



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Senate Bill 1104: Diabetes-Related Complications

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

CHBRP 10-06



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 by statute (California Health and Safety Code, Section 127660, et seq). The program was reauthorized in 2006 and again in 2009. CHBRP's authorizing statute defines legislation proposing to mandate or proposing to repeal an existing health insurance benefit as a proposal that would mandate or repeal a requirement that a health care service plan or health insurer (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 medications 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 and staff 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 or repeal 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 or repeals, 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.

A Report to the 2009-2010 California State Legislature

Analysis of Senate Bill 1104: Diabetes-Related Complications

April 17, 2010

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PREFACE

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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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)¹ regulates health care

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.

service plans that offer coverage for benefits to their enrollees through health plan service contracts. The California Department of Insurance (CDI) regulates health insurers² 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

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.

diabetes. It should be noted that existing law³ mandates that DMHC-regulated plans and CDI-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

³ Health and Safety Code Section 1367.51, and Insurance Code Section 10176.61

- 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 Benefit 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 SB 1104 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, e.g., 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.

SB 1104 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

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	19,487,000	19,487,000	0	0%
Total enrollees with health insurance subject to SB 1104	19,487,000	19,487,000	0	0%
Percentage of enrollees with medical treatment coverage (hospital and provider services; DME, orthotics, prosthetics, supplies) compliant with SB1104 (b)	92.0%	100.0%	8.0%	9%
Percentage of enrollees with medical treatment coverage NOT compliant	8.0%	0.0%	-8.0%	-100%
Percentage of enrollees with benefit coverage for outpatient prescription medications compliant with SB1104 (c)	94.8%	100.0%	5.2%	6%
Percentage of enrollees with benefit coverage for outpatient prescription medications NOT compliant	5.2%	0.0%	-5.2%	-100%
Number of enrollees with medical treatment coverage compliant with SB1104	17,933,000	19,487,000	1,554,000	9%
Number of enrollees with medical treatment coverage NOT compliant	1,554,000	0	-1,554,000	-100%
Number of enrollees with benefit coverage for outpatient prescription medications compliant with SB1104	18,465,000	19,487,000	1,022,000	6%
Number of enrollees with benefit coverage for outpatient prescription medications NOT compliant	1,022,000	0	-1,022,000	-100%
Utilization and Cost— Medical				
Number of enrollees <i>with diabetes</i>	1,100,000	1,100,000	0	0%
Number with medical treatment coverage compliant with SB1104	1,012,000	1,100,000	88,000	9%
Number with medical treatment coverage NOT compliant	88,000	0	-88,000	-100%
Average per-unit cost (d)	\$304	\$304	0	0%
Average number of medical treatment units used per year per enrollee with diabetes	0.54	0.54	0.0039	0.7%
Among those with benefit coverage compliant with SB1104	0.54	0.54	0.0000	0.0%
Among those with benefit coverage NOT compliant with SB1104	0.49	0.54	0.0493	10.0%
Utilization and Cost—Outpatient Prescription Medications				
Number of enrollees with diabetes	1,100,000	1,100,000	-	0%
Among those with benefit coverage compliant with SB1104	1,042,000	1,100,000	58,000	6%
Among those with benefit coverage NOT compliant with SB1104	58,000	0	-58,000	-100%

Table 1. SB 1104 Impacts on Benefit Coverage, Utilization, and Cost, 2010 (cont'd)

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

Source: California Health Benefits Review Program, 2010.

Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS HMOs, Medi-Cal 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.

INTRODUCTION

The California Senate Committee on Health requested on February 12th, 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. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.

Potential Effects of Health Care Reform

On March 23, 2010, the federal government enacted the federal "Patient Protection and Affordable Care Act" (P.L.111-148), which was further 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 1104.

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. These major long-term provisions of P.L.111-148 would require that most U.S. citizens and qualified legal residents have health insurance and that large employers offer health insurance coverage or a tax-free credit to their employees. It would establish state-based health insurance exchanges, with minimum benefit standards, for the small group and individual markets. Subsidies for low-income individuals would be available to purchase into the exchanges. 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 short-term provisions in P.L.111-148 that go into effect within 6 months or less of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. For example:

- Children and young adults up to age 26 years of age would be allowed to enroll onto their parent's health plan or policy (effective 6 months following enactment). This provision may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance.
- A temporary high-risk pool for those with preexisting conditions would be established (effective 90 days following enactment). How California chooses to implement this provision would have implications for health insurance coverage for those high-risk individuals who are currently without health insurance and/or are on California's Major Risk Medical Insurance Plan (MRMIP).

These and other short term provisions would affect CHBRP's *baseline* estimates of the number and source of health insurance for Californians and corresponding total costs for 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 address the *marginal* effects of the mandate bill—specifically, how the state mandate would impact coverage, utilization, costs, and 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 (CHBRP, 2010). 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 law. The California Department of Managed Health Care (DMHC)⁴ regulates health care service plans, which offer coverage for benefits to their enrollees through health plan service contracts. The California Department of Insurance (CDI) regulates health insurers⁵, which 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.

Bill Language

The full text of SB 1104 can be found in Appendix A of this report.

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.

As further described in the *Medical Effectiveness* section, diabetes-related complications include (but are not limited to): diabetic foot ulcers, microvascular diseases, and macrovascular diseases. Examples of microvascular diseases include diabetic neuropathy (nerve disease), diabetic nephropathy (kidney disease), and diabetic retinopathy (eye disease). Examples of macrovascular diseases include cardiovascular and cerebrovascular disease (e.g., heart attack, stroke) and peripheral vascular (arterial) disease (impacting circulation in the extremities).

As further described in the *Medical Effectiveness* section and the *Utilization, Cost, and Benefit Coverage Impacts* section, diagnosis and treatment of the examples listed for diabetes-related complications include broad arrays of hospital and physician services, durable medical equipment, prosthetics, and prescription medications.

⁴ DMHC is the regulatory body established in 2000 to enforce the provisions of the Knox-Keene Health Care Service Plan of 1975, see Health and Safety Code, Section 1340.

⁵ 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.

Analytic Approach and Key Assumptions

SB 1104 would mandate that plans and policies provide coverage for the diagnosis and treatment of diabetes-related complications, but it 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 diabetes-related complications.

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.

Existing California Requirements

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 also be noted, that DMHC-regulated health plans and CDI-regulated insurers must offer at least one policy that includes orthotics/prosthetics, although other plan contracts or policies offered by the health plan or insurer may exclude orthotics and prosthetics.⁶ SB 1104 would not alter this existing mandate, but would require that DMHC-regulated health plans and CDI-regulated policies provide coverage for persons with diabetes for the diagnosis and treatment of diabetes-related complications.

No current California law mandates broad coverage for the diagnosis and treatment of diabetes-related complications. However, current law⁷ requires that health care service plans and insurers cover a specific set of equipment and supplies⁸, prescription items and medications⁹, and

⁶ California Health & Safety Code Section 1367.18 and Insurance Code Section 10123.7

⁷ California Health & Safety Code Section 1367.51 and Insurance Code Section 10176.61

⁸ This is explicitly defined as including: (1) blood glucose monitors and blood glucose testing strips; (2) blood glucose monitors designed to assist the visually impaired; (3) insulin pumps and all related necessary supplies; (4) ketone urine testing strips; (5) lancets and lancet puncture devices; (6) pen delivery systems for the administration of insulin; (7) podiatric devices to prevent or treat diabetes-related complications; (8) insulin syringes; and, (9) visual aids, excluding eyewear, to assist the visually impaired with proper dosing of insulin.

education for the medically necessary treatment of diabetes (as opposed to the treatment of diabetes-related complications). The law does require coverage of “podiatric devices [such as shoes for diabetics] in order to prevent or treat diabetes-related conditions,” but is silent in regards to any other treatment for diabetes-related complications. Benefit coverage is required for the specified equipment and supplies regardless of whether they require a prescription. Self-management education (including nutritional training) must be covered as necessary to enable enrollees to properly use the mandated equipment, supplies, and medications. The mandate also requires that CDI-regulated insurers’ required coinsurance, DMHC-regulated health plans’ required copayments, and deductibles required by either for these mandated benefits not exceed those for similar benefits.

DMHC-regulated plans are also required¹⁰ to cover basic health care services (BHCS). In so far as any treatments of diabetes-related complications fall under the definition of BHCS, coverage for the treatment would be required. DMHC also reviews proposed cost-sharing arrangements and requires that benefits not be subject to “exclusion, exception, reduction, deductible, or copayment that renders the benefit illusory.”¹¹ For example, for outpatient prescription medication benefits, DMHC limits cost sharing to 50%.

Requirements in Other States

Many states have laws mandating coverage of diabetes-related supplies and education (BCBSA, 2009). No other state’s mandates broad coverage for the diagnosis and treatment of diabetes-related conditions.

Currently, 46 states (including California) and the District of Columbia have laws mandating coverage for diabetes treatment including supplies and/or education (BCBSA, 2009). Three other states, Mississippi, Missouri, and Washington, have laws mandating that insurers offer coverage for diabetes treatment and supplies, but do not require that all policies provide coverage for diabetes treatment and supplies (NCSL, 2009).

In other states’ mandates, the terms “equipment” and “supplies” are often used interchangeably and may not be defined. Some states have issued regulatory guidelines further defining the terms. Some state mandates, such as the one in the Texas Insurance Code, has a well-defined set of equipment and supplies specified in law.¹² In the Texas statute, equipment includes blood glucose monitors, including noninvasive glucose monitors and glucose monitors designed to be used by the blind; insulin pumps and associated equipment; insulin infusion devices; and podiatric appliances to prevent complications associated with diabetes. Supplies include test strips for blood glucose monitors; visual reading and urine test strips; lancets and lancet devices; insulin and insulin analogs; injection aids; syringes; prescriptive and nonprescriptive oral agents to control blood sugar levels; and glucagon emergency kits (NCSL, 2009).

⁹ This is explicitly defined as including: (1) insulin; (2) prescriptive medications for the treatment of diabetes; and, (3) glucagon.

¹⁰ Section 1300.67 of the California Code of Regulations, Title 28

¹¹ Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4

¹² Texas Insurance Code, Title 8, Subtitle E, Chapter 1358

Eight states (Arizona, Arkansas, California, Nebraska, New Mexico, Oklahoma, Tennessee, and Texas) have diabetes mandates that explicitly specify coverage for podiatric appliances or devices while whereas two states (Massachusetts and Rhode Island) explicitly include coverage for shoes or shoe inserts under their diabetes mandate (NCSL, 2009).

In 13 states (Colorado, Connecticut, Indiana, Louisiana, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, Oregon, Rhode Island, and Vermont) insurers are required to provide coverage for prosthetic devices, regardless of whether an enrollee has diabetes (NCSL, 2009).

Background of the Disease or Condition

Diabetes affects 2.2 million persons or 8.3 percent of the California population (CDC, 2010). This chronic disease can be separated into four categories. Type 1, sometimes referred to as juvenile-onset diabetes, is an autoimmune disorder that destroys insulin-producing cells. Persons with Type 1 diabetes must use insulin provided via pump or injection for survival. The CDC estimates that 5% to 10% of all diabetes is attributable to Type 1. Type 2 diabetes is the most prevalent form of diabetes, and may also be referred to as adult onset, although a growing number of people now develop this condition early in life. The CDC estimates that more than 90% of diagnosed diabetes is attributable to Type 2, in which the body does not use insulin properly. People with Type 2 diabetes are typically not dependant on the use of insulin for survival and some can manage their condition with diet and exercise or oral medications. Risk factors for Type 2 include obesity, family history of diabetes, older age, race/ethnicity, and physical inactivity. Gestational diabetes, temporarily acquired by some pregnant women, and other types of diabetes, due to genetic conditions, infectious diseases, and other events, account for 1%-10% of diagnosed diabetes in the United States. (CDC, 2008b).

Complications that arise from diabetes can be categorized as macrovascular and microvascular conditions. Heart disease and stroke, both macrovascular conditions, affect persons with diabetes at two to four times the rate of those with no disease (CDC, 2008b). Peripheral vascular disease, where arteries become occluded, is another complication stemming from diabetes. About 75% of adults with diabetes also report high blood pressure or use of hypertension medications (CDC, 2008b).

Microvascular complications from diabetes include diabetic neuropathy, diabetic nephropathy, and diabetic retinopathy. Neuropathy is a series of nerve diseases that impair sensation, ranging from numbness to burning or slicing pain, and impair digestion, or cause carpal tunnel syndrome. The CDC estimates that 60% to 70% of people with diabetes have mild mild-to-severe forms of neuropathy (CDC, 2008b). A severe complication stemming from neuropathy is foot ulcers, which can lead to lower limb amputation. The CDC attributes more than 60% of nontraumatic lower limb amputations to complications from diabetes (CDC, 2008b). In addition, diabetes is the leading cause of kidney (nephropathy) failure in the United States. Almost 200,000 people with end-stage kidney disease related to diabetes were living on chronic dialysis or with a kidney transplant in 2005. Diabetes is also the leading cause of blindness among adults aged 20-74

years. The CDC estimates that diabetic retinopathy contributes 12,000 to 24,000 new cases of blindness each year.

MEDICAL EFFECTIVENESS

As indicated in the *Introduction*, SB 1104 would require DMHC-regulated health plans and CDI-regulated insurers to provide coverage for the diagnosis and treatment of diabetes-related complications. 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 or other small blood vessels)
 - Diabetic nephropathy (i.e., kidney disease)
 - Diabetic neuropathy (i.e., nerve disorders)
 - Diabetic retinopathy (i.e., eye disease)

- Macrovascular diseases (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 disease (i.e., diseases of blood vessels outside the brain and heart)

- 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 diseases and conditions. In contrast, diabetes is only one of several major risk factors for macrovascular diseases. Furthermore, persons with macrovascular diseases receive the same treatments regardless of whether they have diabetes. The medical effectiveness team also focused on the diagnostic tests and treatments for diabetes-related complications that are most frequently used in the United States.

The medical effectiveness review did not address prevention of diabetes-related complications because SB 1104 only addresses coverage for diagnosis and treatment of diabetes-related complications. In addition, control of diabetes is the primary means for preventing diabetes-related complications. Existing law requires Department of Managed Health Care (DMHC)-regulated health plans and California Department of Insurance (CDI)-regulated health insurers to provide coverage for services, supplies, and medications that are used to monitor and control diabetes, such as test strips for blood glucose and urine ketones, blood glucose monitors, prescription medications, insulin, and devices for administering insulin.

Literature Review Methods

A literature search was performed to retrieve studies of the clinical effectiveness of diagnostic tests and treatments for microvascular disease and diabetic foot ulcers. The search was limited to meta-analyses, systematic reviews, and evidence-based guidelines, because syntheses of multiple studies are the strongest forms of evidence of the effectiveness of medical interventions. Meta-analyses, systematic reviews, and evidence-based guidelines regarding diagnosis and treatment

of diabetes-related complications were identified through searches of MEDLINE (PubMed), the Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Clinical Trials, the Cumulative Index of Nursing and Allied Health Literature, EconLit, and Web of Science. In addition, Web sites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were also searched: the Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, National Health Service Centre for Reviews and Dissemination, National Guidelines Clearinghouse, National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

The search was limited to studies published in English from January 2000 to present. Studies that enrolled persons of all ages with Type 1 or Type 2 diabetes were included, as persons with both types of diabetes may experience complications. Abstracts for 509 articles and reports were identified. Twenty-seven meta-analyses, systematic reviews, and evidence-based guidelines were retrieved and reviewed. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to evaluate the evidence for each outcome measure is presented in *Appendix B: Literature Review Methods*. Appendix C includes tables that describe the studies that CHBRP reviewed and their findings.

Services Assessed

Diagnostic tests and treatments for microvascular disease and diabetic foot ulcers include, but are not limited to, the tests and treatments described below. As indicated above, the medical effectiveness review focused on the tests and treatments listed below because they are the most frequently used tests and treatments in the United States.

Diabetic Nephropathy (i.e., kidney disease)

- Outpatient prescription medication

Diabetic Neuropathy (i.e., nerve disorders)

- Outpatient prescription medication

Diabetic Retinopathy (i.e., eye disease)

- Hospital and physician/provider services
 - Eye exams
 - Injection or implantation of medication into the eye
 - Laser treatment
 - Surgery

Diabetic Foot Ulcers

- Hospital and physician/provider services
 - Bioengineered skin substitutes
 - Cellular and biological agents
 - Electrical stimulation
 - Granulocyte-colony stimulating factors
 - Hyperbaric oxygen therapy
 - Surgical debridement
 - Total contact casting

- Durable medical equipment

- Medical supplies for ulcer care
 - Negative pressure wound therapy
 - Wound dressing and debridement

- Prosthetics

- Outpatient prescription medications

Outcomes Assessed

Findings regarding the effectiveness of the most frequently used tests and treatments for microvascular disease and diabetic foot ulcers were reviewed and summarized according to the availability of the evidence, which varied across complications. Outcomes assessed include:

Diabetic Nephropathy (i.e., kidney disease)

- End-stage kidney disease
- Doubling of serum creatinine
- Progression from micro- to macroalbuminuria
- Regression for micro- to normoalbuminuria

Diabetic Neuropathy (i.e., nerve disorders)

- Diagnosis of diabetic autonomic neuropathy
- Reduction of bloating, nausea, and vomiting due to gastroparesis, a condition associated with diabetic autonomic neuropathy
- Reduction of neuropathic pain associated with diabetic peripheral neuropathy or an unspecified form of diabetic neuropathy
- Improvement in neurological function

Diabetic Retinopathy (i.e., eye disease)

- Diagnosis of diabetic retinopathy
- Improvement in visual acuity
- Decrease in vision loss

Diabetic Foot Ulcers

- Detection of foot ulceration
- Resolution of infection
- Debridement of foot ulcers
- Healing of foot ulcers (e.g., proportion of foot ulcers healed completely)
- Reduction of risk of recurrence of foot ulcers
- Reduction of risk of amputation or other surgical procedures

Study Findings

Findings from meta-analyses, systematic reviews, and evidence-based guidelines regarding the effectiveness of diagnostic tests and treatments for diabetic foot ulcers and microvascular complications of diabetes are summarized below. Some findings synthesized in these meta-analyses, systematic reviews, and evidence-based guidelines are from randomized controlled trials (RCTs) that enrolled small numbers of persons. Results of RCTs with small sample sizes may be less accurate than results of RCTs with large sample sizes. In addition, for many treatments, only a small number of RCTs have been conducted. Furthermore, there is very little literature on the effectiveness of durable medical equipment or prosthetics for treatment of diabetes-related complications.

