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# Title

Analysis of Assembly Bill 1185: Chiropractic Services

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Analysis of Assembly Bill 1185 Chiropractic Services

> A Report to the 2005–2006 California Legislature July 5, 2005

> > CHBRP 05-10



Established in 2002 to implement the provisions of Assembly Bill 1996 (*California Health and Safety Code*, Section 127660, et seq.), the California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates. The statute defines a health insurance benefit mandate as a requirement that a health insurer and/or managed care health plan (1) permit covered individuals to receive health care treatment or services from a particular type of health care provide; (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.

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, made up of 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 sound scientific evidence relevant to the proposed mandate but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work though 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 CHBRP's Web site, www.chbrp.org.

## A Report to the 2005–2006 California State Legislature

Analysis of Assembly Bill 1185 Chiropractic Services

July 5, 2005

California Health Benefits Review Program 1111 Franklin Street, 11<sup>th</sup> Floor Oakland, CA 94607 Tel: 510-287-3876 Fax: 510-987-9715 www.chbrp.org

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#### PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 1185, a bill that would require health care service plans and health insurance policies to cover chiropractic services. In response to a request from the California Assembly Committee on Health on May 6, 2005, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127600, et seq., of the California Health and Safety Code.

Wade Aubry, MD, Witney McKiernan, RN, and Edward Yelin, PhD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Scott Haldeman, MD, DC, provided technical assistance with the literature review and clinical expertise for the medical effectiveness analysis. Helen Halpin, PhD, Sara McMenamin, PhD, and Nicole Bellows, MHSA, all of the University of California, Berkeley, prepared the public health impact analysis. Miriam Laugesen, PhD, and Nadereh Pourat, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Robert Cosway, FSA, MAAA, and Chris Girod, FSA, MAAA, of Milliman, provided actuarial analysis. Cynthia Robinson, MPP, Sachin Kumar, BA, and Susan Philip, MPP, of CHBRP staff prepared the background section and synthesized individual sections into a single report. Other contributors include Robert O'Reilly, BS, of CHBRP staff, and Cherie Wilkerson, BA, who provided editing services. In addition, a subcommittee of CHBRP's National Advisory Council (see final pages of this report), Paul G. Shekelle, MD, PhD, of the University of California, Los Angeles, and James N. Weinstein, DO, MS, of the Dartmouth-Hitchcock Medical Center reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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 CHBRP:

California Health Benefits Review Program 1111 Franklin Street, 11<sup>th</sup> Floor Oakland, CA 94607 Tel: 510-287-3876 Fax: 510-987-9715 www.chbrp.org

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Michael E. Gluck, PhD Director



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#### **EXECUTIVE SUMMARY**

#### California Health Benefits Review Program Analysis of Assembly Bill 1185: Chiropractic Services

The California Legislature has asked the California Health Benefits Review Program to conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill 1185. AB 1185 would add Section 1373.122 to the California Health and Safety Code and Section 10127.6 to the Insurance Code relating to health care coverage.

AB 1185 would require a health care service plan or a health insurance policy to provide coverage for chiropractic services. AB 1185 would also require that chiropractic services be made available to an enrollee or subscriber without a referral from a primary care physician and that health plans and insurers contract with a sufficient number of chiropractors to provide "meaningful access to chiropractic services."

Chiropractic services as defined in AB 1185 are those services "described in the Chiropractic Act." The Chiropractic Initiative Act of 1922<sup>1</sup> established the State Board of Chiropractic Examiners and the terms under which licenses may be issued to practitioners of chiropractic. Regulations promulgated by the State Board of Chiropractic Examiners define the scope of practice for chiropractors in California and provide the basis for the licensure and regulation of the chiropractic profession in the state. Chiropractors report treatment of musculoskeletal conditions such as back pain and neck pain account for the majority of care, although they also report treating or advising on a range of other conditions, including allergies, high blood pressure, obesity, and asthma. CHBRP's analysis focuses on the *most frequent* disorders for which people seek treatment from chiropractors: musculoskeletal conditions.

