



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 54: Health Care Coverage: Acupuncture

A Report to the 2007–2008 California Legislature
June 22, 2007

CHBRP 07-7



The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. CHBRP was established in 2002, to implement the provisions of Assembly Bill 1996 (California Health and Safety Code, Section 127660, et seq.) and was reauthorized by Senate Bill 1704 in 2006 (Chapter 684, Statutes of 2006). The statute defines a health insurance benefit mandate as a requirement that a health insurer or managed care health plan (1) permit covered individuals to obtain health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

A small analytic staff in the University of California's Office of the President supports a task force of faculty from several campuses of the University of California, as well as Loma Linda University, the University of Southern California, and Stanford University, to complete each analysis within a 60-day period, usually before the Legislature begins formal consideration of a mandate bill. A certified, independent actuary helps estimate the financial impacts, and a strict conflict-of-interest policy ensures that the analyses are undertaken without financial or other interests that could bias the results. A National Advisory Council, drawn from experts from outside the state of California and designed to provide balanced representation among groups with an interest in health insurance benefit mandates, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment of 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 2007–2008 California State Legislature

Analysis of Assembly Bill 54 Health Care Coverage: Acupuncture

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 54, a bill to mandate coverage for group contractholders for expenses incurred as the result of treatment by licensed acupuncturists. In response to a request from the California Assembly Committee on Health on March 12, 2007, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the California Health and Safety Code.

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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 Assembly Bill 54 (Health Care Coverage: Acupuncture)

The California Assembly Committee on Health requested on March 12, 2007, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 54. In response to this request, CHBRP undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the California Health and Safety Code.

AB 54 is a provider mandate—that is, the bill requires coverage for treatments delivered by a particular profession, in this case, acupuncturists. It applies to every health care service plan that provides coverage for hospital, medical, or surgical expenses and to every issuer of health insurance, and would amend Section 1373.10 of the Health and Safety Code and Section 10127.3 of the Insurance Code. The bill:

- Expands a current mandate to offer coverage into a mandate to provide coverage, and removes certain exceptions.
- Mandates coverage for expenses incurred as a result of treatment by holders of a license to practice acupuncture, as defined by Section 4938 of the Business and Professions code.
- Applies to *group* contracts or policies. The market for individually purchased health insurance is not affected by this bill.
- The coverage shall be under terms and conditions as may be agreed upon by the health plan and group contractholder or health insurer and group policyholder.

The practice of acupuncture involves the stimulation of the body by the precise placement of thin, solid-metal needles in the skin. It has been practiced for centuries in China as a method of promoting overall health and well-being, and has become more available in the United States, especially in California, since the early 1970s.

The impact of AB 54 is contingent on the determination of acceptable terms and conditions by California regulatory agencies. The proposed benefit is also subject to future changes in the Business and Professions code and determinations of scope of practice. According to the California Acupuncture Board, the scope of practice for a licensed acupuncturist includes not only acupuncture (needling), but also other treatments such as massage, moxibustion, and cupping, and the prescription of herbs as dietary supplements.

Because the mandate is not restricted to particular conditions or diseases, CHBRP necessarily limits the analysis of the bill's impact, which CHBRP does in two ways. First, CHBRP does not evaluate treatments other than acupuncture (needling) for this report. Based on the CHBRP current coverage survey, current coverage for acupuncture does not include herbs used as dietary

supplements. CHBRP assumes the terms of coverage with regard to herbal supplements will remain the same postmandate. Second, the mandate would apply to all enrollees; however, CHBRP has made the simplifying assumption to exclude persons under age 18 years due to their low utilization of acupuncture services and the lack of medical literature on its effectiveness in the under-age-18 population.

Medical Effectiveness

Numerous studies of the effectiveness of acupuncture have been conducted. CHBRP's analysis focuses on the strongest and most current evidence of the effectiveness of acupuncture. It emphasizes evidence regarding musculoskeletal and neurological conditions, because they are the types of conditions for which persons in the United States most frequently use acupuncture.

Three types of literature were reviewed:

- Reports by the National Institutes of Health (NIH) in 1997 and by the Institute of Medicine (IOM) in 2005 that assessed evidence of the effectiveness of acupuncture;
- Meta-analyses and systematic reviews of randomized controlled trials (RCTs) published since the literature review for the IOM report was conducted in March 2004; and
- Large, well-designed RCTs on select musculoskeletal and neurological conditions that were published after the literature synthesized in the meta-analyses and systematic reviews.

This literature review analyzes evidence of the effectiveness of needling, a practice unique to acupuncture that is typically covered by health plans that provide acupuncture benefits. Studies of both manual acupuncture and electroacupuncture needling are included.

Many of the RCTs included in the meta-analyses and systematic reviews that CHBRP assessed are of low quality. In many cases, the sample sizes are too small to provide conclusive evidence of the effectiveness of acupuncture. Only recently have researchers begun conducting large, well-designed RCTs on acupuncture.

This report summarizes findings from RCTs that studied four types of comparisons: (1) acupuncture versus no treatment; (2) acupuncture versus sham acupuncture (i.e., needling or pricking points on the body that are not acupuncture points); (3) acupuncture versus other treatments; and (4) acupuncture plus other treatments versus other treatments (i.e., acupuncture as an adjuvant treatment). Findings from studies that compare acupuncture to no treatment are included as well as studies that compare acupuncture to sham acupuncture, because experts disagree as to which type of study is best. Studies that compare acupuncture to no treatment probably overstate the effects of acupuncture, because they do not control for placebo effects, such as patients' and providers' expectations regarding treatment. For this reason, researchers often attempt to control for placebo effects by comparing acupuncture to sham acupuncture. However, such studies may understate the effects of acupuncture, because there is considerable evidence that sham acupuncture is not an inert placebo.

Needle acupuncture versus no treatment

- The preponderance of evidence suggests that needle acupuncture is *more effective* than no treatment in reducing pain and improving the functioning of persons with chronic low back pain, neck disorders, osteoarthritis of the knee, temporomandibular joint dysfunction, and chronic headache.
- The evidence suggests that needle acupuncture *may increase* abstinence from smoking relative to no treatment.

Needle acupuncture versus sham acupuncture

- The preponderance of evidence suggests that needle acupuncture is *more effective* than sham acupuncture for treatment of lateral elbow pain, neck disorders, osteoarthritis of the knee, and postoperative nausea and vomiting.
- The preponderance of evidence suggests that needle acupuncture is *not more effective* than sham acupuncture for treatment in facilitating recovery from cocaine addiction and smoking cessation.
- The evidence of the effectiveness of needle acupuncture relative to sham acupuncture for treatment of chronic low back pain, shoulder pain, and headache is *ambiguous*.
- There is *insufficient evidence* to determine whether needle acupuncture is more effective than sham acupuncture for treatment of acute low back pain, osteoarthritis of the hip and thumb, rheumatoid arthritis, temporomandibular joint dysfunction, epilepsy, vascular dementia, and chemotherapy-induced nausea and vomiting.

Needle acupuncture versus other treatments

- The preponderance of evidence suggests that needle acupuncture is *more effective* than medication or education for osteoarthritis of the knee, more effective than physical therapy for pelvic pain associated with pregnancy, and more effective than medication for chronic headache.
- The preponderance of evidence suggests that needle acupuncture is *as effective as* other treatments for temporomandibular joint dysfunction, smoking cessation, and postoperative nausea and vomiting.
- The evidence of the effectiveness of needle acupuncture relative to other treatments for lateral elbow pain is *ambiguous*.
- There is *insufficient evidence* to determine whether needle acupuncture is more effective than other treatments for acute and chronic low back pain, pelvic pain, neck disorders, osteoarthritis of the hip, and shoulder pain.

Needle acupuncture plus other treatments versus other treatments (i.e., acupuncture needling used as an adjuvant treatment)

- The preponderance of evidence suggests that needle acupuncture is an *effective* adjuvant treatment for chronic low back pain, pelvic pain, stroke, and chemotherapy-induced vomiting.
- The preponderance of evidence suggests that needle acupuncture is *not an effective* adjuvant treatment for facilitating recovery from cocaine addiction and for smoking cessation.
- The evidence of the effectiveness of needle acupuncture as an adjuvant treatment for fibromyalgia and osteoarthritis is *ambiguous*.
- There is *insufficient evidence* to determine whether needle acupuncture is an effective adjuvant treatment for shoulder pain.

Utilization, Cost, and Coverage Impacts

AB 54 would require Knox-Keene licensed health care service plan contracts and insurance policies sold in the group market to provide coverage for acupuncture services. This section presents the current, or baseline, costs and coverage related to acupuncture (needling) for adults, and then details the estimated utilization, cost, and coverage impacts of AB 54 if it were to pass into law.

- According to CHBRP's estimates, there are 17.95 million insured Californians currently enrolled in group health plans regulated under the Knox-Keene Act or insured by group health insurance policies regulated under the California Insurance Code and, therefore, subject to AB 54. The affected population includes 12.10 million adults aged 18 years and older.
- Currently, 86.3% of insured Californians subject to the mandate have coverage for acupuncture. This mandate impacts those who currently do not have coverage (13.7%). Privately insured individuals with acupuncture coverage generally have benefit limits, including a maximum number of annual visits (e.g., 20 visits). In addition, cost-sharing requirements vary by health plan. Most health plans also require referrals from primary care providers. Some health plans limit acupuncture services to the management of neuromusculoskeletal disorders, nausea, and pain.
- About half (50.8%) of those covered under health plans purchased by California Public Employees' Retirement System (CalPERS) do not have coverage for acupuncture. Medi-Cal provides acupuncture benefits at no charge to the members, but the benefit is limited to two visits per month. Healthy Families members are also currently covered for 20 acupuncture visits per year with a \$5 copay per visit.

- Approximately 2.4% of Californians used acupuncture treatments in 2002, according to the 2003 California Health Interview Survey Complementary and Alternative Medicine Supplement (CHIS-CAM). This utilization is higher than the national average (1.1%) or even the average in the western region of the United States (1.9%), according to 2002 National Health Interview Survey data. CHBRP estimates that there would be a negligible change in utilization due to the mandate. Cultural acceptance of acupuncture may be a more important determinant factor in utilization than financial barriers.
- Total net annual expenditures are estimated to increase by \$2.45 million or 0.004%, mainly due to the administrative costs associated with providing coverage for persons who do not currently have it. There is an estimated increase in premiums of \$16.93 million (\$10.94 million for the portion of group insurance premiums paid by private employers, \$2.68 million by CalPERS employers, and \$3.31 million for the portion of group insurance and CalPERS premiums paid by enrollees) and a net increase in member copayments of \$3.06 million, offset by a reduction in *out-of-pocket* expenditures of \$17.55 million among those whose utilizations of acupuncture services are not currently covered by insurance.
- Increases in insurance premiums vary by market segment. Increases as measured by percentage change in per member per month (PMPM) premiums are estimated to range from 0.007% to 0.102% for the various group markets (Table 4). Increases as measured by PMPM premiums are estimated to range from \$0.03 to \$0.33. It is estimated that the premium will increase by \$0.33 PMPM for CalPERS. In the large-group market, the increase in premiums is estimated to range from \$0.03 to \$0.07 PMPM. For members with small-group insurance policies, health insurance premiums are estimated to increase by approximately \$0.08 to \$0.11 PMPM.
- Based on a few studies mostly conducted in European countries, acupuncture has been shown to be cost effective in treating patients with chronic neck pain, back pain, and migraine headache.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 54

	Before Mandate	After Mandate	Increase/ Decrease	Percentage Change After Mandate
Coverage				
Number of individuals subject to the mandate	12,095,000	12,095,000	0	0.000%
Percentage of individuals with coverage	86.3%	100.0%	13.7%	15.890%
Number of individuals with coverage	10,436,600	12,095,000	1,658,400	15.890%
Utilization				
Total number of acupuncture visits covered by insurance	1,492,227	1,729,343	237,117	15.890%
Total number of acupuncture visits paid directly out of pocket annually	237,117	0	-237,117	-100%
Total number of acupuncture visits annually	1,729,343	1,729,343	0	0%
Average cost of an acupuncture visit	\$74.00	\$74.00	0	0%
Expenditures				
Premium expenditures by private employers for group insurance	43,944,936,000	43,955,880,000	10,944,000	0.025%
Premium expenditures for individually purchased insurance	—	—	0	0.000%
CalPERS employer expenditures	2,631,085,000	2,633,766,000	2,681,000	0.102%
Medi-Cal state expenditures ^(a)	4,015,964,000	4,015,964,000	0	0.000%
Healthy Families state expenditures	—	—	0	0.000%
Premium expenditures by employees with group insurance or CalPERS	11,468,688,000	11,471,994,000	3,306,000	0.029%
Member copayments	4,096,879,000	4,099,940,000	3,061,000	0.075%
Out-of pocket expenditures for noncovered services ^(b)	17,547,000	—	(17,547,000)	-100.000%
Total annual expenditures	66,175,099,000	66,177,544,000	2,445,000	0.004%

Source: California Health Benefits Review Program, 2007.

Notes: The population includes employees and dependents covered by employer-sponsored insurance (including CalPERS), or public health insurance provided by a health plan subject to the requirements of the Knox-Keene Health Care Service Plan Act of 1975. All population figures include enrollees aged 18–64 years and enrollees 65 years or older covered by employer-sponsored insurance. Member contributions to premiums include employee contributions to employer-sponsored health insurance and member contributions to public health insurance.

Key: CalPERS = California Public Employees' Retirement System.

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

(b) The expenditures for acupuncture services paid by members who currently do not have acupuncture benefits.

Public Health Impacts

- Three common conditions for which acupuncture is used include: (1) lower back pain, (2) neck pain, and (3) migraine or severe headaches. In 2002, over one-third of the insured adult population aged 18–64 years in the United States reported having at least one of these three conditions in the past 3 months. Only a small fraction of the population currently uses acupuncture for these conditions or for one of the many other health conditions for which acupuncture is utilized.
- The primary health outcomes associated with acupuncture treatment for musculoskeletal and neurological disorders are reduced pain and improved functionality. Although acupuncture needling has been found to be effective for some conditions, AB 54 is not expected to result in an overall increase in utilization in the short term and thus is not expected to have any measurable impact on community health in the 1-year time frame used in this analysis. It is possible that in the longer term, passage of AB 54, along with a potential increase in cultural acceptance of acupuncture as a treatment option, will contribute to an increase in utilization of acupuncture and, therefore, improved health outcomes for persons who do not respond to other treatments.
- Women report higher prevalence of lower back pain, neck pain, and migraines or severe headache. Additionally, women report higher utilization of acupuncture. Although AB 54 is not estimated to result in an overall increase in acupuncture treatment, it is expected that more women will financially benefit from insurance coverage of acupuncture compared to men.
- Although Asians do not have higher prevalence rates for lower back pain, neck pain, and migraines or severe headaches, Asians report the highest utilization of acupuncture and, therefore, more Asians are expected to financially benefit from AB 54 compared to other racial and ethnic groups.
- Acupuncture is used for some health conditions and behaviors associated with premature death, such as smoking cessation and other drug addictions. The medical effectiveness analysis, however, did not find that acupuncture was an effective treatment for these conditions. Therefore, AB 54 is not expected to result in a reduction of premature death.
- No research was found on the economic costs associated with neck pain; however, both lower back pain and migraines have been found to be associated with high economic costs, comparable to those of heart disease, depression, and diabetes. Since there is no expected overall increase in use of acupuncture due to AB 54, there is no expected reduction in economic loss associated with conditions related to acupuncture use in a 1-year time period. However, it is possible that in the longer term, passage of AB 54, along with a potential increase in cultural acceptance of acupuncture as a treatment option, will contribute to an increase in utilization of acupuncture and therefore may reduce economic costs associated with these conditions.

INTRODUCTION

Acupuncture is a centuries-old healing art with origins in traditional Chinese medicine, which aims to restore balance to the body and promote overall health. The growing interest in alternative and complementary care in the United States has included acupuncture (IOM, 2005). Beginning in the early 1970s, acupuncture became more accepted in the United States, and states responded by creating a distinct professional license for the practice of acupuncture that allowed non-physicians to practice (Little Hoover Commission, 2004). In 2004, 40 states had some kind of licensure for acupuncturists, including California (McKinley, 2004). The profession is growing, especially in California. In 2003, the California Board of Acupuncture had licensed 6,300 acupuncturists, about a third of the estimated total U.S. acupuncture workforce, and the majority work in a solo practice (Dower, 2003; Eisenberg et al., 2002).

Acupuncture is a family of practices in which the skin is stimulated with the intention, in the traditional understanding, of normalizing patterns of energy (Qi) that can manifest as disease. Often this is done by inserting thin metal needles at precise points in the skin;¹ however, other techniques are also used (NIH, 1997). Acupuncture is defined by California law in Section 4927(d) of the Business and Profession Code:

“Acupuncture” means the stimulation of a certain point or points on or near the surface of the body by the insertion of needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control, for the treatment of certain diseases or dysfunctions of the body and includes the techniques of electroacupuncture, cupping, and moxibustion.²

In accordance with this definition, the scope of practice for a licensed acupuncturist, according to the California Acupuncture Board, includes not only acupuncture (needling), but also other treatments such as massage, moxibustion, and cupping, and the prescription of herbs as dietary supplements.

Acupuncture can be understood as either a broad or narrow modality of treatment. The former view is associated with traditional Chinese medicine; and the latter view, with what is sometimes referred to as “medical acupuncture.” It is the more narrow understanding of acupuncture as a technique to treat a particular disease or condition that has typically been incorporated into health care systems based on insurance and evaluations of medical effectiveness. The tension in the two views have been manifest in debates regarding the scope of practice of an acupuncturist in California, particularly over the implications of their role as primary care providers (Little Hoover Commission, 2004).³

¹ About 150 points, aligned along 14 main channels or meridians, are used in common practice, but upwards of 2,000 points have been identified (Kaptchuk, 2002).

² Electroacupuncture is a technique for stimulating an acupuncture point by sending a weak electric current through the metal needle. Cupping is a technique that involves warming small cup-like containers that are then placed on the skin, creating suction. Moxibustion is a technique that involves heating an acupuncture point by burning herbs.

³ In 2002, SB 1951 and AB 1943 requested the Little Hoover Commission to report on the State’s regulation of acupuncture and, specifically, to assess the scope of practice and educational requirements for acupuncturists. The Commission found that there is not clear statutory language regarding an acupuncturist’s authority to diagnose a patient and his or her role to serve as a primary care provider (and for example an acupuncturist’s authority to order medical tests), creating confusion about the role of the acupuncturist in the health care system.

Bill Description

Assembly Bill (AB) 54 is a provider mandate—that is, it requires coverage for treatments delivered by a particular profession, in this case, acupuncturists. It applies to every health care service plan that provides coverage for hospital, medical, or surgical expenses and to every issuer of health insurance.⁴ Although acupuncture can be used to treat dental pain, the bill mandate does not apply to specialized health care plans, such as dental plans. The bill amends Section 1373.10 of the Health and Safety Code and Section 10127.3 of the Insurance Code, and it:

- Expands a current mandate to offer coverage into a mandate to provide coverage, and removes exceptions.
- Mandates coverage for expenses incurred as a result of treatment by holders of a license to practice acupuncture, as defined by Section 4938 of the Business and Professions code.
- Applies to group contracts or policies. The market for individually purchased health insurance is not affected by this bill.
- The coverage shall be under terms and conditions as may be agreed upon by the health plan and group contract holder or health insurer and group policyholder.