Diabetic Nephropathy (i.e., kidney disease)

Studies have estimated that 25% to 40% of persons with diabetes develop kidney disease and that the risk of kidney disease increases as persons with diabetes age. In approximately one-third of persons with diabetic kidney disease, end-stage renal disease will develop and require dialysis or a kidney transplant (Strippoli et al., 2006). Blood pressure control is considered an important strategy for reducing the health risks associated with diabetic kidney disease, because high blood pressure (i.e., hypertension) interferes with the proper function of the kidneys.

Outpatient prescription medications

Angiotensin-converting enzyme inhibitors and angiotensin receptor blockers. One meta-analysis synthesized findings from 49 RCTs that assessed the effectiveness of two classes of antihypertensive medications—angiotensin-converting enzyme inhibitors (ACEi) and angiotensin receptor antagonists (ARB)—for slowing the progression of diabetic kidney disease (Strippoli et al., 2006). The meta-analysis found that, compared to a placebo, both ACEi and ARB medications reduced the risk that diabetic kidney disease would progress to end-stage renal disease. ACEi and ARB medications were also associated with changes in biomarkers used to assess the progression of diabetic kidney disease. These medications were more effective than placebos in reducing the risk of doubling of serum creatinine and progression from micro- to macroalbuminuria and in increasing the likelihood that microalbuminuria will regress to normoalbuminuria. The meta-analysis found that ACEi and ARB medications were equally effective in reducing the risk of progression of diabetic kidney disease to end-stage renal disease.¹³

There is *clear and convincing evidence* that, compared to a placebo, angiotensin-converting enzyme inhibitors (ACEi) and angiotensin receptor blockers (ARB) reduce the risk that diabetic kidney disease will progress to end-stage renal disease.

Diabetic Neuropathy (i.e., nerve disease)

Diabetic neuropathies are nerve disorders caused by diabetes.¹⁴ Nerve damage may develop in every organ system, including the gastro-intestinal, cardiovascular, and reproductive systems. Diabetic neuropathy can be categorized as peripheral, autonomic, proximal, or focal. Autonomic neuropathy affects the functioning of nerves associated with internal organs, such as the gastro-intestinal system. Peripheral neuropathy, the most common type of diabetic neuropathy, causes pain, tingling, or numbness in the toes, feet, legs, hands, and arms.

¹³ One RCT compared an ARB to an ACEi and to simultaneous use of both medications in patients with vascular disease or high risk diabetes. The combination of the two drugs was associated with more adverse events without an increase in benefit (ONTARGET, 2008).

¹⁴ Microvascular disease may not be the only cause of diabetic neuropathy. There may be a direct toxic effect from hyperglycemia as well as unknown factors. Nevertheless, microvascular disease plays an important role in causing diabetic neuropathy (Wade Aubry, personal communication, March 2010).

Diagnosis of diabetic autonomic neuropathy

One evidence-based guideline recommends that all patients with Type 2 diabetes should be assessed for neuropathy at the time of diagnosis, and all patients with Type 1 diabetes should be assessed 5 years after diagnosis (AACE, 2007). Annual screening should include history and examination for signs of autonomic dysfunction and testing for heart rate variability.

Outpatient prescription medications for gastroparesis associated with diabetic autonomic neuropathy

Gastroparesis is a severe complication of diabetic autonomic neuropathy. It commonly presents as bloating or nausea and fullness on eating. More severe symptoms include vomiting (intermittent, sudden, or acute and protracted), and severe intermittent hypoglycemia (for persons on glucose-lowering therapy).

A systematic review conducted in conjunction with the development of an evidence-based guideline examined findings from RCTs that have been conducted to assess the efficacy of medications for treatment of gastroparesis (NCCCC, 2008). The systematic review found evidence from four RCTs that three medications are effective: Ilosone (erythromycin), Motilium (domperidone), and Reglan (metoclopramide). Ilosone (erythromycin) significantly increased gastric emptying (i.e., percentage of ingested food retained in the stomach) compared to placebo. Relative to a placebo, both Motilium (domperidone) and Reglan (metoclopramide) were associated with reduction of fullness upon eating, pressure and bloating, nausea, vomiting, and anorexia. However, the RCTs on Ilosone and Reglan enrolled less than 50 people. As noted above, findings from RCTs with small sample sizes may be less accurate than findings from RCTs with large samples.

The relative effectiveness of these medications could not be determined because no head-to-head trials comparing one medication to another were identified.

There is a *preponderance of evidence* that Ilosone (erythromycin), Motilium (domperidone), and Reglan (metoclopramide) improve symptoms associated with gastroparesis compared to a placebo.

Outpatient prescription medications for pain associated with diabetic neuropathy

Meta-analyses and systematic reviews have assessed the effectiveness of three types of medication for reducing pain associated with diabetic neuropathy: antidepressants, anticonvulsants, and aldose reductase inhibitors.

Antidepressants. A meta-analysis identified five RCTs that have examined the effectiveness of tricyclic and tetracyclic antidepressants for relief of diabetic neuropathic pain. Tricyclic and tetracyclic antidepressants are older classes of antidepressant medications for which generic versions are available. A meta-analysis of these RCTs found that tricyclic and tetracyclic

antidepressants are more likely to relieve diabetic neuropathic pain than a placebo (Saarto and Wiffen, 2007).

One drawback of tricyclic and tetracyclic antidepressants is that they tend to cause drowsiness. Cymbalta (duloxetine) is a serotonin and norepinephrine reuptake inhibitor (SNRI), a newer class of antidepressant, which generally has fewer side effects than tricyclic and tetracyclic antidepressants. It is currently available only as a brand name drug. A recent meta-analysis of findings from six RCTs that compared Cymbalta (duloxetine) to a placebo found that persons who received the drug were more likely to experience a reduction in neuropathic pain of 50% or more at 12 weeks following initiation of treatment (Lunn et al., 2009). The meta-analysis found that six persons needed to be treated for one person to experience a reduction in pain of 50% or more. The meta-analysis did not identify any head-to-head trials that compared the effectiveness of Cymbalta (duloxetine) and tricyclic or tetracyclic antidepressants for treatment of diabetic neuropathic pain.

There is *clear and convincing evidence* that tricyclic antidepressants, tetracyclic antidepressants, and Cymbalta (duloxetine) reduce diabetic neuropathic pain compared to a placebo.

Anticonvulsants. Anticonvulsant medications have also been prescribed for neuropathic pain. Meta-analyses have assessed the effectiveness of seven of these medications: Lyrica (pregabalin), Neurontin (gabapentin), Tegretol (carbamazepine), Topamax (topiramate), Trileptal (oxcarbazepine), Lamictal (lamotrigine), and Depakote (valproic acid).

Findings from meta-analyses suggest that five of these drugs are more effective than a placebo for reducing diabetic neuropathic pain. A recent meta-analysis pooled findings from seven RCTs that assessed the efficacy of Lyrica (pregabalin) for treatment of diabetic neuropathic pain (Moore et al., 2009). Lyrica (pregabalin) is currently available only as a brand name medication. Persons who received either 300 milligrams or 600 milligrams of Lyrica (pregabalin) were more likely to experience a reduction in pain relief of 50% or more than persons who received a placebo. Findings were similar regardless of whether persons took Lyrica (pregabalin) for less than 8 weeks or for 8 weeks or more. A meta-analysis of seven RCTs found that persons who received Neurontin (Gabapentin) were more likely to experience pain relief than those treated with a placebo (Wiffen et al., 2005a). Results of single RCTs suggest that three other anticonvulsants—Tegretol (carbamazepine), Topamax (topiramate), and Trileptal (oxcarbazepine) are more effective than a placebo for relieving diabetic neuropathic pain (Gutierrez-Alvarez, et al, 2007; Wiffen et al., 2005b). However, single RCTs provide less persuasive evidence of a medication's effects than multiple RCTs with similar findings.

Two anticonvulsants appear not to be effective for reducing neuropathic pain. A meta-analysis of RCTs that examined the efficacy of Lamictal (lamotrigine) for diabetic neuropathic pain found only one RCT on this topic (Wiffen and Rees, 2007). The RCT found that Lamictal (lamotrigine) was no more effective than a placebo. A meta-analysis that identified two RCTs that compared Depakote (valproic acid) to a placebo reported that the RCTs' findings were inconsistent (Gutierrez-Alvarez et al., 2007).

The meta-analyses did not identify any head-to-head trials of anticonvulsant medications for treatment of diabetic neuropathic pain or any trials that compared anticonvulsant to antidepressant medications. Thus, one cannot determine whether any of these medications are more effective than the others.

There is *clear and convincing evidence* that two anticonvulsant medications—Neurontin (gabapentin), and Lyrica (pregabalin)—reduce neuropathic pain compared to a placebo. Evidence from single RCTs suggests that Tegretol (carbamazepine), Topamax (topiramate), and Trileptal (oxcarbazepine) may also be effective.

Aldose reductase inhibitors. Diabetic polyneuropathy causes pain, and sensory and motor deficiencies in the limbs. It can also lead to foot ulceration. One way to slow the progression of diabetic polyneuropathy is to inhibit the metabolism of glucose by the polyol pathway using aldose reductase inhibitors. We found one meta-analysis by Chalk et al. (2007) that addressed this question. Twenty-nine randomized trials comparing an aldose reductase inhibitor with placebo were included. The meta-analysis assessed the impact of aldose reductase inhibitors on neurological function. There were no statistically significant differences in neurological function between persons who received aldose reductase inhibitors and those who received a placebo.

There is a *preponderance of evidence* that aldose reductase inhibitors are not effective in improving neurological function for those persons with diabetic polyneuropathy.

Diabetic Retinopathy (i.e., eye disease)

Diabetes is the leading cause of blindness among adults age 20-74 years (CDC, 2008b). Early diagnosis and treatment can reduce the risk that diabetic retinopathy (i.e., eye disease) will progress to blindness.

Diagnostic tests

The two major tests used for diagnosis of diabetic retinopathy are ophthalmoscopy and retinal photography. An ophthalmoscope is a tool that enables a clinician to see into the eye. Retinal photography involves the use of specialized cameras to take color photographs of the retina (NHS Centre for Reviews and Dissemination, 1999). Most studies of the accuracy of these tests had small sample sizes which limits the accuracy of their findings.

Ophthalmoscopy. Three systematic reviews have synthesized findings from studies of the accuracy of ophthalmoscopy (Hutchinson et al., 2000; NHS Centre for Reviews and Dissemination, 1999; Singer et al., 1992). The sensitivity and specificity of ophthalmoscopy was compared to several different reference standards including fluorescein angiography, stereoscopic photography, stereoscopic slit lamp biomicroscopy, and 35 millimeter slides.

Estimates of the sensitivity¹⁵ of ophthalmoscopy ranged from 27% to 84%. Estimates of specificity¹⁶ ranged from 62% to 100%.

Retinal photography. Two systematic reviews have synthesized findings from studies of the accuracy of retinal photography (Hutchinson et al., 2000; NHS Centre for Reviews and Dissemination, 1999; Singer et al., 1992). Reference standards included ophthalmoscopy, slit lamp biomicroscopy, and 35 millimeter slides. Estimates of the sensitivity of retinal photography ranged from 47% to 100%. Estimates of specificity ranged from 52% to 100%. The authors of two of the systematic reviews conclude that retinal photography is a more accurate method for diagnosing diabetic retinopathy than ophthalmoscopy (Hutchinson et al., 2000; Singer et al., 1992).

Multi-modal testing. Studies of testing protocols that combined ophthalmoscopy and retinal photography reported higher sensitivity and specificity than studies of either diagnostic test alone (Hutchinson et al., 2000; NHS Centre for Reviews and Dissemination, 1999).

For both ophthalmoscopy and retinal photography, sensitivity and specificity were greater when the tests were performed by ophthalmologists or other eye care specialists than by general practitioners.

The *preponderance of evidence* suggests that retinal photography is a more accurate modality for diagnosing diabetic retinopathy than ophthalmoscopy. Using both tests is more likely to yield accurate results than either test alone. Eye care specialists are more likely than general practitioners to accurately diagnose diabetic retinopathy.

Hospital and physician/provider services (inclusive of medications delivered during an inpatient stay or at provider's office)

Intravitreal antiangiogenesis agents. RCTs have examined the effectiveness of injecting agents that suppress vascular endothelial growth factor into eyes affected by diabetic macular edema (Mohamed et al., 2007; O'Doherty et al., 2008). These treatments are referred to as intravitreal antiangiogenesis agents. These agents include Lucentis, a medication approved by the U.S. Federal Drug Administration (FDA) for the treatment of diabetic retinopathy, and antiangiogenesis agents approved for other purposes. Two RCTs that have compared injection of antiangiogenesis agents to sham injections have found that use of antiangiogenesis agents was associated with improvement in visual acuity. Intravitreal antiangiogenesis agents have also been found to be more effective than focal photocoagulation (a type of laser treatment).

The *preponderance of available evidence* suggests that intravitreal antiangiogenesis agents are effective at improving visual acuity among persons with diabetic macular edema.

¹⁵Sensitivity indicates the percentage of persons with diabetic retinopathy in whom the result of the test is positive.

¹⁶Specificity indicates the percentage of persons who do not have diabetic retinopathy in whom the result of the test is negative.

Corticosteroids—intravitreal injection and surgical implantation. Two meta-analyses and two systematic reviews have evaluated the effectiveness of intravitreal corticosteroids—i.e., the injection of topical corticosteroid medications into the eye (Grover et al., 2008; Mohamed et al., 2007; O’Doherty et al., 2008; Yilmaz, et al. 2009). Triamcinolone acetonide is the topical corticosteroid most frequently used for this purpose. One meta-analysis synthesized findings from four RCTs that compared intravitreal corticosteroids to no treatment, sham injection, or laser treatment (Grover et al., 2008). The authors found that use of intravitreal corticosteroids resulted in improvement in visual acuity relative to the alternatives assessed. The differences were statistically significant at 3 and 12 months following treatment but not at 6 months. However, these RCTs enrolled small numbers of subjects (≤ 80 persons).

Another meta-analysis synthesized findings from two RCTs that compared intravitreal triamcinolone acetonide to subTenon triamcinolone acetonide (STTA) injection (Yilmaz et al., 2009). Intravitreal injection of corticosteroids involves injection directly into the vitreous humor. SubTenon injection is applied adjacent to the vitreous and is less invasive. For macular edema, subTenon injections are generally administered first, with intravitreal injections reserved for more serious cases, or for cases in which subTenon injections have failed to achieve the desired effect. The meta-analysis found that use of intravitreal corticosteroids was associated with greater improvement in visual acuity than STTA at 3 months post treatment, but the benefit was no longer evident at 6 months post treatment (Yilmaz et al., 2009). In addition, the sample sizes for the two RCTs were small (12 and 61 persons, respectively).

Two systematic reviews identified three RCTs that have assessed whether combining intravitreal corticosteroids with laser treatment is associated with greater improvement in visual acuity (Mohamed et al., 2007; O’Doherty et al., 2008). One RCT found that combining the two treatments was more effective than providing intravitreal corticosteroids alone but the other RCTs found no difference in visual acuity.

Three RCTs have compared the effectiveness of surgical implantation of corticosteroids to observation, sham injection, or laser treatment. Results showed that surgical implantation of corticosteroids was associated with greater improvement in visual acuity at 3 months post treatment but that there was no longer a difference at 6 months post treatment (Grover et al., 2008).

There is *clear and convincing evidence* that intravitreal corticosteroids are effective at improving visual acuity relative to no treatment, sham procedure, or laser treatment. However, intravitreal injection does not appear to be more effective than subTenon injection, a less invasive procedure. Surgical implantation of corticosteroids is no more effective than no treatment, sham injection, or laser treatment. Findings from RCTs that assessed the benefit of combining intravitreal corticosteroids with laser treatment are *ambiguous*.

Laser treatment. Laser treatments for diabetic retinopathy were first developed in the 1970s. Two systematic reviews (Mohamed et al., 2007; O’Doherty et al., 2008) have identified 23 large RCTs that evaluated the effectiveness of two types of laser treatment for diabetic retinopathy: focal laser photocoagulation and pan-retinal laser photocoagulation. Focal laser photocoagulation involves placing laser burns over afflicted areas of the retina. In pan-retinal laser

photocoagulation, laser burns are placed over the entire retina, sparing the central macula. Findings from RCTs included in these systematic reviews indicate that both focal laser photocoagulation and pan-retinal laser photocoagulation decrease the risk that persons with diabetic retinopathy will experience vision loss.

Although effective, laser treatments can have a number of serious adverse effects. One study found that 21% of eyes on which photocoagulation was performed using an argon green laser developed either subretinal fibrosis or atrophic creep of the pigment epithelium within one-third of the optic disc diameter from the center of the macula. In 22% fibrosis or atrophic creep *extended* into the centre of the fovea (Lovestam-Adrian et al., 2000).

There is *clear and convincing evidence* that focal laser treatment and pan-retinal laser photocoagulation reduce the risk of vision loss associated with diabetic retinopathy but may also have serious adverse effects.