The intent of AB 1185 is to expand health insurance to cover services performed by chiropractors, as well as to allow an enrollee to self-refer for such services. The bill is silent on whether health plans or insurers can use utilization management techniques that are employed for other medical care services, such as placing limitations on the number of visits or restricting coverage to in-network providers. For the purposes of this analysis, CHBRP assumes that health plans and insurers would not be prohibited from using these utilization management techniques.

AB 1185 would apply to health care services plans licensed by Knox-Keene<sup>2</sup> and to health insurance policies regulated under the California Insurance Code. This includes government-sponsored programs such as Medi-Cal managed care, Healthy Families, and the California Public Employees' Retirement System (CalPERS). Specialized health care service plans, such as vision-only or dental-only plans would be exempt from AB 1185.

<sup>&</sup>lt;sup>1</sup> Chiropractic Initiative Act of California, Stats. 1923, p. xxii

<sup>&</sup>lt;sup>2</sup> Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.

#### I. Medical Effectiveness

The evidence base for assessing the medical effectiveness of chiropractic services is limited. A paucity of well-designed and well-executed studies hampers the evaluation of its effectiveness. The literature on the medical effectiveness of chiropractic services has methodological limitations which preclude *definitive* conclusions on any of the outcomes of chiropractic treatments. Methodological limitations for specific studies are:

- Overall clinical trial design issues
  - Relatively few studies with a true placebo (e.g., effective blinding via sham or fake spinal manipulation) making it virtually impossible for a test patient involved in the trial to be "blind" to the treatment;
  - Because of a lack of definitive evidence about the mix of services provided by chiropractors versus services provided by traditional (allopathic) medical professionals, it is difficult to compare the outcomes of treatment provided by each type of professional for comparable conditions;
  - Comparison groups (i.e., study participants receiving nonmanipulation treatments such as massage, analgesics, medical care, no treatment, or physical therapy) differ from study to study, making the data difficult to synthesize;
  - Many individual studies include outcomes data on a number of different clinical conditions (e.g., low back pain [acute and/or chronic], neck pain [with or without headache], shoulder pain), which creates a challenge when attempting a comprehensive analysis of the data.
- Criteria for inclusion in or exclusion from clinical trials
  - Because the diagnostic categories used in different clinical trials are not always comparable, it is difficult for researchers to combine the results from different studies to determine if the observed outcomes are statistically significant (i.e., did not occur by chance rather than as a result of treatment);
  - Studies that include but do not identify persons with work-related injuries who may receive medical care under their employers' workers' compensation insurance rather than under their health insurance makes it difficult to analyze treatment outcomes for those persons receiving medical care exclusively under health insurance plans potentially affected by AB 1185;.
  - Potential inclusion of physical therapists and medical doctors as providers of spinal manipulation therapy (SMT) hinders the ability to assess the effectiveness of those same services that are delivered exclusively by chiropractors.

- Assessment of patient outcomes
  - There is inconsistency in measurement of pain across studies;
  - The date at which outcomes are measured relative to initiation of chiropractic care (e.g., one week versus one month later) varies across studies;
  - There is a lack of systematic reviews or meta-analyses that aggregate comparable clinical trail data measuring patients' quality of life.

Within the scope and limitations outlined above, CHBRP's review of evidence from those studies that meet its usual standards of scientific rigor (as described in Appendix A), suggests that:

- There is a pattern toward favorable results with respect to
  - o pain relief;
  - o objective clinical signs, for example, physical exams and adverse events;
  - o functional status, such as a decrease in disability or reduction in sick leave.
- There are ambiguous or mixed results with respect to health care utilization and costs.
- There is insufficient evidence with respect to quality of life.