The Council of Acupuncture and Oriental Medicine Associations is sponsoring the bill. The Council and bill author intend to make acupuncture more accessible to Californians. The sponsor notes that acupuncture is an accepted modality of treatment within the California Worker's Compensation System and contends that acupuncture can be an effective treatment, can be less costly than surgery, and sometimes is the preferred treatment among ethnic minorities.

State Activity

California

The Department of Managed Health Care (DMHC) solicits public comments on some of the topics it is considering for evaluation. It is currently accepting comments on acupuncture plans (<http://wps0.dmhc.ca.gov/regulations/#issues>) although this is not a forum for consumer complaints.⁵

The California Worker's Compensation system includes acupuncture within its treatment guidelines and is currently in the process of promulgating a medical treatment utilization schedule for acupuncture. Acupuncture is considered indicated for neck and upper back

⁴ Health care service plans, commonly referred to as health maintenance organizations, are regulated and licensed by the California Department of Managed Health Care (DMHC), as provided in the Knox-Keene Health Care Services Plan Act of 1975. The Knox-Keene Health Care Services Plan Act is codified in the California Health and Safety Code. Health insurance policies are regulated by the California Department of Insurance and are subject to the California Insurance Code.

⁵ DMHC has collected approximately 129 consumer complaints related to acupuncture across a wide range of issues, making it difficult to draw any general conclusion (Personal communication with S Lowenstein, DMHC, June 2007.)

complaints; elbow complaints; forearm, wrist, and hand complaints; low back complaints; knee complaints; ankle and foot complaints; and pain, suffering, and the restoration of function associated with these conditions. The guidelines allow for the extension of the acupuncture treatment schedule if functional improvement is shown (Title 8, California Code of Regulations, section 9792.20 et seq. Final Text of Regulations—May 2007).

Other States

A number of other states have had legislative activity around coverage for acupuncture. In 1996, Washington State passed a law requiring that health insurance plans provide access to every category of licensed health care provider. (Lafferty et al., 2006; WA State Office of the Insurance Commissioner). Oregon has introduced legislation (2007 OR HB 2348) that would require coverage of acupuncture, and provider mandates for acupuncturists were introduced in Vermont and West Virginia in 2006 (Plaza, 2006).

CHBRP Bill Analysis Approach

The impact of the proposed benefit mandate is dependent on future changes in the Business and Professions code and determinations of scope of practice. Because the mandate is not restricted to particular conditions or diseases, CHBRP necessarily limits the analysis of the bill's impact. CHBRP does not evaluate treatments other than acupuncture (needling) for this report. Based on the CHBRP current coverage survey, current coverage for acupuncture does not include herbs used as dietary supplements.⁶ CHBRP assumes the terms of coverage with regard to herbal supplements will remain the same postmandate.

The cost and public health impacts of the bill are contingent on California regulators' determinations regarding the bill's mandate to provide coverage "under terms and conditions as may be agreed upon" by a health plan/health insurer and a group contractholder/policyholder. These determinations would affect acupuncture benefit designs, such as the terms of cost sharing, limits on the number of visits, and other annual benefit limits. CHBRP has approached the analysis of the mandate by assuming that the current baseline level of benefits would be extended to all members with group health insurance. Moreover, CHBRP assumes the practices of utilization review and medical management would continue.

The mandate would apply to all enrollees in group plans; however, CHBRP has made the simplifying assumption to exclude persons under age 18 years due to low utilization of acupuncture services and lack of medical literature on its effectiveness on the under-age-18 population.

⁶ Dietary supplements are treated distinctly from drug products or "conventional" foods by the Food and Drug Administration (FDA).

MEDICAL EFFECTIVENESS

Numerous studies of the effectiveness of acupuncture have been conducted in Asia, Europe, and North America. CHBRP could not analyze all literature on the effectiveness of acupuncture during the time available for this analysis. Given this constraint, CHBRP decided to focus on the strongest and most current evidence. The review also emphasizes evidence regarding musculoskeletal and neurological conditions, because they are the types of conditions for which persons in the United States most frequently use acupuncture (Burke et al., 2006; Cherkin et al., 2002; Lafferty et al., 2006).

Literature Review Methods

Three types of literature on the effectiveness of acupuncture were reviewed. First, reports issued by the National Institutes of Health (NIH) in 1997 and by the Institute of Medicine (IOM) in 2005 were examined. Findings from these reports were based on systematic reviews of the literature on the effectiveness of acupuncture. CHBRP decided to rely on these reports for information about studies of acupuncture published before the literature review for the IOM report was conducted in March 2004.

The second and third components of the literature search concerned literature published since March 2004. The second component consisted of meta-analyses and systematic reviews on the effectiveness of acupuncture for treatment of any type of disease or condition published from 2004 to present. One systematic review on use of acupuncture to treat chronic headache that was published in 2001 was also included, because it is the most current systematic review of findings from studies of the effectiveness of acupuncture for treating this condition (Melchart et al., 2001).

The third component of the literature review was comprised of large, well-designed⁷ randomized controlled trials (RCTs) on headache, low back pain, neck disorders, and osteoarthritis that were published after the literature synthesized in the meta-analyses and systematic reviews. The review of individual RCTs focused on these four conditions, because they are among the most common reasons that persons in the United States use acupuncture and because several large, well-designed RCTs have been published on these topics since the most recent meta-analyses and systematic reviews were completed.

This literature review summarizes findings from the literature on the effectiveness of needling. CHBRP decided to focus on needling because this practice is unique to acupuncture and is

⁷ CHBRP defines “well-designed RCTs” as studies that have (1) sample sizes that are sufficiently large to detect statistically significant differences between the intervention and control groups (100 or more subjects), (2) low attrition rates (less than 20%) or use intent-to-treat methods, and (3) intervention and control groups that are statistically equivalent prior to the intervention with respect to baseline measures of the outcome and important factors associated with the outcome. In light of the 60-day timeline for the report, a decision was made to focus on studies that had the strongest research designs, because they would provide the most precise information about the effectiveness of acupuncture.

typically covered by health plans that provide acupuncture benefits. Studies of both manual acupuncture and electroacupuncture are included. Other procedures often performed by acupuncturists, such as acupressure massage, cupping, and moxibustion, are excluded. Studies of the effectiveness of herbal medications dispensed by acupuncturists are also excluded.

Methodological Considerations

Many of the RCTs included in the meta-analyses and systematic reviews that CHBRP assessed are of low quality (Acupuncture, 1997; Birch, 2006). Researchers who study acupuncture's effect on a single condition may needle different acupuncture points or may needle trigger points instead of acupuncture points (Kaptchuk, 2002; Lewith et al., 2006). In many cases, the sample sizes are too small to provide conclusive evidence of acupuncture's effectiveness. Acupuncture treatments are often not standardized, which makes it difficult to determine whether everyone in a treatment group received the same treatment. Many articles published about these RCTs do not report sufficient information regarding the blinding of subjects and concealment of allocation of subjects to treatment and control groups from researchers analyzing data collected during the study. In 2002, researchers studying acupuncture established the Standards for Reporting Interventions in Controlled Trials in Acupuncture (STRICTA) recommendations to promote better reporting of study results (MacPherson et al. 2002). Recently, researchers have begun publishing comprehensive reports of findings from large, well-designed RCTs on acupuncture (LeWITH et al., 2006).

There is also considerable disagreement about how studies of acupuncture should be designed (Birch, 2006; Langevin et al., 2006; Lewith et al., 2006). Some researchers believe that acupuncture should be compared to "sham acupuncture," a technique that often involves inserting needles in parts of the body other than known acupuncture points. Comparing acupuncture to sham acupuncture reduces the likelihood that participants will be able to guess correctly whether they are in the treatment or control group, which is likely to reduce attrition in the control group. This design also enables researchers to isolate the effect of acupuncture from the placebo effect of receiving treatment. However, there is a growing body of evidence that sham acupuncture is not an inert placebo, because inserting needles in any part of the body elicits a physiological response (Birch, 2006; Langevin et al., 2006; NIH, 1997). Researchers have investigated various methods for administering sham acupuncture without inserting needles (e.g., poking the skin with a toothpick in a guidetube), although there is some evidence that even noninvasive sham acupuncture may induce a physiological response, especially if performed at acupuncture points (Birch, 2006; Kaptchuk, 2002; Langevin et al., 2006; Sherman et al., 2002; Tsukayama et al., 2006). The best design for studies of acupuncture seems to be a three-armed design in which acupuncture is compared to sham acupuncture and either no treatment or another treatment (Langevin et al., 2006).

Comparison of acupuncture with other treatments or as an adjuvant to other treatments is important because other treatments are available for many of the diseases and conditions for which persons in California use acupuncture. For example, analgesic medications, exercise, massage, physical therapy, spinal manipulation (i.e., chiropractic care), steroid injections, and surgery are widely used to treat pain associated with musculoskeletal conditions. Consumers and health professionals need to know how effective acupuncture is relative to other treatments and

whether combining acupuncture with another treatment is more effective than either acupuncture or the other treatment alone.

Outcomes Assessed

The health outcomes assessed vary by disease or condition. Most studies of the effectiveness of acupuncture for musculoskeletal and neurological conditions assess effects on pain and functioning. A few studies on these conditions assess other outcomes such as health status, quality of life, absences from work, and return to work. The primary outcomes evaluated in studies of acupuncture's effects on chemotherapy-induced and postoperative nausea and vomiting are reductions in these side effects of chemotherapy and surgery. Studies of effects of acupuncture as a treatment for cocaine dependence and for smoking cessation are primarily concerned with effects on abstinence.

Study Findings

Findings from the studies included in this review are summarized below. They are grouped by type of comparison (i.e., acupuncture versus no treatment, acupuncture versus sham acupuncture, acupuncture versus other treatments, acupuncture plus other treatments versus other treatments). Findings regarding the effects of acupuncture on a specific disease or condition may be dispersed across all four categories of comparisons. CHBRP decided to organize the findings by type of comparison rather than by disease or condition, because AB 54 would not limit coverage for acupuncture to any specific diseases or conditions. Presenting findings by type of comparison enables policymakers to more easily assess acupuncture's effectiveness across the wide range of diseases and conditions that have been studied.

Two summaries of the findings from the literature review appear at the end of this section of the report. The first summary is a set of bullet points that summarize findings by type of comparison that appears on pages 28 and 29. The second summary is a table that presents findings by type of disease and condition for which the effectiveness of acupuncture was evaluated. This table begins on page 30. Appendix C contains two tables that provide additional information. Table C-2 in Appendix C contains more detailed information on the studies' findings. Table C-1 in Appendix C lists the studies reviewed and describes their characteristics. Appendix B describes the terminology that CHBRP uses to rate the evidence of the effectiveness of interventions.

Acupuncture versus No Treatment

Musculoskeletal conditions

Four meta-analyses and systematic reviews on the effectiveness of acupuncture relative to no treatment for musculoskeletal conditions have been published from 2004 to the present.⁸ The four studies reported that the preponderance of evidence from RCTs suggests that acupuncture is

⁸ In some studies that compared acupuncture to no treatment, persons in both the treatment and the control group were permitted to use over-the-counter (OTC) analgesic medications (e.g., ibuprofen, naproxen) that health plans typically do not cover. Subjects were not allowed to take medications that required a prescription or to use services provided by a health professional (e.g., massage, physical therapy).

an effective treatment for chronic low back pain, neck disorders, osteoarthritis of the knee, and temporomandibular joint dysfunction relative to no treatment (Furlan et al., 2005; McNeely et al., 2006; Trinh et al., 2006; White et al., 2006a; White et al. 2007).⁹ Five RCTs published subsequent to the studies included in the meta-analyses and systematic reviews (Brinkhaus et al., 2006; Thomas et al., 2006; Witt et al., 2006a; Witt et al., 2006b; Witt et al., 2006c) confirmed the studies' findings regarding chronic low back pain, neck disorders, and osteoarthritis of the knee. These RCTs had larger samples and were of higher quality than the RCTs on these conditions that were included in the meta-analyses and systematic reviews. Collectively, the studies contained in the meta-analyses and systematic reviews and those published subsequently found that acupuncture reduced pain associated with these musculoskeletal conditions and improved functioning in the short-term.

Overall, the preponderance¹⁰ of evidence suggests that acupuncture is an *effective* treatment for chronic low back pain, neck disorders, osteoarthritis of the knee, and temporomandibular joint dysfunction relative to no treatment.¹¹

Neurological conditions

A systematic review of studies of the effectiveness of acupuncture for the treatment of headache also found that a preponderance of evidence suggests that acupuncture is effective relative to no treatment (Melchart et al., 2001). Three large, well-designed RCTs on this topic that were published subsequent to the systematic review confirmed this finding (Linde et al., 2005; Melchart et al., 2005; Vickers et al., 2004a). Findings from studies that exclusively assessed persons with migraine (Linde et al., 2005) and tension-type (Melchart et al., 2005) headaches were consistent, suggesting that acupuncture is equally effective for both types of headaches relative to no treatment.

⁹ White and colleagues published two versions of the same meta-analysis on the effectiveness of acupuncture for treatment of osteoarthritis of the knee (White et al., 2006b; White et al., 2007). CHBRP has included both versions in its review because each version contains pertinent material that does not appear in the other version.

¹⁰ The term “preponderance” is defined on page 51 in Appendix B.

¹¹ There are increasing concerns that persons who participate in RCTs may not be representative of persons who use the treatments studied outside clinical trials. If persons enrolled in an RCT are not representative, the results may not be generalizable. Three studies have addressed the generalizability of findings from RCTs on the effectiveness of acupuncture for chronic low back pain, neck disorders, and osteoarthritis (Witt et al., 2006a; Witt et al., 2006b; Witt et al., 2006c). These three studies capitalized on a policy change in Germany under which patients were reimbursed for acupuncture services only if they agreed to participate in studies of the effectiveness of acupuncture. Persons could elect to either enroll in a RCT or participate in a nonrandomized cohort. The study on osteoarthritis found that the participants in the RCT and nonrandomized cohort were similar at baseline and reported similar outcomes following receipt of acupuncture (Witt et al., 2006b). Thus, the study suggests that the favorable results of the RCT on acupuncture for osteoarthritis are generalizable to the population that has this condition. In contrast, the studies on chronic low back pain and neck disorders found that persons who enrolled in the RCTs had less severe pain at baseline than persons in the nonrandomized cohorts (Witt et al., 2006a; Witt et al., 2006c). After adjusting for baseline differences, the study on low back pain found that acupuncture was equally effective for persons in the RCT and the nonrandomized cohort. The study on neck disorders found slightly greater improvement among persons in the nonrandomized cohort even after adjusting for baseline differences. Overall, the low back pain and neck pain disorder studies suggest that persons enrolled in RCTs are not representative of the populations with these conditions, but that their responses to acupuncture treatment were similar.

The preponderance of evidence suggests that acupuncture is an *effective treatment* for chronic headache relative to no treatment.

Addiction disorders

There is also some evidence that acupuncture may be more effective than no treatment in facilitating abstinence from smoking. One meta-analysis identified three RCTs that compared acupuncture to no treatment for smoking cessation (White, et al., 2006b). The authors pooled the results of the three RCTs and found that persons who received acupuncture were 1.9 times more likely to abstain from smoking 6 to 12 months after the study ended than persons who received no treatment. The difference approached statistical significance ($p = 0.06$). However, this finding should be interpreted with caution because the pooled estimate depends heavily on the results of the largest of the three RCTs included, which accounted for over half of the observations included in the pooled analysis.

The evidence suggests that acupuncture *may be more effective* than no treatment in facilitating smoking cessation.

Acupuncture versus Sham Acupuncture

One major limitation of studies that compare acupuncture to no treatment is that they cannot rule out the possibility that improvements that occur in the treatment group are due to a placebo effect. People who receive acupuncture may experience relief from their symptoms because they believe acupuncture will help them and not because acupuncture stimulates a physiological response. Several studies have found that persons who have high expectations of acupuncture are more likely to report improvement in outcomes than persons who have low expectations (Bausell et al., 2005; Kalauokalani et al., 2001; Linde et al., 2007b). Improvement may also be due solely to the attention persons receive from acupuncturists or acupuncturists' enthusiasm about the treatments they provide (Kaptchuk, 2002; Langevin et al., 2006). As discussed above, researchers have recommended that studies should compare acupuncture to "sham acupuncture." However, these studies may understate the effects of acupuncture, because there is evidence that sham acupuncture is not an inert placebo, especially if it involves needling. In addition, there is no consensus as to what constitutes an appropriate sham treatment. For this reason, CHBRP presents findings from meta-analyses, systematic reviews, and RCTs that compare acupuncture to sham acupuncture as reported and does not critique the appropriateness of the sham treatments that were used.

Musculoskeletal conditions

Eight meta-analyses and systematic reviews have assessed the effectiveness of acupuncture versus sham acupuncture for treatment of musculoskeletal conditions.

The meta-analyses and systematic reviews found that acupuncture is more effective than sham acupuncture for treatment of three conditions: osteoarthritis of the knee, neck disorders, and lateral elbow pain. A meta-analysis of studies of acupuncture versus sham acupuncture for osteoarthritis of the knee found that acupuncture was associated with a small reduction in pain in six of seven RCTs that measured this outcome and with a small improvement in function in three

of three RCTs (White et al., 2006a; White et al., 2007). Two systematic reviews that examined four RCTs and controlled clinical trials (CCTs) that compared acupuncture to sham acupuncture for lateral elbow pain reported that a preponderance of evidence suggested that acupuncture was more effective than sham acupuncture in reducing pain and functional impairment in the short-term (Green et al., 2002; Trinh et al., 2004). A meta-analysis of studies of acupuncture versus sham acupuncture for neck disorders reached the same conclusion (Trinh et al., 2006).

Findings regarding the effects of acupuncture relative to sham acupuncture on chronic low back pain and shoulder pain were ambiguous. One meta-analysis and one large RCT published subsequent to the meta-analysis compared acupuncture to sham acupuncture for treatment of chronic low back pain. Two of the four RCTs included in the meta-analysis found that acupuncture was associated with a statistically significant decrease in pain, but the other two did not (Furlan et al., 2005). The large, well-designed RCT published subsequent to the meta-analysis on low back pain found no difference in the change in intensity of pain, function, or disability 8 weeks after randomization, although it also found that acupuncture was associated with better health status and less use of analgesic medication. (Brinkhaus et al., 2006). Similarly, a systematic review of three RCTs that compared acupuncture to sham acupuncture for shoulder pain found that two of the three RCTs reported no statistically significant difference in pain and the other reported a small, statistically significant improvement in functioning (Green et al., 2005).

