purposes specified in paragraphs (1) or (2) of subdivision (c).
10123.86	1367.635	Mastectomies and lymph nodes dissections contract provisions		X	X			X	Allow the length of a hospital stay associated with those procedures to be determined by the attending physician and surgeon in consultation with the patient, consistent with sound clinical principles and processes. No health care service plan shall require a treating physician and surgeon to receive prior approval from the plan in determining the length of hospital stay following those procedures.
10123.83	1367.64	Prostate cancer screening and diagnosis		X	X			X	Every individual or group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, or renewed on or after January 1, 1999, shall be deemed to provide coverage for the screening and diagnosis of prostate cancer, including, but not limited to, prostate specific antigen testing and digital rectal examinations, when medically necessary and consistent with good professional practice.
10123.81	1367.65	Mammography coverage	Yes			X		X	On or after January 1, 2000, every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed shall be deemed to provide coverage for mammography for screening or diagnostic purposes upon referral by a participating nurse practitioner, participating certified nurse midwife, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.

Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
10123.18	1367.66	Cervical cancer screening coverage	Yes	X	X			X	Every individual or group health care service plan contract, except for a specialized health care service plan, that is issued, amended, or renewed, on or after January 1, 2002, and that includes coverage for treatment or surgery of cervical cancer shall also be deemed to provide coverage for an annual cervical cancer screening test upon the referral of the patient's physician, a nurse practitioner, or certified nurse midwife, providing care to the patient and operating within the scope of practice otherwise permitted for the licensee.
10123.2	1367.665	Cancer Screening Test	Yes	X	X			X	Every individual or group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after July 1, 2000, shall be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all terms and conditions that would otherwise apply.
10123.185	1367.67	Osteoporosis coverage						X	Every health care service plan contract that provides hospital, medical, or surgical coverage, that is issued, amended, delivered, or renewed in this state on or after January 1, 1994, shall be deemed to include coverage for services related to diagnosis, treatment, and appropriate management of osteoporosis. The services may include, but need not be limited to, all Food and Drug Administration approved technologies, including bone mass measurement technologies as deemed medically appropriate.
10123.21	1367.68	Jawbone or bone joints coverage	Yes					X	Any provision in a health care service plan contract entered into, amended, or renewed in this state on or after July 1, 1995, that excludes coverage for any surgical procedure for any condition directly affecting the upper or lower jawbone, or associated bone joints, shall have no force or effect as to any enrollee if that provision results in any failure to provide medically-necessary basic health care services to the enrollee pursuant to the plan's definition of medical necessity. (b) For purposes of this section, "plan contract" means every plan contract, except a specialized health care service plan contract, that covers hospital, medical, or surgical expenses.

Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
10123.83	1367.69	OB-GYN as PCPs				X		X	On or after January 1, 1995, every health care service plan contract that provides hospital, medical, or surgical coverage, that is issued, amended, delivered, or renewed in this state, shall include obstetrician-gynecologists as eligible primary care physicians, provided they meet the plan's eligibility criteria for all specialists seeking primary care physician status.
10123.9	1367.7	Prenatal diagnosis of genetic disorders			X		X		On and after January 1, 1980, every health care service plan contract that covers hospital, medical, or surgical expenses on a group basis, and which offers maternity coverage in such groups, shall also offer coverage for prenatal diagnosis of genetic disorders of the fetus by means of diagnostic procedures in cases of high-risk pregnancy. Every health care service plan shall communicate the availability of such coverage to all group contract holders and to all groups with whom they are negotiating.
10119.9	1367.71	General Anesthesia for Dental Procedures	Yes			X		X	Every health care service plan contract, other than a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 2000, shall be deemed to cover general anesthesia and associated facility charges for dental procedures rendered in a hospital or surgery center setting, when the clinical status or underlying medical condition of the patient requires dental procedures that ordinarily would not require general anesthesia to be rendered in a hospital or surgery center setting.
10122.1	1367.8	Physically or mentally impaired persons		X	X			X	No plan issuing, providing, or administering any individual or group health care service plan entered into, amended, or issued on or after January 1, 1981, shall refuse to cover, or refuse to continue to cover, or limit the amount, extent or kind of coverage available to an individual, or charge a different rate for the same coverage solely because of a physical or mental impairment, except where the refusal, limitation or rate differential is based on sound actuarial principles applied to actual experience, or, if insufficient actual experience is available, then to sound underwriting practices.

Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
	1368.2	Hospice Care			X			X	On and after January 1, 2002, every group health care service plan contract, except a specialized health care service plan contract, which is issued, amended, or renewed, shall include a provision for hospice care. (b) The hospice care shall at a minimum be equivalent to hospice care provided by the federal Medicare program pursuant to Title XVIII of the Social Security Act.
	1368.5	Pharmacy Services							Every health care service plan that offers coverage for a service that is within the scope of practice of a duly licensed pharmacist may pay or reimburse the cost of the service performed by a pharmacist for the plan if the pharmacist otherwise provides services for the plan.
10119.7	1367.9	Diethylstilbestrol						X	No health care service plan contract which covers hospital, medical, or surgical expenses shall be issued, amended, delivered, or renewed in this state on or after January 1, 1981, if it contains any exclusion, reduction, or other limitations, as to coverage, deductibles, or coinsurance or copayment provisions applicable solely to conditions attributable to diethylstilbestrol or exposure to diethylstilbestrol.
10126.6	1367.11	Medical transportation services						X	Every health care service plan issued, amended, or renewed on or after January 1, 1987, that offers coverage for medical transportation services, shall contain a provision providing for direct reimbursement to any provider of covered medical transportation services if the provider has not received payment for those services from any other source.
10123.15	1367.215	Pain management medication for terminally ill						X	Every health care service plan contract that covers prescription drug benefits shall provide coverage for appropriately prescribed pain management medications for terminally ill patients when medically necessary. The plan shall approve or deny the request by the provider for authorization of coverage for an enrollee who has been determined to be terminally ill in a timely fashion, appropriate for the nature of the enrollee's condition, not to exceed 72 hours of the plan's receipt of the information requested by the plan to make the decision.

Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
	1367.22	Prescription drug benefits; medically appropriate alternatives.				X		X	A health care service plan contract, issued, amended, or renewed on or after July 1, 1999, that covers prescription drug benefits shall not limit or exclude coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.
	1367.24	Authorization for nonformulary prescription drugs				X		X	If the drug is not on the plan formulary, the participating subscriber's request shall be considered pursuant to the process required by Section 1367.24.
	1370.6	Coverage For Services Related to Clinical Trials	X			X		X	For an enrollee diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer, every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed in this state, shall provide coverage for all routine patient care costs related to the clinical trial if the enrollee's treating physician, who is providing covered health care services to the enrollee under the enrollee's health benefit plan contract, recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the enrollee.
10127.3		reimbursement for acupuncture services	Yes		X		X	X	On and after January 1, 1985, every insurer issuing group disability insurance which covers hospital, medical, or surgical expenses shall offer coverage for expenses incurred as a result of treatment by holders of certificates under Section 4938 of the Business and Professions Code, under such terms and conditions as may be agreed upon between the group policyholder and the insurer; [Section 4938 of B&P: The board shall issue a license to practice acupuncture to any person who makes an application and meets the following requirements...]

Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
	1373.4	Maternity Coverage				X		X	No health care service plan contract that is issued, amended, renewed, or delivered on or after July 1, 2003, that provides maternity coverage shall do either of the following: (1) Contain a copayment or deductible for inpatient hospital maternity services that exceeds the most common amount of the copayment or deductible contained in the contract for inpatient services provided for other covered medical conditions.
10123.89	1374.56	Phenylketonuria; testing and treatment	Yes			X		X	On and after July 1, 2000, every health care service plan contract, except a specialized health care service plan contract, issued, amended, delivered, or renewed in this state that provides coverage for hospital, medical, or surgical expenses shall provide coverage for the testing and treatment of phenylketonuria (PKU) under the terms and conditions of the plan contract.
10119.6	§ 1374.55	Infertility treatments				X	X		On and after January 1, 1990, every health care service plan contract which is issued, amended, or renewed that covers hospital, medical, or surgical expenses on a group basis, where the plan is not a health maintenance organization as defined in Section 1373.10, shall offer coverage for the treatment of infertility, except in vitro fertilization, under those terms and conditions as may be agreed upon between the group subscriber and the plan. Every plan shall communicate the availability of that coverage to all group contract holders and to all prospective group contract holders with whom they are negotiating.
10119.8	§ 1367.3(b)(2)(D)	Screen for blood lead levels in children		X	X		X		For health care service plan contracts within the scope of this section that are issued, amended, or renewed on and after January 1, 1993, screening for blood lead levels in children at risk for lead poisoning, as determined by a physician and surgeon affiliated with the plan, when the screening is prescribed by a physician and surgeon affiliated with the plan. This subparagraph shall be applicable to all children and shall not be limited to children 17 and 18 years of age.



Source		Benefit/Description	Population/Products Affected				Nature of Coverage		Detailed Description
CA Insurance Code	Knox Keene (Health & Safety Code) Section		Exception Made for Specialized Health Care Plan	Ind	Groups Basis	No Mention	Shall Offer Coverage	Shall Cover	
10123.15	§ 1374.72	Biologically based severe mental disorders			X		X		Every group policy of disability insurance which covers hospital, medical, and surgical expenses on a group basis, and which offers coverage for disorders of the brain shall also offer coverage in the same manner for the treatment of the following biologically based severe mental disorders: schizophrenia, schizo-affective disorder, bipolar disorders and delusional depressions, and pervasive developmental disorder. Coverage for these mental disorders shall be subject to the same terms and conditions applied to the treatment of other disorders of the brain; however, an insurer may reserve the right to confirm diagnoses and to review the appropriateness of specific treatment plans as necessary to ensure that coverage under this section is provided for only those diagnostic and treatment services which are medically necessary.
<p>*This document is valid as of Feb, 2005 and subject to changes to the CA Health and Safety Code, the CA Insurance Code and other laws (such as the CA Business and Professions Code) which may impact the source codes used in this document.</p>									



## **Appendix 20: Special Issue of *Health Services Research*: Selected Articles from the Forthcoming Edition Specific to CHBRP**

The journal *Health Services Research (HSR)* provides those engaged in research, public policy formulation and health services management with the latest findings, methods and thinking on important health policy and practice issues. The journal features original empirical articles, a public policy and managerial impact section, a recurrent community health research section, research briefs, a methods section and occasional debates. In a recent national survey published in *Medical Care Research and Review* of 54 journals in the field, the University of Alabama Management and Marketing Department ranked HSR second only to the *New England Journal of Medicine* in perceived quality and third in perceived relevance.

Through a grant from the California Health Care Foundation, *HSR* has elected to dedicate a special issue of their journal to the California's mandate evaluation process, vis-à-vis the articles on the history, methods, processes of the California Health Benefits Review Program. The special edition is scheduled to be published in June, 2006. Included in this appendix are the following selected articles from the forthcoming edition:

**Bellows, Nicole, McMenamain S, Halpin H.** *State Mandated Benefit Review Laws.*

**Halpin H, McMenamain S, Pourat N, Yelin E.** *Mandating Coverage of Pediatric Asthma: Self-Management Training and Education.*

Other appendices in this report include the following papers also in the upcoming *HSR* issue:

**Kominski Gerald, Ripps Jay, Laugesen Miriam, Cosway Robert, Pourat Nadereh.** *The California Cost and Coverage Model: Analyses of the Financial Impacts of Benefit Mandates for the California Legislature.* (Appendix 11)

**Luft Harold, Rappaport Karen, Yelin Edward, Aubry Wade.** *Evaluating Medical Effectiveness for the California Health Benefits Review Program.* (Appendix 10)

**McMenamin Sara, Halpin Helen, Ganiats Ted.** *Assessing the Public Health Impacts of Health Benefit Mandates.* (Appendix 12)



## **State Mandated Benefit Review Laws**

**Nicole Bellows, Helen Ann Halpin, Sara McMenammin**

**Disclaimer:** This paper has been submitted for publication in *Health Services Research*. Dissemination of this preliminary version is intended to provide the California Legislature and other interested parties with detailed descriptions of the methods used by the California Health Benefits Review Program in its reports. Please do not cite or reproduce for any other purpose without consent of the authors and written notification of the California Health Benefits Review Program.