#### II. Utilization, Cost, and Coverage Impacts

#### Coverage

- An estimated 20,485,000 people in California are enrolled in health care plans or have health insurance policies that would be affected by this legislation.
- Around 68% of the affected population currently has coverage that meets the AB 1185 requirement to allow members direct access to a chiropractor. 27% (5,464,000 enrollees) do not have coverage that meets the requirements of AB 1185 because they have no chiropractic coverage. 5% (1,014,000 enrollees) do not have coverage that meets the requirements of AB 1185 because they have coverage contingent on a referral from a primary care physician (PCP).
- If AB 1185 were to become law, approximately 5,464,000 enrollees who do not currently have chiropractic coverage would have coverage, and a further 1,014,000 enrollees would be able to access chiropractic services without a referral.

### Utilization

• AB 1185 is projected to increase the average annual number of chiropractic visits across all enrollees from the present rate of 363, to 464 visits per 1,000 enrollees, an increase of 28%.

### Annual Expenditures

• There is no evidence to suggest that chiropractic coverage will reduce other healthcare costs. Existing research on the cost effectiveness of chiropractic coverage is inconclusive, due to methodological limitations in study designs.

If AB 1185 were to become law:

- Total private employer premiums are projected to increase by a total of \$53,187,000 dollars per year (or \$0.32 per member per month [PMPM]), an increase of 0.150%.
- Individuals who pay for a share of their employer-based insurance, and individuals paying Healthy Families and CalPERS' premiums are projected to increase by a total of \$19,372,000 dollars in additional premiums (\$0.11PMPM), an increase of 0.189%.
- Premium expenditure on individually purchased insurance are projected to increase by a total of \$10,041,000 dollars (\$0.43PMPM), an increase of 0.263%.
- CalPERS' employer costs are projected to increase by a total of \$5,272,000 per year (\$0.55PMPM) or by 0.238%.

- Medi-Cal managed care members currently have coverage for chiropractic services and have direct access to chiropractic services; therefore costs would be likely to remain the same.
- Healthy Families state expenditures are projected to increase by a total of \$993,000 per year (\$0.14PMPM), an increase of 0.231%.
- Copayments associated with chiropractic care are projected to increase by a total of \$30,669,000, an increase of 0.752%.
- Other out-of-pocket costs for chiropractic care presently not covered by insurance are projected to decrease from a total of \$47,957,000 to \$0, (a decrease of 100%) because by virtue of the mandate, the insured population would be covered for chiropractic services. Out-of-pocket expenses for *covered* benefits in the form of copayments would continue to be incurred.

#### Caveats

- Most health care plans and insurers limit utilization of chiropractic services by requiring preauthorization or by limiting the number of visits to chiropractors. CHBRP assumes the same level of utilization management pre- and postmandate by health care plans and insurers.
- Due to the limitations of time and data availability, CHBRP assumes that the populations with and without current coverage are similar with respect to their mix of diagnoses, severity of illness, incidence of spinal-related conditions, and associated demand for chiropractic services.

Total Insured Population <sup>(1)</sup> = 20,485,000	Before Mandate	After Mandate	Increase/ Decrease	% Change After Mandate
Coverage <sup>(2)</sup>				
Number and percentage of insured individuals with chiropractic coverage (no PCP <sup>*</sup> referral required)	14,007,000 (68%)	20,485,000 (100%)	6,478,000	46.2%
Number of insured individuals with chiropractic coverage (PCP referral required)	1,014,000 (5%)		(1,014,000)	-100.0%
Number of insured individuals in California without coverage for the benefit	5,464,000 (27%)	_	(5,464,000)	-100.0%
Unit Cost				
Contracted reimbursement to chiropractors for those with coverage (insurance paid plus copayment)	\$36	\$36	—	0.0%
Reimbursement for those without coverage	\$60	N/A		
Annual Utilization				
Visits per 1,000 for all members**	363	464	101	27.8%
Annual Expenditures				
Private employer premiums	\$35,360,055,000	\$35,413,242,000	\$53,187,000	0.150%
Private employees, CalPERS, or Healthy Families enrollees' premiums	\$10,269,978,000	\$10,289,350,000	\$19,372,000	0.189%
Individually purchased insurance premiums	\$3,818,726,000	\$3,828,767,000	\$10,041,000	0.263%
CalPERS premiums	\$2,212,881,000	\$2,218,153,000	\$5,272,000	0.238%
Medi-Cal premiums	\$3,939,663,000	\$3,939,663,000	—	0.000%
Healthy Families premiums	\$430,246,000	\$431,239,000	\$993,000	0.231%
Copayments	\$4,077,377,000	\$4,108,046,000	\$30,669,000	0.752%
Expenditures for services not covered by insurance	\$47,957,000	\$0	-\$47,957,000	-100.000%
Total annual expenditures	\$60,156,883,000	\$60,228,460,000	\$71,577,000	0.119%