There was insufficient evidence to determine whether acupuncture is more effective than sham acupuncture for treatment of acute low back pain, osteoarthritis of the hip and thumb, rheumatoid arthritis, and temporomandibular joint dysfunction, because the only RCTs that assessed these outcomes had samples that were so small that they may not have had adequate power to detect statistically significant difference. The meta-analysis on low back pain found only one small RCT (n = 40) that compared acupuncture to sham acupuncture for treatment of acute low back pain. The study found no difference in pain. One meta-analysis identified two small RCTs that compared acupuncture to sham acupuncture for treatment of osteoarthritis of the hip and thumb, respectively, both of which reported no statistically significant difference in pain (Kwon et al., 2006). Similarly, a systematic review on acupuncture versus sham acupuncture for rheumatoid arthritis found only two RCTs that had small sample sizes and which reported no statistically significant differences (Casimiro et al., 2005). Likewise, a systematic review of acupuncture and other complementary and alternative treatments for temporomandibular joint dysfunction found only one small RCT (n = 18) that compared acupuncture to sham acupuncture. This RCT also reported no statistically significant difference in pain.

The preponderance of evidence suggests that acupuncture is *more effective* than sham acupuncture for treatment of osteoarthritis of the knee, neck disorders, and lateral elbow pain. The evidence of the effectiveness of acupuncture relative to sham acupuncture on chronic low back pain and shoulder pain is *ambiguous*. There is *insufficient evidence*¹² to determine whether acupuncture is more effective than sham acupuncture for acute low back pain, osteoarthritis of the hip and thumb, rheumatoid arthritis, and temporomandibular joint dysfunction.

¹² Definitions of the terms “ambiguous” and “insufficient” appear on pages 51 and 52 in Appendix B.

Neurological conditions

Three meta-analyses and systematic reviews sought to examine the effectiveness of acupuncture versus sham acupuncture on neurological conditions. One systematic review synthesized findings from 15 small RCTs and CCTs that compared acupuncture to sham acupuncture for treatment of migraine and/or tension-type headaches. The preponderance of evidence from these studies suggests that acupuncture is more effective than sham acupuncture for treatment of headache. However, this finding was only replicated in one of three large, high-quality RCTs published subsequent to the systematic review. Diener and colleagues reported that acupuncture was associated with statistically significant reductions in the number of days with migraine and impairment of activity and with better health status relative to sham acupuncture 26 weeks after treatment was completed (Diener et al., 2006). However, the differences are so small (e.g., 2.3 fewer days with migraine for acupuncture versus 1.5 fewer days for sham acupuncture) that they probably are not clinically important. The other two large RCTs published subsequent to the systematic review found no difference between acupuncture and sham acupuncture for any of the outcomes they measured for treatment of migraine and tension-type headaches, respectively (Linde et al., 2005; Melchart et al., 2005)¹³

Few RCTs have been conducted on the effects of acupuncture on other neurological conditions. A meta-analysis of studies of acupuncture for epilepsy (Cheuk and Wong, 2006) found one RCT that compared acupuncture to sham acupuncture. That study reported no statistically significant difference in the frequency and duration of seizures or quality of life. A systematic review of studies of the effectiveness of acupuncture versus sham acupuncture for treatment of vascular dementia was also attempted (Peng et al., 2007). However, the authors did not report any results because none of the studies on vascular dementia had randomized subjects or compared acupuncture to sham acupuncture.

Overall the preponderance of evidence suggests that acupuncture is *at most marginally more effective* than sham acupuncture in relieving chronic headache. There is *insufficient evidence* to determine whether acupuncture is more effective than sham acupuncture for treatment of epilepsy or vascular dementia.

Addiction disorders

Two meta-analyses evaluated the effectiveness of acupuncture versus sham acupuncture for treatment of addiction. The authors of one meta-analysis synthesized findings from six RCTs and concluded that the preponderance of evidence suggested that acupuncture was no more effective than sham acupuncture in increasing abstinence from smoking (White et al., 2006b). A second

¹³ As with musculoskeletal conditions, questions have arisen regarding the generalizability of findings from RCTs to the population of acupuncture users. The authors of one of the large RCTs on acupuncture for migraine headache addresses these questions by comparing the results of their RCT to the results of an observational study that they conducted simultaneously in the same country (Germany) (Linde et al., 2007a). They found that persons who enrolled in the RCT and received acupuncture were more highly educated, had experienced chronic headache for a longer period of time, and had more frequent headaches, but had better physical and mental health than persons who participated in the observational study. With regard to response to treatment, persons in the observational study reported greater reductions in the number of days with headache but similar improvements in physical and mental health. Thus, persons in the observational study received as much if not greater benefit from acupuncture than persons in the RCT.

meta-analysis identified one RCT that compared auricular acupuncture¹⁴ to sham auricular acupuncture for treatment of cocaine dependence (Gates et al., 2006). That study found that acupuncture was no more effective than sham acupuncture in reducing use of cocaine 8 weeks following treatment.

The preponderance of evidence suggests that acupuncture is *no more effective* than sham acupuncture in facilitating smoking cessation or recovery from cocaine dependence.

Nausea and vomiting associated with other treatments

Two meta-analyses have assessed the effects of acupuncture versus sham acupuncture on nausea and vomiting associated with other treatments. Because this report focuses on needling, only findings from the RCTs included in these meta-analyses that examined needling are discussed. RCTs that evaluated noninvasive acupressure devices, such as wrist bands that stimulate acupuncture points, are excluded. A meta-analysis of studies of the effect of acupuncture on chemotherapy-induced nausea and vomiting found only one RCT that compared acupuncture needling to sham acupuncture (Ezzo et al., 2006). This single RCT found no statistically significant difference in severity of nausea or percentage of patients vomiting within 24 hours of chemotherapy. Another meta-analysis synthesized the results of four RCTs on the effectiveness of acupuncture versus sham acupuncture for the treatment of postoperative nausea and vomiting in women. The authors found that acupuncture reduced the probability that a patient would experience postoperative nausea by 37% but did not affect the probability that a patient would vomit (Lee and Done, 2004). An RCT that was not included in the meta-analysis reported that acupuncture was associated with a statistically significant reduction in postoperative vomiting but did not affect postoperative nausea (Streitberger et al., 2004).

Overall, the preponderance of evidence suggests that acupuncture is *more effective* than sham acupuncture in preventing postoperative nausea and vomiting. There is *insufficient evidence* to determine whether acupuncture is more effective than sham acupuncture in preventing chemotherapy-induced nausea and vomiting.

Acupuncture versus Other Treatments

Musculoskeletal conditions

Eight meta-analyses and systematic reviews reported findings from RCTs and CCTs that compared acupuncture to other treatments for musculoskeletal conditions.

The meta-analyses and systematic reviews found that acupuncture was more effective than certain other treatments for two conditions: osteoarthritis of the knee and pelvic pain during pregnancy. Two meta-analyses synthesized findings from RCTs that compared acupuncture to other treatments for osteoarthritis of the knee (Kwon et al., 2006; White et al., 2006a; White et al., 2007). Two RCTs included in these meta-analyses compared acupuncture to medication and

¹⁴ Auricular acupuncture involves the insertion of acupuncture needles into points in the outer ear. Needling these points (either manually or with electroacupuncture) is hypothesized to send signals via the brain to stimulate healing in the parts of the body associated with these points.

reported that acupuncture was associated with greater reduction in pain and functional impairment and that the difference was statistically significant. Two RCTs compared acupuncture to education about coping with osteoarthritis. One RCT found that acupuncture was associated with a statistically significant improvement in these outcomes and another reported a trend toward a statistically significant improvement. Another RCT reported that acupuncture and transcutaneous electrical nerve stimulation (TENS) were equally effective in treating osteoarthritis of the knee.

A systematic review (Pennick and Young, 2007) summarized findings from two RCTs that compared acupuncture to other treatments for low back pain and pelvic pain in pregnant women. One RCT found that pregnant women who were treated with acupuncture were more likely to report that their treatment was effective relative to women treated with physical therapy. The other RCT found that pregnant women who received acupuncture were more likely to report a decrease in intensity of pain than women treated with a combination of analgesics, physical therapy, sacroiliac belt, and TENS.

Findings from a systematic review summarized findings from three RCTs that compared acupuncture to occlusal splints and other standard stomatognathic treatments for temporomandibular joint dysfunction suggest that the two types of treatments are equally effective (Ernst and White, 1999). In all three RCTs, treatment with acupuncture was found to be as effective as conventional treatments in reducing dysfunction and improving subjects' pressure pain thresholds and ability to perform activities of daily living.

One systematic review of RCTs on lateral elbow pain found ambiguous evidence regarding the effectiveness of acupuncture relative to ultrasound (Trinh et al., 2004). The authors identified two small RCTs on this topic. One of the RCTs reported that persons who obtained acupuncture experienced greater reduction in pain and functional impairment than persons who received ultrasound. The other RCT found no difference in reduction in pain. However, the sample size was so small ($n = 17$) that the study probably did not have sufficient power to detect statistically significant differences between the effects of the two treatments.

There was insufficient evidence to determine how effective acupuncture is relative to other treatments for acute and chronic low back pain, neck disorders, shoulder pain, and osteoarthritis of the hip. For each condition, few RCTs compared acupuncture to the same alternate treatment. In addition, most RCTs had small samples which may not have yielded adequate power to detect statistically significant differences between treatments.

One meta-analysis summarized findings from four RCTs that compared acupuncture to five other treatments for chronic low back pain: education, massage, medication, spinal manipulation, and TENS (Furlan et al., 2005). RCTs that compared acupuncture to massage and spinal manipulation found that acupuncture was less effective than these treatments in decreasing pain and functional impairment associated with chronic low back pain. In contrast, RCTs that compared acupuncture to education, medication, and TENS found that acupuncture was equally effective in improving these outcomes. The meta-analysis on acupuncture for low back pain (Furlan et al., 2005) also identified one RCT that compared acupuncture to naproxen¹⁵ for

¹⁵ Naproxen is the generic name for the brand name drug Aleve.

treatment of acute low back pain. This RCT found that the two treatments were equally effective in alleviating pain.

Another meta-analysis evaluated three RCTs that compared acupuncture to three other treatments for neck disorders: massage, mobilization, and traction (Trinh et al., 2006). In an RCT that compared acupuncture to massage, persons who obtained acupuncture reported a greater reduction in the intensity of neck pain than persons who obtained massage; this difference was statistically significant. An RCT that compared acupuncture to traction also reported that persons who received acupuncture experienced a greater reduction in the intensity of neck pain, but the difference was not statistically significant. A third RCT found that acupuncture was as effective as mobilization in reducing the intensity of pain.

A systematic review examined two RCTs that compared acupuncture to three other treatments for shoulder pain: regional nerve block, steroid injection, and ultrasound. The RCT that compared acupuncture to a regional nerve block found that persons who received acupuncture were slower to obtain relief from pain and were less likely to report a reduction in pain 30 hours after treatment (Green et al., 2005). One small RCT compared acupuncture to both steroid injection and ultrasound. The authors reported no difference in pain.

The meta-analysis published by Kwon and colleagues (2006) summarized findings from two small RCTs that assessed the effectiveness of acupuncture relative to other treatments for osteoarthritis of the hip. One RCT found that acupuncture was more effective than advice and exercise in reducing pain. In contrast, the other RCT found that acupuncture and education were equally effective.

The preponderance of evidence suggests that acupuncture is *more effective* than medication or education for treating osteoarthritis of the knee and *more effective* than physical therapy for pelvic pain associated with pregnancy. Acupuncture is *as effective as* occlusal splints for treatment of temporomandibular joint dysfunction. The evidence of the effectiveness of acupuncture relative to other treatments for lateral elbow pain is *ambiguous*. There is *insufficient evidence* to assess the effectiveness of acupuncture relative to other treatments for acute and chronic low back pain, neck disorders, shoulder pain, and osteoarthritis of the hip.

Neurological conditions

One systematic review (Melchart et al., 2001) and one large, well-designed RCT published subsequent to the systematic review (Diener et al., 2006) compared acupuncture to other treatments for chronic headache. The systematic review summarized findings from nine RCTs that assessed the effectiveness of acupuncture relative to four other treatments: medication, biobehavioral therapy, physical therapy, and a combination of massage and relaxation (Melchart et al., 2001). Three of the four RCTs that compared acupuncture to medication found that acupuncture was more effective for treatment of various types of headaches. A large RCT published subsequent to the systematic review (Diener et al., 2006) found that acupuncture was more effective than prophylactic medication in reducing the intensity of pain and impairment of activity associated with migraine headache and was also associated with improvement in physical health status. In addition, an RCT that investigated the effectiveness of acupuncture

relative to massage and relaxation found that acupuncture was more effective than massage and relaxation for treatment of migraine headache but less effective for treatment of tension-type headaches. Findings from two RCTs that compared acupuncture to physical therapy for tension-type headache were equivocal. An RCT that compared acupuncture to biobehavioral therapy for migraine headache reported no statistically significant differences in outcomes (Melchart et. al., 2001).

Overall, the RCTs that compared acupuncture to other treatments for chronic headache suggest that acupuncture is *more effective* than medication. There is *insufficient evidence* to determine how effective acupuncture is relative to nonpharmacological treatments for chronic headache.

Addiction disorders

One meta-analysis synthesized findings from three RCTs that compared acupuncture to behavioral therapy for smoking cessation (White et al., 2006b). The authors pooled findings from the three RCTs and found no statistically significant difference in the odds of abstinence from smoking 6 months after treatment. The meta-analysis also included a large RCT that reported no difference in odds of abstinence from smoking 13 months after treatment for persons who received acupuncture or nicotine gum.

This meta-analysis suggests that acupuncture is *as effective as* behavioral therapy or nicotine replacement gum in facilitating abstinence from smoking.

Nausea and vomiting associated with other treatments

One meta-analysis synthesized findings from five RCTs that compared the effects of acupuncture and antiemetic medications on nausea and vomiting after surgery (Lee and Done, 2004). Five of five RCTs that compared acupuncture to five different antiemetics reported acupuncture and antiemetics were equally effective in reducing the risk of postoperative vomiting. Similarly, two of three RCTs that compared acupuncture to three different antiemetics found no statistically significant difference in the probability of experiencing nausea.

The preponderance of evidence suggests that acupuncture is *as effective as* antiemetic medication in reducing the risk of postoperative nausea and vomiting.

Acupuncture Needling Plus Other Treatments versus Other Treatments (i.e., Acupuncture Needling Used as an Adjuvant Treatment)

Musculoskeletal conditions

Six meta-analyses and systematic reviews reported findings from RCTs that examined the effectiveness of acupuncture as an adjuvant treatment for musculoskeletal conditions.

The meta-analyses and systematic reviews found that acupuncture is an effective adjuvant to certain other treatment for three musculoskeletal conditions: chronic low back pain, osteoarthritis of the knee, and low back and pelvic pain associated with pregnancy.

One meta-analysis synthesized findings from four RCTs that assessed the effectiveness of acupuncture as an adjuvant treatment for chronic low back pain (Furlan et al., 2005). These four RCTs evaluated the impact of combining acupuncture with four other treatment regimens: physical therapy, exercise plus education, exercise plus medication, and exercise plus physical therapy. All four RCTs reported that adding acupuncture to other treatments was associated with a greater decrease in pain and functional impairment than the comparison treatments alone and that the difference was statistically significant.

Two meta-analyses synthesized findings from four RCTs that evaluated the effectiveness of acupuncture as an adjuvant treatment for osteoarthritis of the knee (Kwon et al., 2006; White et al., 2006a; White et al., 2007). Three of the RCTs examined the effect of combining acupuncture with medication, and one assessed the combination of acupuncture and physical therapy. Two of the three RCTs on medication reported that adding acupuncture to medication was associated with greater decreases in pain and impairment in functioning than medication alone and that these differences were statistically significant. Adding acupuncture to physical therapy did not enhance its effectiveness.

The systematic review that summarized findings from RCTs on the effectiveness of acupuncture for treatment for low back pain and pelvic pain in pregnant women (Pennick and Young, 2007) identified one large RCT (n = 386) that assessed the effectiveness of acupuncture as an adjuvant treatment for pelvic pain. This RCT found that pregnant women who received acupuncture in addition to education and a pelvic belt experienced a 20% decrease in the risk of pain when turning in bed than pregnant women who only received education and a pelvic belt.

Findings regarding the effects of acupuncture as an adjuvant treatment for fibromyalgia were ambiguous. A systematic review identified five RCTs that investigated the effectiveness of acupuncture as an adjuvant to conventional treatments for fibromyalgia (Mayhew and Ernst, 2007). Three of the five RCTs reported that adding acupuncture to conventional treatments was associated with a small but statistically significant decrease in pain. However, the results are difficult to generalize across the RCTs because their authors used different instruments to assess effects on pain and other outcomes.

There is insufficient evidence to determine whether acupuncture is an effective adjuvant treatment for shoulder pain. The authors of a systematic review that assessed the effectiveness of acupuncture as an adjuvant treatment for shoulder pain identified two RCTs that examined acupuncture as an adjuvant to exercise and to mobilization, respectively (Green et al., 2005). One RCT reported that adding acupuncture to exercise is more effective than exercise alone in reducing pain and improving range of motion and functioning. The other RCT found that combining acupuncture and mobilization does not improve outcomes relative to mobilization alone. However, it is difficult to draw any conclusions from these studies because both have such small sample sizes that they may not have adequate power to detect statistically significant differences in outcomes.

The preponderance of evidence suggests that acupuncture is an *effective* adjuvant treatment for chronic low back pain and pelvic pain associated with pregnancy. The evidence of the effectiveness of acupuncture as an adjuvant treatment for fibromyalgia and osteoarthritis of the knee is *ambiguous*. There is *insufficient evidence* to determine whether acupuncture is an effective adjuvant treatment for shoulder pain.

Neurological conditions

Two meta-analyses have synthesized findings from RCTs and CCTs that examined the effectiveness of acupuncture as an adjuvant treatment for stroke (Wu et al., 2006; Zhang et al., 2005). One meta-analysis (Zhang et al., 2005) summarized findings from 14 RCTs and CCTs that assessed the effectiveness of combining acupuncture with medication, occupational therapy, physical therapy, and other standard treatments for the acute phase of stroke (i.e., from 0 to 30 days since occurrence). These studies found that adding acupuncture to standard treatments was associated with statistically significant reductions in the risk of requiring institutional care and the risk of dependency on others to perform activities of daily living and with better neurological functioning. However, these studies found that adding acupuncture did not reduce the risk of death or enhance motor function or quality of life. The other meta-analysis (Wu et al., 2006) summarized three RCTs that evaluated the effectiveness of acupuncture as an adjuvant treatment for stroke during the subacute phase (1 to 3 months since onset) or the chronic phase (over 3 months since onset). In these RCTs, adding acupuncture to standard treatments was associated with statistically significant improvement in neurological functioning but had no effect on motor function.

These meta-analyses suggest that combining acupuncture with standard treatments *improves* most outcomes for persons who have had a stroke.

Addiction disorders

Meta-analyses have been conducted on the effectiveness of acupuncture as an adjuvant treatment for cocaine dependence (Gates et al., 2006) and nicotine addiction (White et al., 2006b). The meta-analysis on cocaine dependence identified six RCTs that examined whether acupuncture enhanced the effectiveness of methadone, neurobehavioral treatment, or multicomponent residential or inpatient treatment. The pooled estimate of findings from RCTs that measured cocaine use in similar ways found no statistically significant difference in the probability of use. Three of four RCTs that examined whether acupuncture is an effective adjuvant treatment for cocaine dependence found that adding acupuncture did not reduce craving for cocaine (Gates et al., 2006).

