EXECUTIVE SUMMARY
Analysis of Senate Bill 1104:
Diabetes-Related Complications

A Report to the 2009-2010 California Legislature
April 17, 2010

CHBRP 10-06
A Report to the 2009-2010 California State Legislature

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Diabetes-Related Complications

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 1104

The California Senate Committee on Health requested on February 12, 2010, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 1104, a bill that would impose a health benefit mandate.

On March 23, 2010, the federal government enacted the federal “Patient Protection and Affordable Care Act” (P.L.111-148), which was amended by the “Health Care and Education Reconciliation Act” (H.R.4872) that the President signed into law on March 30, 2010. These laws (referred to as P.L. 111-148) came into effect after CHBRP received a request for analysis for SB 961. There are provisions in P.L.111-148 that go into effect by 2014, and beyond, that would dramatically affect the California health insurance market and its regulatory environment. For example, the law would establish state-based health insurance exchanges, with minimum benefit standards, for the small group and individual markets. How these provisions are implemented in California would largely depend on regulations to be promulgated by federal agencies, and statutory and regulatory actions to be undertaken by the California state government.

There are also provisions in P.L.111-148 that go into effect within the short term or within 6 months of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. For example, one provision would allow children to enroll onto their parent’s health plan or policy until they turn 26 years of age (effective 6 months following enactment). This may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance. These and other short -term provisions would affect CHBRP’s baseline estimates of the number and source of health insurance for Californians in 2010. Given the uncertainty surrounding implementation of these provisions and given that P.L.111-148 was only recently enacted, the potential effects of these short-term provisions are not taken into account in the baseline estimates presented in this report. It is important to note that CHBRP’s analysis of specific mandate bills typically addresses the marginal effects of the mandate bill—specifically how the state mandate would impact coverage, utilization, costs, and the public health, holding all other factors constant. CHBRP’s estimates of these marginal effects continue to be relevant for the 12 months that would follow implementation of the mandate.

Approximately 19.5 million Californians (51%) have health insurance that may be subject to a health benefit mandate law passed at the state level. Of the rest of the population, a portion is uninsured, and therefore not affected by health insurance benefit mandate laws. Others have health insurance not subject to health insurance benefit mandate laws. Uniquely, California has a bifurcated system of regulation for health insurance subject to state level health benefit mandate laws. The California Department of Managed Health Care (DMHC) regulates health care service plans that offer coverage for benefits to their enrollees through health plan service

1 DMHC is the regulatory body established in 2000 to enforce the provision of the Knox-Keene Health Care Service Plan of 1975, see Health and Safety Code, Section 1340.
contracts. The California Department of Insurance (CDI) regulates health insurers\(^2\) that offer coverage for benefits to their enrollees through health insurance policies.

SB 1104 would place requirements on all DMHC-regulated health plan contracts and all CDI-regulated policies. Therefore, approximately 19.5 million Californians (51%) have health insurance that would be subject to the mandate.

SB 1104 would mandate that plans and policies provide coverage for the diagnosis and treatment of diabetes-related complications. SB 1104 would also require that copayments and deductibles for these benefits not exceed those established for similar benefits within the given plan or policy. SB 1104 does not specify what are to be considered diabetes-related complications and does not specify the scope of the coverage. CHBRP assumes that SB 1104 would require coverage of all services, devices, and medications medically necessary for the diagnosis and treatment of all diabetes-related complications.

Diabetes-related complications commonly include (but are not limited to) diabetic foot ulceration (which can lead to amputations), microvascular diseases, and macrovascular diseases. Microvascular diseases commonly include (but are not limited to) diabetic neuropathy (e.g., nerve disease), diabetic nephropathy (e.g., kidney disease), and diabetic retinopathy (e.g., eye disease). Respectively, these can lead to amputations, kidney failure, and blindness. Macrovascular diseases include (but are not limited to) cardiovascular disease and peripheral vascular disease. Respectively, these can lead to heart attacks, strokes, and amputations. Additional diabetes-related complications exist, but content experts have confirmed to CHBRP that this list contains the most common set. This report focuses on common treatments and services related to the diagnosis and treatment of select diabetes-related complications. However, the mandate is broad and would require coverage of more treatments and services for more diabetes-related conditions than are described in this report.