## **Abstract**

The growth of state mandated health insurance benefits has given rise to concerns regarding the effects of these mandates on increasing premium costs and access to health insurance. More than half of the state legislatures in the United States have enacted laws that establish a process to review proposed and/or existing health insurance mandates. This paper reviews the laws enacted in 26 states active as of September 2004. While recognizing that the enacted laws may differ from the ways that states implement these laws, the mandated benefit review (MBR) laws detail the various approaches states have defined to review health insurance mandates including: the general review strategy, the designated reviewers, the time frames for conducting the analysis, the specific criteria used to evaluate the impact of proposed mandated benefits, and requirements to use actuaries, sources of funding, and state data collection systems. This paper describes the variation across state MBR laws and discusses the advantages and disadvantages of the different approaches.

## **Introduction**

*A state legislator considers a proposal that would require health plans to cover screening for prostate cancer. While she recognizes that prostate cancer is an important problem and that mandating coverage can help increase access to these services, she is also aware of the controversy among medical experts about the value of general prostate cancer screening tests' and is concerned about what effect this mandate will have on the escalating cost of health insurance and the number of uninsured individuals in her state.*

The above scenario represents a dilemma facing many state legislators in considering the enactment of new state health insurance benefit mandates. While wanting to make sure that their constituents have access to the health care services they need, in a budget constrained environment the questions they face become: Of what real value are these benefits to the people

of the state? Have these benefits been proven to be effective in improving health? And how much will a legislative mandate affect the general affordability of health insurance in the state?

State legislatures have addressed some of these questions by passing mandated benefit review (MBR) laws that inform the decision-making process by requiring a review of existing or proposed health insurance benefit mandates. This paper examines the rise of state MBR laws and the different approaches states have taken to conduct such reviews.

## **Background**

State health insurance mandates require that health insurers and/or health insurance products include coverage for a defined group of people (e.g., coverage for dependents, coverage for persons with a specific medical condition); types of providers (e.g. podiatrists, ophthalmologists, chiropractors); or certain treatments, services, pharmaceuticals, or durable medical equipment (e.g., mammograms, diabetes testing strips, orthotics). Additionally, state health insurance benefit mandates can dictate how care will be provided (e.g., minimum lengths of stay in a hospital following childbirth or surgery).

Jensen and Morrisey (1999) describe the history of state benefit mandate law adoption starting with the 1956 Massachusetts law that required dependent coverage for handicapped children. By the late 1990s, there were reportedly over 1,000 state health insurance benefit mandates in effect in the US with a growing number of proposals being introduced and passed in state legislatures each year (Jensen and Morrisey, 1999). While the National Conference of State Legislatures has suggested that the rate of state mandate adoption may have slowed in recent years (NCSL, 2003), other organizations such as the Council for Affordable Health Insurance, which has identified over 1,800 existing state benefit mandates, argue that mandates remain prominent on state legislative agendas (Bunce and Wieske, 2004).

The dramatic expansion of state mandated health insurance benefits in the 1980s and 1990s was likely due to political factors. To begin, those who realized the benefits of health insurance mandates tended to be concentrated interests represented by well-organized groups of health care professionals and persons or parents of persons with a specific medical condition, who have an intense interest in a particular mandate and its outcome. At the same time, the costs of such benefit mandates were usually diffuse and spread over the majority of the population with private health insurance residing in the state, often amounting to only pennies per month on individual health insurance premiums for any one mandate. Consequently, mandated benefit laws were likely to be “political winners” when they had an organized set of interests pushing for them with little resistance from those who would bear the costs (Wilson, 1980).

However, since the late 1990s, when health care costs began to increase rapidly again and the number of uninsured began to grow, the above political formula for success changed. Employers began to balk at rising health insurance premiums and began pressuring insurance companies to look for ways to control costs, while states continued to add new mandated benefits to the coverage offered by health insurers and HMOs. As a result, the health insurance industry began to take a critical view of mandated benefits and began to argue against them based on their impact on increasing premium costs and the escalating number of uninsured.

There has also been a growing concern about the effect of mandates on the cost of health care premiums for workers and for employers’ decisions to provide health insurance to their employees (Battistella and Burchfield, 2000). Additionally, the growth of state regulation on health insurance may have stimulated more employers to switch from offering commercial health plans to offering self-insured plans, due to the protections offered under the Employment Retirement and Income Security Act of 1974 (ERISA), which exempts self-funded plans from

complying with state health insurance laws and regulations.

In response to concerns about the volume of mandates and their consequences and pressure from the insurance industry, several states have adopted MBR laws intended to provide more information on mandates and thus enable legislators to make more informed decisions regarding mandated benefits. While researchers have explored the consequences of mandated benefits (Gabel and Jensen, 1989; Jensen and Gabel, 1992; Gruber, 1994; Jain et al., 2002; Kotagul et al., 2003; Gailbraith et al., 2003), a review of the peer reviewed literature yielded no publications that described in detail the state MBR laws in the US. As such, this paper is the first to analyze and discuss the different approaches states take to review mandated benefits, as described in the state MBR laws.

## **Methodology**

The first step in this analysis was to define what constitutes a state MBR law. We defined MBR laws as those that specifically called for a review of proposed or existing state mandated health insurance benefits. Since the accessibility of prior state statutes varies substantially, we restricted the analysis of MBR laws to those that were active as of September 2004, when we collected the data, and we did not include any MBR legislation that had expired and not been renewed. Also not included as MBR laws are more general state laws that require a fiscal analysis of all proposed legislation and do not specifically target mandated health insurance benefits.

The second major step was to identify which states had MBR laws according to our definition. We queried online databases of the individual state statutes and reviewed the health insurance sections of the state statutes for all 50 states and Washington D.C. to identify those states with active MBR laws as of September 2004. We also reviewed state legislative agendas



to identify those states that had recently passed MBR legislation that had not yet been incorporated into the compiled state statutes, which resulted in identifying one additional MBR law (New Hampshire). For those states where we did not find any statutory reference to a MBR law, we then contacted the state legislative librarian or similar state official to confirm that an active law did not exist during the study period. Next, the list of states with MBR laws were confirmed against other available sources detailing the states that had MBR laws (AAHP, 2003; BCBS, 2004; Gitterman, 2003; Lee, 2003). Where there were discrepancies, we found that differences were due to different inclusion criteria such as whether the MBR law was active at in September 2004.

Having identified the 26 states with MBR laws to be included in our analysis, the next step was to select the components of the MBR laws on which we would report. To accomplish this, we reviewed the laws to identify and catalog their various components. We chose the specific components on which to report based on the extent to which they were relevant to the policy-making process as well as their prevalence in the 26 MBR laws. The components chosen for this analysis include: general review strategy, designated reviewers, time frame for conducting reviews, criteria used in the review, requirements to use actuaries, sources of funding, and state data collection systems. Two of the authors independently created categories and reached consensus on how to best classify the key components of the MBR laws. Two independent coders reviewed the 26 state MBR laws to document inclusion of the major components of the MBR laws with an overall inter-rater reliability of 95%.

## **Findings**

Twenty-six states were found to have MBR laws on their books as of September 2004. Table 1 presents the year the MBR laws were first enacted in each state ranging from 1985

(Arizona and Oregon) to the most recently passed MBR law in 2004 (New Hampshire). Seven of the 26 states adopted MBR laws during the 1980s, although four of these laws have been amended or renewed since their initial enactment. Another seven states adopted MBR legislation during the 1990s and five have been subsequently renewed or amended. Twelve states have adopted MBR legislation since 2000.

### *General Review Strategy*

There are three general strategies for reviewing health insurance mandates in the MBR laws: (1) a prospective review of proposed mandated benefit legislation, (2) a retrospective review of benefit mandates already in the state statutes, and (3) a combination of both prospective and retrospective reviews (Table 2).

The prospective approach dominates in the current statutes, with 18 states using a prospective-only approach. South Carolina is the only state that was conducting an exclusively retrospective analysis in 2004. In the recent past, other states including Texas and Hawaii have also conducted retrospective reviews. At the conclusion of retrospective analyses, the reviewers typically report back to the legislature regarding their findings and recommendations for revising or eliminating specific mandates. Seven states use a combination approach evaluate both the impact that individual mandates prior to their enactment as well as the cumulative effect of all enacted mandates in the state.

### *Designated Reviewers*

Another important distinction between state MBR laws is who is given the primary responsibility for completing the review and submitting it to the intended recipients. Table 2 classifies the 26 states with MBR laws according to five categories of reviewers: (1) the

proponents of the legislation, (2) administrative or legislative personnel, (3) a legislative contractor, (4) a legislatively established commission or task force, and (5) a university.

Six states require that the proponents of the legislation conduct the review. Typically, this model requires that when a mandated benefit is introduced, it must be accompanied by an analysis conducted by the proponents that evaluates the effects the mandate will have on the state according to the criteria specified in the state MBR law before it can be considered for passage.

For the second type of reviewer, administrative or legislative personnel have responsibility for conducting the review. Ten states use this approach to review mandated benefits. In these states, it is often the insurance department, bureau or commissioner who is given responsibility for evaluating mandated benefit proposals. Other states rely on legislative staff for the reviews such as the state's legislative fiscal officer.

North Dakota and Ohio specify that the legislature contract with an external reviewer in evaluating the mandated benefit. North Dakota requires the legislative council to contract with a "private entity" while Ohio specifies that the legislative service commission must retain independent actuaries to conduct the analysis.

Eight states utilize a fourth category of reviewer, a legislatively established commission or task force<sup>1</sup>. This approach may rely on a commission already in existence or may require the creation of a new commission for the specific purpose of reviewing benefit mandate proposals. The types of individuals commonly included on commissions or task forces include members or representatives of: state government, medical professionals, the health care industry, the business community, health care recipients, and academics or researchers.

California is the only state to use the final category of reviewer, a university. In

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<sup>1</sup> Colorado's statutes require two separate reviews. The first review requires the proponents of the review to conduct the review, per the 1992. In 2003, a commission was added that may consider the proponents reviews but must conduct its own review and that of existing mandates. For this reason, Colorado has two primary reviewers.

California's MBR law, the responsibility for reviewing proposed state benefit mandate legislation is granted to the University of California, where health services researchers associated with medical schools and schools of public health review the benefit mandates.

### *Time Frames for Reporting*

Table 2 also details the amount of time reviewers are given to conduct the review, which varies substantially. One approach has been to allot a specific time period to complete the review of each individual mandate. Nine states have adopted this model and the time periods range from 20 days (Georgia) to 24 months (Virginia), with a median of 60 days per review. In four states, there is a specific yearly or twice yearly date on which the reviewers must report their findings for all the mandates they reviewed. Similarly South Carolina, which conducted a retrospective review, specified a one-time report date of January 1, 2005. In seven states, the review must be completed prior to consideration by the legislature and in five states, either no mention of a time frame was identified or the time frame was vague such as "determined by committee chair".

### *Review Criteria*

When determining whether a mandated benefit would be in the interest of the citizens of the state, there is a wide range of criteria that states consider. Of the 26 states with MBR laws, 25 identified specific criteria required for consideration in assessing the effects of the mandated benefit under review. More than 90 individual evaluation criteria were identified in the MBR laws. Based on the consensus of two independent coders, these criteria were classified into seven major categories: (1) cost impacts, (2) social impacts, (3) medical efficacy, (4) public health impacts, (5) political considerations, (6) provider impacts, and (7) quality of care impacts

(Table 3). Because the cost and social impacts had the greatest number of criteria and were most frequently included the MBR laws, these categories were subdivided further to capture variation within them.