The meta-analysis on smoking cessation identified three RCTs that assessed whether acupuncture improved the probability of abstinence from smoking when combined with counseling, education, or nicotine replacement therapy. None of these three RCTs provided conclusive evidence that adding acupuncture to any of these treatments enhanced effectiveness (White et al., 2006b).

These findings suggest that acupuncture is *not an effective* adjuvant treatment for cocaine dependence or smoking cessation.

Nausea and vomiting associated with other treatments

One meta-analysis synthesized findings from three RCTs that examined whether electroacupuncture is an effective adjuvant treatment for chemotherapy-induced vomiting (Ezzo et al., 2006).¹⁶ The RCTs compared persons who received electroacupuncture plus antiemetic medications to persons who received only antiemetics. A pooled estimate of the findings from the three RCTs suggests that combining acupuncture and antiemetics reduces the probability that a patient will experience chemotherapy-induced vomiting. However, the antiemetic regimens prescribed to patients were not consistent with the American Society of Clinical Oncology's recommendations (Ezzo et al., 2006). The results might differ if patients had received recommended antiemetic regimens. In addition, one very small RCT (n = 11) of the administration of manual acupuncture to children reported that combining acupuncture and antiemetic medication yielded a statistically significant reduction in use of rescue antiemetic medication but no difference in the risk of vomiting (Reindl et al., 2006).

The preponderance of evidence suggests that combining acupuncture and antiemetic medication *reduces the risk* of chemotherapy-induced nausea and vomiting.

Summary of Findings

Acupuncture needling versus no treatment

- The preponderance of evidence suggests that acupuncture needling is more effective than no treatment in reducing pain and improving the functioning of persons with chronic low back pain, neck disorders, osteoarthritis of the knee, temporomandibular joint dysfunction, and chronic headache.
- The evidence suggests that acupuncture needling may be effective in facilitating smoking cessation.

Acupuncture needling versus sham acupuncture

- The preponderance of evidence suggests that acupuncture needling is more effective than sham acupuncture for treatment of lateral elbow pain, neck disorders, osteoarthritis of the knee, headache, and postoperative nausea and vomiting.
- The preponderance of evidence suggests that acupuncture needling is not more effective than sham acupuncture for facilitating recovery from cocaine dependence and smoking cessation.

¹⁶ None of these studies investigated effects on chemotherapy-induced nausea.

- The evidence of the effectiveness of acupuncture needling relative to sham acupuncture for treatment of chronic low back pain, shoulder pain, and chronic headache is ambiguous.
- There is insufficient evidence to determine whether acupuncture needling is more effective than sham acupuncture for treatment of acute low back pain, osteoarthritis of the hip and thumb, rheumatoid arthritis, temporomandibular joint dysfunction, epilepsy, vascular dementia, and chemotherapy-induced nausea and vomiting.

Acupuncture needling versus other treatments

- The preponderance of evidence suggests that acupuncture needling is more effective than education or medication for treatment of osteoarthritis of the knee, more effective than physical therapy for treatment of pelvic pain associated with pregnancy, and more effective than medication for chronic headache.
- The preponderance of evidence suggests that acupuncture needling is as effective as other treatments for temporomandibular joint dysfunction, smoking cessation, and postoperative nausea and vomiting.
- The evidence of the effectiveness of acupuncture needling relative to other treatments for lateral elbow pain is ambiguous.
- There is insufficient evidence to determine whether acupuncture needling is more effective than other treatments for acute and chronic low back pain, neck disorders, osteoarthritis of the hip, and shoulder pain.

Acupuncture needling plus other treatments versus other treatments (i.e., acupuncture needling used as an adjuvant treatment)

- The preponderance of evidence suggests that acupuncture needling is an effective adjuvant treatment for chronic low back pain, pelvic pain associated with pregnancy, stroke, and chemotherapy-induced vomiting.
- The preponderance of evidence suggests that acupuncture needling is not an effective adjuvant treatment for facilitating recovery from cocaine dependence and smoking cessation.
- The evidence of the effectiveness of acupuncture needling as an adjuvant treatment for fibromyalgia and osteoarthritis of the knee is ambiguous.
- There is insufficient evidence to determine whether acupuncture needling is an effective adjuvant treatment for shoulder pain.

Table 2. Effectiveness of Acupuncture by Condition and Type of Comparison

Disease or Condition	Acupuncture vs. No Treatment	Acupuncture vs. Sham Acupuncture	Acupuncture vs. Other Treatments	Acupuncture plus Other Treatments vs. Other Treatments
Musculoskeletal Conditions				
Fibromyalgia	No meta-analysis or systematic review*	No meta-analysis or systematic review	No meta-analysis or systematic review	Ambiguous evidence
Lateral elbow pain	No meta-analysis or systematic review	Acupuncture more effective	Ambiguous evidence	No meta-analysis or systematic review
Low back pain, acute	No meta-analysis or systematic review	Insufficient evidence	Insufficient evidence	No meta-analysis or systematic review
Low back pain, chronic	Acupuncture effective	Ambiguous evidence	Insufficient evidence	Acupuncture is an effective adjuvant to education, exercise, medication, and physical therapy
Neck disorders	Acupuncture effective	Acupuncture more effective	Insufficient evidence	No meta-analysis or systematic review
Osteoarthritis of the hip	No meta-analysis or systematic review	Insufficient evidence	Insufficient evidence	No meta-analysis or systematic review
Osteoarthritis of the knee	Acupuncture effective	Acupuncture more effective	Acupuncture more effective than education and medication	Ambiguous evidence
Osteoarthritis of the thumb	No meta-analysis or systematic review	Insufficient evidence	No meta-analysis or systematic review	No meta-analysis or systematic review
Pelvic pain during pregnancy	No meta-analysis or systematic review	No meta-analysis or systematic review	Acupuncture more effective than physical therapy	Acupuncture is an effective adjuvant to education and pelvic belt
Rheumatoid arthritis	No meta-analysis or systematic review	Insufficient evidence	No meta-analysis or systematic review	No meta-analysis or systematic review
Shoulder pain	No meta-analysis or systematic review	Ambiguous evidence	Insufficient evidence	Insufficient evidence
Temporomandibular joint dysfunction	Acupuncture effective	Insufficient evidence	Acupuncture as effective as occlusal splints	No meta-analysis or systematic review

Disease or Condition	Acupuncture vs. No Treatment	Acupuncture vs. Sham Acupuncture	Acupuncture vs. Other Treatments	Acupuncture plus Other Treatments vs. Other Treatments
Neurological Disorders				
Epilepsy	No meta-analysis or systematic review	Insufficient evidence	No meta-analysis or systematic review	No meta-analysis or systematic review
Headache, chronic	Acupuncture effective	Ambiguous evidence	Acupuncture more effective than medication	No meta-analysis or systematic review
Stroke, acute phase	No meta-analysis or systematic review	No meta-analysis or systematic review	No meta-analysis or systematic review	Acupuncture is an effective adjuvant to medication, occupational therapy, physical therapy, and other standard treatments for most outcomes
Stroke, subacute and chronic phase	No meta-analysis or systematic review	No meta-analysis or systematic review	No meta-analysis or systematic review	Acupuncture is an effective adjuvant to standard treatments
Vascular dementia	No meta-analysis or systematic review	Insufficient evidence	No meta-analysis or systematic review	No meta-analysis or systematic review
Addiction Disorders				
Cocaine dependence	No meta-analysis or systematic review	Acupuncture no more effective	No meta-analysis or systematic review	Acupuncture is not an effective adjuvant to methadone, neurobehavioral treatment, or multi-component residential or inpatient treatment
Smoking cessation	Acupuncture may be effective	Acupuncture no more effective	Acupuncture as effective as behavioral therapy and nicotine replacement therapy	Acupuncture is not an effective adjuvant to counseling, education, or nicotine replacement therapy

Disease or Condition	Acupuncture vs. No Treatment	Acupuncture vs. Sham Acupuncture	Acupuncture vs. Other Treatments	Acupuncture plus Other Treatments vs. Other Treatments
Nausea and Vomiting				
Chemotherapy-induced nausea and vomiting	No meta-analysis or systematic review	Insufficient evidence	No meta-analysis or systematic review	Acupuncture is an effective adjuvant to antiemetic medication
Postoperative nausea and vomiting	No meta-analysis or systematic review	Acupuncture more effective	Acupuncture as effective as antiemetic medication	No meta-analysis or systematic review

* “No meta-analysis or systematic review” indicates that no meta-analyses or systematic reviews have been published on this topic since the literature review for the Institute of Medicine (IOM) report (2005) on complementary and alternative medicine was completed in March 2004. The IOM committee reviewed all Cochrane Reviews on the effectiveness of acupuncture published through March 2004 but only reported findings from the one Cochrane Review that reported that acupuncture was an effective treatment. That Cochrane Review (Melchart et al., 2001), which concerns the use of acupuncture to treat chronic headache, is included in this literature review.

UTILIZATION, COST, AND COVERAGE IMPACTS

AB 54 would require Knox-Keene licensed health care service plan contracts and insurance policies sold in the *group market* to provide coverage for acupuncture services. According to CHBRP's estimates, there are 17.95 million insured Californians currently enrolled in group health plans regulated under the Health and Safety Code or insured by group health insurance policies regulated under the Insurance Code and, therefore, subject to AB 54; this includes 12.10 million adults aged 18 years and older. Although AB 54 does not specify an age group, CHBRP made a simplifying assumption to focus only on the *adult* population for the cost impact analysis because acupuncture services are utilized almost entirely by those 18 years of age and older. According to the California Acupuncture Board, the scope of practice for a licensed acupuncturist includes acupuncture (needling), but also other treatments such as massage, moxibustion, and cupping and the prescription of dietary supplements and herbal remedies. As explained in the Introduction, CHBRP does not evaluate treatments other than acupuncture (needling) for this report. As a result, this section presents the current, or baseline, costs and coverage related to acupuncture (needling) for adults, and then details the estimated utilization, cost, and coverage impacts of AB 54 if it were to pass into law (postmandate).

For further details on the underlying data sources and methods, please see Appendix D. A discussion of the current or baseline levels precedes the presentation of the impact estimates for AB 54.

Present Baseline Cost and Coverage

Current Coverage of the Mandated Benefit

Current coverage of acupuncture services was determined by a survey of the seven largest providers of health insurance in California. On the basis of the responses of five health plans and insurers in California,¹⁷ currently 86.3% enrollees have coverage for acupuncture. For plans that provide coverage, survey responses indicated that 98% of the coverage is provided as part of the basic benefit package and 2% of the coverage is provided as an optional benefit ("rider") to purchase. The current level of coverage of mandated benefits also varies by health plan. Some health plans and insurers provide this service by contracting with a company that specializes in acupuncture services. Privately insured individuals with acupuncture coverage generally have benefit limits, including a maximum number of annual visits (e.g., 20 visits). Some combine chiropractic and acupuncture services into a single benefit package. In addition, cost-sharing requirements vary; some health plans require a copayment (\$0–\$50) per office visit, whereas some preferred provider organizations (PPOs) require members to pay all charges in excess of \$25 per visit and \$5,000 per calendar year. Most health plans also require referrals by primary care providers. Some health plans limit acupuncture services to the management of neuromusculoskeletal disorders, nausea, and pain.

¹⁷ The five that responded represent 75% of enrollees in full-service health plans regulated by the Department of Managed Health Care (DMHC) and 78% of the lives covered by comprehensive health insurance products regulated by the California Department of Insurance (CDI).

About half (50.8%) of those covered under health plans purchased by California Public Employees' Retirement System (CalPERS) do not have coverage for acupuncture. Medi-Cal provides acupuncture benefits at no charge to Medi-Cal members, but limits it to two visits per month. Healthy Families members also are not subject to this mandate though they are currently covered for 20 visits per year with a \$5 copay per visit. The premandate per member per month (PMPM) premiums and expenditures in different market segments are detailed in Table 3.

Current Utilization Levels and Costs of the Mandated Benefit

Current utilization levels

According to data from the 2003 California Health Interview Survey Complementary and Alternative Medicine Supplement (CHIS-CAM), the utilization rates for acupuncture services vary among adult subpopulations (age 20 years and over) in California. Specifically, during 2002, 3.9% of Californians with chronic conditions, but no cancer, used acupuncture; 3.4% of Californians with cancers used acupuncture; and only 1.2% of Californians without any chronic conditions or cancer used acupuncture (Goldstein et al., 2005). In the survey, any individuals who responded that they "now had" asthma, any other pulmonary disease, arthritis or rheumatism, back or neck problems, stroke (ever had), diabetes, high blood pressure, or depression or anxiety disorder, was considered to have a chronic condition. CHBRP applied these utilization rates to the respective proportions of the California population: 38.6% of the population report having chronic conditions, but no cancer; 6.4%, report having cancer; and 55.0%, report having no chronic condition or cancer (Goldstein et al., 2005). This yields a weighted average utilization of 2.4%, which is higher than either the national average (1.1%) or the western regional average (1.9%) according to 2002 National Health Interview Survey (NHIS) data (Burke et al., 2006).

A relatively high utilization of acupuncture by Californians may be attributable to the availability of providers and the high concentrations of Asian populations residing in California. California has the largest population of Asians or persons who are Asians in combination with one or more races (4.9 million out of 14.4 million) among the 50 states, based on data recently released by the U.S. Census Bureau News (U.S. Census Bureau, 2007). A higher proportion of Asians, and cultural expectations about health treatments, in a region would predictably increase availability of and exposure to Asian traditional medicine, such as acupuncture (Burke et al. 2006, Goldstein et al. 2005). California accounts for at least one-third of the total US acupuncture workforce, estimated to be between 14,000 and 17,000 acupuncturists (Eisenberg et al., 2002). Both national and California survey data indicate that the utilization of acupuncture among Asians was almost double than that of whites; furthermore, whites in California seemed to be more likely to use acupuncture than all whites in the nation (Burke et al., 2006; Goldstein et al., 2005).

Current average cost of acupuncture services

Acupuncturists, like other health providers, usually charge for their services using Current Procedural Terminology (CPT) codes. An analysis of 2005 claims data indicated that the average number of procedures performed per visit to an acupuncturist was 1.7, at an average cost per procedure of \$37.39, or \$63.37 per visit. Adjusting to 2007 dollars (by applying an 8% annual cost trend over 2 years), CHBRP estimates that the current average cost per visit is \$74. The

claims data also indicated that on an average there were approximately six visits per course of treatment in a year.

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

CHBRP estimated no shift in costs among private or public payers as a result of current coverage. A lack of coverage for acupuncture does result in higher out-of-pocket expenditures for acupuncture services. This is because, currently, some insured group members who are not covered for the acupuncture benefit will choose to pay directly out of pocket for acupuncture treatment. CHBRP estimated that 237,117 such visits occur annually and current out-of-pocket expenditures for these acupuncture services not covered by insurance are approximately \$17.55 million per year.

Public Demand for Coverage

Based on criteria specified under SB 1704 (2006), CHBRP is to report on the extent to which collective bargaining agents negotiate for and the extent to which self-insured plans currently have coverage for the benefits specified under the proposed mandate. Currently, the largest public self-insured plans are CalPERS' PERSCare and PERS Choice preferred provider organizations (PPO) plans. PERSCare and PERS Choice PPOs cover acupuncture with a deductible, coinsurance, and a calendar-year maximum number of visits.

Based on conversations with the largest collective bargaining agents in California, there is no evidence that unions currently include such detailed provisions during the negotiations of their health insurance policies.¹⁸ In order to determine whether any local unions engage in negotiations at such detail, they would need to be surveyed individually, an undertaking beyond the scope of CHBRP's 60-day analysis.

Impacts of Mandated Coverage

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

On the basis of the responses of five health plans and insurers in California,¹⁹ the number of members in the group market covered for acupuncture services would increase by 15.89%. *Levels* of coverage (e.g., number of covered visits per year, when acupuncture is covered for what conditions) is not expected to change. CHBRP estimates that the unit price of acupuncture will stay the same after the mandate, because CHBRP does not anticipate an increase in demand for acupuncture service in the overall market (see Table 1). As a result, the average unit price of acupuncture will remain \$74 per visit after the mandate.

¹⁸ Personal communication with the California Labor Federation and member organizations on January 29, 2007.

¹⁹ The five that responded represent 75% of enrollees in full-service health plans regulated by DMHC and 78% of the lives covered by comprehensive health insurance products regulated by CDI.

How Will Utilization Change as a Result of the Mandate?

CHBRP estimates that there would be no measurable change in utilization due to the mandate for the following reasons:

- **Utilization rates among those with insurance are not different than those without.** Both NHIS and CHIS-CAM data indicated that the differences in utilization of acupuncture services among those who have insurance versus those without insurance is only 0.1% in both California and the nation (Burke et al., 2006; Goldstein et al., 2005). These data indicate that there are other barriers to use of acupuncture services than financial ones.
- **Utilization review and medical management is permitted.** The bill allows plans and insurers to use medical management tools. After the mandate, health plans and insurers can apply similar utilization limits and copayment requirements as a way to manage utilization as they currently do. They can also require a primary care provider referral prior to allowing acupuncture services.
- **Acupuncture may still face barriers of cultural acceptance.** The decision to utilize acupuncture as complementary or alternative medicine (CAM) needs to be made based on mutual awareness and cultural acceptance of acupuncture between patients and their providers. A 2002 Washington State study, conducted 6 years after a state law required private insurance companies to cover complementary and alternative medicine providers, found that only 1.3% of enrollees used acupuncture 6 years after the mandate. The authors concluded that the low utilization might be related to the lack of cultural acceptance and assimilation of the modalities into the broader health care market (Lafferty et al., 2006). Though Californians have a relatively higher cultural acceptance to acupuncture, which leads to a relatively high utilization rate (Burke et al., 2006), acupuncture is still not well assimilated into the broader health care delivery system. Currently, about three-quarters of the state's acupuncturists are in solo practice (Dower, 2003). It is possible that over time, acupuncture use may increase due to the increasing awareness of its effectiveness and cultural acceptance.

To What Extent Does the Mandate Affect Administrative and Other Expenses?

Claims administration costs may go up due to an increase in claims for acupuncture. Health plans and insurers will have to modify some insurance contracts and member materials to reflect the new coverage. Health plans and insurers include a component for administration and profit in their premiums. The estimated impact of this mandate on premiums includes the assumption that plans and insurers will apply their existing administration and profit loads to the marginal increase in health care costs produced by the mandate. Given the utilization rates will remain the same after the mandate, the estimated increase of expenditures is mainly due to the increase of the administrative costs as a proportion of the premium.

Impact of the Mandate on Total Health Care Costs

AB 54 is estimated to increase total net annual expenditures by \$2.45 million or 0.004% for this insured population, due mainly to the administrative costs associated with providing coverage for

persons who do not currently have it. The mandate is estimated to increase premiums by \$16.93 million (\$10.94 million for the portion of group insurance premiums paid by private employers, \$2.68 million by CalPERS, and \$3.31 million for the portion of group insurance and CalPERS premiums paid by enrollees) and member copayments by \$3.06 million, while simultaneously reducing *out-of-pocket* expenditures by \$17.55 million among those whose acupuncture treatments are currently not covered by insurance.