Surgical vitrectomy. Vitrectomy is a form of surgery used for treatment of advanced diabetic retinopathy, including proliferative diabetic retinopathy. Vitrectomy is generally done in cases where intravitreal hemorrhage from proliferative diabetic retinopathy has resulted in blindness that does not clear with rest and time (such as in repeated bleeds). The procedure is done by an ophthalmologist who has had additional training in retinal diseases and uses a cutting device to hollow out a cylindrical area between the lens and the macula and remove vitreous gel. The resultant defect is then filled in with saline (which is a liquid rather than a gel). Two systematic reviews have identified 11 RCTs that have compared surgical vitrectomy to observation or laser treatment (Mohamed et al., 2007; O’Doherty et al., 2008). Findings regarding effects on visual acuity are inconsistent.

Findings regarding the effectiveness of surgical vitrectomy are *ambiguous*.

Diabetic Foot Ulcers

Diabetic foot ulcers that do not heal can become infected. If the infection is not detected and treated promptly, gangrene may develop, requiring amputation of the foot.

Diagnostic tests

One systematic review identified one RCT that examined the effectiveness of routine foot exams for persons with a history of diabetic foot ulcers. The RCT found that persons who received routine foot exams were less likely to experience a recurrence of foot ulcers than persons who did not receive routine foot exams (Singh et al., 2005).

Findings from a single RCT suggest that persons with a history of diabetic foot ulcers who obtain routine foot exams are less likely to experience a recurrence of foot ulcers.

Hospital and physician/provider services (inclusive of medications delivered during an inpatient stay or at provider’s office)

Bioengineered skin substitutes. Bioengineered skin substitutes (BSS) have been developed as an alternative to the use of standard autograft (skin is taken from another area of the body to replace lost skin) to promote healing of foot ulcers. Two systematic reviews summarized findings from nine RCTs that compared BSS to gauze to which saline, paraffin, or hydrogel had been applied (Barber et al., 2008; Hinchcliffe et al., 2008). Diabetic foot ulcers treated with BSS were more likely to heal completely than those treated with gauze plus saline or hydrogel. The only RCT to compare BSS to paraffin gauze reported no difference in the proportion of foot ulcers that healed completely.

There is a *preponderance of evidence* that diabetic foot ulcers treated with bioengineered skin substitutes are more likely to heal completely than diabetic foot ulcers treated with standard dressings.

Cellular and biological agents. Abnormalities in growth factor expression contribute to difficulties in healing diabetic foot ulcers. One systematic review summarized findings from thirteen RCTs that evaluated the effectiveness of cellular and biological agents for improving the healing of diabetic foot ulcers (Hinchcliffe et al., 2008). RCTs have found that the following cellular and biological agents, which are topically applied to the wound, are more effective than a placebo for increasing the likelihood that diabetic foot ulcers will heal or for reducing the size of foot ulcers: epidermal growth factor, platelet autogel, recombinant platelet-derived growth factor, and tretinoin.

There is a *preponderance of evidence* that platelet autogel, recombinant platelet-derived growth factor, tretinoin, and epidermal growth factor improve the healing of diabetic foot ulcers.

Electrical stimulation. A systematic review identified two RCTs that examined the effects of electrical stimulation for the healing of foot ulcers. One showed a greater proportion of patients healing at 12 weeks (Hinchcliffe et al., 2008). The other found no difference in the proportion of patients whose foot ulcers healed. However, the sample sizes for these RCTs were small (40 and 80 persons, respectively). Findings from these small RCTs may not be as accurate as findings from RCTs with larger samples.

The evidence of the effectiveness of electrical stimulation on the healing of foot ulcers is *ambiguous*.

Granulocyte-colony stimulating factors. Treatment of infected diabetic foot ulcers with antibiotics fails in 20% to 30% of cases (Cruciani et al., 2009). Reasons for the failure of antibiotic therapy include antibiotic resistance, inability of the antibiotic to reach the infected site, and inadequate surgical debridement or wound care. Diabetes is also associated with immunological deficiencies, including abnormal neutrophil chemotaxis, phagocytosis, and intracellular killing (Cruciani et al., 2009).

Granulocyte-colony stimulating factor has been evaluated as an adjunct to standard care for infected diabetic foot ulcers because it improves the growth and function of neutrophils¹⁷ in persons with diabetes. It is most often injected subcutaneously, intramuscularly, or intravenously. One meta-analysis pooled findings from five RCTs that examined the effect of adding granulocyte-colony stimulating factor to usual care in people with diabetic foot infection. Adding granulocyte-colony stimulating factor to usual care (with or without a placebo) did not affect resolution of infection or proportion of foot ulcers healed, but it did reduce likelihood that a person would require an amputation or other surgical procedure.

There is *clear and convincing evidence* that adding granulocyte-colony stimulating factors to standard care for infected diabetic foot ulcers reduces the likelihood of amputation or other surgical interventions.

Hyperbaric oxygen therapy. Poor blood supply to the wound bed may contribute to the difficulty of healing diabetic foot ulcers. Hyperbaric oxygen therapy (HBOT) aims to increase oxygen supply to wounds that are not responding to other treatments. HBOT entails breathing pure oxygen in a specially designed chamber (e.g., simulation chambers for deep sea divers suffering pressure problems after resurfacing).

One meta-analysis and two systematic reviews have examined findings from eight RCTs that assessed the effectiveness of adding HBOT to standard wound care regimens for diabetic foot ulcers (Hinchcliffe et al., 2008; Kranke et al., 2004; Roeckl-Wiedmann et al., 2005). The meta-analysis (Kranke et al., 2004) pooled findings from five RCTs and concluded that use of HBOT as an adjunct treatment was associated with a reduction in the risk of major amputation (e.g., lower leg and foot) but did not affect the risk of minor amputation (e.g., toes).

There is *clear and convincing evidence* that adding hyperbaric oxygen therapy to standard care reduces the risk of major amputation in diabetic patients.

Surgical debridement. Debridement is an essential part of the healing process for diabetic foot ulcers. Surgical debridement involves the use of sterile scissors or a scalpel to remove necrotic tissue or contaminated or foreign matter around the wound. One meta-analysis of RCTs on debridement identified one RCT that compared surgical debridement to non-surgical debridement (Edwards et al., 2010). The RCT found that the proportion of foot ulcers healed was similar for ulcers that were debrided surgically and non-surgically. However, the RCT only enrolled 42 persons. RCTs that have small sample sizes are less likely to detect statistically significant differences between interventions than RCTs with large sample sizes.

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

Total contact casting. Pressure is one of the leading causes of diabetic foot ulcers. Removal or relief from pressure (i.e., off-loading) aids in healing of foot ulcers. The "total contact cast" (TCC) is a casting technique that is used to distribute weight along the entire plantar aspect (sole)

¹⁷ Neutrophils are a type of white blood cell that form a critical part of the immune system.

of the foot. It is applied in such a way to contact the exact contour of the foot (McIntosh et al, 2003).

A systematic review identified RCTs that have assessed the effect of TCCs on healing of plantar foot ulcers (Bus et al., 2008). Three RCTs that compared total contact casting to standard care, therapeutic shoes, or a removable diabetic walker found that total contact casting was associated with an increase in the proportion of foot ulcers healed. In contrast, one RCT that compared total contact casting to a non-removable diabetic walker found no difference in the proportion of foot ulcers healed. Findings from these RCTs should be interpreted with caution because all had small sample sizes (≤ 75 persons).

Surgical offloading is another technique for redistributing pressure away from the areas of the foot in which an ulcer has occurred. A systematic review by Bus et al. (2008) identified one RCT that assessed the effectiveness of adding surgical offloading to total contact casting. The RCT found that diabetic foot ulcers treated with Achilles tendon lengthening surgery and total contact casting were no more likely to heal than foot ulcers treated with total contact casting alone. However, persons whose foot ulcers healed were less likely to experience a recurrence. The findings of this RCT should be interpreted with caution because it enrolled only 63 persons.

There is a *preponderance of evidence* that total contact casting increases the likelihood that diabetic foot ulcers will heal relative to standard care, therapeutic shoes, or removable diabetic walkers. Findings from a single RCT suggest that combining Achilles tendon lengthening surgery with total contact casting may reduce the risk of recurrence of diabetic foot ulcers.

Durable medical equipment

The meta-analyses and systematic reviews included in the medical effectiveness review did not identify any RCTs regarding the effectiveness of durable medical equipment (DME) for treatment of diabetic foot ulcers. One systematic review (Bus et al., 2008) cited a small number of observational studies regarding the use of wheelchairs that had inconclusive findings.

The lack of evidence for the effectiveness of DME for diabetic foot ulcers is not evidence of a lack of effect. The forms of DME used most frequently by persons with diabetic foot ulcers or amputations resulting from gangrene and nonhealing foot ulcers include canes, walkers, and wheelchairs. Such devices clearly improve the mobility of persons with foot ulcers or amputations. Greater mobility may, in turn, enhance their ability to perform activities of daily living and instrumental activities of daily living (e.g., grocery shopping, preparing meals) and quality of life.

Medical supplies for ulcer care

Negative pressure wound therapy. Negative pressure wound therapy (NPWT) is a non invasive therapeutic treatment that uses a vacuum source to create vacuum-like pressure in the wound environment. Such pressure promotes the sealing of wounds, by creating a closed moist wound-healing environment and decreases wound area by drawing the wound edges together. The amount of negative pressure can vary from 50 to 175 mmHg (Noble-Bell et al., 2008).

Three systematic reviews assessed four RCTs that compared the effectiveness of NPWT to standard wound dressings (Hinchcliffe et al., 2008; Noble-Bell and Forbes, 2008; Ubbink et al., 2008). The RCTs found that NPWT was associated with an increase in the number of patients whose foot ulcers healed and other measures of wound healing.

There is *clear and convincing evidence* that negative pressure wound therapy improves the healing of diabetic foot ulcers.

Wound bed preparations (dressings). Debridement is critical to the healing of diabetic foot ulcers. Dressing products promote debridement of diabetic foot ulcers by binding to debris which can then be removed with dressing changes. Debridement promotes healing and relieves pressure in the feet of persons with diabetes who have foot ulcers or gangrene with risk of amputation (Edwards et al., 2010).

One meta-analysis identified three RCTs that compared debridement with gauze treated with hydrogel to standard wound care (Edwards et al., 2010). The pooled analysis of findings from these three RCTs found that foot ulcers treated with hydrogel (i.e., water- or glycerin-based gel) were more likely to heal completely than foot ulcers treated with standard wound care. A systematic review (Hinchcliffe et al., 2008) synthesized findings from eight RCTs that compared different dressings to one another. One RCT found that use of zinc oxide tape was associated with a reduction in the size of necrotic wounds relative to hydrogel. Another RCT found that use of a carboxymethylcellulose hydrofiber dressing was associated with a reduction in days to ulcer healing relative to saline-moistened gauze. One RCT reported that polymeric semi-permeable membrane dressing reduced the size of diabetic foot ulcers relative to saline-moistened gauze. However, the sample sizes for these three RCTs were small (< 45 persons). Findings from a single small RCT are not as persuasive as findings from multiple, large RCTs.

There is *clear and convincing evidence* that diabetic foot ulcers treated with hydrogel are more likely to heal than those treated with standard wound dressings. Findings from single RCTs suggest that zinc oxide tape, carboxymethylcellulose hydrofiber dressing, and polymeric semipermeable membrane dressing may also be more effective than standard dressings.

Prosthetics

The meta-analyses and systematic reviews included in the medical effectiveness review did not identify any RCTs that compared persons with diabetes-related amputations who used a prosthesis to persons with diabetes-related amputations who did not use a prosthesis.

A previous CHBRP report summarized findings from studies of prosthetics used by persons who had congenital deformities or had lost an upper or lower limb for any reason (CHBRP, 2006). The report identified a meta-analysis that synthesized findings from 23 studies that compared 18 types of prosthetic ankle-feet mechanisms published from 1983 through 2002 (Hofstad et al.,

2006). Two additional studies have been published since the studies included in the meta-analysis (Hsu et al., 2006; Underwood et al., 2004). Most studies evaluated in the meta-analysis compared various brands of energy-storing feet to solid ankle cushion heel (SACH) feet (Hofstad et al., 2006).¹⁸ Findings from these studies suggest that energy storing prosthetic feet enable persons with a prosthetic lower limb to walk in a manner more similar to persons with intact limbs, to walk farther, and move more confidently when running, walking briskly, or on inclines or declines. However, most evidence comes from small, crossover studies (Hofstad et al., 2006; Hsu et al., 2006; Underwood et al., 2004). Moreover, the meta-analysis did not indicate whether the persons enrolled in the studies had amputation due to diabetes or other causes. Findings from RCTs that enrolled persons with amputations due to other causes, such as injuries, may not generalize to persons with amputations due to diabetes.

The lack of evidence for the effectiveness of prosthetics is not evidence of a lack of effect. Use of prosthetic legs and feet clearly improve the mobility of persons with amputations which may, in turn, enhance their ability to perform activities of daily living and instrumental activities of daily living (e.g., shopping, preparing meals).

Outpatient prescription medications

Antibiotics. Polymicrobial, mixed aerobic/anaerobic infections are common in diabetic foot wounds. A systematic review conducted for the development of an evidence-based practice guideline examined RCTs that assessed the efficacy of adding antibiotic therapy to standard wound care for patients with diabetes with infected ulcers. Two RCTs that compared antibiotics to a placebo found no statistically significant difference in the likelihood that diabetic foot ulcers would heal (McIntosh et al., 2003). Six RCTs that compared one antibiotic to another found that no one was more effective than the others that were assessed. These findings suggest that adding antibiotic use to standard wound care does not increase the likelihood that foot ulcers will heal.¹⁹

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

¹⁸ SACH feet have a heel made from molded polyurethane foam and a rigid keel (top of the foot and arch) that restricts lateral movement (Underwood et al., 2004). Energy-storing prosthetic feet contain a spring that mimics the action of a human foot. The spring contracts when a person's heel strikes the surface he or she is traversing, storing energy. The spring releases when the person lifts the heel and pushes off the toes for his or her next step, providing forward momentum in much the same manner as a human foot (Hsu et al., 2006; Marks and Michael 2001; Underwood et al., 2004).

¹⁹ This finding may be due to the etiology of diabetic foot ulcers. Infection is a consequence rather than a cause of diabetic foot ulcers. Thus, antibiotics may eliminate infections in diabetic foot ulcers, but may not affect the likelihood that a foot ulcer will heal (i.e., that the wound will close).

UTILIZATION, COST, AND BENEFIT 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 persons who are enrolled in DMHC-regulated health plans or CDI-regulated policies have coverage that is compliant with SB1104 for medical treatments and devices for diagnosing or treating diabetes-related complications, and 95% have full 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, 88,000 (8%) do not have coverage that is compliant with SB1104 for wound dressings, DME, and/or prosthetics, and 58,000 (5%) do not have coverage that is compliant with SB1104 for outpatient prescription medications for the diagnosis and treatment of diabetes-related complications. CHBRP is unable to estimate the proportion of overlap between those with non-compliant coverage for medical treatments and outpatient prescription medications.

Based on the responses to the CHBRP carrier coverage survey, CHBRP identified DME, medical supplies, prosthetics, and outpatient prescription medications as the treatments and devices that are not universally covered among all enrollees in DMHC-regulated health plans and CDI-regulated insurance policies when provided in outpatient care settings.

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.

See Appendix D for further calculation details.

For the Cost 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, e.g., 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 medication:

- **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, Table 2 gives examples of services or treatments for which there are possible coverage gaps for the categories medical benefit and for medications, and Tables 3a and 3b describe the pre-mandate coverage of medical treatments and outpatient pharmacy benefits by market segment. 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 (Chernew, 2008). Therefore, 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 prescription 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) are 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 medical supply item. Each enrollee with diabetes receives on average approximately 0.54 units of medical treatment and approximately 23.81 prescriptions per year; this includes those both with and without compliant coverage. Due to the financial

hardship of paying for noncovered services, CHBRP assumes that utilization among enrollees with non-compliant coverage is assumed to be 10% less than that of those with compliant coverage (Chernew, 2008). 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 those without compliant coverage receive approximately 0.49 units and 21.75 prescriptions, respectively.

CHBRP estimates that SB 1104 would result in coverage for about 4,300 additional medical units per year (e.g., piece of DME, a prosthetic or a wound dressing) for the 88,000 enrollees with new benefit coverage, and about 125,000 additional outpatient prescription medications per year for the 58,000 enrollees with new benefit coverage.

CHBRP estimates that SB 1104 also would shift costs from diabetic enrollees to the health plans and insurers. CHBRP estimates a net decrease in enrollee expenses for non-covered benefits of approximately \$120 million/year, and a net 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.) (Selles, 2005), and a wheelchair could be as expensive as between \$20,000 to \$35,000 (Ward, 2010).

Table 2. Examples of Medical Treatments and Outpatient Medications for Which Some Enrollees Would Be Newly Covered Under SB1104

	Diabetes-related complication	Possible coverage gap for some enrollees
Medical treatments		
Durable medical equipment (DME)	Diabetic peripheral neuropathy	Wheelchairs, walkers, crutches
Supplies	Diabetic Foot Ulcers	Wound dressings
Prosthetics	Lower limb amputation (toe, foot, below or above knee)	Artificial limbs
Outpatient Medications		
	Diabetic peripheral neuropathy	Anticonvulsant and antidepressant medications
	Diabetic nephropathy	Antihypertensive medications

Source: California Health Benefits Review Program, 2010.

The mandate applies to enrollees DMHC-regulated plans and CDI-regulated policies in the group (large and small) and individual markets. There are no provisions in the bill that impact utilization management or medical-necessity reviews or the copayment, coinsurance, deductible, or other cost-sharing amounts set by health plans and insurers, although normal mechanisms to manage care are not prohibited.