CHBRP has assumed that the mandate will require coverage for outpatient medications. Although the bill language states that plan contracts and policies “that cover prescription benefits…shall include coverage of prescription medications for the treatment of diabetes-related complications,” and may intend only to address plans and policies already providing an outpatient pharmacy benefit, CHBRP assumes SB 1104 would require all plans and policies to do so. Because all plans and policies, even those without an outpatient pharmacy benefit, cover prescription medications delivered during a hospital stay, CHBRP has interpreted the language of the bill as requiring all plans and policies (even those without an outpatient pharmacy benefit) to cover outpatient medications prescribed for the treatment of diabetes-related complications. However, it should be noted that the language of the bill is not perfectly clear.

SB 1104 would amend a current California mandate that addresses coverage of hospital, medical, or surgical expenses and select equipment and supplies for the management and treatment of diabetes. It should be noted that existing law\(^3\) mandates that DMHC-regulated plans and CDI-

\(^2\) CDI licenses “disability insurers.” Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

\(^3\) Health and Safety Code Section 1367.51, and Insurance Code Section 10176.61
regulated policies provide coverage for supplies and devices for the treatment of diabetes and for podiatric devices (such as shoes for diabetics) to prevent or treat diabetes-related complications. Therefore, the bill would not alter coverage for orthotics (podiatric devices).

Many states have laws mandating coverage of diabetes-related supplies and education. No other states mandate broad coverage for the diagnosis and treatment of diabetes-related conditions.

### Medical Effectiveness

Diabetes-related complications may lead to kidney failure, blindness, and/or amputation.

Diabetes-related complications include (but are not limited to):

- **Microvascular disease (i.e., disease affecting capillaries and other small blood vessels)**
  - Diabetic nephropathy (i.e., kidney disease)
  - Diabetic neuropathy (i.e., nerve disorders)
  - Diabetic retinopathy (i.e., eye disease)

- **Macrovascular disease (i.e., disease affecting large blood vessels, such as large arteries in the brain, heart, and limbs)**
  - Cardiovascular disease (e.g., heart attack, stroke)
  - Peripheral vascular (arterial) disease

- **Diabetic foot ulcers**

The medical effectiveness review focused on microvascular diseases and diabetic foot ulcers because diabetes is the major risk factor for contracting these conditions. The medical effectiveness review did not address macrovascular diseases. Diabetes is only one of several major risk factors for macrovascular diseases, and persons with macrovascular diseases receive the same treatments regardless of whether they have diabetes. The medical effectiveness team focused on the treatments for microvascular diseases and diabetic foot ulcers that are most frequently used in the United States.

Findings regarding the most frequently used treatments for the diabetes-related microvascular diseases (i.e., diabetic nephropathy, diabetic neuropathy, diabetic retinopathy) and diabetic foot ulcers are summarized below.

#### Diabetic Nephropathy (i.e., kidney disease)

*Outpatient Prescription Medications*

- There is clear and convincing evidence that
Angiotensin-converting enzyme inhibitor and angiotensin receptor blocker medications reduce the risk that diabetic kidney disease will progress to end-stage renal disease compared to a placebo.

Angiotensin-converting enzyme inhibitors and angiotensin receptor blockers are equally effective in reducing the risk of progression for diabetic kidney disease.

**Diabetic Neuropathy (i.e., nerve disorders)**

**Outpatient Prescription Medications**

- There is a preponderance of evidence that Ilosone (erythromycin), Motilium (domperidone), and Reglan (metoclopramide) improve symptoms of gastroparesis (e.g., bloating, nausea, vomiting, and fullness on eating), a condition associated with diabetic autonomic neuropathy, compared to a placebo.

- There is clear and convincing evidence that the following antidepressant medications reduce pain associated with diabetic peripheral neuropathy compared to a placebo:
  - Tricyclic antidepressants
  - Tetracyclic antidepressants
  - Cymbalta (duloxetine)

- There is clear and convincing evidence that two anticonvulsant medications reduce pain associated with diabetic neuropathy compared to a placebo:
  - Lyrica (pregabalin)
  - Neurontin (gabapentin)

- Findings from single randomized controlled trials (RCTs) suggest that the following anticonvulsant medications may reduce pain associated with diabetic neuropathy compared to a placebo:
  - Tegretol (carbamazepine)
  - Topamax (topiramate)
  - Trileptal (oxcarbazepine)

- Findings from RCTs that compared the effectiveness of Depakote (valproic acid) and a placebo for relief of pain associated with diabetic neuropathy are inconsistent.