The *cost impacts* category examines the general costs associated with the mandate such as the impact on the total cost of health care in the state, as well as costs for specific stakeholders affected by the mandate including consumers, insurers, employers, and state health insurance programs. Additionally, cost criteria may estimate the costs of *not* passing the mandate such as whether the lack of coverage results in an unreasonable financial burden for individuals and whether the mandated benefit could act as a substitute for more expensive treatment, thereby saving money. All 25 state MBR laws that specified review criteria included at least one cost impact criterion.

Following cost impacts, *social impact* criteria were cited in 20 of the MBR laws. Some of the MBR laws refer more broadly to “social” impacts; however, most laws further define it to include: utilization, insurance coverage, demand, availability, and need. Some criteria in this category assess the current status of the benefit (e.g., the public demand for the service/treatment) while others ask for projections of what impact the passage of the mandate bill will have, such as whether the mandate will increase the use of the service or treatment or encourage the appropriate use of the service or treatment. Other criteria included in this category are whether the lack of coverage results in individuals being unable to receive care or whether individuals avoid necessary care due to lack of coverage.

Twelve of the MBR laws require an examination of the *medical efficacy* of the service or treatment to verify that it is effective in the prevention or treatment of disease or disability. Included in this category are criteria evaluating whether the service or treatment is recognized by the medical community as being effective and efficacious, as well as whether medical efficacy has been demonstrated in the peer reviewed scientific literature.

Criteria for the remaining four categories are less common in MBR laws. The fourth category, *public health impacts*, is included in six of the MBR laws and examines how the mandate will affect the health of the state's population based on reductions in morbidity, mortality, and the effect on the overall health of the community. Next, *political considerations* are considered in four MBR laws and include an examination of the extent of opposition to the mandate and the balancing the trade-offs of the findings from the financial, social, and efficacy review criteria. Four MBR laws also include *provider impacts* and examine criteria such as how the benefit mandate will affect the number and types of providers in the state. Finally, four states also consider *quality of care* criteria, requiring reviewers to evaluate the impact the mandate will have on the quality of health care in the state.

Of the 25 MBR laws that include review criteria, the breadth of criteria included in the laws varies substantially. Four states (Kentucky, Louisiana, South Carolina, and Tennessee) specify only cost impacts as the basis for the review. An additional seven states limit the analysis to cost and social impacts. The remaining 14 MBR laws include at least one of the other five categories. Maine's MBR law specifies the broadest set of criteria, covering all seven major categories and 15 of the 16 subcategories identified.

### *Other Components of State MBR Laws*

The general review strategy, designated reviewer, time frames, and review criteria are aspects of the MBR laws that cut across most of the MBR laws. We also examined three additional characteristics that were less frequently included in the MBR laws but have interesting implications for the review of mandated benefits.

First, we determined whether MBR laws required the use of an actuary in conducting the reviews. Three states (Arizona, California and Ohio) require that an actuary prepare the financial analysis. Four other MBR laws state that the reviewer may obtain assistance from an actuary; however, this inclusion is not required.

Next, we examined whether the MBR law specified who pays for the reviews. While most of the MBR laws do not make a reference to the source of financing, it is often implied that the designated reviewer will bear the cost of conducting the review. Four states (New Jersey, North Dakota, Tennessee, and Virginia) explicitly identify the part of the state budget that funds reviews. Three states refer to external sources of funding. In California, reviews are funded through a health insurer fee determined by the legislature. Colorado's funding for reviews may also be supplemented through insurer fees. Minnesota's MBR law states that the reviewer "may seek and accept funding from sources other than the state to pay for evaluations" as long as the funding source does not influence the outcome.

In addition, three states (Colorado, New Jersey, and Virginia) included language in their statutes regarding data collection systems to be developed for use in conducting reviews of mandated benefits. These three states specified that a system and program of data collection be established for the purposes of assessing the impact of state mandated benefit laws. Specific data to be collected included: costs to employers and insurers, the impact of treatment, the cost

savings in the health care system, and the number of providers.

## **Discussion**

One limitation of this analysis is that it is restricted to the legislative language of enacted state MBR laws and does not examine differences in how the laws have been implemented. The issues around implementation are important in further understanding how MBR laws work to incorporate information into the decision-making process of state legislatures. Future research is needed to examine how MBR have been implemented, how the reviews are received by policy makers, and whether the reviews influence decision-making around mandated benefit legislation. In spite of this limitation, the MBR laws themselves are useful in gaining insight into how state legislatures intend to address the review of mandated health insurance benefits. The various approaches specified in the MBR laws have important advantages and disadvantages worth considering.

### *General Review Strategy*

The first distinctive feature of the MBR laws is the review orientation: prospective or retrospective. There are two main advantages to a prospective approach. First, a prospective approach establishes a process that can continue indefinitely and therefore is not subject to a one-time analysis and adjustment period, as with most retrospective analyses. A second advantage of the prospective approach is that it allows states to incorporate relevant and timely information into the decision-making process prior to the enactment of a health insurance mandate and therefore hopefully reduces the introduction and passage of mandated benefit proposals that have little merit.

One disadvantage of the prospective approach is that it relies on numerous assumptions



to estimate what effects a specific mandated benefit would have on costs, utilization, and population health status. A retrospective approach, on the other hand, allows the reviewers to examine administrative data before and after the adoption of the mandate to assess the impact of the mandated benefit. However, the retrospective approach may produce results suggesting the elimination of existing mandates, which may be much more politically difficult to take away, then to have prevented their passage in the first place.

The combination of prospective and retrospective analyses draws on the strengths of both orientations by estimating the impact of proposed mandates while also evaluating the specific and cumulative effects of the existing mandates.

#### *Designated Reviewers*

Returning to Table 2, the five different approaches for designating responsibility for conducting the reviews each have their strengths and weaknesses. Requiring that the proponents of mandated benefit legislation conduct the review removes any financial or administrative burden associated with conducting the review from the state government. This approach may also prevent the introduction of some mandates since the burden of the analysis is on the proponents. However, permitting the proponents of a bill to conduct the review of a bill's impact raises serious questions about the impartiality of the analysis. Additionally, it is likely that the content and format of information received from the various proponent groups evaluating different mandates will be inconsistent across mandates and thus the results may be difficult for legislators to compare. In addition, the quality of the reviews conducted by proponents is likely to vary considerably depending on the analytic skills, resources and potential biases of the proponents.

State MBR laws that grant responsibility for the reviews to state administrative or

legislative personnel are likely to result in a more consistent review process and report format across various mandated benefits, which should help the legislature to interpret the information. This approach, however, may also place challenges on the reviewer in terms of administrative burden and it leaves the reviewer open to internal influences that could bias the review either towards or against adopting mandates, depending on the views of the state administration in which the reviewers work.

For the two states that require the legislature to contract with an external reviewer, there is less of an administrative burden placed on the legislative staff, as they are only required to identify appropriate contractors and assist in collecting the information needed in order to conduct the review. Additionally, to the extent that the contractor has no political affiliation or financial interest in the outcome of the review, a contractual approach may result in less bias. The main disadvantage to this approach is the expense associated with having external reviewers, particularly if the expense is paid out of legislative or administrative budgets.

The fourth type of reviewer, a legislatively established commission or task force, allows for competing perspectives to evaluate what effects the mandate will have on the state and therefore may help prevent specific biases from dominating any review. Most of the membership of these commissions or task forces is defined to be broadly representative of consumers, the health care industry, and the business community. While this approach is likely to result in less reviewer bias due to the multiple interests represented, there is a potential for difficulties in reaching agreement on the basic assumptions necessary to conduct the analysis. For example, patient advocates and small business representatives may differ on estimates of the expected demand for the mandated treatment or service, particularly when there is a range of estimates available from which to choose.

California's MBR law is distinctive in that it relies directly on the University of California with its five medical schools and two schools of public health and the expertise of its faculty working in medicine, health services research, public policy, economics and public health. While not every state has the ability to use this approach, 44 states and Washington D.C. have at least one accredited medical school and/or school of public health (AAMC 2005, ASPH 2005) and could potentially adopt this approach. The primary disadvantage of designating responsibility for the reviews to a university system is the potential conflict of interest that the university itself may have as an employer in the state with concerns about increasing health care costs for university employees. However, to the extent that responsibility for conducting the reviews is delegated to health services research faculty with no direct interests in the outcome of the legislation, such potential conflicts can be minimized. California's law, for example, explicitly requires a process to examine conflicts-of-interest.

#### *Time Frames for Reporting*

The specified time frame for conducting reviews is another important factor in an analysis of the MBR laws. One advantage of having one-time or periodic reports (e.g., yearly) is that decision-makers can compare the findings on multiple mandates at one point in time instead of viewing them in isolation. However, periodic reporting may not be as useful or timely for mandates as they progress through the legislature. In most state legislatures, there are times during the legislative calendar beyond which new bills may not be introduced and when bills must be referred to the Governor for signature. Thus, states that ensure that reviews are completed prior to their consideration will be most relevant.

For the nine MBR laws that detail a specific time frame (e.g., 60 days), there are

substantial differences on the length of time allotted for reporting on a mandate. The shortest specified time frames are found in the MBR laws of Georgia (20 days) and Kentucky (30 days). These time frames ensure a short turnaround, so that information can be quickly incorporated into the legislative process, however, these laws are also limited in the number and types of review criteria they can examine given the limited time for the review (see Table 3). While one might think that a relatively long time frame would be associated with requirements for a more thorough examination of the mandate, those with the longest time frames (Minnesota with 180 days, Virginia with 24 months) do not appear to include the most comprehensive set of review criteria. The California and New Jersey MBR laws, on the other hand, require that reviews cover a relatively broad set of review criteria in a 60-day time period.

### *Review Criteria*

The aspect of the MBR laws where there appears to be the most variation is the specific review criteria examined and the breadth of criteria covered (see Table 3). One advantage of looking at a limited number of criteria is that it allows for an easier comparison of results across mandates. For example, if the only consideration of the analysis is the impact on monthly health insurance premiums, as is the case with South Carolina and Tennessee, decision-makers can discern the differences between mandates relatively quickly. Additionally, reviews with few criteria may not require as many resources (e.g., professional time and expenses) as reviews that examine many criteria.

While there is no doubt that the cost and social impacts examined by a majority of the MBR laws are important, by analyzing a more comprehensive set of criteria the reviews can provide the state legislature with a greater understanding of a range of implications of a health insurance benefit mandate and prioritize according to costs and medical effectiveness. Of the 26

MBR laws, only twelve utilize an “evidence-based” policy approach by requiring consideration of the scientific literature on medical effectiveness. By relying on the medical effectiveness literature, the reviews may reduce the likelihood that mandates will be enacted for services that have not found to be effective and could potentially harm patients, or for which there is not enough evidence available to assess their effectiveness.

The medical effectiveness criteria can also be used in projecting the impact the mandate will have on the public’s health (McMenamin et al., 2006). Examining public health considerations may be particularly important in defining “value” in state health insurance purchasing decisions. Value in health care has come to mean the improvement in health realized from an investment in health care, rather than just cost-savings.

Within the political considerations category, the most frequently included criterion is the balancing of the social, economic, and medical efficacy considerations. While this criterion is not as concrete as some of the previously discussed criteria, most health policy decisions are based on the examination of these types of trade-offs. Additionally, examining the broader consideration of how mandates could influence the make-up of providers in the state allows decision-makers to better anticipate if a mandate could have important consequences that other reviews do not capture.

The remaining category, quality of care impacts, attempts to explore an aspect of benefit mandates that is perhaps the difficult to capture in a review, but its inclusion in the MBR laws of Hawaii, Maine, Massachusetts, and Ohio signals the growing concerns over the quality of medical care and the desire on the part of the legislature to take the quality of health care provided to the residents of a state into consideration.

### *Other Components of State MBR Laws*

Although these three characteristics of the MBR laws are infrequently mentioned, they are worth examining because they have important implications in how a mandate is reviewed. The use of an actuary in conducting the financial analysis can only yield a more reliable product and the reviews will not be as subject to “number massaging”, particularly for those states that have the proponents of the legislation conduct the review. The use of actuaries, however, is expensive.