Costs or Savings for Each Category of Insurer Resulting from the Benefit Mandate

Increases in insurance premiums vary by market segment (e.g., small-group DMHC-regulated plans versus large-group CDI-regulated plans). Increases as measured by percentage change in PMPM premiums are estimated to range from 0.007% to 0.102% in the affected market segments (Table 4). Increases as measured by PMPM premiums are estimated to range from \$0.03 to \$0.33. The greatest impact on premiums would be on CalPERS and the small-group markets. A substantial portion of the increase in insurance premiums would be due to insurance absorbing a portion of the benefit's cost previously paid for through out-of-pocket expenditures by the insured for acupuncture visits.

It is estimated that the premium will be increased by \$0.33 PMPM for CalPERS, which includes \$0.28 paid by CalPERS employer and \$0.05 paid by employees. In the large-group market, the increase in premiums is estimated to range from \$0.03 to \$0.07 PMPM. For members with small-group insurance policies, health insurance premiums are estimated to increase by approximately \$0.08 to \$0.11 PMPM.

Since this mandate does not apply to the individual market, there are no cost impacts in these markets as a result of the mandate. No cost shifting is expected to occur from the public programs to the privately insured market. As mentioned, the largest portion of the shift in benefit expenditures would be from privately insured individuals' out-of-pocket expenses to health plans, and in turn to the employers and employees who pay premiums to the third parties. For example, among CalPERS member, \$0.33 PMPM of the out-of-pocket expenses (measured as PMPM costs) would be expected to shift to the health plan or insurer.

Long-term cost effectiveness of acupuncture

A limited number of studies have been conducted on the economic implications of complementary and alternative medicine (CAM) therapies, such as acupuncture (Herman, et al., 2005). Based on a few studies conducted primarily in European countries, acupuncture has been shown to be relatively cost effective in treating patients with chronic neck pain (Willich et al., 2006), back pain (Ratcliffe et al., 2006; Witt et al., 2006c), and migraine headache (Vickers et al., 2004b; Wonderling et al., 2004). Cost-effectiveness studies generally report their findings in costs per quality-adjusted life-year (QALY, a year in perfect health is considered equal to 1.0 QALY). For instance, Wonderling and others estimated acupuncture costs about \$18,000 per QALY gained. These estimates mean that the net cost, after accounting for all savings associated with the reduction in adverse health events, is \$18,000 per QALY. Although there is no consensus about the most appropriate threshold, policymakers have routinely accepted

technologies, such as mammography, that cost less than \$50,000 per QALY (Fiore, 1998) as cost effective.

CHBRP's estimated cost and utilization impacts do not include any estimated cost reductions for other health care services because it appears that acupuncture is generally administered as a complement to other treatments as opposed to a substitute (Burke et al., 2006).

Impact on Access and Health Service Availability

CHBRP estimates that the proposed mandate will have no impact on availability of (i.e., the supply of) acupuncture services because the mandate is not expected to substantially increase demand. Expanded coverage under AB 54 could potentially encourage more insured individuals to use acupuncture services and improve access to acupuncturists for those who would like to try this CAM therapy, especially for those who currently do not have coverage for acupuncture. Since the overall increase in insurance premium is minimal, it is unlikely that this mandate will result in an increase of uninsurance rate.

Table 3. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Insurance Plan Type, California, 2007

	Large Group		Small Group		Individual		CalPERS	Medi-Cal		Healthy Families	Total Annual (Public and Private)
	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	HMO	Managed Care 65 yrs and Over	Managed Care Under 65 yrs	Managed Care	
Population currently covered by insurance subject to the mandate	10,354,000	363,000	3,086,000	679,000	Not subject to mandate	Not subject to mandate	791,000	165,000	2,513,000	0	17,951,000
Average portion of premium paid by employer	\$249.51	\$323.69	\$249.52	\$281.52	N/A	N/A	\$277.19	\$181.00	\$120.43	\$76.82	\$50,566,238,000
Average portion of premium paid by employee	\$53.66	\$74.60	\$94.73	\$61.82	N/A	N/A	\$48.92	\$0.00	\$0.85	\$5.78	\$11,494,435,000
Total premium	\$303.17	\$398.28	\$344.26	\$343.34	N/A	N/A	\$326.11	\$181.00	\$121.29	\$82.60	\$62,060,673,000
Member share of expenses for covered benefits (deductibles, copays, etc.)	\$16.35	\$46.30	\$25.58	\$90.75	N/A	N/A	\$16.82	\$0.00	\$0.56	\$2.25	\$4,096,879,000
Member expenses for benefits not covered*	\$0.07	\$0.06	\$0.10	\$0.15	N/A	N/A	\$0.33	\$0.00	\$0.00	\$0.00	\$17,546,000
Total expenditures	\$319.60	\$444.64	\$369.94	\$434.24	N/A	N/A	\$343.25	\$181.00	\$121.85	\$84.85	\$66,175,098,000

Source: California Health Benefits Review Program, 2007.

Notes: The population includes employees and dependents in California who have private group insurance or public group insurance (e.g., CalPERS) under health plans or policies regulated by DMHC or CDI. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-based coverage.

Key: CalPERS = California Public Employees' Retirement System; DMHC = California Department of Managed Health Care; DOI = California Department of Insurance; HMO = health maintenance organization and point of service plans; PPO = preferred provider organization and fee-for-service plans.

*The expenditures for acupuncture services paid by members who currently do not have acupuncture benefits.

Table 4. Postmandate Impacts on Per Member Per Month and Total Expenditures by Insurance Plan Type, California, 2007

	Large Group		Small Group		Individual		CalPERS	Medi-Cal		Healthy Families	Total Annual
	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	HMO	Managed Care 65 yrs and Over	Managed Care Under 65 yrs	Managed Care	
Population currently covered By insurance subject to the mandate	10,354,000	363,000	3,086,000	679,000	Not subject to mandate	Not subject to mandate	791,000	165,000	2,513,000	0	17,951,000
Average portion of premium paid by employer	\$0.06	\$0.02	\$0.08	\$0.07	N/A	N/A	\$0.28	\$0.00	\$0.00	\$0.00	\$13,625,000
Average portion of premium paid by employee	\$0.01	\$0.01	\$0.03	\$0.01	N/A	N/A	\$0.05	\$0.00	\$0.00	\$0.00	\$3,307,000
Total premium	\$0.07	\$0.03	\$0.11	\$0.08	N/A	N/A	\$0.33	\$0.00	\$0.00	\$0.00	\$16,931,000
Covered benefits paid by member (deductibles, copays, etc.)	\$0.01	\$0.03	\$0.01	\$0.09	N/A	N/A	\$0.04	\$0.00	\$0.00	\$0.00	\$3,062,000
Member expenses for benefits not covered*	-\$0.07	-\$0.06	-\$0.10	-\$0.15	N/A	N/A	-\$0.33	\$0.00	\$0.00	\$0.00	-\$17,546,000
Total expenditures	\$0.01	\$0.00	\$0.02	\$0.02	N/A	N/A	\$0.05	\$0.00	\$0.00	\$0.00	\$2,446,000
Percentage impact of mandate											
Insured premiums	0.024%	0.007%	0.031%	0.024%	N/A	N/A	0.102%	0.000%	0.000%	0.000%	0.027%
Total expenditures	0.003%	0.001%	0.006%	0.004%	N/A	N/A	0.015%	0.000%	0.000%	0.000%	0.004%

Source: California Health Benefits Review Program, 2007.

Notes: The population includes employees and dependents in California who have private group insurance or public group insurance (e.g. CalPERS) under health plans or policies regulated by DMHC or CDI. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-based coverage. Number may not match Table 1 exactly due to rounding.

Key: CalPERS = California Public Employees’ Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = health maintenance organization and point of service plans.

*The expenditures for acupuncture services paid by members who currently do not have acupuncture benefits.

PUBLIC HEALTH IMPACTS

Acupuncture therapies are used to treat a variety of health conditions. This report focuses primarily on the use of acupuncture in the treatment of musculoskeletal and neurological disorders, where acupuncture is most commonly used. Based on Milliman’s claims data (2005), within the categories of musculoskeletal and neurological disorders, three common conditions for which acupuncture are used include: (1) lower back pain, (2) neck pain, and (3) migraine or severe headaches. Table 5 details the prevalence of these three health conditions among the insured adult population aged 18–64 years in the United States and shows that over one-third of the respondents reported having at least one of the three conditions in the past 3 months (NHIS, 2002). Lower back pain is the most prevalent of the three conditions, with 26.1% of respondents reporting lower back pain, followed by migraine or severe headache at 17.3%, and neck pain at 14.3%.

Table 5. Prevalence of Lower Back Pain, Neck Pain, and Migraine or Severe Headache in the Past 3 Months

Health Condition*	Percent of Respondents with Pain in Past 3 Months
Lower back pain	26.1 (95% CI = 25.6–26.7)
Neck pain	14.3 (95% CI = 13.8–14.7)
Migraine or severe headache	17.3 (95% CI = 16.8–17.8)
Any of above conditions	37.3 (95% CI = 36.7–37.9)

Source: 2002 National Health Interview Survey, adults 18–64 years with health insurance.

Key: CI = confidence interval.

* Respondents with pain that lasted a whole day or more and not due to minor aches and pains.

Although these conditions are highly prevalent, only a small fraction of the population currently uses acupuncture therapies for these conditions or one of the many other health conditions for which acupuncture is utilized. National estimates indicate that in 2002, 4.1% of the insured adult population has used acupuncture in their lifetime and 1.1% has used acupuncture in the past year (NHIS, 2002). Acupuncture utilization rates differ by region of the country; the western region has a statistically significantly higher utilization rate compared to the rest of the country (NHIS, 2002). In California, it is estimated that 2.4% of insured adults have used acupuncture in the past year.²⁰

²⁰ See page 34 for a description of the assumptions used to generate the utilization estimate for acupuncture services in California.

Impact on Community Health

The *Medical Effectiveness* section finds that acupuncture needling is effective in treating a variety of conditions, including: neck disorders, chronic low back pain, headache, osteoarthritis of the knee, temporomandibular joint dysfunction, lateral elbow pain, and postoperative nausea.²¹ When used as an adjuvant treatment, the evidence suggests that acupuncture needling is also effective in treating pelvic pain, epilepsy, and stroke. When performed correctly, serious complications from acupuncture are rare, and the recommended use of single-use pre-sterilized needles minimizes risk of infection (Cherkin et al., 2003).

The primary health outcomes associated with acupuncture treatment for musculoskeletal and neurological disorders (including lower back pain, neck pain, and migraine or severe headache) are reduction in pain and improvement in functionality. Although acupuncture needling is effective for persons with the aforementioned conditions, in order for AB 54 to have an impact on health outcomes among Californians, the mandate needs to result in an increased utilization of acupuncture among the insured population. As explained in the *Cost* section, AB 54 is expected to shift the costs of acupuncture from out-of-pocket costs to insurer costs; however, it is not expected to result in an overall increase in utilization in the short term. As a result, AB 54 is not expected to have any measurable impact on community health in the 1-year time frame used in this analysis.

It is possible that in the longer term, passage of AB 54 will contribute to an increase in utilization of acupuncture due to an increase in cultural acceptance and greater awareness of coverage for acupuncture treatment and its effectiveness. Additionally, long-run population changes such as the aging of the population and increasing levels of obesity will likely result in an increased need for treatment of musculoskeletal conditions such as osteoarthritis of the knee, for which the evidence suggests that acupuncture is effective. As a result, a long-term increase in utilization of acupuncture would likely yield improved health outcomes such as reduced pain and improved functionality for persons who do not respond to other treatments.

Impact on Community Health Where Gender and Racial Disparities Exist

Gender Disparities

Of the three health conditions examined in this analysis—lower back pain, neck pain, and migraine or severe headache—women report these conditions at statistically significantly higher rates. According to the National Health Interview Survey (NHIS) data, the self-reported prevalence of migraine or severe headache, in particular, is substantially higher in women at 23% compared to 10% of men. This finding is consistent with other studies on severe headaches and migraines, which indicate that migraines are two to three times more prevalent among women, possibly due to hormonal differences (Breslau and Rasmussen, 2001).

²¹ The *Medical Effectiveness* review found that a preponderance of evidence suggests that acupuncture needling was effective in treating these conditions compared to no treatment or sham acupuncture. For some conditions, acupuncture needling was found to be effective when compared to no treatment, however; it was not found to be effective compared to sham acupuncture.

In addition to high prevalence for these health conditions, women also reported using more acupuncture than men. The NHIS data reported in Table 6 is consistent with other data that have found that prevalence of acupuncture use is approximately twice as high among women compared to men (Goldstein et al., 2005; Rafferty et al., 2002).

Table 6. Self-Reported Prevalence of Lower Back Pain, Neck Pain, Migraine, or Severe Headache, and Acupuncture Use, By Gender

	Men (n = 11,274)	Women (n = 13,790)
Health Conditions*		
Lower back pain	24.0 (95% CI = 23.2–24.8)	27.9 (95% CI = 27.1–28.6)
Neck pain	11.6 (95% CI = 11.0–12.2)	16.4 (95% CI = 15.8–17.0)
Migraine or severe headache	10.2 (95% CI = 9.7–10.8)	23.1 (95% CI = 22.4–23.8)
Any of above conditions	31.6 (95% CI = 30.7–32.5)	42.0 (95% CI = 41.1–42.7)
Acupuncture Use		
Ever used acupuncture	3.4 (95% CI = 3.0–3.7)	4.7 (95% CI = 4.4–5.1)

Source: 2002 National Health Interview Survey. Insured adults aged 18–64 years.

Key: CI = confidence interval.

* Respondents with pain that lasted a whole day or more and not due to minor aches and pains.

Although AB 54 is not expected to result in an overall increase in acupuncture treatment, it is expected that more women will financially benefit from insurance coverage of acupuncture compared to men, due to increased coverage.

Racial and Ethnic Disparities

One important factor to examine regarding racial and ethnic disparities is whether minority groups suffer from the specified health conditions more than whites. In examining the three health conditions (lower back pain, neck pain, and migraine or severe headache) by race and ethnicity, it does not appear that minorities report these conditions at higher rates. Lower back pain and neck pain are statistically significantly more prevalent among white adults compared to blacks, Hispanics, and Asians. Migraine or severe headache prevalence is highest among whites and blacks.

Asians have the highest utilization of acupuncture use, with 9.5% having ever used acupuncture in 2002 (Table 7). This finding is consistent with research that has found higher rates of past-year utilization of acupuncture in Asian countries such as Taiwan (11%) and among Chinese immigrants in the United States (14%) (Chen et al., 2007; Wu et al., 2007). Among Asians in the United States, utilization rates were highest for Chinese respondents, with 15% reporting having ever used acupuncture (NHIS, 2002). After Asians, whites have the second highest utilization

rate. Goldstein et al (2005) found similar results among California respondents, with 5.9% of Asians using acupuncture in the past year compared to 3.1% of whites, 2.4% of blacks, and 1.3% of Hispanics.

Table 7. Self-Reported Prevalence of Lower Back Pain, Neck Pain, Migraine or Severe Headache, and Acupuncture Use, By Race and Ethnicity

	White (n = 15,823)	Black (n = 3,513)	Hispanic (n = 4,700)	Asian (n = 783)
Health Conditions*				
Lower back pain	27.7 (95% CI = 27.0–28.4)	23.8 (95% CI = 22.4–25.2)	23.8 (95% CI = 22.5–25.0)	17.0 (95% CI = 14.4–19.6)
Neck pain	15.3 (95% CI = 14.8–15.9)	12.2 (95% CI = 11.1–13.3)	12.9 (95% CI = 11.9–13.9)	8.0 (95% CI = 6.1–10.0)
Migraine or severe headache	17.9 (95% CI = 17.3–18.5)	17.6 (95% CI = 16.3–18.8)	15.6 (95% CI = 14.6–16.7)	11.0 (95% CI = 8.8–13.2)
Any of above conditions	39.5 (95% CI = 38.8 – 40.3)	34.9 (95% CI = 33.3–36.4)	33.1 (95% CI = 31.8–34.5)	25.4 (95% CI = 22.4–28.5)
Acupuncture Use				
Ever used acupuncture	4.5 (95% CI = 4.2–4.9)	2.2 (95% CI = 1.7 – 2.6)	3.2 (95% CI = 2.7–3.7)	9.5 (95% CI = 7.4–11.5)

Source: 2002 National Health Interview Survey. Insured adults aged 18–64 years.

Key: CI = confidence interval.

* Respondents with pain that lasted a whole day or more and not due to minor aches and pains.

Although AB 54 is not expected to result in an overall increase in acupuncture treatment, it is expected that insured Asians will financially benefit the most from insurance coverage of acupuncture.

Reduction of Premature Death and Economic Loss Associated with Disease

Acupuncture is used for some health conditions and behaviors associated with premature death, such as smoking cessation and other drug addictions. The medical effectiveness review, however, did not find that acupuncture was an effective treatment for these conditions. Therefore, AB 54 is not expected to result in a reduction of premature death.

Since acupuncture is used to treat a multitude of health conditions, examining the economic costs associated with acupuncture is difficult to assess. There are substantial economic costs associated with the three conditions for which acupuncture is commonly used (lower back pain, neck pain, and migraine or severe headaches). No research was found that details the economic costs associated with neck pain; however, both low back pain and migraines have been found to be

associated with high economic costs comparable to those of heart disease, depression, and diabetes. (Maetzel and Li, 2002). Guo et al (1999) found that in 1988, 102 million workdays were lost as a result of back pain, and Hu et al. (1999) estimated that migraines cost the United States \$13 billion a year due to missed work and impaired work function, and \$1 billion a year in direct medical costs.

Recent cost-effectiveness analyses of acupuncture treatment for neck pain, low back pain, and migraine or severe headache have found that adding acupuncture to usual care costs more than usual care alone; however, the care is within the standards of cost effectiveness (Ratcliffe et al, 2006; Willich et al., 2006; Wonderling et al., 2004). No research was identified that found that acupuncture decreases the economic costs associated with these conditions through increased productivity. Additionally, since AB 54 is not expected to result in an overall increase in use of acupuncture treatment, there is no expected reduction in economic loss associated with conditions related to acupuncture use in a 1-year time period. However, it is possible that in the longer term, passage of AB 54, along with potential increase in cultural acceptance of acupuncture as a treatment option, will contribute to an increase in utilization of acupuncture and therefore may reduce economic costs associated with these conditions.

APPENDICES

Appendix A: Text of Bill Analyzed

BILL NUMBER: AB 54 AMENDED
BILL TEXT

AMENDED IN ASSEMBLY MARCH 8, 2007

INTRODUCED BY Assembly Member Dymally

DECEMBER 4, 2006

~~An act to amend Section 4600 of the Labor Code, relating to workers' compensation. An act to amend Section 1373.10 of the Health and Safety Code, and to amend Sections 10127.3 and 10176 of the Insurance Code, relating to health care coverage.~~

LEGISLATIVE COUNSEL'S DIGEST

AB 54, as amended, Dymally. ~~Workers' compensation~~
Health care coverage : acupuncture.