- The only RCT to assess the effectiveness of Lamictal (lamotrigine) for pain associated with diabetic neuropathy found that this medication was no more effective than a placebo.

- A preponderance of evidence suggests that aldose reductase inhibitors do not improve the neurological functioning of persons with diabetic polyneuropathy.
Diabetic Retinopathy (i.e., eye disease)

Hospital and Physician/Provider Services (inclusive of medications delivered during an inpatient stay or at a provider’s office; etc.)

- There is a preponderance of evidence that intravitreal injection of antiangiogenesis agents improves visual acuity relative to sham treatment or laser treatment.

- RCTs that have examined the effectiveness of corticosteroids for improving visual acuity have found that:
  - There is clear and convincing evidence that intravitreal injection of corticosteroids improves visual acuity relative to no treatment, sham treatment, or laser treatment.
  - There is a preponderance of evidence that intravitreal injection of corticosteroids is no more effective than subTenon injection (a less invasive technique).
  - There is a preponderance of evidence that that surgical implantation of corticosteroids is no more effective than no treatment, sham treatment, or laser treatment.
  - Findings from studies of the effect of combining intravitreal corticosteroid injection with laser treatment are inconsistent.

- There is clear and convincing evidence that focal laser photocoagulation and pan-retinal laser photocoagulation are associated with a decrease in vision loss associated with diabetic retinopathy.

- Findings from RCTs on the effectiveness of surgical vitrectomy for improving visual acuity are inconsistent.

Diabetic Foot Ulcers

Hospital and Physician/Provider Services

- There is clear and convincing evidence that the following treatments reduce the risk of amputation among persons with diabetic foot ulcers:
  - Granulocyte-colony stimulating factors
  - Hyperbaric oxygen therapy

- There is a preponderance of evidence that the following treatments increase the likelihood that diabetic foot ulcers will heal and/or reduce the size of diabetic foot ulcers:
  - Bioengineered skin substitutes versus gauze treated with saline or hydrogel
  - Certain cellular and biologic agents, including epidermal growth factor, platelet autogel, recombinant platelet-derived growth factor, and tretinoin, versus placebo

- The only RCT to compare surgical debridement of diabetic foot ulcers to nonsurgical management found no difference in the likelihood that foot ulcers would heal.

- Findings from RCTs that have examined the effectiveness of total contact casting have found that:
Total contact casting improves the likelihood that diabetic foot ulcers will heal compared to standard care, therapeutic shoes, and removable diabetic walkers.

Total contact casting is no more effective than a nonremovable diabetic walker.

Combining total contact casting with Achilles tendon lengthening surgery does not improve the likelihood that a diabetic foot ulcer will heal but does reduce the risk of recurrence of foot ulcers.

**Durable Medical Equipment**

- The meta-analyses and systematic reviews did not identify any RCTs regarding the effectiveness of durable medical equipment (DME) for use by persons with diabetic foot ulcers or amputations associated with gangrene and nonhealing foot ulcers. The lack of evidence for the effectiveness of DME is not evidence of a lack of effect. Canes, crutches, walkers, and wheelchairs improve the mobility of persons with foot ulcers or amputations. These devices may, in turn, improve their ability to perform instrumental activities of daily living (e.g., grocery shopping, preparing meals) and quality of life.

**Medical Supplies for Ulcer Care**

- There is clear and convincing evidence that the following treatments increase the likelihood that diabetic foot ulcers will heal:
  - Hydrogel versus gauze or standard wound care
  - Negative pressure wound therapy versus standard dressings

- Findings from single RCTs suggest that the following treatments reduce the size of diabetic foot ulcers or the number of days within which foot ulcers heal:
  - Carboxymethyl-cellulose hydrofiber dressing versus saline gauze
  - Polymeric semi-permeable membrane dressing versus saline gauze
  - Zinc oxide tape versus hydrogel

**Prosthetics**

- The meta-analyses and systematic reviews did not identify any RCTs that compared persons with diabetes whose lower limbs have been amputated who used a prosthesis to persons with diabetes-related amputations who did not use a prosthesis. A previous CHBRP report found that more sophisticated prosthetic feet and ankle mechanisms may be more effective than less sophisticated mechanisms, but the effect is small, and most evidence comes from small cross-over studies. The lack of evidence for the effectiveness of prosthetics is not evidence that prosthetics provide no benefit. Prosthetic feet and legs may improve the mobility of persons with diabetes who have had amputations, which is likely to improve their ability to perform instrumental activities of daily living and their quality of life.
Outpatient Prescription Medications

- There is a preponderance of evidence that adding antibiotic therapy to standard wound care does not improve the healing of diabetic foot ulcers.