This section will present first the current, or baseline, costs and benefit coverage related to the diagnosis and treatment of diabetes-related complications, and then detail the estimated impacts of SB 1104. For further details on the underlying data sources, methods, and assumptions, see Appendix D.

Present Baseline Cost and Benefit Coverage

Current Coverage of the Mandated Benefit

The California Health Benefits Review Program (CHBRP) surveyed the seven largest health plans/insurers in California to estimate the current benefit coverage provisions of the leading health plans/insurers in California. Responses to the survey represent 82.4% of the enrollees in the CDI-regulated policies and 92.0% of enrollees in privately-funded DMHC-regulated plans. Combined, responses to this survey represent 90.4% of privately funded enrollees subject to state mandates.

Tables 3a and 3b shows the distribution of SB 1104-compliant benefit coverage for the diagnosis and treatment of diabetes-related complications among privately and publicly funded health insurance, based on the responses to the CHBRP carrier coverage survey.

Among persons with privately funded health insurance, about 92% have medical treatment coverage compliant with SB 1104, and 95% have outpatient prescription medication coverage compliant with SB 1104. As described in Table 2, gaps in coverage include but are not limited to some items of durable medical equipment, medical supplies, prosthetics, and outpatient prescription medications.

Benefit coverage varies by market segment for both medical treatment coverage and outpatient prescription medication coverage for the diagnosis and treatment of diabetes-related complications.

For medical treatment coverage (DME, supplies, and prosthetics), of those with privately purchased health insurance subject to SB1104, a greater proportion of those enrolled in CDI-regulated policies (92%) than those in DMHC-regulated health plans (90%) have benefit coverage compliant with SB 1104. Benefit coverage for those in privately purchased DMHC-regulated plans ranges from 97% in the large group market, 73% in the small group market, to 50% in the individual market. Among CDI-regulated policies, benefit coverage ranges from 100% in the large- and small-group markets to 83% in the individual market. Among persons with publicly funded health insurance, there is 100% benefit coverage of medical treatments for diabetes-related complications; this includes enrollees in Medi-Cal HMOs (but not Medi-Cal Fee-for-Service), AIM, MRMIP, CalPERS, and the Healthy Families Program.

For outpatient prescription medications for the diagnosis and treatment of diabetes-related complications, approximately 95% of persons in the privately insured market have SB 1104-compliant benefit coverage. Of those with privately purchased health insurance subject to SB1104, a greater proportion of those in DMHC-regulated plans (97%) than those in CDI-regulated policies (78%) have such benefit coverage. Benefit coverage for those in privately purchased DMHC-regulated plans ranges from 100% in the small-group markets, 96% in the

large group market, to 95% in the individual market. Among CDI-regulated policies, benefit coverage ranges from 98% in the large-group market, 89% in the small-group market, to 58% in the individual market. Among persons with publicly funded health insurance, there is 100% outpatient prescription medication coverage for the diagnosis and treatment of diabetes-related complications; this includes enrollees in Medi-Cal HMOs (but not Medi-Cal Fee-for-Service), AIM, MRMIP, CalPERS, and the Healthy Families Program.

Table 3a. Current SB 1104-Compliant Coverage of Medical Treatments for Diabetes-Related Complications (a) by Market Segment, California, 2010

DMHC-regulated plans	
Large group	97%
Small group	73%
Individual	50%
All	90%
CDI-regulated policies	
Large group	100%
Small group	100%
Individual	83%
All	92%
CalPERS	97%
Medi-Cal	100%
Healthy Families	100%
MRMIP	100%
AIM	100%
Total	92%

Source: California Health Benefits Review Program, 2010.

(a) Includes inpatient hospital and physician/provider services; supplies for ulcer care; durable medical equipment (DME); inpatient prescription medications; and prosthetics and orthotics.

Table 3b. Current Coverage Outpatient Pharmacy Benefits (a) by Market Segment and Generic/Branded Medications, California, 2010

	Enrollees Subject to State-Level Mandates	No Coverage	Generic Only Coverage	Brand and Generic Coverage
DMHC-regulated plans, Privately funded				
Large group	9,445,000	3.7%	0.0%	96.3%
Small group	2,394,000	0.0%	0.0%	100.0%
Individual	785,000	4.5%	0.0%	95.5%
All	12,624,000	3.2%	0.0%	96.8%
CDI-regulated policies				
Large group	324,000	1.8%	0.0%	98.2%
Small group	935,000	0.2%	10.6%	89.2%
Individual	1,179,000	11.9%	30.0%	58.1%
All	2,438,000	3.7%	18.6%	77.7%
DMHC-regulated plans, Publicly funded				
CalPERS HMOs(a)	820,000	3.7%	0.0%	96.3%
Medi-Cal HMOs	2,791,000	0.0%	0.0%	100.0%
Healthy Families/MRMIP/AIM	814,000	0.0%	0.0%	100.0%
Total	19,487,000	2.7%	2.4%	94.8%

Source: California Health Benefits Review Program, 2010.

(a) An outpatient pharmacy benefit is not specific to outpatient medications prescribed for diabetes or diabetes-related complications. Prescription medications are commonly covered as Outpatient Pharmacy Benefits, but they may also be covered as Medical Benefits.

Current Utilization Levels and Costs of the Mandated Benefit

Current utilization levels

Approximately 1,100,000 enrollees with health insurance subject to this mandate (5.6% of people enrolled in DMHC-regulated plans and/or CDI-regulated policies) are diagnosed with and receive treatment for diabetes.

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 one medical supply item. 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, utilization among enrollees with non-compliant coverage is assumed to be 10% less than that of those with compliant coverage (Chernew, 2008). 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. Appendix D summarizes assumptions used to estimate utilization differences between those with and without insurance coverage.

Unit price

CHBRP estimates an average cost of \$304 per unit 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, deductibles, etc.) of \$45 for medical services and \$14 for prescription medications. This is calculated based on average amounts paid by insurers plus average enrollee cost-sharing for each unit.

The baseline costs associated with the mandate given current benefit coverage levels, utilization, and unit price are presented in Table 4.

Extent to Which Costs Resulting From Lack of Benefit Coverage Are Shifted to Other Payers, Including Both Public and Private Entities

Of the \$120 million in premandate costs for non-covered services, CHBRP estimates that all such costs are borne by the diabetic enrollees.

Public Demand for Benefit Coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under CHBRP's authorizing statute), CHBRP reports on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans (which are not regulated by DMHC or CDI and so not subject to state-level mandates) currently have, coverage for the benefits specified under the proposed mandate.

Currently, the largest public self-insured plans are the PPO plans offered by CalPERS. These plans provide coverage and benefits similar to those offered in the group health insurance market subject to the mandate.

To further investigate public demand, CHBRP also utilized the mandate-specific health plan and insurer survey to ask carriers administering plans or policies for other (non-CalPERS) self-insured group health insurance programs whether the relevant coverage and benefits differed from what is offered in the commercial markets. The responding carriers indicated that there were no substantive differences, again suggesting that the market is meeting public demand.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include coverage for diagnosis and treatment of diabetes-related complications in their health insurance policy negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.²⁰

Given the lack of specificity in labor-negotiated benefits and the general match between health insurance subject to the mandate and self-insured health insurance (not subject to state level mandates), CHBRP concludes that public demand for coverage is essentially satisfied by the current state of the market.

Impacts of Mandated Benefit Coverage

How Would Coverage Change as a Result of the Mandate?

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

Prescription medications are commonly covered as Outpatient Pharmacy Benefits, but they may also be covered as Medical Benefits (McDonald, 2008). 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.

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 benefit coverage, and about 125,000 additional outpatient prescription medications per year for the 58,000 enrollees with new benefit coverage.

How Would Changes in Coverage Related to the Mandate Affect the Benefit of the Newly Covered Service and the Per-Unit Cost?

Impact on supply, health benefit, and per-unit cost

Because 92% of enrollees subject to this mandate in the state of California currently have coverage for medical care services and devices for the diagnosis and treatment of diabetes-related complications, and 95% have coverage for related medications, CHBRP assumes that this

²⁰ Personal communication with the California Labor Federation and member organizations, January 2009.

mandate will have no measurable impact on the supply, health benefit, or per-unit costs of such treatments or services.

How Would Utilization Change as a Result of the Mandate?

For the purposes of this analysis CHBRP examines coverage for select medical treatments (DME, supplies, prosthetics) and for outpatient prescription medication benefits. This simplifying assumption was made because these items are typically covered when they are used as part of covered inpatient hospitalization and other post acute care or outpatient care settings. CHBRP examined these treatments and services are covered “medical benefits” and that prescription medications are covered as both “medical benefits” and as “outpatient pharmacy benefits” (McDonald, 2008). CHBRP assumes that SB 1104 would increase coverage for diabetes-related complication treatments, supplies and medications and would thereby allow an increase in utilization of these services by people with diabetes who do not currently have complete coverage of these items. This postmandate increase in utilization would be due to the CHBRP assumption that those enrollees with premandate coverage that is not compliant with SB 1104 would have lower premandate utilization due to the financial hardship of paying for non-covered supplies and treatments (Chernew, 2008). Based on data from a recent study examining the impact of decreasing copayments on medication adherence for diabetes patients (Chernew, et al., 2008), CHBRP has estimated that premandate utilization among enrollees with noncompliant coverage would be approximately 10% lower than that among those with compliant coverage (see Appendix D for further details). CHBRP thus assumed that utilization among enrollees with noncompliant coverage *premandate* would thus increase by 10% *postmandate*, and that these changes would apply to medical treatments (e.g., DME, prosthetics, and medical supplies) and prescription medications.

Impact of the Mandate on Administrative and Other Expenditures, and on Total Health Care Costs

Table 4 shows the premandate per member per month premiums and total expenditures by market segment, and Table 5 shows these breakdowns for postmandate.

There are four components to total expenditures: premium expenditures by employers and enrollees, including administrative expenditures by plans and insurers; other employer and state expenditures for public programs (CalPERS, Medi-Cal, and Healthy Families); enrollee out of pocket expenses for covered benefits (cost sharing); and enrollee expenses for non-covered benefits. Under SB 1104, CHBRP estimates a net increase of \$49,552,000 in total expenditures—or 0.0647% of expenditures—for DMHC-regulated plans and CDI-regulated insurers and enrollees in California.

The breakdown of how these small increases in expenditures are distributed among premiums and cost sharing is summarized below.

- Statewide, employers' (including CalPERS) share of premium increases is estimated to be \$47,786,000 (0.1098%).
- Statewide, individually purchased plan premiums are estimated to increase by approximately \$83,803,000 (1.3984%).
- Statewide, enrollees' share of premium increases in group plans regulated by DMHC or CDI is estimated to be \$13,888,000 (0.1083%).
- Statewide, employer premiums for CalPERS' HMOs are estimated to be \$3,163,000 (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.
- Statewide, total out-of-pocket expenses (copayments, deductibles, and other forms of cost sharing) by all enrollees with diabetes are estimated to increase by \$21,225,000 (0.3561%).
- Statewide, enrollees' expenses for previously non-covered services are estimated to decrease by approximately \$120,313,000.

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 non-covered 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.) (Selles, 2005), and a wheelchair could be as expensive as between \$20,000 to \$35,000 (Ward 2010).

There is an administrative cost associated with expanding coverage for diabetes-related complications by health plans and insurers. All health plans and insurers include a component for administration and profit in their premiums. The estimated impact of SB 1104 on premiums includes the assumption that DMHC-regulated plans and CDI-regulated insurers would apply their existing administration and profit loads to the marginal increase in health care costs produced by the mandate. CHBRP estimates a net increase in total expenditures of \$49,552,000 (0.0647%) post-mandate. Of that amount, approximately \$12 million would be due to changes in utilization, and the remaining \$37.5 million would be due to changes in administrative costs.

Impact on cost offsets

CHBRP estimates no measurable savings or offsets in other health care costs due to SB 1104 since the bill is not expected to measurably reduce or increase use of other types of health care services. While CHBRP recognizes that there may be some instances in which increased coverage may increase access and/or provide earlier access to treatments/services for diabetes-related complications, and that other types of health care services may increase or decrease for such persons, CHBRP cannot measure the number or magnitude of such potential offsets and so has not estimated their potential impact.

Impact on long-Term term costs

CHBRP cost analyses assume that mandates have an impact on annual expenditures that are short-term, in that they affect costs within a 1-year time frame, but also ongoing, in that the impacts continue indefinitely into the future. CHBRP estimates no measurable long-term impacts of the mandate beyond the ongoing annual impacts presented above.

Impacts for Each Category of Payer Resulting From the Benefit Mandate

Changes in premium and PMPM amounts by payer category

The shift in expenditures from enrollees with diabetes to health plans and insurers ranges in increases in premiums as follows:

- Large-group market: an estimated premium increase of 0.1001% (\$0.3633 PMPM) among DMHC-regulated plans, and 0.0388% (\$0.1753 PMPM) among CDI-regulated policies.
- Small-group market: an estimated premium increase of 0.0718% (\$0.2270 PMPM) in the DMHC-regulated market, and 0.3481% (\$1.1352 PMPM) in the CDI-regulated market.
- Individual market: an estimated premium increase of 0.2827% (\$1.0308 PMPM) in the DMHC-regulated market, and 2.8971% (\$5.2370 PMPM) in the CDI-regulated individual market.
- CalPERS: 0.0968% premium change (\$0.3782 PMPM)
- Medi-Cal: 0% premium change (\$0.0000 PMPM).

The projected cost impacts as a result of SB 1104 are summarized in Table 5.

Changes in the number of uninsured persons as a result of premium increases

CHBRP estimates the impact on the number of insured when the premium increase (or decrease) faced by any segment of the population is at least a 1% increase.²¹ CHBRP estimates premium increases of 1.4% among enrollees subject to the mandate. Using CHBRP's standard methodology, premium changes associated with SB 1104 are projected to lead to a net increase of approximately 3,000 uninsured Californians.

CHBRP does not anticipate other changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, or changes in employer contribution rates.

²¹ See http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php for more information on CHBRP's methods for calculating the number of uninsured as a result of premium changes.

Impact on public programs

CHBRP estimates that the mandate would produce no measurable impact on enrollment among persons with publicly funded health insurance or on utilization of covered benefits among those with publicly funded health insurance.

Impact on Access and Health Service Availability

CHBRP estimates that the mandate would produce no measurable impact on access and health service availability.

Table 4. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2010

	DMHC-Regulated							CDI-Regulated			Total Annual
	Privately Funded			CalPERS HMOs(b)	Medi-Cal HMOs		Healthy Families Program HMOs (d)	Privately Funded			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in plans/policies subject to SB 1104	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Average portion of premium paid by Employer	\$290.96	\$223.84	\$0.00	\$332.10	\$223.00	\$113.00	\$93.19	\$346.40	\$246.40	\$0.00	\$51,713,067,000
Average portion of premium paid by Employee	\$72.11	\$92.31	\$364.68	\$58.61	\$0.00	\$0.00	\$11.78	\$105.37	\$79.68	\$180.77	\$18,813,408,000
Total Premium	\$363.07	\$316.14	\$364.68	\$390.70	\$223.00	\$113.00	\$104.97	\$451.77	\$326.08	\$180.77	\$70,526,476,000
Enrollee expenses for covered benefits (Deductibles, copays, etc)	\$19.77	\$25.74	\$64.43	\$20.15	\$0.00	\$0.00	\$1.52	\$58.78	\$116.51	\$44.19	\$5,961,186,000
Enrollee expenses for benefits not covered	\$0.35	\$0.19	\$0.75	\$0.35	\$0.00	\$0.00	\$0.00	\$0.16	\$0.95	\$3.78	\$120,313,000
Total Expenditures	\$383.19	\$342.08	\$429.86	\$411.20	\$223.00	\$113.00	\$106.50	\$510.72	\$443.54	\$228.74	\$76,607,975,000

Source: California Health Benefits Review Program, 2010.

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Of these CalPERS HMO members, about 58% or 475,600 are state employees.

(c) Medi-Cal HMO state expenditures for members over 65 years of age include those who also have Medicare coverage.

(d) Healthy Families Program state expenditures include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program.

Table 5. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2010

	DMHC-Regulated							CDI-Regulated			Total Annual
	Privately Funded			CalPERS HMOs (b)	Medi-Cal HMOs		Healthy Families Program HMOs (d)	Privately Funded			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in Plans/Policies Subject to State Mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in Plans/Policies Subject to AB/SB 1104	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Average portion of premium paid by Employer	\$0.2911	\$0.1614	\$0.0000	\$0.3215	\$0.0000	\$0.0000	\$0.0000	\$0.1344	\$0.8582	\$0.0000	\$50,950,000
Average portion of premium paid by Employee	\$0.0722	\$0.0656	\$1.0308	\$0.0567	\$0.0000	\$0.0000	\$0.0000	\$0.0409	\$0.2770	\$5.2370	\$97,691,000
Total Premium	\$0.3633	\$0.2270	\$1.0308	\$0.3782	\$0.0000	\$0.0000	\$0.0000	\$0.1753	\$1.1352	\$5.2370	\$148,641,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$0.0617	\$0.0314	\$0.1278	\$0.0617	\$0.0000	\$0.0000	\$0.0000	\$0.0288	\$0.1689	\$0.6720	\$21,225,000
Enrollee expenses for benefits not covered	-\$0.3484	-\$0.1943	-\$0.7508	-\$0.3484	\$0.0000	\$0.0000	\$0.0000	-\$0.1613	-\$0.9475	-\$3.7807	-\$120,313,000
Total Expenditures	\$0.0767	\$0.0641	\$0.4079	\$0.0916	\$0.0000	\$0.0000	\$0.0000	\$0.0427	\$0.3566	\$2.1283	\$49,553,000
Percentage Impact of Mandate											
Insured Premiums	0.1001%	0.0718%	0.2827%	0.0968%	0.0000%	0.0000%	0.0000%	0.0388%	0.3481%	2.8971%	0.2108%
Total Expenditures	0.0200%	0.0187%	0.0949%	0.0223%	0.0000%	0.0000%	0.0000%	0.0084%	0.0804%	0.9304%	0.0647%

Source: California Health Benefits Review Program, 2010.