Existing law provides for regulation of health care service plans by the Department of Managed Health Care. Existing law provides for regulation of health insurers by the Insurance Commissioner. A willful violation of the provisions governing health care service plans is a crime. Existing law requires health care service plans and health insurers to offer coverage for acupuncture under a group plan or policy, with certain exceptions.

This bill would require health care service plans and health insurers to provide, rather than to offer, coverage for acupuncture under a group plan or policy, and would delete the exceptions from that requirement. Because the bill would impose new requirements on health care service plans, the willful violation of which would be a crime, it 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.

~~Existing workers' compensation law generally requires employers to secure the payment of workers' compensation, including acupuncture treatment, for injuries incurred by their employees that arise out of, or in the course of, employment.~~

~~Existing law requires the administrative director to adopt a medical treatment utilization schedule, as specified, that is required to address the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases.~~

~~This bill would define acupuncture treatment to mean treatment~~

~~based upon these guidelines or, prior to the adoption of these guidelines, the specified guidelines published by the Council of Acupuncture and Oriental Medicine Association and the Foundation for Acupuncture Research, including specified information.~~

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

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

SECTION 1. Section 1373.10 of the Health and Safety Code is amended to read:

1373.10. ~~-(a) - On~~
~~and after January 1, 1985, every~~ Every health care service plan ~~-, that is not a health maintenance organization or is not a plan that enters exclusively into specialized health care service plan contracts, as defined by subdivision (n) of Section 1345, which~~ that provides coverage for hospital, medical, or surgical expenses, shall ~~offer~~ provide coverage to group ~~contract holders~~ contractholders for expenses incurred as a result of treatment by holders of ~~certificates~~ licenses under Section 4938 of the Business and Professions Code, under ~~such~~ terms and conditions as may be agreed upon between the health care service plan and the group ~~contract holder~~ contractholder .

~~— A health care service plan is not required to offer the coverage provided by this section as part of any contract covering employees of a public entity.~~

~~— (b) For the purposes of this section, "health maintenance organization" or "HMO" means a public or private organization, organized under the laws of this state, which does all of the following:~~

~~— (1) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physician services, hospitalization, laboratory, X ray, emergency and preventive services, and out of area coverage.~~

~~— (2) Is compensated, except for copayments, for the provision of basic health care services listed in paragraph (1) to enrolled participants on a predetermined periodic rate basis.~~

~~— (3) Provides physician services primarily directly through physicians who are either employees or partners of the organization, or through arrangements with individual physicians or one or more groups of physicians, organized on a group practice or individual practice basis.~~

SEC. 2 Section 10127.3 of the Insurance Code is amended to read:

10127.3. ~~On and after January 1, 1985, every~~
Every insurer issuing group ~~disability~~ health insurance ~~which covers hospital, medical, or surgical expenses~~ shall ~~offer~~ provide coverage for expenses incurred as a result of treatment by holders of ~~certificates~~ licenses

under Section 4938 of the Business and Professions Code, under ~~such~~ terms and conditions as may be agreed upon between the group policyholder and the insurer.

~~An insurer is not required to offer the coverage provided by this section as part of any policy covering employees of a public entity.~~

SEC. 3. Section 10176 of the Insurance Code is amended to read:

10176. In ~~disability~~ health insurance, the policy may provide for payment of medical, surgical, chiropractic, physical therapy, speech pathology, audiology, acupuncture, professional mental health, dental, hospital, or optometric expenses upon a reimbursement basis, or for the exclusion of any of those services, and provision may be made therein for payment of all or a portion of the amount of charge for these services without requiring that the insured first pay the expenses. The policy shall not prohibit the insured from selecting any psychologist or other person who is the holder of a certificate or license under Section 1000, 1634, 2050, 2472, 2553, 2630, 2948, 3055, or 4938 of the Business and Professions Code, to perform the particular services covered under the terms of the policy, the certificate holder or licensee being expressly authorized by law to perform those services.

~~If the insured selects any person who is a holder of a certificate under Section 4938 of the Business and Professions Code, a disability insurer or nonprofit hospital service plan shall pay the bona fide claim of an acupuncturist holding a certificate pursuant to Section 4938 of the Business and Professions Code for the treatment of an insured person only if the insured's policy or contract expressly includes acupuncture as a benefit and includes coverage for the injury or illness treated. Unless the policy or contract expressly includes acupuncture as a benefit, no person who is the holder of any license or certificate set forth in this section shall be paid or reimbursed under the policy for acupuncture.~~

Nor shall the policy prohibit the insured, upon referral by a physician and surgeon licensed under Section 2050 of the Business and Professions Code, from selecting any licensed clinical social worker who is the holder of a license issued under Section 4996 of the Business and Professions Code or any occupational therapist as specified in Section 2570.2 of the Business and Professions Code, or any marriage and family therapist who is the holder of a license under Section 4980.50 of the Business and Professions Code, to perform the particular services covered under the terms of the policy, or from selecting any speech-language pathologist or audiologist licensed under Section 2532 of the Business and Professions Code or any registered nurse licensed pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code, who possesses a master's degree in psychiatric-mental health nursing and is listed as a psychiatric-mental health nurse by the Board of Registered Nursing or any advanced practice registered nurse certified as a clinical nurse specialist pursuant to Article 9 (commencing with Section 2838) of Chapter 6 of Division 2 of the Business and Professions Code who participates in expert clinical practice in the specialty of psychiatric-mental health nursing, or any respiratory care practitioner certified pursuant to Chapter 8.3 (commencing with Section 3700) of Division 2 of the Business and Professions Code to

perform services deemed necessary by the referring physician, that certificate holder, licensee or otherwise regulated person, being expressly authorized by law to perform the services.

Nothing in this section shall be construed to allow any certificate holder or licensee enumerated in this section to perform professional mental health services beyond his or her field or fields of competence as established by his or her education, training, and experience. For the purposes of this section, "marriage and family therapist" means a licensed marriage and family therapist who has received specific instruction in assessment, diagnosis, prognosis, and counseling, and psychotherapeutic treatment of premarital, marriage, family, and child relationship dysfunctions that is equivalent to the instruction required for licensure on January 1, 1981.

An individual ~~disability~~ health insurance policy, which is issued, renewed, or amended on or after January 1, 1988, which includes mental health services coverage may not include a lifetime waiver for that coverage with respect to any applicant. The lifetime waiver of coverage provision shall be deemed unenforceable.

SEC. 4. 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.

[Remaining introduced text was stricken.]

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for AB 54.

Numerous studies of the effectiveness of acupuncture have been conducted in Asia, Europe, and North America. This literature is especially large because acupuncture is used to treat a wide variety of diseases and conditions. CHBRP could not review all of this literature during the time available for this review. In light of this constraint, CHBRP decided to focus on the strongest and most current evidence of the effectiveness of acupuncture.

Three types of literature were reviewed. First, the National Institutes of Health (NIH) Consensus Statement on Acupuncture and the Institute of Medicine's (IOM) report on complementary and alternative medicine were examined to identify diseases and conditions for which the authors found strong evidence that acupuncture was effective (IOM, 2005; NIH, 1997). Second, meta-analyses and systematic reviews published since the literature review for the IOM report was conducted in 2004 were assessed. One earlier systematic review on the effectiveness of acupuncture for treatment of headache was also included, because it is the most recent systematic review on this topic (Melchart et al., 2001). Third, individual randomized controlled trials (RCTs) published since the meta-analyses and systematic reviews, that were well-designed and had large samples were reviewed.²² These studies were included because their authors used research methods superior to most previous studies of acupuncture, which typically had small sample sizes and did not use rigorous research methods.

The literature review was limited to studies of the effectiveness of acupuncture needling. This practice is unique to acupuncture and is typically covered by health plans that provide acupuncture benefits. Studies of both manual acupuncture and electroacupuncture are included. Only studies published in English from 1997 to the present were included. Three databases that exclusively index studies on traditional Chinese medicine (i.e., EastView CAJ-Med, Traditional Chinese Database System, and WanFang Data COJ [Chinese Medicine Premier]) were excluded. Although these databases contain many publications on acupuncture, they were not searched because less than 1% of them are written in English. CHBRP could not translate articles from Chinese to English during the limited time available for this review. In addition, many of the studies are not written in a standardized format and do not contain the information needed to assess their quality. Finally, these databases are difficult to search because they do not use standardized methods to index publications (Murphy and Fang, 2007).

The following databases of literature on acupuncture were searched: PubMed, CINAHL, and the Cochrane Library, including the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials.

²² Individual studies with nonrandomized designs were not reviewed in accordance with CHBRP's hierarchy of evidence. Many meta-analyses, systematic reviews, and RCTs have been published on acupuncture. In such cases, CHBRP relies primarily on these types of studies and does not review nonrandomized studies.

Five hundred and twenty abstracts were reviewed for the literature review for AB 54. A total of 30 studies were included in the current review. These studies consisted of 23 meta-analyses and systematic reviews and 7 individual RCTs.

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 the five domains described above. 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 have strong research designs 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 an unfavorable effect.

The evidence is presented as “ambiguous/conflicting” if none of the studies of an outcome have strong research designs and/or 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 is used where there is little if any evidence of an intervention’s effect.

The search terms used to locate studies relevant to the AB 54 were as follows.

PubMed

Medical Subject Headings (MeSH) & Keywords

NOTES: all terms labeled as “[MeSH]” are Medical Subject Headings that were searched without qualification to retrieve the concept both as MeSH and keyword. Terms listed in lower case were only entered as keywords in the search to retrieve recently published articles that have not been indexed with MeSH terms. Some keywords map directly to MeSH terms.

Acupuncture[MeSH]
Acupuncture Therapy[MeSH]
Acupuncture Therapy/standards[MeSH]
Electroacupuncture[MeSH]
Moxibustion[MeSH]
Transcutaneous Electric Nerve Stimulation[MeSH]
Cupping
electroanesthesia
electroanaesthesia
electroanalgesia

Musculoskeletal Diseases[MeSH]
Nervous System Diseases[MeSH]
Antineoplastic Agents[MeSH]
Arm Injuries[MeSH]
Athletic Injuries[MeSH]
Back Injuries[MeSH]
Craniocerebral Trauma[MeSH]
Dislocations [MeSH]
Fractures, Bone[MeSH]
Fractures, Cartilage[MeSH]
Hand Injuries[MeSH]
Hip Injuries[MeSH]
Leg Injuries[MeSH]
Neck Injuries[MeSH]
Neoplasms[MeSH]
Spinal Cord Injuries[MeSH]
Spinal Injuries[MeSH]
Sprains And Strains[MeSH]
Temporomandibular Joint Dysfunction Syndrome[MeSH]

temporomandibular joint syndrome
Tendon Injuries[MeSH]
arthritis
back pain
bursitis
fracture
fractures
joint injury
muscle pain
nausea
neck pain
osteoarthritis
shoulder pain
tendonitis

Acupuncture/economics [MeSH]
Acupuncture/trends[MeSH]
Acupuncture Therapy/statistics and numerical data[MeSH]
Acupuncture Therapy/economics[MeSH]
Acupuncture Therapy/trends[MeSH]
Acupuncture Therapy/utilization[MeSH]

Ambulatory Care Facilities[MeSH]
Ambulatory Care Facilities/statistics and numerical data[MeSH]
Cost-Benefit Analysis[MeSH]
Costs and Cost Analysis[MeSH]
Health Services Needs and Demand[MeSH]
Mean Number[MeSH]
Medical Audit[MeSH]
Outcome Assessment (Health Care) [MeSH]
Outpatients/statistics and numerical data[MeSH]
Physician's Practice Patterns[MeSH]
Physician's Practice Patterns/statistics & numerical data[MeSH]
Reimbursement Mechanisms[MeSH]
Treatment Outcome[MeSH]
Utilization Review[MeSH]
/utilization[MeSH]
/economics[MeSH]
efficacy
mean
office visits
“duration of treatment”
“mean number of sessions”
“acupuncture sessions”
“acupuncture treatments”
“weeks in treatment”

Search phrase added where applicable to retrieve non-indexed articles:

(publisher [sb] OR in process [sb] OR pubmednotmedline [sb])

CINAHL (Cumulative Index to Nursing and Allied health Literature)

NOTE: terms searched in all searchable fields.

acupuncture
electroacupuncture
electroanaesthesia
electroanesthesia
electroanalgesia
transcutaneous electric nerve stimulation

Limiters: Publication Type: Clinical Trial, Practice Guidelines, Systematic Review
Language: English

COCHRANE LIBRARY

Terms used to search:

NOTE: all terms searched in Title, Abstracts, or Keywords

acupuncture
electroacupuncture
electro-acupuncture

temporomandibular joint syndrome
temporomandibular pain

costs
utilization

Appendix C: Description of Studies on the Medical Effectiveness of Acupuncture

Appendix C describes the studies of the medical effectiveness of acupuncture included in this review.

Table C-1. Description of Published Studies on the Medical Effectiveness of Acupuncture

Studies of Musculoskeletal Disorders

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Fibromyalgia	Mayhew and Ernst, 2007	Systematic review	Acupuncture plus other treatments vs. other treatments	Five randomized controlled trials (RCTs) that enrolled 316 persons with fibromyalgia ^(a)	Not reported
Lateral elbow pain	Green et al., 2002	Systematic review	Acupuncture vs. sham acupuncture; Acupuncture plus other treatments vs. other treatments	Three RCTs that enrolled 190 persons over age 16 yrs who had lateral elbow pain for more than 3 weeks and no history of significant trauma or inflammatory conditions	Not reported
Lateral elbow pain	Trinh et al., 2004	Systematic review	Acupuncture vs. sham acupuncture; Acupuncture vs. other treatments	Six RCTs and controlled clinical trials (CCTs) that enrolled 282 persons with pain due to tennis elbow, lateral epicondyle pain, lateral elbow pain, lateral epicondylitis, or any pain originating from the extensor tendon	Not reported
Low back pain	Furlan et al., 2005	Meta-analysis	Acupuncture vs. no treatment; Acupuncture vs. sham acupuncture; Acupuncture vs. other treatment; Acupuncture plus other treatments vs. other treatments	35 RCTs that enrolled 2,861 adults with acute or chronic low back pain not caused by a specific pathological entity (e.g., arthritis, infection, tumor) or associated with sciatica or pregnancy	Australia, Canada, China, Germany, Italy, Japan, Morocco, Norway, Poland, Sweden, United Kingdom, United States, Vanuatu

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Low back pain, chronic	Brinkhaus, et al., 2006	RCT	Acupuncture vs. no treatment; Acupuncture vs. sham acupuncture	298 adults aged 40–75 yrs who had low back pain for more than 6 months, had not had vertebral column surgery, and whose back pain was not associated with another disease or condition (e.g., autoimmune disease, compression fracture)	Germany
Low back pain, chronic	Thomas et al., 2006	RCT	Acupuncture vs. no treatment	241 adults aged 18-65 who had non-specific low back pain for 4 to 52 weeks who had not had spinal surgery and who did not have other severe conditions (e.g., hemophilia, prolapsed central disc)	United Kingdom
Low back pain, chronic	Witt et al., 2006c	RCT plus nonrandomized cohort	Acupuncture vs. no treatment	11,630 adults (3,093 randomized) who had low back pain for more than 6 months, had not had vertebral column surgery, and whose back pain was not associated with another disease or condition (e.g., autoimmune disease, compression fracture)	Germany
Low back pain and pelvic pain	Pennick and Young, 2007	Systematic review	Acupuncture vs. other treatments; Acupuncture plus other treatments vs. other treatments	Three RCTs that enrolled 546 women who reported pregnancy-related low-back or pelvic pain	Sweden
Neck disorders	Trinh et al., 2006	Meta-analysis	Acupuncture vs. no treatment; Acupuncture vs. sham acupuncture, sham electroacupuncture, or sham laser; Acupuncture vs. other treatments	Ten RCTs and CCTs that enrolled 661 adults with chronic mechanical neck pain	China, Germany, New Zealand, United Kingdom, United States
Neck disorders	Witt et al., 2006a	RCT plus nonrandomized cohort	Acupuncture vs. no treatment	14,161 adults (3,766 randomized) with chronic neck pain for more than 6 months who had not had vertebral column surgery and whose neck pain	Germany

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
				was not associated with another disease or condition (e.g., compression fracture, congenital deformation)	
Osteoarthritis of the knee	White et al., 2006a and White et al., 2007 ²³	Meta-analysis	Acupuncture vs. no treatment; Acupuncture vs. sham acupuncture; Acupuncture vs. other treatment; Acupuncture plus other treatments vs. other treatments	13 RCTs that enrolled 2,362 persons with osteoarthritis of the knee	Europe, Far East, North America
Osteoarthritis of the knee, hip, or thumb	Kwon et al., 2006	Meta-analysis	Acupuncture vs. no treatment; Acupuncture or electroacupuncture vs. sham acupuncture; Acupuncture or electroacupuncture vs. other treatments; Acupuncture or electroacupuncture plus other treatments vs. other treatments	18 RCTs that enrolled 1,891 persons with peripheral joint osteoarthritis of the knee, hip, or thumb	Not reported
Osteoarthritis of the knee or hip	Witt et al., 2006b	RCT plus nonrandomized cohort	Acupuncture vs. no treatment	3,633 adults (712 randomized) aged 40 yrs. or older diagnosed with osteoarthritis of the knee or hip for more than 6 months that was confirmed by radiologic evidence and who experienced pain at least 15 of the previous 30 days	Germany
Rheumatoid arthritis	Casimiro et al., 2005	Systematic review	Acupuncture or electroacupuncture vs. sham acupuncture or sham electroacupuncture	Two RCTs that enrolled 84 adults with rheumatoid arthritis	Not reported
Shoulder pain	Green et al., 2005	Systematic review	Acupuncture vs. sham acupuncture; Acupuncture vs. other treatments; Acupuncture plus other treatments	Nine RCTs and CCTs that enrolled 525 persons over age 16 yrs who had shoulder pain or disorder for more	Not reported

²³ White and colleagues published two versions of the same meta-analysis on the effectiveness of acupuncture for treating osteoarthritis of the knee (White et al., 2006a; White et al., 2007). Both versions were used in this systematic review because each contained pertinent material that did not appear in the other version.