As stated previously, a majority of the MBR laws do not specify a funding source for the reviews and many of those that do indicate that funding is tied to administrative or legislative budgets. While this funding approach seems reasonable for conducting reviews of state legislation, one drawback is that their funding could be threatened in economically lean years. In three states (Maryland, Tennessee, and Washington), for example, there is mention that supplementary funding *may* be available.

In contrast, California’s approach of relying on insurer fees to fund the reviews designates a stable-, off-budget financing mechanism and enables the reviewers to hire the staff necessary to support them in producing consistent and high-quality reports to serve the information needs of the state legislature. In utilizing this approach, however, it is important that insurers have no influence over either how the review is conducted or the findings. Additionally, one potential disadvantage to this approach is that insurers could pass along the costs of the reviews to consumers. Still, since the costs of conducting the reviews are small in comparison to total health care expenditures, it is unlikely that the costs of conducting these reviews would ever reach a level where the state population and legislature would need to consider whether the reviews provide enough value to justify this expense.

The final characteristic examined is the establishment of a system for data collection, as specified in the MBR laws of Colorado, New Jersey, and Virginia. These MBR laws have the advantage of being able to view and access information on mandates in one central location so that comparisons can be made across numerous mandates and reviewers can more efficiently access previously collected information when conducting the reviews. In establishing this system, however, the state will need to designate resources towards the data collection process and maintenance of the data, including ensuring the privacy of information when necessary.

## **Conclusions**

The number of states that have enacted MBR laws has increased substantially in recent years. As state legislatures continue to grapple with proposed mandated health insurance benefits, more than half the states have legislated a strategy to inject more information on proposed mandates into the policy decision-making process. In the past, the only information available to legislators and their staffs when considering health insurance benefit mandates has been that provided by the interests that have a stake in the outcome.

Given the number of bills introduced into state legislatures every year, it would be impossible for staff to conduct in depth analyses of the impacts of every bill. MBR laws provide a formal mechanism that designates responsibility for the review and the content of the review to an accountable group. This is not to suggest that political considerations do not also play an important role in the fate of any particular proposed or existing mandate, but it ensures that a minimum set of information about a mandate is available prior to decision-making.

When drafting MBR laws, states are faced with important questions like: Are there sufficient funds to support an independent commission to conduct reviews? Is there capacity in the administrative or legislative branch to take on the review function? What aspects of the

mandates are most important for analysis and how thorough should the review be? What is a reasonable time frame in which reviews should be conducted? And how will reviews be incorporated into legislative debate and decision-making?

Our research has found that different states have come to different conclusions on these questions and if future MBR laws are established, they will likely continue to vary depending on the values and perceived needs of the state legislatures. While there will likely be politics embedded in any mandate review process, taking this function out of the hands of the proponents of the legislation, who likely have a direct financial interest in the outcome, is likely to increase the potential for more objective analyses.

With regards to the review criteria, it is important that states will increasingly look beyond the basic economic implications and consider a broader scope of criteria, particularly with regards to the examination of the literature on the medical efficacy and the potential implications for the health status of the population. By examining criteria in addition to cost, state decision-makers position themselves to mandate only those benefits that add real value to the state's health care system measured by benefits that are relatively cost-effective and contribute to the overall health of the state's population.

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**Table 1: Statutory References of State Benefit Mandate Review Laws, 2004**

State	Reference	First Year Enacted	Year(s) Renewed or Amended
AZ	Arizona Revised Statutes. Title 20, Article 3, Sections 181-182.	1985	2003
AR	Arkansas Code. Title 23, Subtitle 3, Chapter 79, Subchapter 9, Sections 901-905.	2001	NA
CA	California Law. Health and Safety Code 127660-127665.	2002	NA
CO	Colorado Revised Statutes. Title 10, Article 16, Sections 103 and 103.3	1992	2003
FL	Florida Statutes. Title XXXVII, Chapter 624, Part I, Section 624.215.	1987	1991, 1992
GA	Georgia Code. Title 33, Chapter 24, Sections 60-67.	1989	NA
HI	Hawaii Revised Statutes. Chapter 23, Sections 51-52	1987	1990, 1996
IN	Indiana Code. Title 27, Article 1, Chapter 3, Section 30. 2003	2003	NA
KS	Kansas Statutes. Chapter 40, Article 22, Section 2248-2249.	1990	NA
KY	Kentucky Revised Statutes. Title II, Chapter 6, Section 30, 6.948.	2003	NA
LA	Louisiana Revised Statutes. Title 24, Section 603.1.	1997	1999
ME	Maine Revised Statutes. Title 24A, Chapter 33, Section 2752.	1997	2001
MD	Maryland Code. Title 15, Subtitle 15, Sections 1501-1502.	1998	1999, 2000, 2003, 2004
MA	Massachusetts General Laws of Massachusetts. Title 1, Chapter 3, Section 38C.	2002	NA
MN	Minnesota Statutes. Chapter 62J, Section 26.	2003	NA
NH	New Hampshire Statutes. Title XXXVII, Chapter 400-A, Section 39-a; Senate Bill 430	2004	NA
NJ	New Jersey Statutes. Title 17B, Chapter 27D, Sections 1-5.	2003	NA
ND	North Dakota Century Code. Title 54, Chapter 03, Section 28.	2001	NA
OH	Ohio Revised Code. Title 1, Chapter 103, Section 14.4 – 14.6	2001	NA
OR	Oregon Revised Statutes. Title 17, Chapter 171, Sections 171.870-171.880.	1985	NA
PA	Pennsylvania Code. Title 28, Sections 931.1-931.4.	1987	1993, 2003
SC	South Carolina Code of Laws. Title 38, Chapter 71, Section 285.	2002	NA
TN	Tennessee Code. Title3, Chapter 2, Section111.	2004	NA
VA	Code of Virginia. Title 2.2, Sections 2503-2505.	1990	1997, 2001, 2003
WA	Revised Code of Washington. Title 48, Chapter 48.47, Sections 005-900.	1997	NA
WI	Wisconsin Statutes. Chapter 601, Section 601.423.	1987	NA

**Table 2: Components of State MBR Laws**

State	Review Strategy	Responsibility for Conducting the Review	Time Frame for Analyses
AZ	Prospective	Proponents	Prior to consideration
AR	Prospective/ Retrospective	Commission/Task Force	Yearly
CA	Prospective	University	60 days
CO <sup>2</sup>	Prospective/ Retrospective	Proponents; Commission/Task Force	Determined by committee chair
FL	Prospective/ Retrospective	Proponents	NS
GA	Prospective	Admin./Legis. Personnel	20 days
HI	Prospective	Admin./Legis. Personnel	Prior to consideration
IN	Prospective/ Retrospective	Commission/Task Force	Yearly
KS	Prospective	Proponents	Prior to consideration
KY	Prospective	Admin./Legis. Personnel	30 days
LA	Prospective	Admin./Legis. Personnel	Prior to consideration
ME	Prospective	Admin./Legis. Personnel	Prior to consideration
MD	Prospective/ Retrospective	Commission/Task Force	Twice yearly
MA	Prospective	Admin./Legis. Personnel	90 days
MN	Prospective	Admin./Legis. Personnel	180 days
NH	Prospective	Admin./Legis. Personnel	NS
NJ	Prospective	Commission/Task Force	60 days
ND	Prospective	Legislative contract	Prior to consideration
OH	Prospective	Legislative contract	60 days
OR	Prospective	Proponents	Prior to consideration
PA	Prospective	Commission/Task Force	120 days
SC	Retrospective	Commission/Task Force	One-time report
TN	Prospective/ Retrospective	Admin./Legis. Personnel	Yearly
VA	Prospective/ Retrospective	Commission/Task Force	24 months
WA	Prospective	Proponents	Prior to consideration
WI	Prospective	Admin./Legis. Personnel	NS

<sup>2</sup> Colorado is unique in that the statutes contain two primary reviewers: (1) the proponents of the legislation as specified in the 1992 provision and (2) a commission established in 2003 which must also produce a review.

**Table 3: Review Criteria Specified in State MBR Laws\***

	Sum	AZ	AR	CA	CO	FL	GA	HI	KS	KY	LA	ME	MD	MA	MN	NH	NJ	ND	OH	OR	PA	SC	TN	VA	WA	WI
Cost Impacts	25	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦
Consumers	16	♦	♦	♦	♦	♦	♦	♦	♦			♦	♦	♦				♦		♦				♦		♦
Insurers	16	♦	♦	♦	♦	♦	♦			♦			♦				♦	♦	♦	♦	♦			♦	♦	♦
Employers	9		♦	♦								♦	♦	♦			♦		♦		♦			♦		
State Programs	3			♦								♦													♦	
Social Impacts	20	♦	♦	♦	♦	♦	♦	♦	♦			♦	♦	♦	♦	♦	♦	♦	♦	♦	♦					♦
Utilization	18	♦	♦	♦	♦	♦	♦	♦	♦			♦	♦	♦	♦		♦	♦		♦	♦					♦
Coverage	16	♦	♦	♦	♦	♦		♦	♦			♦	♦		♦		♦		♦	♦	♦					♦
Demand	12	♦	♦	♦	♦	♦		♦	♦			♦	♦				♦				♦					♦
Availability	6		♦	♦								♦	♦				♦				♦					
Need	3											♦					♦				♦					
Medical Efficacy	12		♦	♦								♦	♦	♦	♦	♦	♦			♦	♦			♦	♦	
Public Health	6			♦				♦				♦		♦	♦											♦
Political	4											♦				♦	♦				♦					
Providers	4							♦				♦		♦										♦		
Quality of Care	4							♦				♦		♦					♦							
TOTAL out of all 16 categories		7	10	12	7	7	5	9	6	2	1	15	10	9	6	4	11	5	6	7	11	1	2	5	10	6
TOTAL out of 7 major categories		2	3	4	2	2	2	5	2	1	1	7	3	6	4	4	4	2	3	3	4	1	1	3	4	2

\*The Indiana MBR law does not specify any review criteria



## **State Mandated Benefit Review Laws**

**Nicole Bellows, Helen Ann Halpin, Sara McMenammin**

**Disclaimer:** This paper has been submitted for publication in *Health Services Research*. Dissemination of this preliminary version is intended to provide the California Legislature and other interested parties with detailed descriptions of the methods used by the California Health Benefits Review Program in its reports. Please do not cite or reproduce for any other purpose without consent of the authors and written notification of the California Health Benefits Review Program

**HSR-04-0317.R2**

**An Analysis of California Assembly Bill 2185:**

**Mandating Coverage of Pediatric Asthma Self- Management Training and Education**

Helen Ann Halpin, Sara B. McMenamin, Nadereh Pourat, and Edward Yelin

**Disclaimer:** This paper has been submitted for publication in *Health Services Research*. Dissemination of this preliminary version is intended to provide the California Legislature and other interested parties with detailed descriptions of the methods used by the California Health Benefits Review Program in its reports. Please do not cite or reproduce for any other purpose without consent of the authors and written notification of the California Health Benefits Review Program

## **ABSTRACT**

**Objective:** To summarize for the California Legislature the evidence on the medical effectiveness of pediatric asthma self-management training and education (PASMTE), including the use of peak flow meters, spacers and nebulizers and the impact that mandated coverage of these services and devices under AB 2185 would have on total health care expenditures, monthly premiums, health services utilization and the public's health.

**Medical Effectiveness Findings:** The review of the literature finds that PASMTE is medically effective and has favorable effects on the health of children with symptomatic asthma, as well as reduces asthma-related emergency room visits and hospitalizations. There was inadequate evidence to assess the effectiveness of the three medical devices independently of PASMTE.

**Cost and Utilization Findings:** 100% of children in HMO plans in California are already covered for PASMTE, with fewer having coverage for the specific medical devices. However, despite full coverage of PASMTE in HMOs, these services are underutilized. We expect that the enactment of AB 2185 would increase utilization of PASMTE among children who are currently covered by 10% as a result of increased awareness of current coverage by all HMOs and increased awareness of the importance of these services. We estimate that this increased utilization by children who are already covered may result in a total statewide premiums increase of \$170,000 or 0.006 percent, equal to one to two cents PMPM.