Utilization, Cost, and Coverage Impacts

Approximately 19,487,000 persons in California are enrolled in health plans or policies that would be subject to SB 1104. Currently, in California, 92% of these enrollees have coverage that is compliant with SB 1104 for medical treatments and devices for diagnosing or treating diabetes-related complications, and 95% have SB 1104-compliant coverage for outpatient prescription medications for these purposes.

Approximately 1,100,000 (5.6%) of enrollees subject to SB 1104 have diagnosed diabetes. CHBRP estimates that of these diabetic enrollees, 1,100,000 (100%) have SB 1104-compliant coverage for hospital and physician/provider services and for orthotics. However, approximately 88,000 (8%) do not have SB 1104-compliant benefit coverage for some medical treatments (wound dressings, some items of durable medical equipment (DME), and/or prosthetics). CHBRP also estimates that 58,000 (5%) do not have benefit coverage that is compliant with SB 1104 for outpatient prescription medications. CHBRP is unable to estimate the proportion of overlap between those with non-compliant coverage for medical treatments and outpatient prescription medications.

The list of all services or treatments for the diagnosis or treatment of diabetes-related complications is extensive and potentially ineffable. CHBRP’s approach for estimating the potential cost and utilization impacts of SB1104 assumed that of enrollees identified as having a diabetes diagnosis, a portion has one or more diabetes-related complication(s), and a portion does not. However, due to the nature of physicians’ coding, whereby physicians may code a diabetic patient who is being treated for a complication as either “diabetes-with-complications,” or “diabetes,” CHBRP considered all diabetic enrollees so as not to inadvertently overlook any diagnoses or treatments of diabetes-related complications. Thus, CHBRP makes the simplifying assumption of examining all DME, medical supplies, prosthetics, and outpatient prescription medications for enrollees with diabetes.

For the Utilization, Cost, and Benefit Coverage Impacts section, CHBRP refers to durable medical equipment (DME), medical supplies, and prosthetics as medical treatments. These medical treatments, as well as outpatient prescription medications related to diabetes-related complications are described, below, with indications as to whether benefit coverage is currently compliant with SB 1104.

Medical treatments:

- **Hospital and physician/provider services** (e.g., dilated retinal exams for retinopathy; foot exams for foot ulcers; medications delivered during an
inpatient stay or at provider’s office; etc.): benefit coverage SB 1104-compliant for 100% of enrollees

- **Durable medical equipment (DME)** (e.g., Canes, crutches, wheelchairs, walkers, etc., for foot ulcers/amputations): benefit coverage SB 1104-compliant for 92% of enrollees

- **Medical supplies for ulcer care provided for home use** (e.g., Hydrogel, negative pressure therapy, or zinc oxide tape for foot ulcers): benefit coverage SB 1104-compliant for 92% of enrollees

- **Prosthetics (e.g., prosthetic feet and legs for amputations)**: benefit coverage SB 1104-compliant for 92% of enrollees

- **Orthotics (e.g., diabetic shoes for diabetic neuropathy)**: benefit coverage SB 1104-compliant for 100% of enrollees

*Outpatient prescription medications:*

- **Outpatient Prescription Medications** (e.g., antidepressants for neuropathy, antibiotics for foot ulcers, or antihypertensives for diabetic nephropathy): benefit coverage SB 1104-compliant for 95% of enrollees

Table 1 summarizes the benefit coverage, utilization, and cost impacts of SB 1104. Overall, CHBRP estimates that SB1104:

- Would not change coverage for:
  - Hospital and physician/provider services (including inpatient prescription medications)
  - Orthotics/diabetic shoes

- Would increase benefit coverage for:
  - Outpatient prescription medications
  - Durable medical equipment (DME)
  - Prosthetics
  - Medical supplies (e.g., for diabetic foot ulcers) provided for home use

Enrollees with these gaps in coverage do not currently utilize these supplies and treatments at the same level as those without such coverage gaps, because the added costs of paying for non-covered supplies and treatments creates a financial hardship that results in reduced utilization. Since SB 1104 would change benefit coverage for those enrollees with current gaps in coverage, CHBRP estimates there would be some increase in utilization of some medical treatments (DME, prosthetics, and/or supplies), and some increase in utilization of outpatient medications among enrollees with diabetes who do not currently have benefit coverage that is compliant with SB 1104 and who, therefore, currently have reduced utilization due to a lack of benefit coverage.