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
			vs. other treatments	than 3 weeks who did not also have neck or arm pain and who did not have a history of other diseases or conditions that cause shoulder pain	
Temporo-mandibular joint dysfunction	Ernst and White, 1999	Systematic review	Acupuncture vs. no treatment; Acupuncture vs. other treatments	Three RCTs that enrolled 205 persons with temporomandibular joint dysfunction or craniomandibular disorder	Scandinavian countries
Temporo-mandibular dysfunction	McNeely et al., 2006	Systematic review	Acupuncture vs. no treatment; Acupuncture vs. sham acupuncture; Acupuncture vs. other treatments	Two RCTs that enrolled 73 adults with temporomandibular joint dysfunction who had no previous surgery in the temporomandibular region and no serious comorbidities	Not reported

Studies of Neurological Disorders

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Epilepsy	Cheuk and Wong, 2006	Meta-analysis	Acupuncture vs. sham acupuncture	Three RCTs that enrolled 184 persons with any type of epilepsy	China, Norway
Headache, migraine or tension	Melchart et al., 2001	Systematic review	Acupuncture vs. no treatment; Acupuncture or electroacupuncture vs. sham acupuncture; Acupuncture or electroacupuncture vs. other treatments	24 RCTs and CCTs that enrolled 1,087 persons with migraine, tension-type, cluster, or other types of chronic or recurrent headache that was not caused by another condition (e.g., brain tumor)	Austria, China, Denmark, Finland, France, Germany, Israel, Italy, Sweden, United Kingdom
Headache, migraine or tension	Vickers et al., 2004a	RCT	Acupuncture vs. no treatment	301 adults aged 18–65 yrs who had an average of 2 headaches per month, had not used acupuncture in the past 12 months, did not also have cluster headache, and whose did not have a specific etiology (e.g., brain tumor)	United Kingdom

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Headache, migraine	Diener et al., 2006	RCT	Acupuncture vs. sham acupuncture; Acupuncture vs. other treatments	794 adults aged 18–65 yrs diagnosed with migraine at least 26 weeks prior to the study who had 2–6 migraine attacks in 4 weeks, and who did not also have other types of headaches	Germany
Headache, migraine	Linde et al., 2005	RCT	Acupuncture vs. no treatment; Acupuncture vs. sham acupuncture	302 adults aged 18–65 yrs diagnosed with migraine who had had migraines for at least 1 year and had 2–8 migraine attacks per month in the past 3 months, and who did not also have other types of headaches	Germany
Headache, migraine	Linde et al., 2007a	RCT and nonrandomized cohort	Acupuncture vs. no treatment; Acupuncture vs. sham acupuncture	877 adults (145 randomized) aged 18–65 yrs diagnosed with migraine who had had migraines for at least 1 year and had 2–8 migraine attacks per month in the past 3 months	Germany
Headache, tension	Melchart et al., 2005	RCT	Acupuncture vs. no treatment; Acupuncture vs. sham acupuncture	270 adults aged 18–65 yrs diagnosed with migraine who had had chronic or episodic tension-type headaches for at least 1 year and had at least 8 days with headache per month in the past 3 months, and who did not also have other types of headaches	Germany
Stroke, acute phase	Zhang et al., 2005	Meta-analysis	Acupuncture plus other treatments vs. other treatments	14 RCTs and CCTs that enrolled 1,208 persons with any type of stroke in the acute phase (occurred within 30 days)	China, Sweden, Taiwan, United Kingdom
Stroke, subacute and chronic phase	Wu et al., 2006	Meta-analysis	Acupuncture plus other treatments vs. other treatments	Five RCTs that enrolled 368 persons with hemorrhagic or ischemic stroke in the subacute phase (1 to 3 months since onset) or	China, United States

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
				chronic phase (over 3 months since onset)	
Vascular dementia	Peng et al., 2007	Systematic review	Acupuncture or electroacupuncture vs. sham acupuncture	Persons diagnosed with vascular dementia	Not reported

Studies of Addiction Disorders

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Cocaine dependence	Gates et al., 2006	Meta-analysis	Auricular acupuncture vs. no treatment; Auricular acupuncture vs. sham acupuncture; Auricular acupuncture vs. other treatments; Auricular acupuncture plus other treatments vs. other treatments	Seven RCTs that enrolled 1,433 persons who were dependent on cocaine or crack cocaine	Not reported
Smoking cessation	White et al., 2006b	Meta-analysis	Acupuncture vs. no treatment; Acupuncture vs. sham acupuncture; Acupuncture vs. other treatments; Acupuncture plus other treatments vs. other treatments	20 RCTs that enrolled 3,913 smokers of any age	Canada, China, France, Italy, New Zealand, Norway, Singapore, United Kingdom, United States

Studies of Nausea and Vomiting

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Chemotherapy-induced nausea and vomiting	Ezzo et al., 2006	Meta-analysis	Acupuncture vs. sham acupuncture; Electroacupuncture plus other treatment vs. other treatment	Four RCTs that enrolled 214 persons with cancer who received chemotherapy	Not reported
Postoperative	Lee and	Meta-analysis	Acupuncture or electroacupuncture	Four RCTs that enrolled 344	Not reported

Condition	Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
nausea and vomiting	Done, 2004		vs. sham acupuncture; Acupuncture vs. other treatments	persons who had undergone surgery	

(a) For all meta-analyses and systematic reviews listed in this table, the total numbers of studies and numbers of persons enrolled reflect only those studies included in these reviews for which persons in the treatment group received either manual needling or electroacupuncture. Studies that assessed acupressure or other noninvasive forms of acupuncture are not included in the numbers of studies and enrollees.

Table C-2. Summary of Findings from Studies of the Medical Effectiveness of Acupuncture

Acupuncture versus No Treatment

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Low back pain, chronic	<ul style="list-style-type: none"> • Meta-analysis (2 RCTs, 90 persons)²⁴ • Large, well-designed RCTs published after meta-analysis (3 RCTs, 3,632 persons)²⁵ 	<ul style="list-style-type: none"> • Statistically significant in the short term for both pain in 5 of 5 studies, for functioning in 4 of 4 studies, for physical health in 2 of 2 studies, and for disability in 1 of 1 study 	<ul style="list-style-type: none"> • Decrease in pain and disability and improvement in functioning and physical health in the short term 	<ul style="list-style-type: none"> • For studies in meta-analysis, pooled SMD = -0.73 (95% CI = -1.19, -0.28) for pain and SMD = 0.63 (95% CI = 0.19, 1.08) for functioning • For subsequent RCTs, decrease in pain from 8% to 27%, improvement in functioning from 9% to 22%, and 5 to 7 point increase in physical health on SF-36 scale 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture reduces chronic low back pain and improves functioning in the short-term relative to no treatment
Neck disorders	<ul style="list-style-type: none"> • Meta-analysis (1 RCT, 30 persons) • Large, well-designed RCTs published after meta-analysis (1 RCT, 3,766 persons)²⁶ 	<ul style="list-style-type: none"> • Statistically significant for pain in 2 of 2 studies and for quality of life in 1 of 1 study 	<ul style="list-style-type: none"> • Less pain in 2 of 2 studies • Improvement in quality of life in 1 study 	<ul style="list-style-type: none"> • For small study, SMD = -0.74 (95% CI = -1.49, 0.00) • For large study, 23% greater decrease in pain 3 months after treatment and improvements on 10 quality of life subscales ranged from 3% to 19% 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture reduces neck pain relative to no treatment

²⁴ For all meta-analyses and systematic reviews listed in this table the total numbers of studies and numbers of persons enrolled reflect only those studies included in these reviews for which persons in the treatment group received either manual needling or electroacupuncture. Studies that assessed acupressure or other noninvasive forms of acupuncture are not included in the numbers of studies and enrollees.

²⁵ Findings for 11,630 persons enrolled in the nonrandomized arm of this study are not reported.

²⁶ Findings for 9,615 persons enrolled in the nonrandomized arm of this study are not reported.

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Osteoarthritis of the hip	<ul style="list-style-type: none"> • Large, well-designed RCTs published after the meta-analysis (1 RCT, 169 persons) 	<ul style="list-style-type: none"> • Statistically significant for pain, functioning, and physical health status 3 months after end of study 	<ul style="list-style-type: none"> • Decrease in pain and improvement in functioning and physical health status 	<ul style="list-style-type: none"> • 45% reduction in pain, 37% improvement in functioning, and 6% increase in physical health status 	<ul style="list-style-type: none"> • Evidence from a single RCT suggests that acupuncture is more effective than no treatment in reducing pain associated with osteoarthritis of the hip and improving functioning and physical health status
Osteoarthritis of the knee	<ul style="list-style-type: none"> • Meta-analysis (2 RCTs, 243 persons) • Large, well-designed RCTs published after the meta-analysis (1 RCT, 463 persons) 	<ul style="list-style-type: none"> • Statistically significant in 3 of 3 studies 	<ul style="list-style-type: none"> • Decrease in pain; improvement in functioning and physical health status 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture is more effective than no treatment in reducing pain associated with osteoarthritis of the knee and improving functioning and physical health status
Temporo-mandibular joint dysfunction	<ul style="list-style-type: none"> • Systematic review (2 RCTs with 155 persons) 	<ul style="list-style-type: none"> • Statistically significant in 2 of 2 studies 	<ul style="list-style-type: none"> • Greater pressure pain threshold and better scores for indices of dysfunction, self-reported symptoms, and activities of daily living 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture reduces dysfunction and symptoms associated with temporomandibular joint dysfunction and improves pressure pain threshold and ability to perform activities of daily living relative to no treatment.

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Headache	<ul style="list-style-type: none"> Systematic review (1 RCT, 30 persons) Large, well-designed RCTs published after systematic review (3 RCTs, 729 persons) 	<ul style="list-style-type: none"> Statistically significant for frequency of headache in 3 of 4 studies, physical health in 3 of 3 studies, medication use in 3 of 4 studies, pain in 2 of 3 studies, and disability in 2 of 2 studies Not statistically significant for sick days in 1 of 1 study 	<ul style="list-style-type: none"> Larger decrease in frequency of headaches, use of medication, pain, disability, and greater improvement in physical health No difference in sick days 	<p>Among studies that used consistent measures</p> <ul style="list-style-type: none"> decrease in days with headache ranged from 1.4 to 5.8 days over a 3-week period increase in score on SF-36 physical health scale ranged from 4 to 5 points decrease in score on pain scale ranged from 3 to 5 points decrease in score on disability scale ranged from 9 to 12 points No effect on sick days 	<ul style="list-style-type: none"> Preponderance of evidence suggests that acupuncture reduces frequency of headaches, decreases pain disability, and use of medication and increases physical health relative to no treatment Insufficient evidence to determine whether acupuncture affects the number of sick days due to headache
Smoking cessation	<ul style="list-style-type: none"> Meta-analysis (3 RCTs, 393 persons) 	<ul style="list-style-type: none"> Approaching statistical significance 	<ul style="list-style-type: none"> Higher odds of abstinence from smoking 6 to 12 months after end of study 	<ul style="list-style-type: none"> Pooled OR = 1.91 (95% CI = 0.98, 3.70) 	<ul style="list-style-type: none"> Preponderance of evidence suggests that acupuncture may increase abstinence from smoking relative to no treatment

Acupuncture versus Sham Acupuncture

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Lateral elbow pain	<ul style="list-style-type: none"> Systematic review (4 RCTs and CCTs, 225 persons) 	<ul style="list-style-type: none"> Statistically significant for pain and functional impairment in 4 of 4 studies 	<ul style="list-style-type: none"> Decrease 	<ul style="list-style-type: none"> Not reported consistently 	<ul style="list-style-type: none"> Preponderance of evidence from small studies suggests that acupuncture is more effective than sham acupuncture in reducing lateral elbow pain and functional impairment in the short-term

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Low back pain, acute	<ul style="list-style-type: none"> • Meta-analysis (1 RCT, 40 persons) 	<ul style="list-style-type: none"> • No statistically significant difference in pain or functioning 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Insufficient evidence to determine whether acupuncture is more effective than sham acupuncture in decreasing acute low back pain and improving functioning
Low back pain, chronic	<ul style="list-style-type: none"> • Meta-analysis (4 RCTs, 342 persons) • Large, well-designed RCTs published after meta-analysis (1 RCT, 219 persons) 	<ul style="list-style-type: none"> • Statistically significant for pain in the short term in 2 of 3 studies and for physical health status in 1 of 1 study • Not statistically significant for functioning in 3 of 3 studies, in return to work in 2 of 2 studies, and in disability in 1 of 1 study 	<ul style="list-style-type: none"> • Decrease in pain in the short-term in 2 of 3 studies • Improvement in physical health status in 1 of 1 study • No difference in functioning, disability or return to work 	<ul style="list-style-type: none"> • For meta-analysis, pooled WMD in pain = -17.79 (95% CI = $-25.5, -10.07$) • For subsequent RCT, 4.3-point improvement in physical health status on SF-36 scale but no difference in pain • No effect on functioning, disability or return to work 	<ul style="list-style-type: none"> • The evidence regarding the effect of acupuncture relative to sham acupuncture on low back pain is ambiguous • Preponderance of evidence suggests that acupuncture is no more effective than sham acupuncture in improving functioning, and probability of returning to work • Insufficient evidence to determine whether acupuncture is more effective than sham acupuncture in reducing disability and improving physical health status
Neck disorders	<ul style="list-style-type: none"> • Meta-analysis (2 RCTs and CCTs, 114 persons) 	<ul style="list-style-type: none"> • Statistically significant for pain intensity in 1 of 2 studies 	<ul style="list-style-type: none"> • Less-intense pain in 2 of 2 studies 	<ul style="list-style-type: none"> • SMDs were -0.72 and -1.73 points on a 10-point scale 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture is more effective than sham acupuncture in reducing the intensity of pain due to neck disorders
Osteoarthritis of the hip	<ul style="list-style-type: none"> • Meta-analysis (1 RCT, 67 persons) 	<ul style="list-style-type: none"> • No statistically significant difference in pain 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Insufficient evidence to determine whether acupuncture is more effective than sham acupuncture in reducing pain due to osteoarthritis of the hip

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Osteoarthritis of the knee	<ul style="list-style-type: none"> • Meta-analysis (6 RCTs, 1135 persons) 	<ul style="list-style-type: none"> • Statistically significant for pain in 5 of 6 studies • Statistically significant for functioning in 2 of 3 studies 	<ul style="list-style-type: none"> • Decrease in pain in 5 of 6 studies • Improvement in functioning in 2 of 3 studies 	<p>Among studies that used the same measures</p> <ul style="list-style-type: none"> • For pain, reduction of 0 to 2.3 points on a 20-point scale • For functioning, improvement of 2.8 to 6.8 points on a 68-point scale 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture is associated with a small reductions in pain and a small improvement in functioning relative to sham acupuncture
Osteoarthritis of the thumb	<ul style="list-style-type: none"> • Meta-analysis (1 RCT, 12 persons) 	<ul style="list-style-type: none"> • No statistically significant difference in pain 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Insufficient evidence to determine whether acupuncture is more effective than sham electroacupuncture in reducing pain due to osteoarthritis of the thumb
Rheumatoid arthritis	<ul style="list-style-type: none"> • Systematic review (2 RCTs, 84 persons) 	<ul style="list-style-type: none"> • Acupuncture = no statistical significant difference in pain • Electro-acupuncture = statistically significant 	<ul style="list-style-type: none"> • Acupuncture = no difference • Electro-acupuncture = better 	<ul style="list-style-type: none"> • Acupuncture = no effect • Electro-acupuncture = 67% improvement 24 hours post treatment relative to control group and 5% relative improvement 4 months post treatment 	<ul style="list-style-type: none"> • Insufficient evidence that acupuncture and electroacupuncture are more effective than sham acupuncture in treating pain associated with rheumatoid arthritis or improving functioning
Shoulder pain	<ul style="list-style-type: none"> • Systematic review (3 RCTs, 154 persons) 	<ul style="list-style-type: none"> • No statistically significant difference in pain in 2 of 3 studies 	<ul style="list-style-type: none"> • No difference in 2 of 3 studies 	<ul style="list-style-type: none"> • No effect in 2 of 3 studies 	<ul style="list-style-type: none"> • The evidence that acupuncture is more effective than sham acupuncture in treating shoulder pain is ambiguous

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Temporo-mandibular joint dysfunction	<ul style="list-style-type: none"> • Systematic review (1 RCT, 18 persons) 	<ul style="list-style-type: none"> • No statistically significant difference in pain 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Insufficient evidence to determine whether acupuncture is more effective than sham acupuncture in reducing pain associated with temporomandibular joint dysfunction
Epilepsy	<ul style="list-style-type: none"> • Meta-analysis (1 RCT, 34 persons) 	<ul style="list-style-type: none"> • No statistically significant in frequency or duration of seizures or in quality of life 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Insufficient evidence to determine whether acupuncture is more effective than sham acupuncture in reducing the frequency and duration of seizures or the quality of life for persons with epilepsy
Headache	<ul style="list-style-type: none"> • Systematic review (15 RCTs and CCTs, 489 persons) • Large, well-designed RCTs published after meta-analysis (3 RCTs, 1,028 persons) 	<ul style="list-style-type: none"> • Statistically significant in 8 of 18 studies • Trend toward statistically significant in 3 of 18 studies • No difference in 7 of 18 studies 	<ul style="list-style-type: none"> • Better in 11 of 18 studies • No difference in 7 of 18 	<ul style="list-style-type: none"> • Difficult to quantify because outcomes reported inconsistently 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture is more effective than sham acupuncture for the treatment of headaches; however, 2 of 3 large RCTs found no statistically significant difference and 1 found differences that were statistically significant but probably not clinically important
Vascular dementia	<ul style="list-style-type: none"> • Systematic review (1 review)²⁷ 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • Insufficient evidence to assess the effectiveness of acupuncture for vascular dementia because there are no RCTs and few high-quality CCTs

²⁷ The authors of this systematic review did not report any results because they determined that none of the studies of the effect of acupuncture on vascular dementia met their criteria for inclusion in their systematic review. Reasons for exclusion included lack of randomization, use of Western medicine in the control group, and use of acupuncture in combination with another therapy, such as acupoint-injection, herbal drugs, and moxibustion. Peng et al., 2007.