**Public Health Findings:** It is estimated that the public health impact of the mandate, as a result of new utilization of PASMTE by 10% of children who are already covered, would reduce the number of school days missed due to asthma per year by 158,000, the number of children reporting restricted activity days by 6,020, the number of emergency department visits by 350, and the number of hospitalizations by 1,105.

**Legislative Action:** AB 2185 passed the legislature after being amended six times. The bill as it



was signed into law did not mandate coverage for PASMTE, since all HMOs in California presently reported covering these services. However, the bill retained the mandate for coverage of the three medical devices, as their coverage was not as universal across health plans.

## **INTRODUCTION**

In February 2004, the California State Assembly introduced Assembly Bill 2185 (AB 2185) that would require health service plans regulated and licensed by the California Department of Managed Care, as provided in the Knox-Keene Health Care Services Plan Act of 1975 (Knox-Keene), to cover self-management training and education for treating pediatric asthma, including the coverage of three medical devices (peak flow meters, nebulizers and spacers). The proposed mandate applies to all insured children (ages 0-17 years) with symptomatic asthma who are enrolled in a Knox-Keene licensed health maintenance organization (HMO) or a point-of-service (POS) plan that covers out-patient prescription drugs. It does not apply to children in preferred provider organization (PPO) plans, or to children enrolled in self-funded employer plans, as they are exempt from states mandates by ERISA.

Asthma is a chronic inflammatory disease of the airways that is the most common chronic condition in childhood, affecting approximately 4.8 million children in the US (CDC 1996). Childhood asthma that is poorly managed may result in acute episodes, often requiring emergency department visits and hospitalizations. This paper describes the available evidence regarding the effect of pediatric asthma self-management training and education (PASMTE) and the use of peak flow meters, nebulizers and spacers on asthma-related health outcomes and health services utilization for children with symptomatic asthma in the state of California. In addition, this paper estimates changes in utilization of health services and devices following

passage of the bill and the resulting impact of changes in utilization on total health care costs and monthly HMO premiums in the state, as well as the estimated public health impact of mandating these benefits. Finally, this paper concludes with a legislative update on the status of AB 2185.

### **REVIEW OF MEDICAL EFFECTIVENESS LITERATURE**

For the review of the literature on medical effectiveness of PASMTE, trials were identified from the MEDLINE (1983 – October 2003) and Cochrane databases, including the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials (CENTRAL). The search was limited to English language abstracts and to studies involving children ages 0-17 years. Only trials conducted in the US were reviewed, because (1) “usual care” differs substantially across nations, and (2) expectations and support for school attendance, as well as health care use vary substantially. The review included the following types of studies: clinical trials, controlled clinical trials, randomized controlled trials, meta-analyses, and systematic reviews. Trials that included adults with asthma were excluded unless data were presented separately for children. Due to the difficulty of distinguishing between educational and self-management interventions, any trial that included an educational or self-management component was reviewed. The scope of the literature search included effects of self-management training and education interventions for children with asthma, benefits of written self-management action plans, effectiveness of peak airflow-based written action plans, and results of monitoring interventions and behavioral-enhancement interventions. In addition, the review of the scientific research on the medical effectiveness of peak flow meters in monitoring pediatric asthma and the medical effectiveness of nebulizers and spacers as delivery devices for asthma medications for children were reviewed. At least two reviewers screened the title and abstract of each citation identified to determine eligibility for inclusion. Full text articles

were obtained and reviewers reapplied the initial eligibility criteria (Luft et al 2005).

A recent meta-analysis (Wolf et al. 2003) published in the Cochrane Database of Systematic Reviews was identified. The meta-analysis, titled “Educational Interventions for Asthma in Children,” included 32 trials published between 1980 and 1998. In updating these findings, we identified 16 additional trials published between 1998 and 2003. Of the primary trials selected, the results of randomized clinical trials were given more weight than nonrandomized trials (as the latter may be subject to bias).

To evaluate the evidence for each outcome, the following grading system was used: (1) Favorable: findings are uniformly favorable, many or all are statistically significant; (2) Pattern toward favorable: findings are favorable, but many are not statistically significant; (3) Ambiguous/mixed evidence: some significantly favorable, and some significantly unfavorable findings; (4) Pattern toward no effect/weak evidence: studies generally find no effect, but this may be due to a lack of statistical power; (5) Unfavorable: statistical evidence of no effect in the literature with sufficient statistical power to make this assessment; (6) Insufficient evidence to make a “call”: few relevant findings; difficult to discern a pattern.

Meta-analyses and randomized controlled trials were used to estimate the mean effects for specific outcomes. Where possible, we reviewed the original studies referenced in the meta-analyses and summarized the results in the natural units. For those trials where outcomes were reported in natural units, weighted averages for each outcome measure were computed without confidence intervals. For outcomes where there was more than one trial, we estimated a weighted average percentage change, using the sample size for each trial and the estimated proportionate change expected in the experimental group (Luft et al 2005).

## **MEDICAL EFFECTIVENESS OF PEDIATRIC SELF-MANAGEMENT TRAINING**

## **AND EDUCATION**

The components of pediatric asthma management may include the following: medications for the treatment of asthma; outpatient asthma visits every 1 to 6 months (depending on severity); asthma education for children and parents (individual or group classes); peak airflow meter measurement at home (patients require a peak flow meter for self-monitoring); spirometry testing (measurement of the air entering and leaving the lungs) by a physician during outpatient visits; home environmental screening by a health care provider (for allergens, tobacco, pollutants and irritants); nurse managers for high-risk patients; referral to an asthma specialist as necessary; allergen immunotherapy (typically lasts 3 to 5 years); annual influenza vaccinations; and treatment of upper respiratory symptoms (rhinitis/sinusitis) and gastroesophageal reflux (which can create heartburn or more serious problems).

The results of the review of the scientific research on the medical effectiveness of PASMTE are organized into five major effects: health outcomes, knowledge and self-efficacy, disability, health services utilization, and quality-of-life. Table 1 summarizes the findings of all of the trials reviewed for each outcome, including the number of trials reviewed, the observed direction of the effect of PASMTE, the estimated mean effect where this could be assessed, and a summary of the evidence. Only those outcomes for which the summary of the evidence found a favorable or a pattern towards favorable effects are reported. The full citations for the literature review are included in an electronic appendix.

**Health Outcomes:** The review of the literature on PASMTE showed favorable effects for five health outcomes including the number of days of asthma symptoms (Fireman et al. 1981; Evans et al. 1987; Bonner et al. 2002; Yoos et al. 2002; Krishna et al. 2003), symptom-free days (Wilson et al. 1996; Brown et al. 2002), symptom scores (subjective measures of how much a

patient is bothered by symptoms or how often a patient experiences asthma symptoms) (Christiansen et al. 1997; Bartholomew et al. 2000; Brown et al. 2002), peak expiratory flow rate (PEFR) (a measure of lung function as the maximum rate of airflow that can be achieved during a sudden forced expiration from a position of full inspiration) (Christiansen et al. 1999; Guendelman et al. 2002), and nocturnal asthma (Wilson et al. 1996; Georgiou et al. 2003; Krishna et al. 2003). In addition, the evidence on the effect of PASMTE on asthma severity showed a pattern toward favorable effects (LeBaron et al. 1985; Whitman et al. 1985; Wilson et al. 1996; Perrin et al. 1992; Bartholomew et al. 2000; Homer et al. 2000; Harish et al. 2001; Yoos et al. 2002; Georgiou et al. 2003; Huss et al. 2003).

**Knowledge and Self-Efficacy:** The effects of PASMTE were assessed on the child's and care-giver's knowledge of asthma and its management, as well as its effects on self-efficacy. Self-efficacy is measured as a belief in one's capabilities to organize and execute the sources of action required to manage asthma (Bandura 1994). A favorable effect was observed in the child's knowledge (Christiansen et al. 1997; Rubin et al. 1986; LeBaron et al. 1985; Whitman et al. 1985; Parcel et al. 1980; Shegog et al. 2001; Bartholomew et al. 2000; Perrin et al. 1992) and a pattern toward favorable effects was observed for knowledge of caregivers of children with asthma (Persuad et al. 1996; Krishna et al. 2003). In addition, PASMTE was found to have favorable effects on self-efficacy (Bonner et al. 2002; Shegog et al. 2001; Evans et al 1987; Rubin et al. 1986; Whitman et al. 1985; Kubly et al. 1984; Parcel et al. 1980; Bartholomew et al. 2000; LeBaron et al. 1985).

**Disability Days:** The review of the literature on PASMTE showed favorable effects in reducing school absences measured as the mean number of days children with asthma were absent from school (Fireman et al. 1981; Christiansen et al. 1997; Persaud et al. 1996; Wilson et

al. 1996; Perrin et al. 1992; Evans et al. 1987; Rubin et al. 1986; Krishna et al. 2003). In addition, one trial found favorable effects on reducing the number of restricted activity days children with asthma experience (Guendelman et al. 2002). The review of the literature on the proportion of children with asthma who reported any school absences following PASMTE found a pattern toward favorable effects (Guendelman et al. 2002; Georgiou et al. 2003).

**Health Services Utilization:** The three utilization measures that were classified as having favorable effects include emergency department utilization measured as the mean number of emergency room visits for children with asthma (Alexander et al. 1988; Clark et al. 1986; Rubin et al. 1986; Lewis et al. 1984; Fireman et al. 1981; Christiansen et al. 1997; Shields et al. 1990; Krishna et al. 2003; Harish et al. 2000; Homer et al. 2000; Kelly et al. 2000; Greineder et al. 1999), hospitalizations (Christiansen et al. 1997; Clark et al. 1986; Lewis et al. 1984; Fireman et al. 1981; Bartholomew et al. 2000; Greineder et al. 1999; Kelly et al. 2000), and utilization rates for asthma medications such as inhaled corticosteroids (cromolyn) (Lukacs et al. 2002; Krishna et al. 2003; Bonner et al. 2002). In addition, a pattern toward weak or no effect was found for the effect of PASMTE on acute and urgent physician visits (Evans et al. 1987; Krishna et al. 2000; Homer et al. 2000; Brown et al. 2002; Lukacs et al. 2002).

**Quality-of-Life:** The World Health Organization defines health-related quality of life as an “individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.” The review found that evidence on quality-of life effects in children could be classified as favorable (Evans et al. 1987; Fireman et al. 1980; Perrin et al. 1992; Georgiou et al. 2003), while the effects on caregivers could be classified as a pattern toward favorable (Brown et al. 2002).

## **MEDICAL EFFECTIVENESS OF MEDICAL DEVICES**

## **Description of Medical Devices**

The standard asthma medication delivery system is the metered dose inhaler (MDI). The MDI is a small, pressurized can that contains aerosol medicine. Spacers, if needed, are used in conjunction with an MDI. A spacer device is a tube attached to the inhaler, which acts as a reservoir to hold the medication that is sprayed by the inhaler. Spacer devices remove the need for coordination between actuation of an MDI and inhalation. The spacer reduces the velocity of the aerosol, so that a larger proportion of the particles can be inhaled and deposited in the lungs. Spacer volumes range from 170 mL to 750 mL and shapes vary. Consequently, the effects on physiological function vary with the size of these devices.

A nebulizer is a medical device that delivers liquid medication to the recipient's airways in the form of a mist. Nebulizer compressors use air or oxygen under pressure to force air through tubing into a cup filled with liquid medicine. The force of the air breaks the liquid into tiny mist-like particles that can be inhaled deeply into the airways. Nebulizers have three main parts: a cup that holds the medication; a mouthpiece or mask attached to a "T"-shaped part; and a plastic tube that connects the mouthpiece to the compressor. There are home and hospital nebulizers, as well as portable units (Health A to Z 2003). Nebulizers are easy for the patient to use and require only the usual inspiration and expiration through the connection to the nebulizer.

