EXECUTIVE SUMMARY
Analysis of Assembly Bill 30:
Health Coverage:
Inborn Errors of Metabolism

A Report to the 2006-2007 California Legislature
August 24, 2007

CHBRP 07-08
The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. CHBRP was established in 2002 to implement the provisions of Assembly Bill 1996 (California Health and Safety Code, Section 127660, et seq.), and was reauthorized by Senate Bill 1704 in 2006 (Chapter 684, Statutes of 2006). The statute defines a health insurance benefit mandate as a requirement that a health insurer or managed care health plan (1) permit covered individuals 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; or (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.

A small analytic staff in the University of California’s Office of the President supports a task force of faculty from several campuses of the University of California, as well as Loma Linda University, the University of Southern California, and Stanford University, to complete each analysis within a 60-day period, usually before the Legislature begins formal consideration of a mandate bill. A certified, independent actuary helps estimate the financial impacts, and a strict conflict-of-interest policy ensures that the analyses are undertaken without financial or other interests that could bias the results. A National Advisory Council, drawn from experts from outside the state of California and designed to provide balanced representation among groups with an interest in health insurance benefit mandates, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, www.chbrp.org.
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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 30

The California Assembly Committee on Health requested on June 26, 2007, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 30. In response to this request, CHBRP undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as codified in Section 127600, et seq. of the California Health and Safety Code.

AB 30 would require coverage for the testing and treatment of inborn errors of metabolism (IEM) by health care service plans regulated by the California Department of Managed Health Care (DMHC) and health insurance products regulated by the California Department of Insurance (CDI). AB 30 would add Section 1374.4 to the Health and Safety Code and Section 10123.90 to the Insurance Code.

Currently, health plans and insurers are required to provide coverage for the testing and treatment of phenylketonuria (PKU), one of the more common IEM disorders.1

Persons with IEM have genetic disorders that affect their ability to digest foods and metabolize nutrients. Left untreated, these disorders result in death, coma, seizures, and/or chronic, disabling conditions such as mental retardation, cardiovascular disease, encephalopathy, liver disorders, and renal failure. These disorders are rare, occurring on average in 1 birth in 5,000 in California. On average, about 105 newborns are identified each year with a non-PKU IEM disorder. In the insured population subject to this mandate, CHBRP estimates there are 687 persons with a non-PKU IEM disorder.

State Programs for Screening and Treatment
Currently, all newborns are tested for IEM disorders as part of the California Newborn Screening Program to promote early identification and treatment of over 75 hereditary and congenital disorders. The Newborn Screening Program can identify over 40 IEM disorders. Testing is a covered benefit for enrollees with private or publicly financed health insurance.

Treatment of IEM disorders is a covered benefit for residents who qualify for two public programs administered by the California Department of Health Care Services: the California Children’s Services (CCS) program and the Genetically Handicapped Person’s Program (GHPP). Beneficiaries of these programs include those insured by Medi-Cal and the Healthy Families Program. Few privately insured California residents meet the eligibility requirements for these programs unless their income is less than $40,000 per year. For residents eligible for coverage through GHPP, the application process poses a barrier to timely treatment of newborns. For

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1 Health and Safety Code Section 1374.56 and Insurance Code Section 10123.89
example, privately insured residents must provide proof of denial by their insurance as part of the application process.

**Current Law**

Senate Bill (SB) 148, enacted in 1999, requires health plans and insurers to provide coverage for the testing and treatment of PKU. Under current law, treatment of PKU includes “those formulas and special food products that are part of a diet prescribed by a licensed physician and managed by a health care professional in consultation with a physician who specializes in the treatment of metabolic disease and who participates in or is authorized by the plan, provided that the diet is deemed medically necessary to avert the development of serious physical or mental disabilities or to promote normal development or function as a consequence of phenylketonuria (PKU).”

**Requirements of AB 30**

AB 30 would extend this treatment requirement to non-PKU IEM disorders. For the purpose of the bill, an IEM is defined as “an inheritable disorder of biochemistry detected through the California newborn screening program.”

The definition of treatment in AB 30 does not specify the medical nutrition therapy used to treat these disorders. The definition sets a floor by requiring, at a minimum, enteral formulas and special food products that are part of a diet prescribed by a physician. This definition, similar to the definition in current law for PKU, defines these treatments as the following:

- **Formula** means an enteral product or enteral products for use at home that are prescribed by a physician and surgeon or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments, as medically necessary for the treatment of inborn errors of metabolism.