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Cocaine dependence	<ul style="list-style-type: none"> • Meta-analysis (1 RCT, 192 persons) 	<ul style="list-style-type: none"> • No statistically significant difference in craving or severity of addiction 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Single study of moderate size suggests that auricular acupuncture is not more effective than sham acupuncture in reducing craving for cocaine or severity of addiction
Smoking cessation	<ul style="list-style-type: none"> • Meta-analysis (6 RCTs, 1,050 persons) 	<ul style="list-style-type: none"> • No statistically significant difference in abstinence from smoking 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture does not increase abstinence from smoking relative to sham acupuncture
Chemotherapy-induced nausea and vomiting	<ul style="list-style-type: none"> • Meta-analysis (1 RCTs, 80 persons) 	<ul style="list-style-type: none"> • Not statistically significant for severity of nausea or % vomiting within 24 hours 	<ul style="list-style-type: none"> • No difference in severity of nausea or % vomiting within 24 hours 	<ul style="list-style-type: none"> • No effect on severity of nausea or % vomiting within 24 hours 	<ul style="list-style-type: none"> • Insufficient evidence to determine whether acupuncture is more effective than sham acupuncture in reducing severity of nausea or probability of vomiting
Postoperative nausea and vomiting	<ul style="list-style-type: none"> • Meta-analysis (4 RCTs, 344 persons) • RCT published after the meta-analysis (1 RCT, 220 persons) 	<ul style="list-style-type: none"> • Statistically significant difference for risk of nausea in 3 of 5 studies • Statistically significant for risk of vomiting in 3 of 5 studies • Not statistically significant for 2 of 3 studies of use of rescue antiemetics 	<ul style="list-style-type: none"> • Lower risk of nausea and vomiting in 3 of 5 studies • No difference for 2 of 3 studies of use of rescue antiemetics 	<ul style="list-style-type: none"> • For risk of nausea, pooled RR = 0.63 (95% CI = 0.45, 0.89) • For risk of vomiting pooled RR = 0.66 (95% CI = 0.40, 1.11) • No effect for 2 of 3 studies of rescue antiemetics 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture is more effective than sham acupuncture in reducing the risk of postoperative nausea • The evidence of the effectiveness of acupuncture relative to sham acupuncture on vomiting and the use of antiemetics is ambiguous

Acupuncture versus Other Treatments

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Lateral elbow pain	<ul style="list-style-type: none"> Systematic review (2 RCTs, 57 persons) 	<ul style="list-style-type: none"> Statistically significant in 1 of 2 comparisons with ultrasound 	<ul style="list-style-type: none"> Decrease in 1 of 2 comparisons with ultrasound 	<ul style="list-style-type: none"> Not reported 	<ul style="list-style-type: none"> The evidence regarding the effectiveness of acupuncture relative to ultrasound for treatment of lateral elbow pain is ambiguous
Low back pain, acute	<ul style="list-style-type: none"> Meta-analysis (1 RCT, 57 persons) 	<ul style="list-style-type: none"> Not statistically significant for 1 comparison with naproxen 	<ul style="list-style-type: none"> No difference 	<ul style="list-style-type: none"> No difference 	<ul style="list-style-type: none"> Insufficient evidence to determine the effectiveness of acupuncture relative to naproxen in reducing acute low back pain
Low back pain, chronic	<ul style="list-style-type: none"> Meta-analysis (4 RCTs, 414 persons) 	<ul style="list-style-type: none"> Statistically significant for comparisons with massage and spinal manipulation Not statistically significant for comparisons with education, medication, and transcutaneous electrical nerve stimulator (TENS) 	<ul style="list-style-type: none"> Lower decrease in pain and less improvement in functioning than massage and spinal manipulation No difference in pain or functioning relative to education, medication, and TENS 	<ul style="list-style-type: none"> Not reported consistently 	<ul style="list-style-type: none"> Insufficient evidence to determine the effectiveness of acupuncture relative to education, massage, medication, spinal manipulation, and TENS in reducing chronic low back pain and improving functioning, because only one or two studies have compared each of these treatments to acupuncture
Low back pain or pelvic pain in pregnant women	<ul style="list-style-type: none"> Systematic review (2 RCTs, 160 persons) 	<ul style="list-style-type: none"> Statistically significant for comparison with a combination of analgesics, physical therapy, sacroiliac belt, and TENS Trend toward 	<ul style="list-style-type: none"> Greater decrease in intensity of pain relative to analgesics, physical therapy, sacroiliac belt, and TENS Greater self-reported 	<ul style="list-style-type: none"> 60% in the acupuncture group reported decrease in intensity of pain vs. 14% in the group that used various other treatments 	<ul style="list-style-type: none"> Preponderance of evidence suggests that acupuncture is more effective than physical therapy for treatment of low back and pelvic pain during pregnancy

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
		statistically significant for comparison with physical therapy alone	effectiveness relative to physical therapy alone	<ul style="list-style-type: none"> • 24% more likely to report acupuncture effective compared to physical therapy alone 	
Neck disorders	<ul style="list-style-type: none"> • Meta-analysis (3 RCTs and CCTs, 212 persons) 	<ul style="list-style-type: none"> • Not statistically significant for massage, mobilization, and traction 	<ul style="list-style-type: none"> • Less intense pain relative to traction • No difference for massage and mobilization 	<ul style="list-style-type: none"> • For comparison with traction, 38% more subjects reported improvement • No effect for comparisons with massage and mobilization 	<ul style="list-style-type: none"> • Insufficient evidence to determine the effectiveness of acupuncture relative to massage, mobilization, and traction in reducing intensity of neck pain because only one study compared acupuncture to each of these other treatments.
Osteoarthritis of the hip	<ul style="list-style-type: none"> • Meta-analysis (2 RCTs, 77 persons) 	<ul style="list-style-type: none"> • Statistically significant difference for 1 comparison with advice and exercise • Not statistically significant for 1 comparison with education 	<ul style="list-style-type: none"> • Decrease relative to advice and exercise • No difference relative to education 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • Insufficient evidence to determine the effectiveness of acupuncture relative to education or advice and exercise in reducing pain due to osteoarthritis of the hip
Osteoarthritis of the knee	<ul style="list-style-type: none"> • Meta-analysis (4 RCTs, 496 persons) 	<ul style="list-style-type: none"> • Statistically significant for 2 of 2 comparisons with medication and 1 of 2 comparisons for education • Not statistically significant for 1 comparison with TENS 	<ul style="list-style-type: none"> • Decrease in pain and improvement in functioning for 2 of 2 comparisons with medication and 2 of 2 comparisons with education • No difference relative to TENS 	<ul style="list-style-type: none"> • For comparisons with medication, among studies that used the same measures, 4 point decrease in pain on 20-point scale and 12 point improvement in functioning on a 68- 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture is more effective than medication and education in reducing pain and improving functioning • Insufficient evidence to determine the

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
				point scale <ul style="list-style-type: none"> • For comparisons with education, not reported consistently • For comparisons with TENS, no effect 	effectiveness of acupuncture relative to TENS in reducing pain and improving functioning
Shoulder pain	<ul style="list-style-type: none"> • Systematic review (2 RCTs and CCTs, 210 persons) 	<ul style="list-style-type: none"> • Statistically significant for 1 comparison with regional nerve block • Not statistically significant for 1 comparison each with steroid injection and ultrasound 	<ul style="list-style-type: none"> • Less effective than regional nerve block • No difference relative to steroid injection and ultrasound 	<ul style="list-style-type: none"> • 65 minutes longer to achieve pain relief with acupuncture compared to regional nerve block • 33% difference in intensity of pain 30 hours after treatment that favored regional nerve block • No effect for steroid injection and ultrasound 	<ul style="list-style-type: none"> • Insufficient evidence to determine the effectiveness of acupuncture relative to regional nerve block, steroid injection, and ultrasound in relieving shoulder pain
Temporo-mandibular joint dysfunction	<ul style="list-style-type: none"> • Systematic review (3 RCTs, 205 persons) 	<ul style="list-style-type: none"> • No statistically significant difference for 3 of 3 comparisons with stomatognathic treatments and occlusal splints 	<ul style="list-style-type: none"> • No difference in dysfunction, symptoms, and pressure pain threshold 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture is as effective as stomatognathic treatments and occlusal splints in reducing dysfunction and symptoms and improving pressure pain threshold and ability to perform activities of daily living

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Headache	<ul style="list-style-type: none"> • Systematic review (9 RCTs, 598 persons) • Large, well-designed RCTs published after meta-analysis (1 RCT, 477 persons) 	<ul style="list-style-type: none"> • Statistically significant for 4 of 5 comparisons with medication, 1 of 2 comparisons with physical therapy, and 1 comparison with a combination of massage and relaxation; • Not statistically significant for 1 comparison with biobehavioral program 	<ul style="list-style-type: none"> • More effective for 4 of 5 comparisons with medication and 1 of 2 comparisons with physical therapy • No difference relative to biobehavioral program • Less effective than physical therapy and the combination of massage and relaxation 	<ul style="list-style-type: none"> • Difficult to quantify because outcomes were reported inconsistently 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture is more effective than medication • The evidence of the effectiveness of acupuncture relative to physical therapy is ambiguous • Insufficient evidence to determine the effectiveness of acupuncture relative to a biobehavioral program, and the combination of massage and relaxation.
Smoking cessation	<ul style="list-style-type: none"> • Meta-analysis (3 RCTs, 825 persons) 	<ul style="list-style-type: none"> • Not statistically significant for 3 comparisons with smoking cessation counseling and 1 comparison with nicotine replacement therapy 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture is as effective as smoking cessation counseling and nicotine replacement therapy in facilitating smoking cessation
Postoperative nausea and vomiting	<ul style="list-style-type: none"> • Meta-analysis (4 RCTs, 405 persons) 	<ul style="list-style-type: none"> • Not statistically significant for nausea in 2 of 3 comparisons with 3 different antiemetic drugs, for vomiting in 6 of 6 comparisons with 4 different drugs, or in use of rescue antiemetics in 1 comparison with 1 drug 	<ul style="list-style-type: none"> • No difference in nausea for 2 of 3 comparisons and no difference in vomiting or use of rescue antiemetics in any of the comparisons with antiemetic drugs 	<ul style="list-style-type: none"> • No effect on nausea in 2 of 3 comparisons and no effect on vomiting or use of rescue antiemetics in any of the comparisons 	<ul style="list-style-type: none"> • The preponderance of evidence suggests that acupuncture is as effective as antiemetic drugs in alleviating postoperative nausea and vomiting and reducing use of rescue antiemetics

Acupuncture plus Other Treatments vs. Other Treatments

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Fibromyalgia	<ul style="list-style-type: none"> Systematic review (5 RCTs, 316 persons) 	<ul style="list-style-type: none"> Statistically significant for 3 of 5 studies of acupuncture plus conventional treatments for fibromyalgia 	<ul style="list-style-type: none"> Decrease in pain in 3 of 5 studies 	<ul style="list-style-type: none"> Generally small and short-lived – not measured consistently 	<ul style="list-style-type: none"> The evidence of the effectiveness of combining acupuncture with other treatments for fibromyalgia is ambiguous
Low back pain, chronic	<ul style="list-style-type: none"> Meta-analysis (4 RCTs, 289 persons) 	<ul style="list-style-type: none"> Statistically significant for acupuncture plus physical therapy alone, exercise and education, exercise and medication, and exercise and physical therapy 	<ul style="list-style-type: none"> Decrease in pain and improvement in functioning for acupuncture plus physical therapy alone, exercise and education, exercise and medication, exercise and physical therapy 	<ul style="list-style-type: none"> Not reported consistently 	<ul style="list-style-type: none"> Preponderance of evidence suggests that combining acupuncture with exercise and/or physical therapy decreases chronic low back pain and improves functioning
Osteoarthritis of the knee	<ul style="list-style-type: none"> Meta-analysis (4 RCTs, 1,244 persons) 	<ul style="list-style-type: none"> Statistically significant for 2 of 3 studies of acupuncture plus medication Not statistically significant for 1 study of acupuncture plus physical therapy 	<ul style="list-style-type: none"> Decrease in pain and improvement in functioning for 3 of 3 studies of acupuncture plus medication No difference for acupuncture plus physical therapy 	<ul style="list-style-type: none"> For medication, 0 to 8 point reduction in pain on 20-point scale and 0- to 17-point improvement in pain on a 68-point scale For physical therapy, no effect 	<ul style="list-style-type: none"> The evidence of the effectiveness of combining acupuncture with medications used to treat osteoarthritis is ambiguous Insufficient evidence to determine whether combining acupuncture with physical therapy is more effective than physical therapy alone
Pelvic pain in pregnant women	<ul style="list-style-type: none"> Systematic review (1 RCT, 386 persons) 	<ul style="list-style-type: none"> Statistically significant difference in pain when turning in bed for acupuncture plus 	<ul style="list-style-type: none"> Decrease in pain when turning in bed for acupuncture plus education and pelvic 	<ul style="list-style-type: none"> 20% decrease in risk of pain when turning in bed for acupuncture plus 	<ul style="list-style-type: none"> Single, large RCT suggests that combining acupuncture with education and pelvic belt

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
		education and pelvic belt <ul style="list-style-type: none"> No statistically significant difference in pain during waking hours 	belt <ul style="list-style-type: none"> No difference in pain during waking hours 	education and pelvic belt <ul style="list-style-type: none"> No effect on risk of pain during waking hours 	reduces pain when turning in bed but does not affect symptoms during waking hours
Shoulder pain	<ul style="list-style-type: none"> Systematic review (2 RCTs, 59 persons) 	<ul style="list-style-type: none"> Statistically significant difference for 1 study of acupuncture plus exercise No statistically significant difference for 1 study of acupuncture plus mobilization 	<ul style="list-style-type: none"> Better for acupuncture plus exercise No difference for acupuncture plus mobilization 	<ul style="list-style-type: none"> 9% increase in composite measure of pain, range of motion, and functioning for acupuncture plus exercise No effect for acupuncture plus mobilization 	<ul style="list-style-type: none"> Insufficient evidence to determine whether acupuncture combined with exercise is more effective than exercise alone in treating shoulder pain
Stroke, acute phase	<ul style="list-style-type: none"> Meta-analysis (14 RCTs and CCTs, 1,208 persons) 	<ul style="list-style-type: none"> Statistically significant for acupuncture plus standard treatments for acute stroke on measures of mortality, institutional care and global neurological deficit, trend toward statistical significance for dependency Not statistically significant for acupuncture plus standard treatments for death, motor function, and quality of life 	<ul style="list-style-type: none"> Decrease in need for institutional care, dependency, and global neurological deficit No difference in death, motor function, and quality of life 	<ul style="list-style-type: none"> Pooled OR = 0.58 (95% CI = 0.35, 0.96) for death or institutional care, pooled OR = 0.66 (95% CI = 0.43, 0.99) for death or dependency, pooled SMD = 1.17 (95% CI = 0.30, 2.04) for reduction in global neurological deficit No effect on death, motor function, and quality of life 	<ul style="list-style-type: none"> Preponderance of evidence from small studies suggests that combining acupuncture with standard treatments for stroke reduces need for institutional care, dependency, and global neurological deficit but does not affect the risk of death, motor function, or quality of life

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Stroke, subacute and chronic phase	<ul style="list-style-type: none"> • Meta-analysis (14 RCTs, 368 persons) 	<ul style="list-style-type: none"> • Statistically significant for acupuncture plus standard treatments for acute stroke on measures of global neurological deficit • Not statistically significant for acupuncture plus standard treatments for death, motor function 	<ul style="list-style-type: none"> • Decrease in global neurological deficit • No difference in motor function 	<ul style="list-style-type: none"> • Cannot be determined due to wide confidence intervals 	<ul style="list-style-type: none"> • Preponderance of evidence from small studies suggests that combining acupuncture with other treatments reduces global neurological deficit in persons who have had a stroke but does not affect motor function
Cocaine dependence	<ul style="list-style-type: none"> • Meta-analysis (6 RCTs, 1,241 persons) 	<ul style="list-style-type: none"> • No statistically significant difference in cocaine use, cocaine craving, or severity of addiction 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Preponderance of evidence from studies with high drop out rates suggests that adding auricular acupuncture to methadone, neurobehavioral treatment, or multi-component residential or inpatient treatment does not reduce cocaine use, cocaine craving, or severity of addiction
Smoking cessation	<ul style="list-style-type: none"> • Meta-analysis (3 RCTs, 682 persons) 	<ul style="list-style-type: none"> • No statistically significant difference in abstinence from smoking for acupuncture plus smoking cessation counseling or nicotine gum 	<ul style="list-style-type: none"> • No difference 	<ul style="list-style-type: none"> • No effect 	<ul style="list-style-type: none"> • Preponderance of evidence suggests that acupuncture does not enhance the effects of smoking cessation counseling, education, or nicotine gum

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Chemotherapy-induced nausea or vomiting	<ul style="list-style-type: none"> • Meta-analysis (3 RCTs, 134 persons) • RCT published after the meta-analysis (1 RCT, 11 persons) 	<ul style="list-style-type: none"> • Statistically significant in 3 of 3 studies of electroacupuncture plus antiemetics for % vomiting • Statistically significant in 1 study of manual acupuncture for use of rescue antiemetics but not for nausea and vomiting 	<ul style="list-style-type: none"> • Lower % vomiting in 3 of 3 studies electro-acupuncture but not in 1 study of manual acupuncture • Less use of antiemetic medication in 1 study of manual acupuncture • No difference in nausea in 1 study of manual acupuncture 	<ul style="list-style-type: none"> • For electro-acupuncture, pooled RR = 0.76 (95% CI = 0.60, 0.97) • Not reported in 1 study of manual acupuncture 	<ul style="list-style-type: none"> • Preponderance of evidence from 3 small RCTs suggests that combining electroacupuncture and antiemetics reduces incidence of acute vomiting among persons receiving chemotherapy • Insufficient evidence to assess the effects of manual acupuncture as an adjuvant to antiemetic medication

Key: CCTs = controlled clinical trials; CI = confidence interval; OR = odds ratio; RCTs = randomized controlled trials; RR = relative risk ratio; SMD = standardized mean difference; TENS = transcutaneous electrical nerve stimulator; WMD = weighted mean difference.

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, 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 and provides data and analyses per the provisions of CHBRP authorizing legislation.

Data Sources

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

Private Health Insurance

1. The latest (2005) California Health Interview Survey (CHIS), which is utilized to estimate insurance coverage for California's population and distribution by payer (i.e., employment-based, privately purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over 40,000 households. More information on CHIS is available at www.chis.ucla.edu/
2. The latest (2006) California Employer Health Benefits Survey is utilized to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured),
 - premiums for plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations (HMOs)),
 - premiums for policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations (PPOs)), and
 - premiums for high deductible health plans (HDHP) for the California population covered under employment-based health insurance.

This annual survey is released by the California Health Care Foundation/Center for Studying Health System Change (CHCF/HSC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Center for Studying Health System Change. More information on the CHCF/HSC is available at:

www.chcf.org/topics/healthinsurance/index.cfm?itemID=127480

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/). 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 preferred provider organizations (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 MEDSTAT 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 (2006 Group Health Insurance Survey) contains data from six major California health plans regarding their 2005 experience.
 - Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
 - These data are reviewed for generalizability 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, 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 these seven firms represents 82% of enrollees in full-service health plans regulated by DMHC and 46% of lives covered by comprehensive health insurance products regulated by CDI.

Public Health Insurance

5. Premiums and enrollment in DMHC- and CDI-regulated plans by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their family members who receive their benefits through CalPERS. Enrollment information is provided for fully funded, Knox-Keene licensed health care service plans—which is about 75% of CalPERS total enrollment. CalPERS self-funded plans—approximately 25% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from health plans' evidence of coverage (EOCs) publicly available at www.calpers.ca.gov.
6. Enrollment in Medi-Cal Managed Care (Knox-Keene licensed plans regulated by DMHC) is estimated based on CHIS and data maintained by the Department of Health Services (DHS). DHS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts which summarize the current scope of benefits. CHBRP assesses enrollment information online at: www.dhs.ca.gov/admin/ffdmb/mcss/RequestedData/Beneficiary%20files.htm.
7. Enrollment data for other public programs: Healthy Families, Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP) are estimated

based on CHIS and data maintained by the Major Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating plans under these programs must comply with all requirements of the Knox-Keene Act, and thus these plans are affected by changes in coverage for Knox-Keene licensed plans. CHBRP does not include enrollment in the Post-MRMIB Guaranteed-Issue Coverage Products as these individuals are already included in the enrollment for individual health insurance products offered by private carriers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. The 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 services 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 people with insurance.
- The projections do not include people covered under self-insured employer plans because those plans are not subject to state-mandated minimum benefit requirements.
- 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 absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for 1 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.
- 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 coverage. If a mandate increases health insurance costs, then some employer groups or individuals may elect to drop their coverage. 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, members or insured 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 the insured person, 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 insurance may now elect to enroll in an insurance plan postmandate because they perceive that it is to their economic benefit to do so.
- Health plans may react to the mandate by tightening their 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).
- Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the plan 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 these plan types. Utilization also differs within California due to differences in the health status of the local commercial 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 health plans and providers. 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

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.

No information was submitted directly by interested parties for this analysis.

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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California Health Benefits Review Program Committees and Staff

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

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

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

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