Peak flow meters (PFMs) are plastic handheld devices used for home monitoring of lung function as part of a comprehensive asthma self-management plan. Peak flow meters measure the peak expiratory flow (the patient's ability to push air out of the lungs). These devices help patients and doctors monitor and manage asthma. For example, readings from a peak flow meter can help the patient implement an action plan and change medication doses as needed. Most peak flow readings fall into three zones—green, yellow or red. A reading in the red zone indicates a

significant drop in peak flow rate and signals a medical alert where immediate action is needed.

### **Literature Review on Medical Devices for Pediatric Asthma Management**

The outcomes reviewed on the effectiveness of medical devices for children with asthma included physiological measures of lung function (Forced Expiratory Volume in one second [FEV1], peak expiratory flow (PEF), and forced expiratory flow (FEF)), health care utilization (unscheduled medical visits and hospital admissions), and public health impact (missed days of school). FEV1 is the volume of air expired in the first second of maximal expiration after a maximal inspiration. PEF rate is the rate of maximum flow at the outset of forced expiration, which is reduced in proportion to the severity of airway obstruction. FEF 25-75% is the forced expiratory flow in the middle half of an expiration and indicates any obstruction in the airways.

Many of the trials on medical devices reviewed had small sample sizes. Meta-analysis could not be used to combine results of small trials because of differences in the devices and medications used and the outcomes measured across trials. Thus, this analysis reviews the evidence qualitatively. Furthermore, because almost all of the trials were conducted in a controlled setting where a health care professional delivered the medication using one of the devices, children and their parents using self-administered devices may not experience the same effects on their own.

Finally, the effectiveness of asthma medication delivery devices and peak flow meters could not be separated from the effects from PASMTE. A child and parent who are given a spacer device without instruction would not be able to use it properly. According to the American Academy of Allergy, Asthma, and Immunology, “For all devices, training and education of patients and family or professional caregivers who administer these medications to patients, for the proper and effective use of these devices is an essential component of inhalation



therapy. It is so important, in fact, that proper inhalation technique should be constantly ensured, demonstrated at routine physician visits, for example, with re-education and re-training as necessary” (American Academy of Allergy, Asthma, and Immunology 2004). The results of the review of the medical effectiveness of medical devices for asthma management are organized around the three specific medical devices: spacers, nebulizers and peak flow meters.

**Effectiveness of Spacers:** The evidence from literature is not of sufficient quality to draw conclusions about the effectiveness of spacers in children with asthma (Cunningham and Crain, 1994; Pedersen, 1983; Rachelefsky et al. 1986; Becker et al. 1985). In the published trials, when comparing the change in outcome after initiation of spacers to baseline measurements, the effectiveness of spacers was favorable. The spacers were also more effective when compared against a placebo. However, the evidence with respect to a comparison of MDIs with spacers versus MDIs alone depends on the specific outcome measures; thus, the conclusion is that there is inadequate evidence to assess the effectiveness of these devices independent of PASMTE.

**Effectiveness of Nebulizers:** Trials that compared nebulizers to MDIs with spacers were reviewed (Cates et al. 2003; Brocklebank et al. 2001; Rao and Rizvi 2002; Leversha et al. 2000; Ploin et al. 2000; Dewar et al. 1999; Schuh et al. 1999; Wildhaber et al. 1999; Batra et al. 1997; Chou et al. 1995). However, there is no clear or consistent evidence that treatment with nebulizers is more effective in improving clinical outcomes than MDIs with spacers. The literature was classified as showing a pattern toward no effect/weak evidence. The trials had inadequate statistical power to demonstrate clinical equivalence and cannot exclude a clinical benefit of nebulizers.

**Effectiveness of Peak Flow Meters:** Because peak flow meters are monitoring devices (not treatments or medication delivery systems), and are generally used in conjunction with

patient education in asthma self-management, the clinical efficacy of peak flow meters by themselves cannot be determined. Therefore, the literature on the use of peak flow meters on their own was classified as insufficient evidence.

## **UTILIZATION, COST, AND COVERAGE IMPACTS**

**Baseline Utilization and Cost:** The mandated services under AB 2185 include PASMTE and three medical devices (peak flow meters, nebulizers and spacers). In estimating the impact of the proposed mandate on costs, utilization and premiums, the relevant services are defined to include physician visits; laboratory and radiology diagnostic tests; patient and parent self-management training and education on a group or individual basis; and the three medical devices. Health services utilization associated with poor management of childhood asthma includes emergency department visits and inpatient hospital stays.

For the utilization and cost analysis, children with symptomatic asthma were defined as having had at least one of the following events in the last year: one prescription asthma medication, one asthma-related emergency department visit, one asthma-related hospitalization, one asthma-related outpatient visit, or to have used asthma-related devices and tests. Under these criteria, about 10.1 percent of children aged 0 to 17 years enrolled in HMOs in California have symptomatic asthma. However, approximately 12 percent of these children do not have coverage for outpatient prescription drugs and thus would not be affected by AB 2185. This analysis assumes similar costs and rates of utilization for children covered under group and individual insurance due to lack of data on specific utilization rates for each market.

Using data from the 2001 California Health Interview Survey (CHIS) and commercially available databases from Milliman USA (Milliman 2003), the analysis found that approximately 337,000 children in California have symptomatic asthma, are insured through the individual or

group markets, are enrolled in an underwritten Knox-Keene licensed plans, and have outpatient prescription drug coverage.

We further estimated the current baseline utilization rates, costs per service, and costs per member per month (PMPM) for children with symptomatic asthma in the group and individual insurance markets. For every 1,000 covered children with asthma, there are 3,000 prescriptions, 300 asthma-related equipment and devices, and 536 sessions of asthma training and education. In addition there are 1.8 office visits, 0.011 inpatient days, and 0.4 emergency room visits per pediatric asthma patient per year. The costs are estimated to be \$57 per prescription, \$50 per device, and \$80 per training and education session (individual, group, and patient education materials), while the PMPM costs are estimated at \$7.03 PMPM per ambulatory visit, \$3.70 PMPM per inpatient stay, and \$1.88 PMPM per emergency room visit.

**Baseline Coverage:** Based on a survey of the eight largest commercial HMOs operating in California at the time of the study, we found that coverage of pediatric asthma services in commercial HMOs in California is extensive. All commercial HMOs cover pediatric asthma-related inpatient care, ambulatory care, and emergency department visits for 100 percent of enrolled children. In addition, asthma self-management training (100%), individual health education (100%), patient education materials (98%), group health education (91%), and spacers (94%), nebulizers (94%) and peak flow meters (75%) are also widely covered for children. Thus, the mandate will have no impact on the coverage of PASMTE but will increase coverage for the medical devices to 100% of children in HMOs.

**Impact of Mandate on Utilization:** Even though asthma self-management training and individual health education are covered by 100% of HMOs in California, utilization of these services by children with asthma remains low at 54%. It is not clear why utilization is so low. It

may be because families and providers are not aware of the coverage or that physicians are not aware of the effectiveness of these services. We expect the passage of the bill to create new demand. PASMET is already covered 100 percent, but passage of the bill will increase awareness of three things: 1) that PASMET services are covered by all HMOs, 2) that all HMOs will now cover the medical devices, which require training and education for their proper use, and 3) that these services are very effective in reducing adverse events for children with asthma. The bill, in effect, informs people of the existing coverage, the new coverage of the devices, and the effectiveness of the services. It is assumed that this increased awareness will stimulate new utilization. The current rate at which children receive training and education is approximately 54 percent for all children with symptomatic asthma enrolled in HMOs and POS plans (CHIS 2001). Utilization of PASMTE services for enrolled children is estimated to increase by 10 percentage points (to 64%) in the year following the mandate. This projected increase in the utilization of PASMTE is based on the expected increased demand as a result of increased awareness of patient families and providers through media attention and the activities of advocacy organizations following the enactment of the bill. This percentage increase in utilization was determined by the consensus of an expert panel and represents expert opinion; the actual change in utilization of the benefit as a result of the bills passage may be higher or lower than this assumption. All estimates are made for just one year following adoption of the mandate, and only point estimates are provided to the legislature, even though there is uncertainty associated with all estimates. It is our experience that trying to communicate uncertainty about estimates by using ranges or confidence intervals actually creates more confusion than clarity, due to many legislators unfamiliarity with statistics.

The review of the medical effectiveness of PASMTE programs suggests that, following

enactment of the mandate, the assumed increase in utilization of the services by 10% of currently covered children will result in a mean reduction in the number of inpatient hospitalizations for children with symptomatic asthma by 30 percent and the mean number of emergency room visits would be reduced by 26 percent. The evidence from the literature review on medical effectiveness also suggests that there would be little to no impact on outpatient visits. The effects on hospitalizations and emergency room visits identified in the literature review were observed as part of trials and therefore may not be achieved at the same levels when implemented in a population because the trials were conducted under tightly controlled circumstances. Thus, all estimates of health services utilization impacts should be viewed as upper bounds.

**Impact on Administrative and Other Expenses:** The mandate is expected to increase the administrative expenses for health plans, but not disproportionately to the increase in health care costs. An increase in PASMTE claims may increase administration costs, as plans would have to modify their insurance contracts and member materials and may have to contract with new providers specializing in asthma education. Health plans include a component for administration and profit in their premiums, which may be sufficient for covering increased administrative costs. No effect on per-unit cost of the service is expected, because this legislation does not propose an increase in the number of children who have health insurance coverage, but rather mandates a change in the types of services available to children with coverage.

**Impact on Total Health Care Costs:** Total expenditures (including total premiums and out-of-pocket expenditures) would increase by an estimated \$170,000 or 0.006 percent. The impact varies in the large- and small-group as well as individual markets (Table 2). The impact on total expenditures in the HMO large group and individual markets is estimated to be 0.005 percent while the impact in the HMO small group market is estimated to be 0.007 percent. This

is the net effect of the mandate on costs, factoring in both the new costs associated with new utilization of services, as well as the estimated cost savings resulting from reduced asthma-related emergency room visits and hospitalizations (estimated as 0.002% or 25% of the increase). After the mandate, the overall cost increase would be borne by HMOs and PPOs in the large, small, and individual markets. The total premium increase of \$170,000 would amount to approximately one to two cents PMPM.

## **PUBLIC HEALTH IMPACTS**

### **Present Baseline Health Outcomes**

In California, 14 percent of insured children aged 1-17 years have ever been diagnosed with asthma (CHIS 2001). However, nearly one-quarter of these children did not experience any symptoms in the past year. This means that approximately 10 percent of insured children in California have symptomatic asthma (i.e., asthma for which they experienced symptoms in the past year) (CHIS 2001). Of those children with symptomatic asthma, almost two-thirds report they take medicine for their asthma, and almost half report they experience asthma symptoms at least once a month (CHIS 2001). Children who experience asthma symptoms are more likely to miss school and be restricted in their activities compared to children without asthma.

Although a review of the medical evidence suggests there are many categories of public health outcomes associated with PASMTE programs, there were only four public health outcomes for which quantitative estimates of the effects of the mandate could be made due to lack of population-based baseline data for California's children. The four public health outcomes for which quantitative estimates could be made include mean number of days of school missed, percentage of children with asthma reporting restricted-activity days, and mean number of emergency department visits and hospitalizations.

The baseline data suggest that adolescents in California with symptomatic asthma missed an average of 1.2 days of school in the last month, and, of the 40% who missed any school, an average of 2.9 days of school were missed per month (CHIS 2001). This translates into approximately 400,000 days of school missed among California children with symptomatic asthma. Prior to the mandate, 71 percent of children with symptomatic asthma with health insurance reported that they experienced restricted physical activity due to their asthma (CHIS 2001). In terms of health care utilization, one percent of children with asthma were hospitalized because of their disease in the past year, and three percent had emergency department visits due to asthma symptoms (Milliman USA 2003). Half of adolescents (aged 12-17 years) with asthma in California report that a doctor explained to them how to recognize asthma attacks (51%) or how to avoid the things that make their asthma worse (54%) (CHIS 2001).