#### Table 1. Summary of Coverage, Utilization, and Cost Effects of AB 1185

Source: California Health Benefits Review Program, 2005.

*Notes:* (1) The population includes individuals and their dependents in California, who have private insurance (group and individual), or are enrolled in public plans subject to the Health and Safety Code, including **the California Public Employees' Retirement System** (CalPERS), Medi-Cal, or Healthy Families. This figure excludes individuals who work for firms that self-insure. (2) Coverage typically has some restrictions, such as visit limits.

\*Primary care physician. \*\*This is an average across multiple plan types and coverage levels. Utilization varies by level of coverage and plan type–see utilization discussions in Coverage, Utilization, Cost section for further details.

#### **III.** Public Health Impacts

- Approximately 20% of people report that they have used chiropractic services in their lifetime. National and regional estimates on the annual use of chiropractic services vary from 4% to 11%. Of those that use chiropractic services, a majority of care is for musculoskeletal disorders such as back and neck pain.
- It is estimated that as a result of this mandate 250,000 more Californians will use at least one chiropractic service each year. It is possible that these newly covered people will have increases in health status, as suggested by the medical effectiveness literature, such as increased pain relief, increases in objective measures of health status such as range of motion, strength, or flexibility, and increased functional status. However, due to the methodological limitations of the literature, it is not possible to quantify the overall effect of chiropractic care or to quantify the overall impact of the proposed legislation on public health.
- There is evidence that females use more chiropractic services than males and that minority racial and ethnic groups are less likely to receive chiropractic services. Due to insufficient evidence, it is not possible to estimate the impact of AB 1185 on access to chiropractic care or health outcomes for specific gender or racial and ethnic groups.
- Although there is evidence of significant economic loss associated with musculoskeletal disorders such as back pain, there is insufficient evidence to conclude that AB 1185 would result in reductions in these economic losses.

#### **INTRODUCTION**

The California Legislature has asked the California Health Benefits Review Program to conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 1185. AB 1185 would add Section 1373.122 to the California Health and Safety Code and Section 10127.6 to the Insurance Code relating to health care coverage and would apply to health care services plans licensed by Knox-Keene<sup>3</sup> and to health insurance policies regulated under the California Insurance Code.<sup>4</sup>

AB 1185 would require health care service plans and insurance policies to provide coverage for chiropractic services. AB 1185 would also require that chiropractic services be made available to an enrollee or subscriber without a referral from a primary care physician. Health plans and insurers would also be required to contract with a sufficient number of chiropractors to provide "meaningful access to chiropractic services."

Chiropractic services are defined in AB 1185 as those services "described in the Chiropractic Act." The Chiropractic Initiative Act of 1922<sup>5</sup> established the State Board of Chiropractic Examiners and the terms under which licenses may be issued to practitioners of chiropractic. Regulations promulgated by the State Board of Chiropractic Examiners provide the basis for the licensure and regulation of the chiropractic profession in California.<sup>6</sup>