For this analysis, utilization of medical treatments (medical supplies, items of DME, prosthetic devices) is measured in aggregated units. Utilization of outpatient prescription medications is measured as the number of prescriptions filled. The unit of medical treatment may include one artificial limb; one item of DME; or item of a medical supply. Each enrollee with diabetes – including those with and without SB 1104-compliant coverage – receives on average approximately 0.54 units of medical treatment and approximately 23.81 prescriptions per year. The utilization differs, however, between enrollees with and without compliant coverage; specifically, estimated utilization among enrollees with non-compliant coverage is 10% less than
that of those with compliant coverage. Thus, each enrollee with diabetes who has compliant coverage receives on average approximately 0.54 units of medical treatments and approximately 23.92 prescriptions per year, and these numbers among those with non-compliant coverage are 0.49 and 21.75, respectively.

CHBRP estimates an average cost of $304 per unit of medical treatment (supplies, equipment, and/or prosthetic devices) provided and $85 per outpatient prescription medication provided for the diagnosis and treatment of diabetes-related complications. For enrollees with coverage for these services, this includes average cost-sharing (e.g., copayments, coinsurance deductibles, etc.) of $45 for medical services and $14 for prescription medications.

SB1104 would extend benefit coverage for the diagnosis and treatment of diabetes-related complications. CHBRP estimates that 92% of enrollees with diabetes currently have SB 1104-compliant coverage for related medical treatments, and 95% have SB 1104-compliant coverage for outpatient prescription medications. Therefore, SB 1104 would expand coverage to an additional 8% of enrollees for medical treatment and to 5% of enrollees for outpatient prescription medications.

CHBRP estimates that SB 1104 would result in coverage for about 4,300 additional medical treatment units per year for the 88,000 enrollees with new medical treatment coverage, and about 125,000 additional prescriptions per year for the 58,000 enrollees with new outpatient prescription medication coverage.

CHBRP estimates that SB 1104 also would shift costs from diabetic enrollees to the health plans and insurers. CHBRP estimates a decrease in enrollee expenses for noncovered benefits of approximately $120 million/year, and an increase in enrollee out-of-pocket expenses for covered benefits of approximately $21 million/year. The decrease in enrollee expenses for non-covered benefits would vary between enrollees, depending on the supplies or treatments used; for example, a prosthetic device could cost up to $2500 for the device alone (e.g., not including fitting, physician visits, etc.), and a wheelchair could be as expensive as $20,000 or $35,000.

Statewide, these changes in coverage would impact costs as follows:

- Statewide, total net annual expenditures are estimated to increase by $49,552,000, or 0.0647%, for the year following implementation of the mandate, mainly due to the administrative costs associated with providing coverage for the benefit to persons who do not currently have it.

- Approximately $120,313,000 in expenses for previously noncovered benefits would shift from patients to health plans and insurers. However, patients would incur $21,225,000 in out-of-pocket expenses as part of cost sharing (copayments, coinsurance, etc.) for the newly covered benefits. Statewide, the net shift would be $99,088,000.

The mandate is estimated to increase premiums by about $148,640,000. The distribution of the impact on premiums is as follows:
Total premiums for private employers purchasing group health insurance are estimated to increase by $47,786,000, or 0.1098%.

Total employer premium expenditures for California Public Employees’ Retirement System health maintenance organizations (CalPERS HMOs) are estimated to increase by $3,163,000, or 0.0968%. Of the amount CalPERS would pay in additional total premiums, about 58% or $1,835,000 would be the cost borne by the General Fund for CalPERS HMO enrollees who are state employees.

Enrollee contributions toward premiums for group insurance regulated by DMHC or CDI are estimated to increase by $13,888,000, or 0.1083%.

Total premiums for purchasers of individual market health insurance are estimated to increase by $83,803,000, or 1.3984%.