### **Impact of the Proposed Mandate on Public Health**

Although all California children with symptomatic asthma who are enrolled in HMOs currently have coverage for PASMTE, a 10 percentage-point increase in the utilization of PASMTE services (from 54% to 64%) is estimated following the bill's enactment for these presently covered children. For all of the public health outcomes assessed, the effects identified in the literature review from clinical trials may not be achieved at the same levels when implemented in the population because the trials were conducted in tightly controlled circumstances that do not necessarily represent how care is provided in the real world. In addition, there could be variations from insurer to insurer that could affect actual health outcomes. Thus, all estimates of the effects of the mandate on the public's health should be viewed as upper bounds. If fewer additional covered children newly receive services as a result of the mandate, or if the actual interventions are less effective than what was observed in clinical

trials, the public health benefits of this mandate would be less.

**School Absences:** Forty percent of children with symptomatic asthma who would be affected by the mandate (135,000 children) missed school in the past month due to illness, with a reported average of 1.2 days of school missed per month per asthmatic child (CHIS 2001). The evidence suggests that PASMTE leads, on average, to a reduction of 44 percent in the number of school days missed by asthmatic children. Based on our assumption that 10 percent of children with symptomatic asthma will newly receive asthma self-management services, the bill may result in a reduction of approximately 17,600 days of missed school each month due to asthma, or approximately 158,000 fewer days per year, assuming a 9-month school year.

**Restricted-Activity Days:** More than 70 percent of children with symptomatic asthma report that their physical activity is limited because of their asthma (CHIS, 2001). The evidence suggests that PASMTE leads to a 25 percent reduction in the percentage of children reporting restrictive activity due to asthma. The analysis suggests that for the 10 percent of already covered children with asthma who would newly use the services following the bill's passage, approximately 6,020 fewer children would report limitations in physical activity due to asthma.

**Emergency Department Visits:** The mean number of annual asthma-related emergency department visits per child with symptomatic asthma is 0.04 per year (Milliman USA 2003). This translates into 13,485 asthma-related emergency department visits per year in California for children with symptomatic asthma who would be affected by the mandate. The evidence suggests that PASMTE leads, on average, to a decrease in the mean number of emergency department visits of 26 percent. Thus, for the 10 percent of already covered children who would newly use the services following passage of the bill, the analysis suggests that there would be approximately 350 fewer emergency department visits per year for asthmatic children.



**Hospitalizations:** An estimated one percent of children with asthma or 3, 370 children in California who would be affected by the mandate are hospitalized each year for asthma-related conditions (Milliman USA 2003). The evidence suggests that PASMTE leads, on average, to a 30 percent reduction in the mean number of asthma-related hospitalizations. Based on this evidence, for the 10% of already covered children who will newly use PASMTE services following the bill's passage, there would be approximately 1,105 fewer hospitalizations for asthma-related conditions among children with symptomatic asthma.

**Other Significant Public Health Effects:** A review of the literature on the effectiveness of PASMTE identified other health outcomes. However, quantitative estimates of the impact on children in California with symptomatic asthma could not be made because baseline data were not available. These outcomes include an overall reduction in asthma severity for children, fewer days of asthma symptoms, more symptom-free days, reduced nocturnal asthma, and improvement in lung function measured by PEF. In addition, literature on the impact of PASMTE suggests that children and, in some cases, their caregivers report an increase in the quality of their life and increased knowledge about asthma and its management. Finally, evidence suggests that children who have had PASMTE perceive they are more capable of organizing and executing the actions required to manage their asthma.

## **LEGISLATIVE ACTION**

The CHBRP analysis of SB 2185 found that all children insured by HMOs and POS plans in California have coverage for PASMTE, but fewer children are currently covered for the three mandated medical devices, particularly peak flow meters (75%). The review of the medical effectiveness literature found that PASMTE produces favorable health status, health services utilization, and quality of life outcomes for children with symptomatic asthma.

However, little evidence was found on the effects of peak flow meters, spacers and nebulizers independent of training and education on how to use them properly. The impact of the proposed mandate on health care costs in California was estimated to increase utilization of already covered PASMTE services, as well as increased use of newly covered medical devices. The total health care expenditures are estimated to increase by only \$170,000 and increase the average cost of the HMO premium by one to two cents PMPM. The estimated public health impacts in the first year following the mandate include 1,105 fewer asthma-related hospitalizations, 350 fewer asthma-related emergency department visits, 6,020 fewer children with asthma experiencing restricted activity days and 158,000 fewer days missed from school.

The final CHBRP report analyzing AB 2185 was submitted to the legislature on April 14, 2004. Several interest groups testified at committee hearings subsequently held on the bill and most submitted written documentation for their support or opposition to the proposed mandate. Groups supporting the bill included the American Lung Association, the Asthma and Allergy Foundation of America, the California School Nurses Organization, Health Access California, the Latino Issues Forum, the Gray Panthers, California School Employees, and the American Academy of Pediatrics. The positions of these groups supported the coverage of the medical devices. They argued that peak flow meters were one of the basic tools that all asthmatic children need to monitor their asthma, and that spacers and nebulizers enable children to properly administer their asthma medications. The American Lung Association also supported the bill based on their position that training and education in asthma self-management by children helps “reduce asthma attacks, severity of attacks, and helps children live full, quality lives.”

Groups opposing the bill included the California Chamber of Commerce, the National Federation of Independent Businesses, and the California Association of Physician Groups

(CAPG). Based on their concern that AB 2185, along with other mandates that were being considered, would increase premiums that would lead to increased numbers of uninsured, the Chamber of Commerce called on the legislature to adopt a moratorium on all new benefit mandates. CAPG strongly opposed the PASMTE provisions of the bill because they would “set a dangerous precedent by mandating the practice of medicine” and that “legislative mandates dictating doctors’ conduct undermines the doctor-patient relationship.”

Since CHBRP sent its report on AB 2185 to the legislature in April 2004, the bill was amended six times, twice in the State Assembly and four times in the State Senate. The bill as amended was approved by greater than two-thirds bipartisan majorities in the Assembly Health Committee (80%), Assembly Appropriations Committee (80%), on the Assembly Floor (69%), in the Senate Insurance Committee (78%) and on the Senate Floor (74%). The most significant change made to the bill was the deletion of the mandate to provide coverage for PASMTE, since the HMO plans in the state reported that 100 percent of children in affected plans already had coverage for these services. The bill, as it was enrolled and signed into law by the California Governor on September 23, 2004 mandates coverage only for the three medical devices (peak flow meter, spacer and nebulizer) to make them equally available to children across HMO and POS plans. The bill also states that “education for pediatric asthma, including education to enable an enrollee to properly use the devices, shall be consistent with current professional medical practice.” The bill effectively assumes that the education and training in the use of these devices would be provided under the PASMTE services currently covered by the plans.

Even though the final bill did not include mandated coverage for PASMTE, but only for the three medical devices, the original CHBRP estimated impacts of the bill are not expected to change significantly. In our original analysis, we assumed that there would be no increase in

coverage for PASMET as a result of the mandate. Whether or not the final bill included a mandate for coverage of PASMET, coverage will remain at 100%. The utilization impacts we estimated are a result of the new demand stimulated by the bill's passage, not by increasing coverage for PASMET. Thus, regardless of whether or not the bill includes PASMET, we assume that utilization of PASMET will increase along with the increased coverage for the devices and as a result of the increased awareness of full coverage and effectiveness. This is because the original estimated new utilization and costs associated with the bill's passage were not a function of any new coverage, but were a function of the expected impact of the bill's passage on increased patient and provider awareness of these covered services and their importance, resulting in a 10% increase in utilization. We anticipate that enactment of the bill mandating coverage only for medical devices will also stimulate new demand and increase utilization of these services by 10% of children with asthma who will benefit from their medical effectiveness, and will produce the estimated public health benefits..

What the legislation did not do was to address the question of the availability and accessibility of PASMTE, as well as the three medical devices, for children with symptomatic asthma in California who are not enrolled in HMO plans – those who are in PPO plans, Medicaid, the state's children's health insurance program (Healthy Families) and self-insured employer plans, as well as those who are uninsured. In fact, the mandate will affect fewer than half of the children in California with symptomatic asthma, including 389,000 who are in non-HMO/POS plans and 83,000 without any health insurance coverage (CHIS 2001). The bill targets those who already have relatively comprehensive coverage for pediatric asthma services. Thus, while the costs associated with the mandate are only pennies per month per enrollee and the health benefits are estimated to affect thousands of children, the mandate will do little overall

to increase access to PASMTE and associated medical devices for the majority of children in California who suffer from asthma and are not enrolled in an HMO.

In addition, the utilization of PASMTE services is relatively low in California's HMO and POS plans, even though they are fully covered. Only about half of symptomatic children report receiving any training or education about the management of their asthma. While a mandated benefit may be expected to increase awareness of the availability of the services covered by HMO and POS plans, the key to increasing appropriate use of these services is more likely to come from holding health plans and health care providers accountable for the delivery of PASMTE to their asthmatic patients (Casalino et al 2003), and from more effectively educating patients, their families and health care professionals about the health benefits of PASMTE in reducing asthma symptoms, related disability, and the adverse outcomes associated with pediatric asthma if it is not properly managed.

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**Table 1. Summary of Evidence on the Effectiveness of PASMTE**

<b>Outcome Measures</b>	<b># of Trials</b>	<b>Direction of Effect (Mean percent Change)</b>	<b>Evidence Score</b>
<b>Health Effects</b>			
Days of Asthma Symptoms	5	Decrease	Favorable
Symptom-Free Days	2	Increase	Favorable
Symptom Scores	3	Decrease	Favorable
PEFR	2	Increase	Favorable
Nocturnal Asthma	3	Decrease	Favorable
Asthma Severity	10	Decrease	Pattern Toward Favorable
<b>Self-Efficacy and Knowledge</b>			
Self-Efficacy of Children	9	Increase	Favorable
Child's Knowledge	13	Increase	Favorable
Caregiver's Knowledge	2	Increase	Pattern Toward Favorable
<b>Disability Effects</b>			
School Absences – Mean Days	8	Decrease (-44%)	Favorable
Restricted Activity Days	1	Decrease (-25%)	Favorable
School Absences - % Children Absent	2	Decrease (-43%)	Pattern Toward Favorable
<b>Health Services Utilization</b>			
Emergency Department Use	13	Decrease (-26%)	Favorable
Mean Hospitalizations	9	Decrease (-30%)	Favorable
Use of Medications (Inhaled Corticosteroids, Cromolyn)	3	Increase in Rx Decrease in Dose	Favorable
Acute/Urgent MD Visits	5	Decrease	Pattern Toward Favorable
<b>Quality of Life</b>			
Child's Quality of Life	4	Increase	Favorable
Caregiver's Quality of Life	1	Increase	Pattern Toward Favorable

**Table 2, Post-mandate Impacts of AB 2185 on Per Member Per Month (PMPM) Cost and Total Expenses, California, Calendar Year 2004**

	Large Group		Small Group		Individual	Total
	HMO	POS	HMO	POS		
<b>A. PMPM \$</b>						
<b>Impact of Mandate</b>						
1A. Insured Premiums						
Total Premium	\$0.013	\$0.012	\$0.019	\$0.0018	\$0.008	\$170,000
Average Portion of Premium Paid by Employer						
Average Portion of Premium Paid by Employer	\$0.010	\$0.009	\$0.014	\$0.014	\$0.000	\$130,000
Average Portion of Premium Paid by Employee						
Average Portion of Premium Paid by Employee	\$0.003	\$0.003	\$0.005	\$0.004	\$0.008	\$50,000
2B. Covered Benefits Paid by Member (Deductibles, Copays, etc.)						
Covered Benefits Paid by Member (Deductibles, Copays, etc.)	\$0.0001	\$0.001	\$0.001	\$0.0012	\$0.0013	\$10,000
3C. Total Cost of Covered Benefits						
Total Cost of Covered Benefits	\$0.0136	\$0.0136	\$0.0203	\$0.0203	\$0.0102	\$18200,000
4D. Benefits Not Covered						
Benefits Not Covered	-\$0.001	-\$0.001	-\$0.002	-\$0.002	-\$0.0001	(\$20,00)
5E. Total Expenditures						
Total Expenditures	\$0.0124	\$0.0124	\$0.01821	\$0.01821	\$0.01021	\$1780,000
<b>B. Percentage Impact of Mandate On</b>						
1A. Insured Premium						
Insured Premium	0.0067%	0.0056%	0.0081%	0.0079%	0.0049%	0.0068%
2B. Total Expenditures						
Total Expenditures	0.0056%	0.0055%	0.0079%	0.0078%	0.0059%	0.0067%

Source: California Health Benefits Review Program, 2003





## **Appendix 21: CHBRP Budget and Operating Costs**

The spreadsheets in this document (Attachments 1-6), indicate the budget history of the California Health Benefits Review Program representing revenue allocations, expenditures and fund balances for the three fiscal years of operation. The fiscal year is from July 1 through June 30 of the following year.