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by DMHC or CDI. This population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Of these CalPERS members, about 58% or 475,600 are state employees.

(c) Medi-Cal HMO state expenditures for members over 65 years of age include those who also have Medicare coverage.

(d) Healthy Families Program state expenditures include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program.

PUBLIC HEALTH IMPACTS

SB 1104 would mandate that DMHC-regulated plans and CDI-regulated policies cover the diagnosis and treatment of diabetes-related complications. Complications include both microvascular (i.e., diabetic peripheral neuropathy, foot ulcers, lower limb amputations) and macrovascular (i.e., peripheral vascular disease, heart attacks, stroke) conditions. As discussed in the *Utilization, Cost, and Benefit Coverage Impacts* section, medical services and treatments that are not always covered for all of the enrollees subject to SB 1104 include durable medical equipment (DME) (e.g., canes, crutches, wheelchairs, walkers), prosthetics (for lower limbs), wound care supplies, and prescription medications.

This section presents the estimated public health impact SB 1104, followed by an analysis examining the potential for reduction in gender and racial/ethnic disparities in health outcomes, and the potential for the mandate to reduce premature death and societal economic losses as a result of diabetes-related conditions.

Baseline Public Health Information About Diabetes-Related Complications

In 2008, the prevalence of diabetes was 8.3 percent of the overall California population (including the elderly and uninsured), an increase from 5.2 percent in 1994 (CDC, 2010). Using insurance claim data, CHBRP estimates a diabetes prevalence rate of 5.6% for the California insured population subject to SB 1104. This lower prevalence rate may be due in part to the disease being more prevalent in the aged—22.2% of persons aged 65-74 years are diabetic compared with 11.5% of those 45-64 years (CDC, 2008c).

Calculating the prevalence of diabetes-related complications is difficult (see *Utilization and Cost* section for description of the simplifying assumption for this analysis). For example, Barrett et al. reviewed a series of studies calculating the prevalence rate for diabetic peripheral neuropathy (DPNP) among persons with diabetes and found results ranging between 26% and 47% depending on the case definitions (both painful and nonpainful DPNP) and test sensitivity used to detect DPNP (Barrett et al., 2007). As presented in the *Medical Effectiveness* section, DPNP and related pain is treated with one of five drug classes, all of which have demonstrated efficacy in improving quality of life (Barrett et al., 2007).

Complications stemming from diabetes may present years after initial diagnosis. For example, diabetes is the leading cause of lower limb amputations and stems from a cascade of complicating events. A person with diabetes may be diagnosed with asymptomatic diabetic neuropathy which eventually escalates to a non-healing foot ulcer and possibly toe, foot, or above the knee amputation. About 85% of lower limb amputations are attributed to foot ulcers (CDC, 2003). The CDC estimates that, in 2002, 16.2% of Californians with diabetes experienced a history of foot ulcers (CDC, 2003). In 2005, lower limb amputations affected 3.9/1,000 persons with diabetes (Table 6). Although amputation is rare, it is a serious and life-altering event. Proper care of less severe complications through the use of medically effective prescription medications and foot ulcer remedies prevent serious complications that could affect mobility, productivity, and quality of life (see *Medical Effectiveness* section).

Data from the U.S. Centers for Disease Control and Prevention (CDC) show the rates of other diabetes-related complications that were severe enough to warrant hospitalizations (Table 6). These are the diabetes-related complications that escalated to a hospitalization and represent a fraction of the complications experienced in the outpatient setting.

Table 6. U.S. Rates of Diabetes-related Related Complications

Diabetes -Related Complication	Rate per 1,000 persons with diabetes
Diabetic neuropathy	6.8
Foot ulcers	6.9
Total lower limb amputation	3.9
Toe	2.3
Foot	0.7
Below knee	1.2
Above knee	0.6

Source: CDC, National Diabetes Surveillance System, 2010.

Impact of the Proposed Mandate on Public Health

According to the analysis in the *Utilization, Cost, and Benefit Coverage Impacts* section, CHBRP estimates that 1,100,000 enrollees (5.6% of the population with health insurance subject to SB 1104) have diabetes. Of that population, CHBRP estimates that about 92% of persons in the privately insured market have SB 1104-compliant coverage for diabetes-related complication medical treatments, and 95% have SB 1104-compliant outpatient prescription medication coverage. The remaining enrollees (88,000 and 58,000 enrollees respectively) have partial coverage that may not include all wound dressings, DME, prosthetics, and outpatient prescription medications.

As presented in the *Medical Effectiveness* section, the evidence for effective treatments varies according to intervention. The evidence related to DME and prosthetics is sparse and not generalizable to the impacts of SB 1104 (Bus et al., 2008). The lack of evidence for the effectiveness of DME for diabetic foot ulcers is not evidence of no effect. The use of DME, such as wheelchairs or crutches, presumably would affect the productivity, mobility, and quality of life of those enrollees with diabetes-related amputations or foot ulcers. The evidence presented in the *Medical Effectiveness* section concludes there is some evidence that sophisticated wound care dressings for foot ulcers are more effective than standard dressings, and foot ulcers treated with hydrogel dressings are more likely to heal than those treated with standard dressings. Additionally, there is a preponderance of evidence that prescription medications, in general, are very effective in reducing pain.

The *Utilization, and Cost* section estimates that SB 1104 would extend coverage for medical treatments (i.e., DME, wound dressings, and prosthetics) to about 88,000 enrollees with diabetes

and that the number of medical treatment “units” (e.g., a prosthetic, a wheelchair, or a hydrogel wound dressing) used by the subset of this population who have diabetes-related complications would increase by 4,300 units per year²². The increased utilization of treatments is likely to delay or reduce complications such as amputation, but the magnitude cannot be estimated.

Additionally, CHBRP estimates the bill would extend coverage of outpatient prescription medications to about 58,000 diabetic enrollees resulting in 125,000 additional prescriptions filled per year by the subset of diabetics with diabetes-related complications²³. The increased utilization of services and treatment is likely to delay or reduce complications such as neuropathic pain (chronic pain related to the nervous system), kidney failure, or premature death, but the magnitude cannot be estimated.

CHBRP estimates that SB 1104 also would produce a shift from the newly covered enrollees’ expenses for non-covered treatments and prescription medications to health plans and insurers. CHBRP estimates that enrollees who are newly covered would receive about \$1,100/year net reduction in expenses for some medical treatments and medications.

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.

Impact on the Health of the Community Where Gender and Racial Disparities Exist

Several competing definitions of “health disparities” exist. CHBRP relies on the following definition: *A health disparity/inequality is a particular type of difference in health or in the most important influences of health that could potentially be shaped by policies; it is a difference in which disadvantaged social groups (such as the poor, racial/ethnic minorities, women, or other groups that have persistently experienced social disadvantage or discrimination) systematically experience worse health or greater health risks than more advantaged group.* (Braveman, 2006)

CHBRP investigated the effect that SB 1104 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health

²² CHBRP estimates that the partially covered population uses 0.49 medical treatment units per year (Table 1). Using the Chernew study (2008) that estimates a 10% increase in utilization upon full coverage, CHBRP calculated the following: $10\% \times 0.49 = 0.049$, [which estimates the difference in use of medical treatment units pre- and post-mandate for the 88,000 diabetics]. Therefore, $88,000 \times 0.049 =$ about 4,300 additional units post-mandate.

²³ CHBRP estimates that the partially covered population uses 21.75 prescription medications per year (Table 1). Using the Chernew study (2008) that estimates a 10% increase in utilization upon full coverage, CHBRP calculated the following: $10\% \times 21.75 = 2.16$ [which estimates the difference in use of prescription medications pre- and post-mandate for the 58,000 diabetics]. Therefore, $58,000 \times 2.16 =$ about 125,000 additional units post-mandate.

indicators (KFF, 2007). One important contributor to racial and ethnic health disparities is differential rates of insurance, where minorities are more likely than whites to be uninsured; however, disparities still exist within the insured population (Kirby et al 2006, Lillie-Blanton and Hoffman 2005). Since SB 1104 would only affect the insured population, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the prevalence and treatment of diabetes-related complications outside of disparities attributable to differences in insured and uninsured populations.

Impact on Gender Disparities

The burden of diabetes and diabetes-related complications is disproportionately borne by males in California. The California Diabetes Program estimates that, in 2005, 7.6% of California males and 6.3% of females had diabetes (CDP, 2010).

Table 7 summarizes differences in rates of diabetes-related complications resulting in hospitalizations for males and females in the United States. Nationally, 23% more males than females were hospitalized for complications of diabetic neuropathy in 2003 and 61% more males than females were hospitalized for diabetic foot ulcers. In 2005, 42% more males than females experienced hospitalizations for lower limb amputations (CDC, 2010). CHBRP found no evidence related to treatment disparities between genders.

Table 7. United States Gender Disparities in Diabetes-Related Complications

Diabetes-related Complications	Hospital discharge rate (per 1,000 diabetic population)	
	Males	Females
Diabetic neuropathy	7.6	6.2
Diabetic foot ulcers/inflammation/infection	8.8	5.4
Lower limb amputations	5.5	2.3

Source: CDC, National Diabetes Surveillance System, 2010.

Although gender 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.

Impact on Racial/Ethnic Disparities

No data were found identifying racial/ethnic disparities in diabetes-related complications, but presumably disparities in the disease itself would translate to higher rates of complications for those groups more often diagnosed with diabetes. The burden of diabetes is disproportionately borne by minority races/ethnicities in California. The California Diabetes Program estimates that the state’s diabetes prevalence is highest for Blacks, followed by American Indian/Alaskan Natives/Pacific Islanders and Latinos. Whites and Asians have the lowest prevalence of diabetes (Table 8) (CDP, 2008). CHBRP found no evidence related to treatment disparities between races/ethnicities. However, in the TRIAD study, Tseng et al. reported that Latinos and African

Americans experienced higher rates of cost-related medication underutilization compared with whites, Asian-Pacific Islanders and others (Tseng et al. 2008).

Table 8. Prevalence of Diabetes by Race and Ethnicity

Race/Ethnicity	Prevalence of Diabetes (%)
Blacks	11.2%
American Indian/Alaskan Natives/Pacific Islanders	10.0%
Latinos	7.7%
Whites	7.1%
Asians	7.1%

Source: CDC, National Diabetes Surveillance System, 2010.

Although racial and 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.

The Extent to Which the Proposed Service Reduces Premature Death and the Economic Loss Associated with Disease

Both premature death and economic loss associated with disease are two measures used by economists and public health experts as a way to assess the impact of a condition or disease. Premature death is often defined as death before the age of 75 (Cox, 2006).

Premature Death

Diabetes is ranked as the seventh leading cause of death in the U.S., and the mortality rate for persons with diabetes is about two times that of those who are disease free (CDC, 2008b). Frequently death occurs from complications of diabetes rather than the disease itself. In 2005, 7,697 California adults died from diabetes (CDC, 2008a). Racial disparities among persons with diabetes extend to mortality rates, with blacks almost two times more likely to die from diabetes than whites (CDC, 2007).

CHBRP estimates that an additional 4,300 medical treatment “units” and 125,000 prescriptions per year will benefit the enrollees who are newly covered for these treatments. This increase may contribute to a reduction in renal (kidney) failure, amputation, or premature deaths, but the magnitude cannot be estimated. For example, coverage for antihypertensive medications for diabetic nephropathy may prevent or delay renal failure, reducing the need for dialysis or deaths from complications of renal failure.

Economic Loss

Total health care cost for the treatment of diabetes and its complications in California is about \$24.5 billion. Direct medical costs (e.g., hospitalizations, medical care, and treatment supplies)

account for about \$18.7 billion annually, with another \$5.8 billion spent on indirect costs (i.e., disability payments, time lost from work, and premature death) (CDP, 2009).

Another indicator of economic loss due to diabetes-related complications is ability to carry out daily activities. In 2004, 38% of California adults with diabetes reported having at least one day of poor health (of the last 30 days) where their daily activities were limited. Of the same population, almost 70% reported having at least one day of poor mental or physical health (of the last 30 days) (CDC, 2010).

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.

Long Term Public Health Impacts

As presented in the *Utilization, Cost* section, SB 1104 is expected to increase premiums in the individual market by approximately 1.4%, thus increasing the number of uninsured by approximately 3,000 people. Losing one's health insurance has many harmful consequences. Compared to those who remain insured, persons who lose their health insurance report more reduced access to needed health care and receive fewer services (Kasper et al., 2000). A review of the literature on insurance status and health found that compared to the insured, uninsured persons obtain less preventive, diagnostic, and therapeutic care; are diagnosed at more advanced stages of illness; and have a higher risk of death (Hadley, 2003). In addition to the issues of health and health care access, the loss of health insurance can also cause substantial stress and worry due to lack of health insurance as well as financial instability if health problems emerge (Lave et al., 1998). 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 may 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.

APPENDICES

Appendix A: Text of Bill Analyzed

BILL NUMBER: SB 1104 INTRODUCED
BILL TEXT

INTRODUCED BY Senator Cedillo

FEBRUARY 17, 2010

An act to amend Section 1367.51 of the Health and Safety Code, and to amend Section 10176.61 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 1104, as introduced, Cedillo. Health care coverage: diabetes-related complications.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires specified health care service plan contracts and health insurance policies to provide coverage for certain equipment, supplies, and medications for the treatment of diabetes, including podiatric devices to prevent or treat diabetes-related complications. Existing law also requires a plan or insurer to provide coverage for diabetes outpatient self-management training, education, and medical nutrition therapy necessary to enable an enrollee or insured to properly use the equipment, supplies, and medications.

This bill would require health care service plan contracts and health insurance policies to also provide coverage for the diagnosis and treatment of diabetes-related complications, as specified. Because a willful violation of this requirement by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the

state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1367.51 of the Health and Safety Code is amended to read:

1367.51. (a) 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:

- (1) Blood glucose monitors and blood glucose testing strips.
- (2) Blood glucose monitors designed to assist the visually impaired.
- (3) Insulin pumps and all related necessary supplies.
- (4) Ketone urine testing strips.
- (5) Lancets and lancet puncture devices.
- (6) Pen delivery systems for the administration of insulin.
- (7) Podiatric devices to prevent or treat diabetes-related complications.
- (8) Insulin syringes.
- (9) Visual aids, excluding eyewear, to assist the visually impaired with proper dosing of insulin.

(b) 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, that covers prescription benefits shall include coverage for the following prescription items if the items are determined to be medically necessary:

- (1) Insulin.
- (2) ~~Prescriptive~~ *Prescription* medications for the treatment of diabetes.
- (3) Glucagon.

(c) *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, 2011, and that covers hospital, medical, or surgical expenses, shall provide coverage for*

the diagnosis and treatment of diabetes-related complications. With respect to contracts that cover prescription benefits, the coverage required by this subdivision shall include coverage of prescription medications for the treatment of diabetes-related complications. For purposes of this subdivision, "diabetes-related complications" includes, but is not limited to, diabetic peripheral neuropathy.

~~(e)~~

(d) The copayments and deductibles for the benefits specified in subdivisions (a) ~~and~~, (b), and (c) shall not exceed those established for similar benefits within the given plan.

~~(d)~~

(e) Every plan shall provide coverage for diabetes outpatient self-management training, education, and medical nutrition therapy necessary to enable an enrollee to properly use the equipment, supplies, and medications set forth in subdivisions (a) and (b), and additional diabetes outpatient self-management training, education, and medical nutrition therapy upon the direction or prescription of those services by the enrollee's participating physician. If a plan delegates outpatient self-management training to contracting providers, the plan shall require contracting providers to ensure that diabetes outpatient self-management training, education, and medical nutrition therapy are provided by appropriately licensed or registered health care professionals.

~~(e)~~

(f) The diabetes outpatient self-management training, education, and medical nutrition therapy services identified in subdivision ~~(d)~~(e) shall be provided by appropriately licensed or registered health care professionals as prescribed by a participating health care professional legally authorized to prescribe the service. These benefits shall include, but not be limited to, instruction that will enable diabetic patients and their families to gain an understanding of the diabetic disease process, and the daily management of diabetic therapy, in order to thereby avoid frequent hospitalizations and complications.

~~(f)~~

(g) The copayments for the benefits specified in subdivision ~~(d)~~(e) shall not exceed those established for physician office visits by the plan.

~~(g)~~

(h) Every health care service plan governed by this section shall disclose the benefits covered pursuant to this section in the plan's evidence of coverage and disclosure forms.

~~(h)~~

(i) A health care service plan may not reduce or eliminate coverage as a result of the requirements of this section.

~~(i)~~

(j) Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for prescription drugs.

SEC. 2. Section 10176.61 of the Insurance Code is amended to read:

10176.61. (a) Every insurer issuing, amending, delivering, or renewing a ~~disability-health~~ insurance policy on or after January 1, 2000, ~~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:

- (1) Blood glucose monitors and blood glucose testing strips.
- (2) Blood glucose monitors designed to assist the visually impaired.
- (3) Insulin pumps and all related necessary supplies.
- (4) Ketone urine testing strips.
- (5) Lancets and lancet puncture devices.
- (6) Pen delivery systems for the administration of insulin.
- (7) Podiatric devices to prevent or treat diabetes-related complications.
- (8) Insulin syringes.
- (9) Visual aids, excluding eyewear, to assist the visually impaired with proper dosing of insulin.

(b) Every insurer issuing, amending, delivering, or renewing a ~~disability-health~~ insurance policy on or after January 1, 2000, that covers prescription benefits shall include coverage for the following prescription items if the items are determined to be medically necessary:

- (1) Insulin.
- (2) ~~Prescriptive~~ Prescription medications for the treatment of diabetes.
- (3) Glucagon.