State expenditures for Medi-Cal HMOs are estimated to be unaffected, because Medi-Cal HMOs already are compliant with the requirements of SB 1104.

State expenditures for Healthy Families are estimated to be unaffected, because Healthy Families already are compliant with the requirements of SB 1104.

The estimated premium increases in the individual market may result in approximately 3,000 newly uninsured persons.

Public Health Impacts

Some of the many consequences of diabetes-related conditions include kidney failure, debilitating neuropathic pain (chronic pain related to the nervous system), and/or amputations. Although SB 1104 would increase coverage for a relatively small population, it may have a substantial impact for this group. Reducing expenses for previously uncovered treatments, treating early stages of diabetic nephropathy, reducing symptoms related to diabetes-related complications, or improving mobility through coverage of durable medical equipment and prosthetics, especially for those who have delayed or forgone care due to lack of coverage, will improve the health status, quality of life, and productivity for the enrollees who utilize those new benefits.

• CHBRP estimates that SB 1104 would extend coverage for medical treatments (i.e., walkers, prosthetics, or wound dressings) to about 88,000 diabetic enrollees and that the number of medical treatment “units” (e.g., an individual prosthetic or a hydrogel wound dressing or a wheelchair) used by the subset of this population who have diabetes-related complications would increase by 4,300 units per year. The increased utilization of treatments is likely to delay or reduce complications such as amputation.

• Additionally, CHBRP estimates the bill would extend coverage of outpatient prescription medication to about 58,000 diabetic enrollees resulting in 125,000 additional prescription
medications filled per year by the subset of diabetics with diabetes-related complications. The increased utilization of treatment is likely to delay or reduce complications such as neuropathic pain, kidney failure, or premature death.

- SB 1104 also would produce a shift from the newly covered enrollees’ expenses for non-covered treatments and prescription medications to the health plan or insurer. CHBRP estimates these enrollees would receive a net reduction in expenses for some medical treatments and medications of approximately $1,100/year per newly covered enrollee with diabetes.

- Although gender and racial/ethnic disparities are present among those with diabetes-related complications, CHBRP found no evidence to determine whether SB 1104 would impact the disparities in health status or outcomes.

- SB 1104 may reduce economic losses, such as lost work days or decreased work productivity, due to enrollees with new coverage experiencing improved control of symptoms from diabetes-related complications or improved mobility, but the magnitude cannot be estimated.

- CHBRP estimates that SB 1104 will increase premiums in the individual market by 1.4%, thus increasing the number of uninsured by approximately 3,000 people. Losing one’s health insurance has many harmful consequences beyond the health outcomes presented in this analysis. Effective 2014, P.L.111-148 may diminish SB 1104’s effects on the increase of the uninsured.

Additionally, CHBRP notes that the overall prevalence of diabetes in California is increasing concomitant with a reduction in age of diabetes diagnosis. This will most likely increase utilization of DME, wound supplies, prosthetics, and outpatient prescription medications over the long term as diabetes-related complications develop. Thus, the additional coverage provided by SB 1104 would continue to benefit proportionately more enrollees.
Table 1. SB 1104 Impacts on Benefit Coverage, Utilization, and Cost, 2010

<table>
<thead>
<tr>
<th>Benefit Coverage</th>
<th>Before Mandate</th>
<th>After Mandate</th>
<th>Increase/Decrease</th>
<th>Change After Mandate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total enrollees with health insurance subject to state-level benefit mandates (a)</td>
<td>19,487,000</td>
<td>19,487,000</td>
<td>0</td>
<td>0%</td>
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<tr>
<td>Total enrollees with health insurance subject to SB 1104</td>
<td>19,487,000</td>
<td>19,487,000</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Percentage of enrollees with medical treatment coverage (hospital and provider services; DME, orthotics, prosthetics, supplies) compliant with SB1104 (b)</td>
<td>92.0%</td>
<td>100.0%</td>
<td>8.0%</td>
<td>9%</td>
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<tr>
<td>Percentage of enrollees with medical treatment coverage NOT compliant</td>
<td>8.0%</td>
<td>0.0%</td>
<td>-8.0%</td>
<td>-100%</td>
</tr>
<tr>
<td>Percentage of enrollees with benefit coverage for outpatient prescription medications compliant with SB1104 (c)</td>
<td>94.8%</td>
<td>100.0%</td>
<td>5.2%</td>
<td>6%</td>
</tr>
<tr>
<td>Percentage of enrollees with benefit coverage for outpatient prescription medications NOT compliant</td>
<td>5.2%</td>
<td>0.0%</td>
<td>-5.2%</td>
<td>-100%</td>
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<tr>
<td>Number of enrollees with medical treatment coverage compliant with SB1104</td>
<td>17,933,000</td>
<td>19,487,000</td>
<td>1,554,000</td>
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<tr>
<td>Number of enrollees with medical treatment coverage NOT compliant</td>
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<td>-100%</td>
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<tr>
<td>Number of enrollees with benefit coverage for outpatient prescription medications compliant with SB1104</td>
<td>18,465,000</td>
<td>19,487,000</td>
<td>1,022,000</td>
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<tr>
<td>Number of enrollees with benefit coverage for outpatient prescription medications NOT compliant</td>
<td>1,022,000</td>
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<td>-1,022,000</td>
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Utilization and Cost—Medical