- **Special food product** means a food product that is both of the following:
  - Prescribed by a physician and surgeon or nurse practitioner for the treatment of inborn errors of metabolism and is consistent with the recommendations and best practices of qualified health professionals with expertise germane to, and experience in the treatment and care of, inborn errors of metabolism. It does not include a food that is naturally low in protein, but may include a food product that is specially formulated to have less than one gram of protein per serving.
  - Used in place of normal food products such as those sold at a grocery store for the general population.

**Medical Effectiveness**

Newborn screening facilitates prompt diagnosis and treatment of IEM disorders. In some cases, newborn screening can enable clinicians to identify infants with IEM disorders before they experience acute illness or chronic, disabling conditions. In other cases, results of screening tests can help clinicians diagnose and treat children who experience acute illness due to IEM disorders.

IEM disorders may be divided into three major categories:

- Protein disorders

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2 “Enteral” commonly refers to a substance given via the digestive tract.
- Fatty acid oxidation disorders
- Carbohydrate disorders

Although treatment varies across IEM disorders, it usually encompasses one or more of the following:
- Special formulas that do not contain the nutrients a person cannot metabolize
- Special food products (as described above)
- Vitamin supplements
- Amino acid and enzyme supplements
- Prescription drugs

- Protein disorders are treated by eating a combination of foods that are naturally low in protein and special food products that are formulated to have less protein than conventional foods. Special formulas that exclude nutrients that persons with these disorders cannot metabolize are also prescribed for many protein disorders. Vitamin supplements, amino acid supplements, carnitine (an enzyme cofactor that is not present in adequate quantities in persons with certain protein disorders), and/or prescription drugs may be prescribed as well, depending on the disorder.

- Treatment of fatty acid disorders involves avoiding fasting, eating foods that are naturally low in fat, and taking carnitine. A special formula and vegetable oil containing essential fatty acids may also be prescribed for persons with certain fatty acid disorders.

- Carbohydrate disorders are treated by restricting consumption of dairy products and other foods that contain lactose, galactose, and other carbohydrates.

This Medical Effectiveness analysis relies primarily on treatment guidelines based on consensus among experts. Information was primarily obtained from two review articles and three reference books that synthesized findings from the relatively sparse peer-reviewed literature on treatment of IEM disorders and the experience of experts on these conditions. In a few cases, supplemental information was obtained from articles published in peer-reviewed journals.

There are no published randomized controlled trials (RCTs) or nonrandomized studies with comparison groups that assess the effectiveness of special formulas or special food products for IEM disorders relative to no medical nutrition therapy. Most studies on treatment for these disorders are case studies of individual patients or small groups of patients, or present findings from surveys of clinicians. The lack of controlled studies is probably due to the rarity of these disorders and their potentially lethal consequences.

The lack of controlled studies is not as great a concern for IEM disorders as for many other conditions because IEM disorders are single-cause conditions for which the scientific basis and rationale for treatment are strong. Extensive research has been conducted on the roles of individual enzymes in metabolizing nutrients. Once a person has been diagnosed with an IEM, clinicians can draw upon evidence from case series of prior patients with the disorder to develop effective therapeutic regimens.
Utilization, Cost, and Coverage Impacts

Coverage

- Currently 100% of the privately and publically insured population have coverage for testing to detect IEM disorders. Testing is provided as part of the California Newborn Screening Program operated by the Department of Public Health.

- Currently about 39% of the insured population of California, an estimated 8,096,000, have coverage for the medical nutrition therapy of IEM disorders other than PKU—standard treatment includes formulas, special food products, and/or supplements. Coverage varies by market segment:
  - Coverage for medical nutrition therapy is available to 100% of individuals who qualify for the California Children’s Services (CCS) program or the Genetically Handicapped Person’s Program (GHPP). Medi-Cal and Healthy Families Program beneficiaries qualify for these programs.
  - Coverage for medical nutrition therapy is not available to enrollees in the California Public Employee’s Retirement System (CalPERS).
  - In the privately insured market, coverage is available to about 25% of enrollees in health plans regulated by the DMHC and 58% of those insured by health insurance products regulated by the CDI.

- Among the insured population, approximately 687 are diagnosed with a non-PKU IEM disorder. About 301 currently have coverage for medical nutrition therapy and the remaining 386 would gain coverage for this benefit if AB 30 was enacted into law.