(c) *Every health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2011, shall provide coverage for the diagnosis and treatment of diabetes-related complications. With respect to policies that cover prescription benefits, the coverage required by this subdivision shall include coverage of prescription medications for the treatment of diabetes-related complications. For purposes of this subdivision,*

"diabetes-related complications" includes, but is not limited to, diabetic peripheral neuropathy.

~~(e)~~

(d) The coinsurances and deductibles for the benefits specified in subdivisions (a) ~~and~~, (b), and (c) shall not exceed those established for similar benefits within the given policy.

~~(d)~~

(e) Every *health* insurer shall provide coverage for diabetes outpatient self-management training, education, and medical nutrition therapy necessary to enable an insured to properly use the equipment, supplies, and medications set forth in subdivisions (a) and (b) and additional diabetes outpatient self-management training, education, and medical nutrition therapy upon the direction or prescription of those services by the insured's participating physician. If ~~an~~ *a health* insurer delegates outpatient self-management training to contracting providers, the insurer shall require contracting providers to ensure that diabetes outpatient self-management training, education, and medical nutrition therapy are provided by appropriately licensed or registered health care professionals.

~~(e)~~

(f) The diabetes outpatient self-management training, education, and medical nutrition therapy services identified in subdivision ~~(d)~~(e) shall be provided by appropriately licensed or registered health care professionals as prescribed by a health care professional legally authorized to prescribe the services.

~~(f)~~

(g) The coinsurances and deductibles for the benefits specified in subdivision ~~(d)~~(e) shall not exceed those established for physician office visits by the insurer.

~~(g)~~

(h) Every ~~disability~~ *health* insurer governed by this section shall disclose the benefits covered pursuant to this section in the insurer's evidence of coverage and disclosure forms.

~~(h)~~ ~~An~~

(i) A *health* insurer may not reduce or eliminate coverage as a result of the requirements of this section.

~~(i)~~

(j) This section does not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity,

Medicare supplement, long-term care, or disability income insurance, except that for accident-only, specified disease, and hospital indemnity insurance coverage, benefits under this section only apply to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy. Nothing in this section may be construed as imposing a new benefit mandate on accident-only, specified disease, or hospital indemnity insurance.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for SB 1104, a bill that would require all DMHC-regulated health plan contracts and all CDI-regulated policies to provide coverage for the diagnosis and treatment of diabetes-related complications.

As previously detailed in the Introduction, diabetes-related complications include (but are not limited to): diabetic foot ulcers, microvascular diseases, and macrovascular diseases. Examples of microvascular diseases include diabetic neuropathy (nerve disease), diabetic nephropathy (kidney disease) and diabetic retinopathy (eye disease). Examples of macrovascular diseases include cardiovascular and cerebrovascular disease (e.g., heart attack, stroke) and peripheral vascular disease affecting circulation in the extremities).

The literature search was limited to studies published in English from January 2000 to present. Studies that enrolled persons of all ages with Type 1 or Type 2 diabetes were included, as persons with both types of diabetes may experience complications. The following databases of peer-reviewed literature were searched: MEDLINE (PubMed), the Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Clinical Trials, the Cumulative Index of Nursing and Allied Health Literature, EconLit, and Web of Science. In addition, Web sites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: and the Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, National Health Service Centre for Reviews and Dissemination, National Guidelines Clearinghouse, National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

Owing to the large amount of literature on diabetes-related complications, CHBRP restricted its review of the medical effectiveness literature to meta-analyses, systematic reviews, and evidence-based guidelines. Such syntheses of multiple studies are the strongest forms of evidence of the effectiveness of medical interventions. The medical effectiveness review focused on microvascular diseases and diabetic foot ulcers because diabetes is the major risk factor for contracting these diseases and conditions. In contrast, diabetes is only one of several major risk factors for macrovascular diseases.

Two reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria. Abstracts for 1454 articles, meta-analyses, evidence-based guidelines and systematic reviews were identified. Twenty-seven meta-analyses, systematic reviews, and evidence-based guidelines were retrieved and reviewed.

In making a “call” for each outcome measure, the team and the content expert consider the number of studies as well the strength of the evidence. To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design
- Statistical significance
- Direction of effect
- Size of effect
- Generalizability of findings

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome.

- Clear and convincing evidence
- Preponderance of evidence
- Ambiguous/conflicting evidence
- Insufficient evidence

The conclusion states that there is “clear and convincing” evidence that an intervention has a favorable effect on an outcome, if most of the studies included in a review are well-implemented randomized controlled trials and report statistically significant and clinically meaningful findings that favor the intervention.

The conclusion characterizes the evidence as “preponderance of evidence” that an intervention has a favorable effect if most but not all five criteria are met. For example, for some interventions the only evidence available is from nonrandomized studies or from small RCTs with weak research designs. If most such studies that assess an outcome have statistically and clinically significant findings that are in a favorable direction and enroll populations similar to those covered by a mandate, the evidence would be classified as a “preponderance of evidence favoring the intervention.” In some cases, the preponderance of evidence may indicate that an intervention has no effect or has an unfavorable effect.

The evidence is presented as “ambiguous/conflicting if their findings vary widely with regard to the direction, statistical significance, and clinical significance/size of the effect.

The category “insufficient evidence” of an intervention's effect indicates that available evidence is not sufficient to determine whether or not a health care service is effective. It is used when no research studies have been completed or when only a small number of poorly designed studies are available. It is not the same as “evidence of no effect”. A health care service for which there is insufficient evidence might or might not be found to be effective if more evidence were available.

Search Terms

The search terms used to locate studies relevant to SB 1104 were as follows.

MeSH Terms Used to Search PubMed

Bandages
Cardiovascular Diseases/complications
Cardiovascular Diseases/etiology
Cardiovascular Diseases/therapy
Clinical Trials
Costs and Cost Analysis
Diabetes Complications
Diabetes Complications/epidemiology
Diabetes Complications/therapy
Diabetic Angiopathies
Diabetic Coma
Diabetes Complications
Diabetes Complications/diagnosis
Diabetes Complications/therapy
Diabetic Foot
Diabetic Ketoacidosis
Diabetic Nephropathies
Diabetic Retinopathy
Durable Medical Equipment/economics
Durable Medical Equipment/utilization
Efficiency, Organizational
Employment
Employment/statistics & numerical data
Health Care Costs
Health Status Disparities
Healthcare Disparities
Hyperglycemic Hyperosmolar Nonketotic Coma
Insurance Coverage
Insurance, Health
Random Allocation
Sex Factors
Sick Leave/statistics & numerical data
Social Class
Socioeconomic Factors
Therapeutic use
Efficiency, Organizational
Employment
Employment/statistics & numerical data
Publisher

Pubmednotmedline
Systematic
In process
MM Diabetes Mellitus/CO
MM Diabetic Angiopathies+
MM Diabetic Coma+
MM Diabetic Ketoacidosis
MM Diabetic Nephropathies
MM Diabetic Neuropathies+

Keywords used to search PubMed, Cochrane Library, EconLit, Web of Science, and relevant web sites

absenteeism
bandages
chronic wound care
comparative assessment
cost
cost analysis
cost containment
cost effective
cost effectiveness
cost of illness
cost offset
cost savings
cost shifting
costs
debridement
diabet*
diabetes complication*
diabetes complication*
diabetic angiopath*
diabetic coma
diabetic complication*
diabetic complication
diabetic complications
diabetic foot*
diabetic ketoacidosis*
diabetic nephropath*
diabetic retinopath*
diabetic SAME Angiopath*
diabetic SAME Coma
diabetic SAME Foot
diabetic SAME Ketoacidosis

diabetic SAME Nephropath*
diabetic SAME Neuropath*
diabetic SAME Retinopath*
diabetic shoes
disparit*
disparities
disparity
durable medical equipment
durable medical equipment
economic*
English, epidemiolog*
ethnic
gender
health care costs
health care utilization
hyperglycemic hyperosmolar nonketotic coma
hyperglycemic SAME hyperosmolar SAME nonketotic SAME coma
hyperosmolar hyperglycemic nonketotic syndrome
hyperosmolar SAME hyperglycemic SAME nonketotic SAME syndrome
incidence
insurance
insured
long term impact*
meta-analysis
morbidity
orthotics
practice guideline
prevalence
price elasticity
productivity
prosthetics
race
racial
retrospective comparison
sick leave
socioeconomic
systematic review
utilization reviews
wound care
wound dressing
wound dressing*
clinical AND trial
random*

Publication Types:

Clinical trial

Comparative Study

Controlled Clinical Trial

Meta-Analysis

Practice Guideline

Randomized Control Trial

Systematic Reviews

Appendix C: Summary Findings on Medical Effectiveness

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Interventions

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Diabetic nephropathy					
<i>Treatments</i>					
Angiotensin-converting enzyme inhibitors (ACEi) and angiotensin receptor blockers (ARBs)	Strippoli et al., 2006	Meta-analysis	Angiotensin-converting enzyme inhibitors (ACEi) vs. placebo or no treatment; Angiotensin receptor blockers (ARBs) vs. placebo or no treatment; ACEi vs. ARBs	Patients with type 1 or type 2 diabetes	N/A
Diabetic neuropathy					
<i>Diagnostic Tests</i>					
Screening for neuropathy: signs for autonomic dysfunction, heart rate variability.	Rodbard et al., 2007	Evidence-based guideline	N/A	Patients with type 1 or type 2 diabetes	N/A

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Interventions (cont'd)

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Diabetic neuropathy					
<i>Treatments</i>					
Medications to treat gastroparesis: Ilosone (Erythromycin)	National Collaborating Centre for Chronic Conditions, 2008 ¹	Evidence-based guideline	Ilosone vs. placebo	Patients with Type 1 or type 2 diabetes	N/A
Medications to treat gastroparesis: Motilium (Domperidone)	National Collaborating Centre for Chronic Conditions, 2008 ²⁴	Evidence-based guideline	Motilium vs. placebo	Patients with type 1 or type 2 diabetes	N/A
Medications to treat gastroparesis: Reglan (Metoclopramide)	National Collaborating Centre for Chronic Conditions, 2008 ¹	Evidence-based guideline	Reglan vs. placebo	Patients with type 1 or type 2 diabetes	N/A
Antidepressants	Saarto and Wiffen, 2007	Meta-analysis	Antidepressant vs. placebo	Patients with type 1 or type 2 diabetes	N/A
Cymbalta (Duloxetine)	Lunn et al., 2009	Meta-analysis	Cymbalta vs. placebo	Patients with type 1 or type 2 diabetes	N/A
Antiepileptic/ Anticonvulsant medications	Gutierrez-Alvarez et al., 2007	Meta-analysis	Depakote vs. placebo; Trileptal vs. placebo; Topamax vs. placebo	Patients with type 1 or type 2 diabetes	N/A

²⁴ Prepared on behalf of the National Institute for Health and Clinical Excellence

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Interventions (cont'd)

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Diabetic neuropathy					
<i>Treatments</i>					
Lamictal (Lamotrigine)	Wiffen and Rees, 2007	Meta-analysis	Lamictal vs. placebo	Patients with type 1 or type 2 diabetes	N/A
Lyrica (pregabalin)	Moore et al., 2009	Meta-analysis	Lyrica vs. placebo	Patients with type 1 or type 2 diabetes	N/A
Neurontin (gabapentin)	Wiffen et al., 2005a	Meta-analysis	Neurontin vs. placebo	Patients with type 1 or type 2 diabetes	N/A
Tegretol (carbamazepine)	Wiffen et al., 2005b	Meta-analysis	Tegretol vs. placebo	Patients with type 1 or type 2 diabetes	N/A
Aldose reductase inhibitors	Chalk et al., 2007	Meta-analysis	Aldose reductase inhibitors vs. placebo or usual care	Patients with type 1 or type 2 diabetes	N/A
Diabetic retinopathy					
<i>Diagnostic Tests</i>					
Ophthalmoscopy	Singer et al., 1992	Systematic review	Ophthalmoscopy vs. seven-field fundus stereoscopic photography or fluorescein angiography or both	Patients with type 1 or type 2 diabetes	N/A

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Interventions (cont'd)

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Diabetic retinopathy					
<i>Diagnostic Tests</i>					
Ophthalmoscopy and retinal photography	Hutchinson et al., 2000	Systematic review	Ophthalmoscopy vs. slit-lamp biomicroscopy or other alternative screens; Retinal photography vs. multiple (usually 5 or 7) field stereo photography or other alternative screens	Patients with type 1 or type 2 diabetes	N/A
Ophthalmoscopy and retinal photography	NHS Centre for Reviews and Dissemination, 1999	Systematic review	Ophthalmoscopy vs. slit-lamp biomicroscopy or other alternative screens; Retinal photography vs. multiple (usually 5 or 7) field stereo photography or other alternative screens	Patients with type 1 or type 2 diabetes	N/A
<i>Treatments</i>					
Interventions for diabetic retinopathy	Mohamed et al., 2007	Systematic Review	Focal laser treatment vs. observation; Intravitreal antiangiogenesis agents vs. sham injections; Intravitreal steroids vs. observation, sham injection, or laser treatment; Pan-retinal laser photocoagulation vs. deferment or observation; Surgical vitrectomy vs. observation	Patients with type 1 or type 2 diabetes	N/A

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Interventions (cont'd)

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Diabetic retinopathy					
<i>Treatments</i>					
Interventions for diabetic macular edema	O'Doherty et al., 2008	Systematic Review	Focal laser treatment vs. observation; Intravitreal antiangiogenesis agents vs. sham injections Intravitreal steroids vs. observation, sham injection, or laser treatment; Surgical vitrectomy vs. observation	Patients with type 1 or type 2 diabetes	N/A
Intravitreal steroids	Grover et al., 2008	Meta-analysis	Steroids placed in eye (intravitreal steroids) vs. standard of care	Patients with type 1 or type 2 diabetes	N/A
Intravitreal steroids	Yilmaz et al., 2009	Meta-analysis	Intravitreal steroids vs. no treatment or subTenon triamcinolone acetonide (STTA) injection	Patients with type 1 or type 2 diabetes	N/A
Diabetic foot ulcers					
<i>Diagnostic Tests</i>					
Comprehensive foot examination	Singh et al, 2005	Systematic Review	Not stated	Patients with type 1 or type 2 diabetes	N/A

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Interventions (cont'd)

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Diabetic foot ulcers					
<i>Treatments</i>					
Interventions to enhance the healing of chronic ulcers of the foot in diabetes	Hinchcliffe et al., 2008	Systematic review	Bioengineered skin grafts vs. standard care; Cellular or biologic agents vs. placebo; Electrical stimulation vs. no treatment Granulocyte-colony stimulating factors vs. standard treatment; Hyperbaric oxygen (HBO) vs. standard care; Negative pressure therapy vs. standard dressings; Surgical debridement vs. non-surgical debridement; Wound dressing vs. standard dressings (saline or Vaseline)	Patients with type 1 or type 2 diabetes	N/A
Antibiotics	McIntosh et al., 2003	Evidence-based guideline	Antibiotic vs. placebo; One antibiotic vs. another antibiotic	Patients with type 1 or type 2 diabetes	N/A
Bioengineered skin substitutes (BSS)	Barber et al., 2008	Systematic review	BSS vs. saline gauze BSS vs. paraffin gauze BSS vs. hydrogel	Patients with type 1 or type 2 diabetes	N/A
Debridement	Edwards et al., 2010	Meta-analysis	Debridement vs. no debridement or an alternate method of debridement	Patients with type 1 or type 2 diabetes	N/A

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Interventions (cont'd)

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Diabetic foot ulcers					
<i>Treatments</i>					
Granulocyte-colony stimulating factors	Cruciani et al., 2009	Meta-analysis	Granulocyte-colony stimulating factors and usual treatment vs. treatment as usual with or without placebo	Patients with type 1 or type 2 diabetes	N/A
Hyperbaric oxygen therapy (HBOT)	Kranke et al., 2004	Meta-analysis	Wound care regimens which included HBOT vs. similar regimens that excluded HBOT (with or without sham therapy)	Patients with type 1 or type 2 diabetes	N/A
Hyperbaric oxygen therapy (HBOT)	Roeckl-Wiedmann et al., 2005	Systematic Review	Wound care regimens which included HBOT vs. similar regimens that excluded HBOT (with or without sham therapy)	Patients with type 1 or type 2 diabetes	N/A
Negative pressure wound therapy (NPWT)	Noble-Bell and Forbes, 2008	Systematic Review	NPWT vs. standard dressing or a control treatment (alginates, hydrocolloids, foams, hydrogels, or saline moistened gauze)	Patients with type 1 or type 2 diabetes	N/A
Negative pressure wound therapy (NPWT)	Ubbink et al., 2008	Systematic Review	NPWT vs. standard dressing or a control treatment (alginates, hydrocolloids, foams or hydrogels)	Patients with type 1 or type 2 diabetes	

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Interventions (cont'd)

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Diabetic foot ulcers					
<i>Treatments</i>					
Offloading interventions	Bus et al., 2008	Systematic Review	Total contact casting vs. standard treatment; Surgical offloading vs. conservative offloading	Patients with type 1 or type 2 diabetes	N/A
Prosthetic ankle-feet	Hofstad et al., 2006	Meta-analysis	Studies made one of two types of comparisons between 18 different types of prosthetic ankle-foot mechanisms: (1) one or more types of energy-storing feet to one or more types of solid ankle cushion heel feet; (2) two different types of energy-storing feet	Adults with transfemoral, through-knee, or transtibial (below the knee) amputations	N/A
Prosthetic ankle-feet	Hsu et al., 2006	Non-randomized study w/o comparison group—repeated measures on the same group of subjects	Compares the effectiveness of three types of prosthetic feet: (1) C-Walk foot; (2) Flex-Walk foot; and (3) SACH foot	8 men with unilateral transtibial amputations who could walk at least 107.28 meters per minute on a treadmill, and had no major medical problems aside from amputation	Not stated