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<thead>
<tr>
<th></th>
<th>Before Mandate</th>
<th>After Mandate</th>
<th>Increase/Decrease</th>
<th>Change After Mandate</th>
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<tbody>
<tr>
<td>Number of enrollees with diabetes</td>
<td>1,100,000</td>
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<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Number with medical treatment coverage compliant with SB1104</td>
<td>1,012,000</td>
<td>1,100,000</td>
<td>88,000</td>
<td>9%</td>
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<td>Number with medical treatment coverage NOT compliant</td>
<td>88,000</td>
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<tr>
<td>Average per-unit cost (d)</td>
<td>$304</td>
<td>$304</td>
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<td>0%</td>
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<tr>
<td>Average number of medical treatment units used per year per enrollee with diabetes</td>
<td>0.54</td>
<td>0.54</td>
<td>0.0039</td>
<td>0.7%</td>
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<tr>
<td>Among those with benefit coverage compliant with SB1104</td>
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<tr>
<td>Among those with benefit coverage NOT compliant with SB1104</td>
<td>0.49</td>
<td>0.54</td>
<td>0.0493</td>
<td>10.0%</td>
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Utilization and Cost—Outpatient Prescription Medications

<table>
<thead>
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<th>Before Mandate</th>
<th>After Mandate</th>
<th>Increase/Decrease</th>
<th>Change After Mandate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of enrollees with diabetes</td>
<td>1,100,000</td>
<td>1,100,000</td>
<td>-</td>
<td>0%</td>
</tr>
<tr>
<td>Among those with benefit coverage compliant with SB1104</td>
<td>1,042,000</td>
<td>1,100,000</td>
<td>58,000</td>
<td>6%</td>
</tr>
<tr>
<td>Among those with benefit coverage NOT compliant with SB1104</td>
<td>58,000</td>
<td>0</td>
<td>-58,000</td>
<td>-100%</td>
</tr>
<tr>
<td>Table 1. SB 1104 Impacts on Benefit Coverage, Utilization, and Cost, 2010 (cont’d)</td>
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<tr>
<td><strong>Utilization and Cost</strong>—<strong>Outpatient Prescription Medications</strong> (cont’d)</td>
<td></td>
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</tr>
<tr>
<td><strong>Before Mandate</strong></td>
<td><strong>After Mandate</strong></td>
<td><strong>Increase/Decrease</strong></td>
<td><strong>Change After Mandate</strong></td>
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<tr>
<td>Average cost per outpatient prescription</td>
<td>$85</td>
<td>$85</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Average number of outpatient prescriptions per year per enrollee with diabetes</td>
<td>23.81</td>
<td>23.92</td>
<td>0.11</td>
<td>0.5%</td>
</tr>
<tr>
<td>Among those with benefit coverage compliant with SB1104</td>
<td>23.92</td>
<td>23.92</td>
<td>0.00</td>
<td>0.0%</td>
</tr>
<tr>
<td>Among those with benefit coverage NOT compliant</td>
<td>21.75</td>
<td>23.92</td>
<td>2.17</td>
<td>10.0%</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>$43,519,324,000</td>
<td>$43,567,110,000</td>
<td>$47,786,000</td>
<td>0.1098%</td>
</tr>
<tr>
<td>Premium expenditures for individually purchased insurance</td>
<td>$5,992,795,000</td>
<td>$6,076,598,000</td>
<td>$83,803,000</td>
<td>1.3984%</td>
</tr>
<tr>
<td>Premium expenditures by persons with group insurance, CalPERS HMOs, Healthy Families Program, AIM, or MRMIP (e)</td>
<td>$12,820,614,000</td>
<td>$12,834,502,000</td>
<td>$13,888,000</td>
<td>0.1083%</td>
</tr>
<tr>
<td>CalPERS HMO employer expenditures (f)</td>
<td>$3,267,842,000</td>
<td>$3,271,005,000</td>
<td>$3,163,000</td>
<td>0.0968%</td>
</tr>
<tr>
<td>Medi-Cal HMOs state expenditures</td>
<td>$4,015,596,000</td>
<td>$4,015,596,000</td>
<td>$0</td>
<td>0.0000%</td>
</tr>
<tr>
<td>Healthy Families Program state expenditures (g)</td>
<td>$910,306,000</td>
<td>$910,306,000</td>
<td>$0</td>
<td>0.0000%</td>
</tr>
<tr>
<td>Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)</td>
<td>$5,961,186,000</td>
<td>$5,982,411,000</td>
<td>$21,225,000</td>
<td>0.3561%</td>
</tr>
<tr>
<td>Enrollee expenses for noncovered benefits</td>
<td>$120,313,000</td>
<td>$0</td>
<td>-$120,313,000</td>
<td>-100%</td>
</tr>
<tr>
<td><strong>Total Annual Expenditures</strong></td>
<td>$76,607,976,000</td>
<td>$76,657,528,000</td>
<td>$49,552,000</td>
<td>0.0647%</td>
</tr>
</tbody>
</table>