Utilization

- CHBRP has estimated the current utilization of prescribed medical nutritional therapy to be consistent with the medically necessary treatment. Despite the barriers to access to such treatment, clinical experts at the metabolic centers (where patients receive comprehensive treatment from multidisciplinary practitioner teams) perceive that parents and providers obtain the necessary products regardless of insurance status to avert the devastating consequences of forgoing treatment. As a result, CHBRP estimated no increase in utilization for these products due to the mandate.

- AB 30 does not preclude carriers from charging copayment, coinsurance, deductible, or other cost-sharing for this benefit. The bill also does not preclude carriers from conducting utilization or medical necessity reviews.

Costs

- CHBRP has estimated an average annual cost of $6,000 per patient for the medical nutrition therapy necessary for treatment. This cost is based on the experience of metabolic centers approved by California Children’s Services (CCS) throughout California that provide treatment for children and adults with IEM disorders.
• Total net annual expenditures are estimated to increase by $415,000 annually or 0.0006% mainly due to the administrative costs associated with providing coverage for persons who do not currently have it.

• Prior to the mandate, enrollees without coverage for medical nutrition therapy incurred an estimated $2,315,000 in out-of-pocket expenses annually. Postmandate, that $2,315,000 in out-of-pocket expenses would be shifted to health plans and insurers. However, enrollees would incur an additional $27,000 in co-payments for the newly covered benefits.

• The mandate is estimated to increase premiums by about $2.7 million. The distribution of the impact on premiums is as follows:
  o Total premiums for private employers are estimated to increase by $1,830,000, or 0.0042%.
  o Total employer premium expenditures for CalPERS are estimated to increase by $145,000, or 0.0055%.
  o Premiums paid by employees covered by group insurance (including CalPERS) would increase by an estimated $479,000 or 0.0042%.
  o Total premiums for those with individually purchased insurance are estimated to increase by $249,000, or 0.0045%.
Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 30

<table>
<thead>
<tr>
<th></th>
<th>Before Mandate</th>
<th>After Mandate</th>
<th>Increase/ Decrease</th>
<th>Change After Mandate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coverage</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of individuals subject to the mandate</td>
<td>20,687,000</td>
<td>20,687,000</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Percentage of individuals with coverage for medical nutrition therapy</td>
<td>39.1%</td>
<td>100.0%</td>
<td>60.9%</td>
<td>156%</td>
</tr>
<tr>
<td>Number of individuals with coverage for medical nutrition therapy</td>
<td>8,096,100</td>
<td>20,687,000</td>
<td>12,590,900</td>
<td>156%</td>
</tr>
<tr>
<td><strong>Utilization and Cost</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number using medical nutrition therapy</td>
<td>687</td>
<td>687</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Number of those using medical nutrition therapy who have coverage for the benefit</td>
<td>301</td>
<td>687</td>
<td>386</td>
<td>128%</td>
</tr>
<tr>
<td>Number of those using medical nutrition therapy who do not have coverage for the benefit</td>
<td>386</td>
<td>0</td>
<td>-386</td>
<td>-100%</td>
</tr>
<tr>
<td>Average per annum cost</td>
<td>$6,000</td>
<td>$6,000</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Expenditures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premium expenditures by private employers for group insurance</td>
<td>$43,944,936,000</td>
<td>$43,946,766,000</td>
<td>$1,830,000</td>
<td>0.0042%</td>
</tr>
<tr>
<td>Premium expenditures for individually purchased insurance</td>
<td>$5,515,939,000</td>
<td>$5,516,188,000</td>
<td>$249,000</td>
<td>0.0045%</td>
</tr>
<tr>
<td>CalPERS employer expenditures</td>
<td>$2,631,085,000</td>
<td>$2,631,230,000</td>
<td>$145,000</td>
<td>0.0055%</td>
</tr>
<tr>
<td>Medi-Cal state expenditures (a)</td>
<td>$4,015,964,000</td>
<td>$4,015,964,000</td>
<td>0</td>
<td>0.0000%</td>
</tr>
<tr>
<td>Healthy Families state expenditures</td>
<td>$627,766,000</td>
<td>$627,766,000</td>
<td>0</td>
<td>0.0000%</td>
</tr>
<tr>
<td>Premium expenditures by individuals with group insurance or CalPERS</td>
<td>$11,515,939,000</td>
<td>$11,516,418,000</td>
<td>$479,000</td>
<td>0.0042%</td>
</tr>
<tr>
<td>Individual out-of-pocket expenditures (deductibles, copayments, etc.)</td>
<td>$5,153,127,000</td>
<td>$5,153,154,000</td>
<td>$27,000</td>
<td>0.0005%</td>
</tr>
<tr>
<td>Expenditures for non-covered services (b)</td>
<td>$2,315,000</td>
<td>$0</td>
<td>-$2,315,000</td>
<td>-100%</td>
</tr>
<tr>
<td><strong>Total annual expenditures</strong></td>
<td>$73,407,071,000</td>
<td>$73,407,486,000</td>
<td>$415,000</td>
<td>0.0006%</td>
</tr>
</tbody>
</table>