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Interventions (cont'd)

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Diabetic foot ulcers					
<i>Treatments</i>					
Prosthetic ankle-feet (cont'd.)	Underwood et al., 2004	Non-randomized study w/o comparison group—repeated measures on the same group of subjects	Energy-storing Flex-Foot foot vs. SAFE II foot	11 persons with unilateral transtibial amputations due to trauma, who could ambulate without assistive devices, and did not have a cardiovascular, musculoskeletal, or neurological condition	Canada
Total contact casting	McIntosh et al., 2003	Evidence-based guideline	Total contact casting vs. standard care, therapeutic shoe or diabetic walker	Patients with type 1 or type 2 diabetes	N/A

Table C-2. Findings of Studies That Examined the Effectiveness of Specific Interventions

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
Diabetic Nephropathy						
Diabetic nephropathy						
<i>Treatments</i>						
Angiotensin-converting enzyme inhibitors (ACEi) – vs. placebo	All cause mortality in patients with diabetic kidney disease	1 meta-analysis of 49 Level I-II studies	<ul style="list-style-type: none"> • Not statistically significant 	<ul style="list-style-type: none"> • No effect 	No difference	<ul style="list-style-type: none"> • Somewhat generalizable
Angiotensin receptor blockers (ARBs)— vs. placebo	All cause mortality in patients with diabetic kidney disease	1 meta-analysis of 49 Level I-II studies	<ul style="list-style-type: none"> • Not statistically significant 	<ul style="list-style-type: none"> • No effect 	No difference	<ul style="list-style-type: none"> • Somewhat generalizable
Angiotensin-converting enzyme inhibitors (ACEi) vs. Angiotensin receptor blockers (ARBs)	All cause mortality in patients with diabetic kidney disease	1 meta-analysis of 49 Level I-II studies	<ul style="list-style-type: none"> • Not statistically significant 	<ul style="list-style-type: none"> • No effect 	No difference	<ul style="list-style-type: none"> • Somewhat generalizable
Angiotensin-converting enzyme inhibitors (ACEi)— vs. placebo	End stage kidney disease	1 meta-analysis of 49 Level I-II studies	<ul style="list-style-type: none"> • Statistically significant 	<ul style="list-style-type: none"> • Favors ACEi 	RR = 0.60 (95% CI=0.39, 0.93)	<ul style="list-style-type: none"> • Somewhat generalizable
Angiotensin receptor blockers (ARBs)— vs. placebo	End stage kidney disease	1 meta-analysis of 49 Level I-II studies	<ul style="list-style-type: none"> • Statistically significant 	<ul style="list-style-type: none"> • Favors ARBs 	RR = 0.78 (95% CI=0.67, 0.91)	<ul style="list-style-type: none"> • Somewhat generalizable

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
Angiotensin-converting enzyme inhibitors (ACEi)—vs. placebo	Doubling of serum creatinine	1 meta-analysis of 49 Level I-II studies	• Statistically significant	• Favors ACEi	RR = 0.68 (95% CI=0.47,1.00)	• Somewhat generalizable
Diabetic Nephropathy						
Angiotensin receptor blockers (ARBs)—vs. placebo	Doubling of serum creatinine	1 meta-analysis of 49 Level I-II studies	• Statistically significant	• Favors ARBs	RR = 0.79 (95% CI=0.67,0.93)	• Somewhat generalizable
Angiotensin-converting enzyme inhibitors (ACEi) –vs. placebo	Progression from micro-to macroalbuminuria	1 meta-analysis of 49 Level I-II studies	• Statistically significant	• Favors ACEi	RR = 0.45 (95% CI=0.29, 0.69)	• Somewhat generalizable
Angiotensin receptor blockers (ARBs)—vs. placebo	Progression from micro-to macroalbuminuria	1 meta-analysis of 49 Level I-II studies	• Statistically significant	• Favors ARBs	RR = 0.49 (95% CI=0.32, 0.75)	• Somewhat generalizable
Angiotensin-converting enzyme inhibitors (ACEi) –vs. placebo	Regression for micro-to normoalbuminuria	1 meta-analysis of 49 Level I-II studies	• Statistically significant	• Favors ACEi	RR = 3.06 (95% CI=1.76, 5.35)	• Somewhat generalizable
Angiotensin receptor blockers (ARBs)—vs. placebo	Regression for micro-to normoalbuminuria	1 meta-analysis of 49 Level I-II studies	• Statistically significant	• Favors ARBs	RR = 1.42 (95% CI=1.05, 1.93)	• Somewhat generalizable
Diabetic Neuropathy						
Diabetic autonomic						

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
neuropathy						
Diagnostic Tests						
Screening for neuropathy: signs for autonomic dysfunction, heart rate variability (no comparison stated)	Diagnosis of diabetic neuropathy	1 evidence-based guideline of Level I studies	• N/A	• Favors screening	• N/A	• Generalizable--- U.S. guideline
Diabetic Neuropathy						
Treatments						
Medications to treat gastroparesis: Ilosone (Erythromycin)--vs. placebo	Percentage of ingested food retained in the stomach	1 evidence-based guideline of 1 Level I study	• N/A	• Favors Ilosone	• N/A	• Generalizable – UK guideline
Medications to treat gastroparesis: Motilium (Domperidone)— vs. placebo	Reduction of bloating, nausea and fullness on eating or vomiting	1 evidence-based guideline of 1 Level I study	• N/A	• Favors Motilium	• N/A	• Generalizable – UK guideline
Medications to treat gastroparesis: Reglan (Metoclopramide)--- vs. placebo	Reduction of bloating, nausea and fullness on eating or vomiting	1 evidence-based guideline of 2 Level I studies	• N/A	• Favors Reglan	• N/A	• Generalizable – UK guideline
Diabetic peripheral neuropathy						
Treatments						
Cymbalta	50% reduction in	1 meta-	• Statistically	• Favors	• RR = 1.65 (95%	• Somewhat

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
(Duloxetine)— vs. placebo	neuropathic pain at 12 weeks	analysis of 6 Level I studies	significant	Cymbalta	CI=1.34, 2.03) Number needed to treat (NNT) = 6 (95% CI = 5, 10) ²⁵	generalizable
Diabetic Neuropathy						
Diabetic polyneuropathy						
<i>Treatments</i>						
Aldose reductase inhibitors— vs. placebo or usual care	Improvement in neurological function	1 meta- analysis of 29 Level II studies	• Not statistically significant	• No difference	• No effect	• Somewhat generalizable
Diabetic neuropathy—type not specified						
<i>Treatments</i>						
Antidepressants— tricyclic or tetracyclic medications— vs. placebo	Number of patients with moderate or better relief of pain.	1 meta- analysis of 5 Level I-II studies	• Statistically significant	• Favors tri-or tetracyclic anti- depressants	• RR = 12.4 (95% CI=5.2,29.2) • Number needed to treat (NNT) = 1.3 (95% CI = 1.2, 1.5)	• Somewhat generalizable
Depakote (valproic acid) vs. placebo	50% or greater reduction in pain	1 meta- analysis of 2 Level II studies	• Not consistent across studies reviewed	• Inconsistent	• Inconsistent	• Somewhat generalizable
Lamictal	50% or greater	1 meta-	• Not	• No effect	• No effect	• Somewhat

²⁵ The relative risk and number needed to treat are for a dose of 60 milligrams (mg) per day. The relative risk for a dose of 120 mg per day is similar. No statistically significant difference was found between persons who received a dose of 20 mg per day and persons receiving a placebo or usual care. Chalk et al., 2007.

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
(Lamotrigine)— vs. placebo	reduction in pain	analysis of 1 Level II study	statistically significant			generalizable
Lyrica (pregabalin)— vs. placebo	30% or 50% reduction in pain at end of study	1 meta- analysis of 7 Level I studies	<ul style="list-style-type: none"> • Statistically significant 	<ul style="list-style-type: none"> • Favors Lyrica 	<ul style="list-style-type: none"> • 30% pain relief • [300mg] RR = 1.3 (95% CI=1.1,1.6) • [300 mg, > 8 weeks] RR = 1.1 (95% CI = 0.9,1.4) • [600mg] RR = 1.5 (95% CI = 1.3,1.7) • [600mg, > 8 weeks] RR = 1.3 (95% CI=1.1,1.5) • 50% pain relief • [300mg] RR = 1.5 (95% CI= 1.2, 1.8) • [300 mg, > 8 weeks] RR = 1.3 (95% CI = 1.1,1.6) • [600mg] RR = 1.7 (95% CI=1.5, 2.0) • [600 mg, > 8 weeks] RR = 1.5 (95% CI=1.3,1.8) 	<ul style="list-style-type: none"> • Somewhat generalizable
Neurontin (gabapentin)— vs. placebo	50% or greater reduction in pain	1 meta- analysis of 4 Level	<ul style="list-style-type: none"> • Statistically significant 	<ul style="list-style-type: none"> • Favors Neurontin 	<ul style="list-style-type: none"> • RR = 2.21 (95% CI=1.65,2.96) • Number needed to 	<ul style="list-style-type: none"> • Somewhat generalizable

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
		I-II studies			treat (NNT) = 2.9 (95% CI = 2.2, 4.3)	
Tegretol (carbamazepine)—vs. placebo	Reduction in intensity of pain	1 meta-analysis of 1 Level II study	<ul style="list-style-type: none"> Statistically significant 	<ul style="list-style-type: none"> Favors Tegretol 	<ul style="list-style-type: none"> RR = 1.47 (95% CI=1.10, 1.97) 	<ul style="list-style-type: none"> Somewhat generalizable
Trileptal (oxcarbazepine) vs. placebo	50% or greater reduction in pain	1 meta-analysis of 1 Level II study	<ul style="list-style-type: none"> Statistically significant 	<ul style="list-style-type: none"> Favors Trileptal 	<ul style="list-style-type: none"> RR = 1.57 (95% CI=1.01, 2.44) 	<ul style="list-style-type: none"> Somewhat generalizable
Topamax (topiramate) vs. placebo	50% or greater reduction in pain	1 meta-analysis of 1 Level II study	<ul style="list-style-type: none"> Statistically significant 	<ul style="list-style-type: none"> Favors Topamax 	<ul style="list-style-type: none"> RR = 1.46 (95% CI=1.08, 1.96) 	<ul style="list-style-type: none"> Somewhat generalizable
Diabetic Retinopathy						
<i>Diagnostic Tests</i>						
Ophthalmoscopy	Detection of diabetic retinopathy	3 systematic reviews of 39 Level II-III studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Range of Sensitivity Score: 27 (95% CI: NR). 84 (95% CI: 72-93) Range of Specificity Score: 62 (95% CI: 56-68). 100 (95% CI: 92-100) 	<ul style="list-style-type: none"> Somewhat generalizable

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
Retinal photography	Detection of diabetic retinopathy	2 systematic reviews of 31 Level III studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Range of Sensitivity Score: 47 (95% CI: 23-71). 100 (95% CI: 97-100) Range of Specificity Score: 52 (95% CI: 33-70). 100 (95% CI: 99-100) 	<ul style="list-style-type: none"> Somewhat generalizable
Diabetic Retinopathy						
<i>Treatments</i>						
Intravitreal antiangiogenesis agents— vs. sham injections	Improved visual acuity	2 systematic reviews of 2 Level II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors intravitreal antiangiogenesis agents 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Intravitreal antiangiogenesis agents vs. focal photocoagulation	Improved visual acuity	2 systematic reviews of 2 Level II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors intravitreal antiangiogenesis agents 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Intravitreal steroids —i.e., placement of a steroid medication in the eye vs. no treatment, sham procedure, or laser treatment	Improved visual acuity	1 meta-analysis of 4 Level I-II studies	<ul style="list-style-type: none"> Statistically significant 	<ul style="list-style-type: none"> Favors use of intravitreal steroids 	<ul style="list-style-type: none"> RR = 2.85 (95% CI = 1.59, 5.10) for one or more lines of improvement (visual acuity) at 3 months; RR = 1.25 (95% CI = 0.66, 2.38) at 6 	<ul style="list-style-type: none"> Generalizable— studies conducted in developed countries

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
					months; RR 2.17 (95% CI=1.15, 4.11) at 24 months ²⁶	
Intravitreal steroids vs. subTenon triamcinolone acetonide (STTA) injection	Improved visual acuity	1 meta-analysis of 6 Level II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors intravitreal steroids at 3 months but no difference at 6 months 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Diabetic Retinopathy						
Intravitreal steroids plus laser treatment vs. intravitreal steroids	Improved visual acuity	2 systematic reviews of 3 Level II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Surgical implantation of steroids vs. no treatment, sham treatment, or laser treatment	Improved visual acuity	2 meta-analyses of 3 Level II studies	<ul style="list-style-type: none"> Statistically significant at 3 months but not at 6 months 	<ul style="list-style-type: none"> Favors surgical implantation of steroids at 3 months but no difference at 6 months 	<ul style="list-style-type: none"> WMD²⁷ = -0.08 (95% CI = -0.16,-0.01) at 3 months;²⁸ no effect at 6 months 	<ul style="list-style-type: none"> Somewhat generalizable
Focal laser treatment— vs. observation	Decrease in risk of vision loss	2 systematic reviews of 17 Level	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors focal laser treatment 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable

²⁶ Statistical findings are derived from meta-analysis conducted by Grover et al, 2008.

²⁷ WMD = weighted mean difference

²⁸ Statistical findings were obtained from a meta-analysis conducted by Yilmaz et al., 2009..

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
		I, II, III studies				
Pan-Retinal Laser Photocoagulation—vs. observation	Decrease in risk of vision loss	1 systematic review of 6 Level I-II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors pan-retinal laser photocoagulation 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Vitrectomy vs. observation	Improved visual acuity	2 systematic reviews of 7 Level I-II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Vitrectomy vs. laser treatment	Improved visual acuity	2 systematic reviews of 4 Level I-II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Diabetic Foot Ulcers						
<i>Diagnostic Tests</i>						
Comprehensive foot examination	Reduction in the risk of recurrence of foot ulceration	1 systematic review of 1 Level I-II study	<ul style="list-style-type: none"> Statistically significance 	<ul style="list-style-type: none"> Favors foot examination 	<ul style="list-style-type: none"> RR = 0.52 (95% CI = 0.29, 0.93) 	<ul style="list-style-type: none"> Somewhat generalizable

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
<i>Treatments</i>						
Antibiotics—antibiotic vs. placebo	Healing of foot ulcers—multiple measures	Evidence-based guideline based on 2 Level I-II studies	<ul style="list-style-type: none"> • Not statistically significant 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Generalizable--- guideline from developed country
Antibiotics—comparison of different antibiotics	Healing of foot ulcers—multiple measures	Evidence-based guideline based on 6 Level I-II studies	<ul style="list-style-type: none"> • Not statistically significant 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Generalizable--- guideline from developed country
Diabetic Foot Ulcers						
<i>Treatments (cont'd).</i>						
Bioengineered skin substitutes (BSS)—BSS vs. saline gauze	Proportion of foot ulcers healed completely	2 systematic reviews of 6 Level I-II studies	<ul style="list-style-type: none"> • No formal test of statistical significance 	<ul style="list-style-type: none"> • Favors BSS 	<ul style="list-style-type: none"> • Not stated 	<ul style="list-style-type: none"> • Somewhat generalizable
Bioengineered skin substitutes (BSS)—BSS vs. paraffin gauze	Proportion of foot ulcers healed completely	2 systematic reviews of 1 Level I-II study	<ul style="list-style-type: none"> • No formal test of statistical significance 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • Not stated 	<ul style="list-style-type: none"> • Somewhat generalizable

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
Bioengineered skin substitutes (BSS)— BSS vs. hydrogel	Proportion of foot ulcers healed completely	2 systematic reviews of 2 Level I-II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors BSS 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Cellular and biological agents: Epidermal growth factor — vs. placebo	Higher rate of foot ulcer healing	1 systematic review of 3 Level II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors epidermal growth factor 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Cellular and biological agents: Platelet autogel vs. placebo	Reduction in ulcer area	1 systematic review of 4 Level II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors platelet autogel 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Cellular and biological agents: Recombinant platelet-derived growth factor — vs. placebo	Proportion of foot ulcers healed	1 systematic review of 2 Level II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors recombinant platelet-derived growth factor 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Cellular and biological agents: Tretinoin vs. placebo	Proportion of foot ulcers healed	1 systematic review of 1 Level II study	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors tretinoin 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
	Reduction in ulcer area and depth	1 systematic review of 1 Level II study	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors tretinoin 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Debridement with hydrogel vs. gauze or standard wound care	Proportion of foot ulcers healed completely	1 meta-analysis of 3 Level I-II studies; 1 systematic review of 3 Level II studies	<ul style="list-style-type: none"> Statistically significant²⁹ 	<ul style="list-style-type: none"> Favors hydrogel 	<ul style="list-style-type: none"> RR=1.84 (95% CI=1.3-2.61)¹ 	<ul style="list-style-type: none"> Generalizable
Electrical— vs. no electrical stimulation	Proportion of foot ulcers resolving wound	1 systematic review of 2 Level II-III studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Diabetic Foot Ulcers						

²⁹ Statistical findings from the meta-analysis conducted by Edwards et al, 2010.