The funds have annually been deposited into UC Account number 446657, which is subdivided into fund numbers. Each fund number has a two-year span, therefore, there are overlapping years of fund operation. The fund numbers in the account are 18092, 18093, 18094, then repeat with 18092, etc.

Spreadsheet 1 indicates the cumulative allocation and expense figures since the inception of the program. Spreadsheets 2 through 6 are fiscal year summaries in each fund category.

As is indicated at the bottom of each spreadsheet, the revenue expended by the program is from non-General Fund sources, rather, they were generated as fees levied by the Department of Managed Health Care and the Department of Insurance on health service plans and health insurers. This revenue generation is in compliance with Chapter 7, Part 2 of Division 107 of the Health & Safety Code, AB 1996 [2001].

The account is further divided into Sub categories from which designated functions are recorded. The Subs include: 02 = Contracts, temporary employment, 03 = core staff salaries, 06 = employee benefits, 08 = unallocated category.

Encumbrances are essentially earmarked funds for special program purposes, such as professional actuarial services. In this case, the encumbrances are for dedicated expenses related to a contract CHBRP has with Milliman Inc.

Memos are essentially funds dedicated to specific reoccurring expenses such as projected salaries. Because salaries are projected to the end of the fiscal year, the figure represents a lien on the account. Funds in this account have not been used for any form of Executive compensation.



Cummulative Account Summary for the  
**CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM**  
 Covering the Period  
 June 30, 2003 - December 9, 2005

AB1996  
 University of California: Dibision of Health Affairs

Account * 447657	Fund	Fiscal Year 05-06		Inception to Date 03-05		Encumbrance**	Ledger Balance	Memo-Lien***	Operating Balance
		Appropriation	Expenditures	Appropriation	Expenditures				
	18092	1,408,068.15	416,369.21	1,632,754.40	641,055.46	148,695.26	843,003.68	213,334.94	629,668.74
	18093			917,821.65	917,821.65	0.00	0.00	0.00	0.00
	18094	89,699.71	50,270.88	577,269.65	537,840.82	39,428.83	0.00	0.00	0.00
<b>Total-447657</b>		<b>\$ 1,497,767.86</b>	<b>\$ 466,640.09</b>	<b>\$ 3,127,845.70</b>	<b>\$ 2,096,717.93</b>	<b>\$ 188,124.09</b>	<b>\$ 843,003.68</b>	<b>\$ 213,334.94</b>	<b>\$ 629,668.74</b>

↓

**Total amount of funds received since inception of program.**

↓

**Fund categories earmarked or encumbered for expenditure through Dec 2005**

↓

**Funds remaining in account for expenditure through June 30, 2006.**

\* Non-State General Fund revenue source:

In compliance with AB 1996 [2001], Chapter 7, Part 2, these funds are generate from fees levied by the Department of Managed Health Care and the Department of Insurance against health insurers and health service plans

\*\* Encumbrances such as professional actuarial services are earmarked.

\*\*\* Memos related to projected salaries are recorded as liens on the account. No funds are used for any form of Executive compensation.

## CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

Initial Allocation through June 30, 2003

Fund: 18092\*

Fiscal Year 2002-2003

Account 447657	Sub	Curr Month Financial	Fiscal Year		Inception to Date		Encumbrance	Ledger Balance	Memo-Lien	Operating Balance
			Appropriation	Financial	Appropriation	Financial				
	02									
	03	13,558.59		15,200.95		15,200.95		(15,200.95)		(15,200.95)
	06									
	08		500,000.00		500,000.00			500,000.00		500,000.00
		13,558.59	500,000.00	15,200.95	500,000.00	15,200.95	0.00	484,799.05	0.00	484,799.05
<b>Fund Balance</b>		<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Revenue</b>		<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Expenditure</b>		<b>13,558.59</b>	<b>500,000.00</b>	<b>15,200.95</b>	<b>500,000.00</b>	<b>15,200.95</b>	<b>0.00</b>	<b>484,799.05</b>	<b>0.00</b>	<b>484,799.05</b>
<b>TOTAL</b>		<b>(13,558.59)</b>	<b>(500,000.00)</b>	<b>(15,200.95)</b>	<b>(500,000.00)</b>	<b>(15,200.95)</b>	<b>0.00</b>	<b>484,799.05</b>	<b>0.00</b>	<b>484,799.05</b>

\*Non-State General Fund revenue source:

In compliance with AB 1996 [2001], Chapter 7, Part 2, these funds are generated from fees levied by the Department of Managed Health Care and the Department of Insurance against health insurers and health service plans.

## CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

Allocation through June 30, 2004

Fund: 18093\*

Fiscal Year 2003-2004

Account/CC Sub	Curr Month Financial	Fiscal Year		Inception to Date		Encumbrance	Ledger Balance	Memo-Lien	Operating Balance
		Appropriation	Financial	Appropriation	Financial				
02	31,697.46	273,241.68	273,511.48	273,241.68	273,511.48		(269.80)		(269.80)
03	18,263.04	326,041.07	248,377.02	326,041.07	248,377.02	16,672.46	60,991.59		60,991.59
04	(2,260.34)	2,260.34		2,260.34			2,260.34		2,260.34
05	(517.15)	75,000.00	17,695.23	75,000.00	17,695.23		57,304.77		57,304.77
06	7,208.52	63,964.89	61,644.88	63,964.89	61,644.88		2,320.01		2,320.01
08		633,456.02		633,456.02			633,456.02		633,456.02
447657	54,391.53	1,373,964.00	601,228.61	1,373,964.00	601,228.61	16,672.46	756,062.93	0.00	756,062.93
<b>Fund Balance</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Revenue</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Expenditure</b>	<b>54,391.53</b>	<b>1,373,964.00</b>	<b>601,228.61</b>	<b>1,373,964.00</b>	<b>601,228.61</b>	<b>16,672.46</b>	<b>756,062.93</b>	<b>0.00</b>	<b>756,062.93</b>
<b>TOTAL</b>	<b>(54,391.53)</b>	<b>(1,373,964.00)</b>	<b>(601,228.61)</b>	<b>(1,373,964.00)</b>	<b>(601,228.61)</b>	<b>16,672.46</b>	<b>756,062.93</b>	<b>0.00</b>	<b>756,062.93</b>

\*Non-State General Fund revenue source:

In compliance with AB 1996 [2001], Chapter 7, Part 2, these funds are generated from fees levied by the Department of Managed Health Care and the Department of Insurance against health insurers and health service plans.

## CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

Allocation through June 30, 2005

Fund: 18093

Fiscal Year: 2004-2005

Account/CC Sub	Curr Month Financial	Fiscal Year		Inception to Date		Encumbrance	Ledger Balance	Memo-Lien	Operating Balance
		Appropriation	Financial	Appropriation	Financial				
02		173,308.40	173,308.40	446,819.88	446,819.88				
03	1,434.15	101,087.57	100,253.10	349,464.59	348,630.12		834.47		834.47
04		2,930.50		2,930.50			2,930.50		2,930.50
05		11,057.18	14,822.15	28,752.41	32,517.38	41.50	(3,806.47)		(3,806.47)
06		28,209.39	28,209.39	89,854.27	89,854.27				
447657	1,434.15	316,593.04	316,593.04	917,821.65	917,821.65	41.50	(41.50)	0.00	(41.50)
<b>Fund Balance</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Revenue</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Expenditure</b>	<b>1,434.15</b>	<b>316,593.04</b>	<b>316,593.04</b>	<b>917,821.65</b>	<b>917,821.65</b>	<b>41.50</b>	<b>(41.50)</b>	<b>0.00</b>	<b>(41.50)</b>
<b>TOTAL</b>	<b>(1,434.15)</b>	<b>(316,593.04)</b>	<b>(316,593.04)</b>	<b>(917,821.65)</b>	<b>(917,821.65)</b>	<b>41.50</b>	<b>(41.50)</b>	<b>0.00</b>	<b>(41.50)</b>

\*Non-State General Fund revenue source:

In compliance with AB 1996 [2001], Chapter 7, Part 2, these funds are generated from fees levied by the Department of Managed Health Care and the Department of Insurance against health insurers and health service plans.

## CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

Allocation through June 30, 2005

Fund: 18094\*

Fiscal Year: 2004-2005

Account/CC Sub	Curr Month Financial	Fiscal Year		Inception to Date		Encumbrance	Ledger Balance	Memo-Lien	Operating Balance
		Appropriation	Financial	Appropriation	Financial				
02	39,805.63	233,680.00	248,502.38	233,680.00	248,502.38		(14,822.38)		(14,822.38)
03	18,289.30	276,500.00	195,442.13	276,500.00	195,442.13	92,935.72	(11,877.85)		(11,877.85)
04		5,000.00		5,000.00			5,000.00		5,000.00
05	218.11	13,490.00	616.50	13,490.00	616.50		12,873.50		12,873.50
06	7,104.76	38,637.00	43,008.93	38,637.00	43,008.93		(4,371.93)		(4,371.93)
08		52,317.65		52,317.65			52,317.65		52,317.65
447657	65,417.80	619,624.65	487,569.94	619,624.65	487,569.94	92,935.72	39,118.99	0.00	39,118.99
<b>Fund Balance</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Revenue</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Expenditure</b>	<b>65,417.80</b>	<b>619,624.65</b>	<b>487,569.94</b>	<b>619,624.65</b>	<b>487,569.94</b>	<b>92,935.72</b>	<b>39,118.99</b>	<b>0.00</b>	<b>39,118.99</b>
<b>TOTAL</b>	<b>(65,417.80)</b>	<b>(619,624.65)</b>	<b>(487,569.94)</b>	<b>(619,624.65)</b>	<b>(487,569.94)</b>	<b>92,935.72</b>	<b>39,118.99</b>	<b>0.00</b>	<b>39,118.99</b>

\*Non-State General Fund revenue source:

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## CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

Allocation through June 30, 2005

Fund: 18092\*

Fiscal year: 2005-2006

Account/CC Sub	Curr Month Financial	Fiscal Year		Inception to Date		Encumbrance	Ledger Balance	Memo-Lien	Operating Balance
		Appropriation	Financial	Appropriation	Financial				
02				3,818.47	3,818.47				
03		130.25	130.25	216,373.13	216,373.13			0.01	(0.01)
04				2,260.34	2,260.34				
05				1,463.53	1,463.53				
06				770.78	770.78				
447657	0.00	130.25	130.25	224,686.25	224,686.25	0.00	0.00	0.01	(0.01)
<b>Fund Balance</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Revenue</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Expenditure</b>	<b>0.00</b>	<b>130.25</b>	<b>130.25</b>	<b>224,686.25</b>	<b>224,686.25</b>	<b>0.00</b>	<b>0.00</b>	<b>0.01</b>	<b>(0.01)</b>
<b>TOTAL</b>	<b>0.00</b>	<b>(130.25)</b>	<b>(130.25)</b>	<b>(224,686.25)</b>	<b>(224,686.25)</b>	<b>0.00</b>	<b>0.00</b>	<b>0.01</b>	<b>(0.01)</b>

\*Non-State General Fund revenue source:

In compliance with AB 1996 [2001], Chapter 7, Part 2, these funds are generated from fees levied by the Department of Managed Health Care and the Department of Insurance against health insurers and health service plans.