*Source: California Health Benefits Review Program, 2010.*

*Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS HMOs, MediCal HMOs, Healthy Families Program, AIM, MRMIP) individuals enrolled in health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance. (b) Medical treatment coverage includes hospital and physician/provider services; supplies for ulcer care; durable medical equipment (DME); and prosthetics and orthotics. Medical treatment coverage not compliant may exclude coverage for some or all of the following: DME, supplies, or prosthetics. (c) Prescription medications are commonly covered as Outpatient Pharmacy Benefits, but they may also be covered as Medical Benefits. CHBRP assumes that medications not covered, premandate, through an outpatient pharmacy benefit would be covered, postmandate, through the Medical Benefit. This assumes that diabetic enrollees would gain coverage for medications for the treatment of diabetes-related complications but would not gain coverage for the many other medications generally covered by an Outpatient Pharmacy Benefit. (d) Unit includes an aggregate of DME, prosthetics, and medical supplies. (e) Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public insurance. (f) Of the CalPERS employer expenditures, about 58% of the impact, or $1,835,000, would be an impact on state expenditures for CalPERS members who are state employees. (g) Healthy Families Program state expenditures include expenditures for 7,000 covered by the Major Risk Medical Insurance Program (MRMIP) and 7,000 covered by the Access for Infants and Mothers (AIM) program. Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees’ Retirement System health maintenance organizations; CDI=California Department of Insurance; DME = durable medical equipment; DMHC=Department of Managed Health Care.
Acknowledgements

This report provides an analysis of the medical, financial, and public health impacts of Senate Bill 1104, a bill to mandate coverage of diagnosis and treatment of diabetes-related complications. In response to a request from the California Senate Committee on Health on February 17, 2010, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program’s authorizing statute. Edward Yelin, PhD, Janet Coffman, MPP, PhD, Mi-Kyung (Miki) Hong, MPH, Chris Tonner, MPH, and Wade Aubry, MD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Stephen L. Clancy, MLS, AHIP, of the University of California, Irvine, conducted the literature search. Joy Melnikow, MD, MPH, Stephen McCurdy, MD, MPH, and Dominique Ritley, MPH, all of the University of California, Davis, prepared the public health impact analysis. Robert Kaplan, PhD, Tanya G. K. Bentley, PhD, and Dasha Cherepanov, PhD, all of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, of Milliman, provided actuarial analysis. Steven Chen, PharmD, of the University of Southern California, and Mayer Davidson, MD, of Charles Drew University, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, and Garen Corbett, MS, of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Cherie Wilkerson provided editing services. A subcommittee of CHBRP’s National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty 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 CHBRP’s authorizing legislation, UC contracts with a certified actuary, Milliman Inc., to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. 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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