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
Granulocyte-colony stimulating factors (G-CSF) plus usual care vs. treatment as usual with or without placebo	Resolution of infection	1 meta-analysis of 5 Level I-II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Granulocyte-colony stimulating factors (G-CSF) plus usual care vs. treatment as usual with or without placebo	Proportion of foot ulcers healed	1 meta-analysis of 5 Level I-II studies	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Granulocyte-colony stimulating factors (G-CSF) plus usual care vs. treatment as usual with or without placebo	Reduction in amputation or other surgical intervention	1 meta-analysis of 5 Level I-II studies	<ul style="list-style-type: none"> Statistically significant 	<ul style="list-style-type: none"> RR=0.37 (95%CI=0.20-0.68) [reduction in risk of any surgical interventions] RR=0.41 (95%CI=0.18-0.95) [reduction in risk of amputation] 	<ul style="list-style-type: none"> Favors G-CSF 	<ul style="list-style-type: none"> Somewhat generalizable

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
Diabetic Foot Ulcers						
Hyperbaric oxygen therapy (HBOT)—vs. similar regimens that excluded HBOT	Reduction in risk of major amputation	1 meta-analysis of 5 Level II studies; 2 systematic reviews of 3 Level II studies	<ul style="list-style-type: none"> Statistically significant 	<ul style="list-style-type: none"> RR=0.31 (95% CI=0.13-0.71)³⁰ 	<ul style="list-style-type: none"> Favors hyperbaric oxygen therapy 	<ul style="list-style-type: none"> Somewhat generalizable
Hyperbaric oxygen therapy (HBOT)—vs. similar regimens that excluded HBOT	Reduction in risk of minor amputation	1 meta-analysis of 5 Level II studies; 2 systematic reviews of 3 Level II studies	<ul style="list-style-type: none"> Not statistically significant 	<ul style="list-style-type: none"> No difference 	<ul style="list-style-type: none"> No effect 	<ul style="list-style-type: none"> Somewhat generalizable
Negative pressure wound therapy (NPWT) vs. standard dressing or a control treatment (alginates, hydrocolloids, foams or hydrogels)	Number of patients achieving complete foot ulcer healing	1 systematic review of 1 Level II study	<ul style="list-style-type: none"> Statistically significant 	<ul style="list-style-type: none"> Favors NPWT 	<ul style="list-style-type: none"> OR = 2.0 (95% CI=1.0, 4.0); NNT = 6 (CI= 4, 64) 	<ul style="list-style-type: none"> Somewhat generalizable

³⁰ Statistical findings are derived from meta-analysis conducted by Kranke et al, 2004.

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
	Time to wound closure	2 systematic reviews of 2 Level II studies	<ul style="list-style-type: none"> Statistically significant 	<ul style="list-style-type: none"> Favors NPWT 	<ul style="list-style-type: none"> Median of 21 days shorter ($p < 0.01$) Mean of 20 days shorter (± 14.9) 	<ul style="list-style-type: none"> Somewhat generalizable
	Reduction in size of foot ulcer	2 systematic reviews of 4 Level II studies	<ul style="list-style-type: none"> Not consistently reported across studies reviewed 	<ul style="list-style-type: none"> Favors NPWT 	<ul style="list-style-type: none"> Mean difference of reduction in wound surface area: 20.4 cm² with NPWT vs. 9.5 cm² in gauze group³¹ Mean reduction in wound depth after treatment: -16.4% vs. -7.7% for moist dressing 	<ul style="list-style-type: none"> Somewhat generalizable
	Time to become ready for surgical closure of foot ulcer	1 systematic review of 1 Level II study	<ul style="list-style-type: none"> Statistically significant 	<ul style="list-style-type: none"> Favors NPWT 	<ul style="list-style-type: none"> Mean difference = -- 4.45 days (95% CI: -7.87, -1.03) 	<ul style="list-style-type: none"> Somewhat generalizable
Prosthetic ankle-foot mechanisms-- energy-storing foot vs. SACH ³² foot	Gait efficiency	1 meta-analysis of 8 Level IV studies and 1	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Inconsistent 	<ul style="list-style-type: none"> Somewhat generalizable

³¹ Wound surface area findings derived from outcomes in Ubbink et al., 2008.

³² The solid ankle cushion heel (SACH) foot is a frequently prescribed type of prosthetic foot that provides stability but does not enable a person to use the prosthetic foot to propel forward motion (Underwood et al., 2004). The energy-storing foot (also known as the dynamic response foot) contains springs and internal plate that stores energy when the heel of the foot strikes the surface on which a person is walking and releases energy when the person pushes off the toe for his or her next step (Hsu et al., 2006).

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
		Level IV study				
	Oxygen consumption when walking	1 meta-analysis of 8 Level IV studies and 1 Level IV study	<ul style="list-style-type: none"> • Inconsistent 	<ul style="list-style-type: none"> • Inconsistent 	<ul style="list-style-type: none"> • Inconsistent 	<ul style="list-style-type: none"> • Somewhat generalizable
	Ability to run or walk briskly	1 meta-analysis of 3 Level IV studies	<ul style="list-style-type: none"> • Statistically significant 	<ul style="list-style-type: none"> • Favors energy-storing foot 	<ul style="list-style-type: none"> • Not stated 	<ul style="list-style-type: none"> • Somewhat generalizable
Prosthetic ankle-foot mechanisms--energy-storing foot vs. SAFE II ³³ foot	Stability during walking	1 Level IV study	<ul style="list-style-type: none"> • Statistically significant 	<ul style="list-style-type: none"> • Favors energy-storing foot 	<ul style="list-style-type: none"> • Not stated 	<ul style="list-style-type: none"> • Somewhat generalizable
Surgery (Achilles tendon lengthening) and total contact casting vs. total contact casting	Proportion of foot ulcers healed	1 systematic review of 1 Level II-III study	<ul style="list-style-type: none"> • No formal test of statistical significance 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • Not stated 	<ul style="list-style-type: none"> • Somewhat generalizable

³³ The SAFE II foot has a solid ankle cushion heel and a flexible keel (top part of the foot) that provides a greater range of movement than the SACH foot (Underwood et al., 2004).

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
Surgery (Achilles tendon lengthening) and total contact casting vs. total contact casting	Rate of recurrence of foot ulcers	1 systematic review of 1 Level II-III study	<ul style="list-style-type: none"> • No formal test of statistical significance 	<ul style="list-style-type: none"> • Favors augmenting total contact casting with surgery 	<ul style="list-style-type: none"> • Not stated 	<ul style="list-style-type: none"> • Somewhat generalizable
Surgical debridement vs. conventional non-surgical management	Proportion of foot ulcers healed	1 meta-analysis of 1 Level I-II study	<ul style="list-style-type: none"> • Not statistically significant 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Generalizable
Total contact casting --- vs. nonremovable diabetic walker	Proportion of foot ulcers healed	1 systematic review of 1 Level I study	<ul style="list-style-type: none"> • Not statistically significant 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Somewhat generalizable
Total contact casting --- vs. standard care, therapeutic shoe or removable diabetic walker	Proportion of foot ulcers healed	Evidence-based guideline based on 3 Level I-II studies; 1 systematic review of 3 Level I studies	<ul style="list-style-type: none"> • N/A 	<ul style="list-style-type: none"> • Favors total contact casting 	<ul style="list-style-type: none"> • N/A 	<ul style="list-style-type: none"> • Generalizable

Table C-2. Findings of Studies that Examined the Effectiveness of Specific Interventions (cont'd)

Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
Diabetic Foot Ulcers						
Wound bed preparation (e.g., dressings): zinc oxide tape vs. hydrogel	Reduction in size of foot ulcer	1 systematic review of 1 Level II study	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors zinc oxide tape 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Wound bed preparation (e.g., dressings): carboxymethyl-cellulose hydrofiber dressing vs. saline-moistened gauze	Days to foot ulcer healing	1 systematic review of 1 Level II study	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors carboxymethyl-cellulose hydrofiber dressing 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable
Wound bed preparation (e.g., dressings): polymeric semi-permeable membrane dressing vs. wet-to-dry saline gauze	Proportion of foot ulcers healed	1 systematic review of 1 Level II study	<ul style="list-style-type: none"> No formal test of statistical significance 	<ul style="list-style-type: none"> Favors polymeric semi-permeable membrane dressing 	<ul style="list-style-type: none"> Not stated 	<ul style="list-style-type: none"> Somewhat generalizable

Sources: Barber et al., 2008; Bus et al., 2008; Chalk et al., 2007; Cruciani et al., 2009; Edwards et al., 2010; Grover et al., 2008; Gutierrez-Alvarez et al., 2007; Hinchcliffe et al., 2008; Hofstad et al., 2006; Hsu et al., 2006; Hutchinson et al., 2000; Kranke et al., 2004; Lunn et al., 2009; McIntosh et al., 2003; Mohamed et al., 2007; Moore et al., 2009; National Collaborating Centre for Chronic Conditions, 2008; NHS Centre for Reviews and Dissemination, 1999; Noble-Bell and Forbes, 2008; O'Doherty et al., 2008; Rodbard et al., 2007; Roeckl-Wiedmann et al., 2005; Saarto and Wiffen, 2007; Singer et al., 1992; Singh et al., 2005; Strippoli et al., 2006; Ubbink et al., 2008; Underwood et al., 2004; Wiffen et al., 2005a; Wiffen et al., 2005b; Wiffen and Rees, 2007; Yilmaz et al., 2009.

Appendix D: Cost Impact Analysis: Data Sources, Caveats, and Assumptions

This appendix describes data sources, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the Cost Team, which consists of CHBRP task force members and staff, specifically from the University of California, Los Angeles, and Milliman Inc. (Milliman). Milliman is an actuarial firm that provides data and analyses per the provisions of CHBRP's authorizing legislation.

Data Sources

In preparing cost estimates, the Cost Team relies on a variety of data sources as described below.

Health Insurance

1. The latest (2007) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payer (i.e., employment-based, individually purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over approximately 53,000 households. More information on CHIS is available at www.chis.ucla.edu. The population estimates for both adults and children from 2007 were adjusted to reflect the following trends as of 2009 from the data sources listed: 1) the increase in the total non-institutionalized population in California, from the California Department of Finance; 2) the decrease in private market coverage (both group- and individual-level), from the CHBRP Annual Premium and Enrollment Survey, and 3) the increase in all types of public coverage, from enrollment data available from the Centers for Medicare & Medicaid Services, the California Medical Statistics Section, and the Managed Risk Medical Insurance Board. The residual population after accounting for these trends was assumed to be uninsured.
2. The latest (2009) California Employer Health Benefits Survey (CHCF, 2009) is used to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured and therefore not subject to state level health benefit mandates),
 - premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
 - premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and

- premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.
 - This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: www.chcf.org/topics/healthinsurance/index.cfm?itemID=133543.
3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:
- The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
 - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2009 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2008 experience.
 - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
 - These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.
4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents 95.9% of the persons with privately funded health insurance subject to state mandates. This figure represents 98.0% of enrollees in full service (non-specialty), privately funded DMHC-regulated health plan contracts and 85.3% of enrollees in full service (non-specialty), privately funded CDI-regulated policies.

Publicly Funded Insurance Subject to State Benefit Mandates

5. Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries—about 74% of CalPERS total enrollment. CalPERS self-funded plans—approximately 26% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOCs) documents publicly available at www.calpers.ca.gov.
6. Enrollment in Medi-Cal Managed Care (DMHC-regulated health plans) is estimated based on CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at <http://www.dhcs.ca.gov/dataandstats/statistics/Pages/BeneficiaryDataFiles.aspx>.
7. Enrollment data for other public programs—Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Managed Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating health plans under these programs must comply with all requirements for DMHC-regulated health plans, and thus these plans are affected by state-level benefit mandates. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual market health insurance offered by DMHC-regulated plans or CDI-regulated insurers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

The projected cost estimates are estimates of the costs that would result if a certain set of assumptions were exactly realized. Actual costs will differ from these estimates for a wide variety of reasons, including:

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated benefits (and, therefore, the services covered by the benefit) before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.

Additional assumptions that underlie the cost estimates presented in this report are:

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.

When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see:

http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew, et al., 2005; Hadley, 2006; Glied and Jack 2003). Chernew et al. estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, while Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1-percent increase in premiums (about -0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e., ($\{-0.088/80\} \times 100 = -0.11$). This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured persons for every 1-percent increase in premiums. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured please see:

http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

There are other variables that may affect costs, but which CHBRP did not consider in the cost projections presented in this report. Such variables include, but are not limited to:

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization

reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.

- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, postmandate, because they perceive that it is to their economic benefit to do so.
- Medical management: Health plans and insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the health insurance types CHBRP modeled (HMO—including HMO and point of service (POS) plans—and non-HMO—including PPO and fee for service (FFS) policies), there are likely variations in utilization and costs by type. Utilization also differs within California due to differences in the health status of the local population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between providers and health plans or insurers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.
- Compliance with the mandate: For estimating the postmandate coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical postmandate coverage rates for populations subject to the mandate are assumed to be 100%.

Bill Analysis-Specific Caveats and Assumptions: Cost and Utilization

- SB1104 would increase benefit coverage to include all services and treatments for diabetes-related complications. For example, if, premandate, a health plan did not provide coverage for durable medical equipment, the plan or policy would be required, postmandate, to cover pieces of DME, such a wheelchair, if the wheelchair were deemed medically necessary for the treatment of a diabetes-related complication such as diabetic neuropathy.
- Because the list of all services or treatments for the diagnosis or treatment of diabetes-related complications is extensive and potentially ineffable, the CHBRP approach for estimating the potential cost and utilization impacts of SB1104 took a twofold approach:
 - 1) Qualitative approach: We categorized and gave examples of the types of such medical treatments and prescription medications for which benefit coverage gaps had been identified, as follows (see also Table 2 in the Cost and Utilization section of the main document):

- a) Medical Treatments
 - 1. Durable medical equipment, including but not limited to wheelchairs and walkers
 - 2. Prosthetic devices, including but not limited to prosthetic limbs
 - 3. Medical supplies, including but not limited to wound dressings for the care of foot ulcers
 - b) Outpatient Prescription medications
- 2) Quantitative approach: To estimate numeric values for utilization and per-person costs, we took the following steps:
- a) From MedStat 2006-2008 claim data, we identified claimants who had a diagnosis of diabetes (ICD-9 codes 249.0-249.9, 250.0-250.9, 357.2, 362.0)
 - b) CHBRP assumed that of those claimants 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," the MedStat analysis described here considered all diabetic claimants so as not to inadvertently overlook any claims for diagnosis or treatment of diabetes-related complications.
 - c) For those claimants with diabetes diagnoses, we identified all claims in the MedStat 2008 database with any of the following MedStat category labels: durable medical equipment (DME); prosthetics/orthotics; or outpatient prescription medications. These cover the four categories of items used in this analysis as follows:
 - MedStat DME category:*
 - 1. Durable medical equipment, including but not limited to wheelchairs and walkers
 - 2. Medical supplies, including but not limited to wound dressings for the care of foot ulcers
 - MedStat Prosthetics/Orthotics category:*
 - 3. Prosthetic devices, including but not limited to prosthetic limbs
 - MedStat Prescription Drug category:*
 - 4. Prescription medications: CHBRP assumed that any medications prescribed on an inpatient basis are covered; CHBRP therefore included medications prescribed for diabetic claimants on an outpatient basis only
 - d) CHBRP estimated utilization of DME, prosthetics, medical supplies, and outpatient prescription medications among diabetic claimants with and without benefit coverage in two steps:

1. CHBRP estimated utilization *among diabetic enrollees with benefit coverage* based on the above analysis of MedStat claims;
 2. CHBRP estimated utilization *among diabetic enrollees without benefit coverage* by assuming that *diabetic enrollees without benefit coverage would* utilize these treatments/services at a rate that is **10% lower** than the utilization rate of diabetic enrollees *with* coverage. This estimate was based on evidence from a recent analysis by Chernew and colleagues (Chernew, 2008) which showed that reductions in copays for generic and non-generic medications among diabetes patients resulted in 7%-14% increases in medication adherence. This analysis also suggested an elasticity of demand for diabetes medications of -0.136, indicating that a 100% decrease in out-of-pocket expenses would generate a 13.6% increase in utilization. Because of cost-sharing, CHBRP estimated that costs would decrease by less than 100% among those who gain benefit coverage with SB 1104 and therefore that utilization among those without SB 1104-compliant coverage premandate would be 10% lower than that among those with compliant coverage. CHBRP thus assumed that utilization among enrollees with noncompliant coverage *premandate* would thus increase by 10% *postmandate*, and that these changes would apply to medical treatments (e.g., DME, prosthetics, and medical supplies) and prescription medications.
- e) CHBRP estimated unit costs as the total cost divided by total utilization
- o CHBRP notes that these utilization and average unit cost estimates may *overestimate* the impact of SB 1104 because the analysis done in this way includes too many claims of DME (including supplies), prosthetics/orthotics, and outpatient prescription medications, some of which may not have been used specifically for the diagnosis or treatment of diabetes-related complications. On the other hand, the estimate may *underestimate* the impact of SB 1104, because the analyzed claims database only includes DME (including supplies), prosthetics/orthotics, and outpatient prescription medications that are covered premandate. Items such as DME *for those enrollees without premandate benefit coverage for those items*, which *would* be covered as a result of SB 1104, do not appear in this claims data.

Appendix E: Information Submitted by Outside Parties

In accordance with CHBRP policy to analyze information submitted by outside parties during the first two weeks of the CHBRP review, the following parties chose to submit information.

The following information was provided by the bill author's office.

Norton A. Many patients may never fill new prescriptions. American Diabetes Association. February, 17, 2020. Available at: www.diabetes.org/news-research/news/diabetes-in-the-news/many-patients-may-never-fill-new-prescriptions.html. Accessed March 22, 2010.

Pelletier E, Shim B, Ben-Joseph R, Caro J. Economic outcomes associated with microvascular complications of type 2 diabetes mellitus: Results from a US claims data analysis. *Pharmacoeconomics*. 2009;27:479-490.

Ritzwoller DP, Ellis JL, Korner EJ, Hartsfield CL, Sadosky A. Comorbidities, healthcare service utilization and costs for patients identified with painful DPN in a managed-care setting. *Current Medical Research and Opinions*. 2009;25:1319-1328.

This information is available upon request.

For information on the processes for submitting information to CHBRP for review and consideration please visit: http://www.chbrp.org/recent_requests/index.php.

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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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