*Source: California Health Benefits Review Program, 2007.*

*Notes:* The population includes individuals and dependents covered by employer sponsored insurance (including CalPERS), individually purchased insurance, or public health insurance provided by a health plan subject to the requirements of the Knox-Keene Health Care Service Plan Act of 1975. All population figures include enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment sponsored insurance. Member contributions to premiums include employee contributions to employer sponsored health insurance and member contributions to public health insurance.

*Key:* CalPERS = California Public Employees’ Retirement System

(a) Medi-Cal state expenditures for members under 65 years of age include expenditures for Major Risk Medical Insurance Program (MRMIP) and Access for Infants and Mothers (AIM) program.

(b) The expenditures for medical nutrition therapy for non-PKU IEM disorders paid by enrollees who currently do not have benefit for such treatments.
Public Health Impacts

- Of the 834,373 California babies born between July 7, 2005, and December 31, 2006, a total of 158 newborns were identified with one of the non-PKU IEM disorders, where the primary treatment is the use of medical nutrition therapy, resulting in a prevalence of approximately 1 in 5,000 newborns.

- AB 30 will not result in an increase in utilization of medical nutrition therapy for the treatment of non-PKU IEM disorders and is therefore not expected to result in measurable improved health outcomes. AB 30 will, however, increase insurance coverage for this benefit to 386 individuals with a non-PKU IEM disorder and therefore will likely reduce the administrative burden and financial hardship associated with these disorders when health plans deny claims for medical nutrition therapy.

- No research was identified that found gender differences in the prevalence of non-PKU IEM disorders. Overall, the proportion of newborns identified with IEM disorders is comparable to the racial and ethnic distribution of births in California. Since there are no measurable gender or racial/ethnic differences in the prevalence of IEM disorders and AB 30 is not anticipated to affect utilization of medical nutrition therapy, AB 30 is not expected to have a measurable impact on gender, racial, or ethnic disparities in health.

- For infants with non-PKU IEM disorders, the use of medical nutrition therapy is essential for the prevention of serious and costly health effects, including premature death. The costs of medical nutrition therapy for these disorders are minimal compared to the broader costs of screening programs and the medical costs associated with not getting proper and timely treatment. Since AB 30 is not expected to increase utilization of medical nutrition therapy, this mandate is not expected to have a measurable impact on premature death or the economic loss associated with non-PKU IEM disorders.
ACKNOWLEDGEMENTS

Edward Yelin, PhD, Janet Coffman, MPP, PhD, and Wade Aubry, MD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Penny Coppernoll-Blach, MLIS, of the University of California, San Diego, conducted the literature search. William L. Nyhan MD, PhD, of the University of California, San Diego, and Debra G. Hook, MPH, of the University of California, Irvine, provided technical assistance with the literature review and expert input on the analytic approach. Helen Halpin, PhD, and Nicole Bellows, PhD, of the University of California, Berkeley, prepared the public health impact analysis. Gerald Kominski, PhD, Meghan Cameron, MPH, and Nadereh Pourat, PhD, all of the University of California, Los Angeles, prepared the cost impact analysis. Robert Cosway, FSA, MAAA, provided actuarial analysis. Cynthia Robinson, MPP, of CHBRP staff prepared the background section and contributed to combining the individual sections into a single report. Sarah Ordody, BA, provided editing services. A subcommittee of CHBRP’s National Advisory Council (see final pages of this report) and a member of the CHBRP Task Force, Theodore Ganiats, MD, of the University of California, San Diego, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature’s request.

CHBRP gratefully acknowledges all of these contributions but assumes full responsibility for all of the report and its contents. Please direct any questions concerning this report to:

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP Faculty Task Force comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The CHBRP staff coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others.

As required by the CHBRP authorizing legislation, UC contracts with a certified actuary, Milliman Inc. (Milliman), to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

The National Advisory Council provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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