The current scope of practice for the chiropractic profession can be found in Article 1, Section 302 of the *Laws and Regulations Relating to the Practice of Chiropractic*. Under this section, chiropractors may manipulate and adjust the spinal column and other joints of the human body, as well as use "all necessary mechanical, hygienic, and sanitary measures incident to the care of the body." This includes, but is not limited to, air, cold, diet, exercise, heat, light, massage, physical culture, rest, ultrasound, water, and physical therapy techniques in the course of chiropractic manipulations. Chiropractors can also make use of x-ray and thermography equipment for the purposes of diagnosis but not for the purpose of treatment. Section 302 also lists limitations on the scope of chiropractic practice, for example, "A chiropractic license does not authorize the holder thereof … to use any drug or medicine included in material medica" (see Appendix E for a complete description of the scope of practice for chiropractic).

The CHBRP analysis did not assess the medical effectiveness of chiropractic services on all disorders chiropractors may potentially treat. CHBRP took this approach because analyzing the impact of expanded access for every potential type of treatment or procedure a chiropractor may perform is not feasible within a 60-day timeframe. Instead, the CHBRP analysis focused on the *most frequent* disorders for which people seek treatment from chiropractors: musculoskeletal disorders such as back and neck pain. This interpretation was also supported by written material provided by Assembly Member Koretz's office which stated that: AB 1185 aims to ensure that

<sup>&</sup>lt;sup>3</sup> Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.

<sup>&</sup>lt;sup>4</sup> Specialized health care service plans, such as vision-only or dental-only plans would be exempt.

<sup>&</sup>lt;sup>5</sup> Initiative Measure, Stats.1923, p. xxii

<sup>&</sup>lt;sup>6</sup> California Board of Chiropractic Examiners: Laws and Regulations Relating to the Practice of Chiropractic and Sections 1000 et seq., California Business and Professions Code (Appendix E)

those who prefer chiropractic for the treatment of their back, neck, shoulder, and hand pain can access it on an equal basis as other treatments."<sup>7</sup>

AB 1185 would prohibit plans from requiring a referral from a PCP, but the bill is silent on whether health plans or insurers can use other utilization management techniques such as:

- Requiring enrollees who reside or work in a specific geographic area served by the health plan or insurer to receive services from contracted providers within that service area;
- Imposing authorization requirements after a certain number of visits;
- Imposing limits on the number of visits or annual dollar limits or copayments;
- Providing coverage for all or part of chiropractic services through a separate specialized health care service plan.

For the purposes of this analysis, CHBRP assumes that health plans and insurers would not be prohibited from using these utilization management techniques.

As mentioned, AB 1185 would require that health plans and insurers contract with a "sufficient number" of chiropractors to provide "meaningful access to chiropractic services."

Based on discussions with legislative staff, the intent of AB 1185 is to expand access to chiropractors for "chiropractic services." Although other health providers, such as osteopaths and physical therapists, may perform spinal manipulations and massages, the authors of the legislation intend to expand access to chiropractors as the providers of chiropractic services.

To comply with AB 1185, plans and insurers would need not only to contract with a sufficient number of chiropractors, but also to conduct a network analysis to determine that the geographical distance and travel time to contracted providers would meet the standard of "meaningful" access. The extent of changes needed in plans' provider networks is dependent on the access standards that would be applied under AB 1185. Already-existing accessibility standards for Knox-Keene-licensed plans require that "[w]ithin each service area of a plan, basic health care services and specialized health care services shall be readily available and accessible to each of the plan's enrollees" (California Code of Regulations, Title 28, Division 1, Chapter 2, Article 7, § 1300.67.2). Further, applications for Knox-Keene licenses require plans to describe the geographical area they serve and to demonstrate that "throughout the geographic regions designated as the plan's Service Area, a comprehensive range of primary, specialty, institutional and ancillary services are readily available at reasonable times to all enrollees and, to the extent feasible, that all services are readily accessible to all enrollees." The Department of Managed Health Care states that it evaluates "the geographic aspects of availability and accessibility" in part by taking into account "the actual and projected enrollment of the plan based on the residence and place of work of enrollees within and, if applicable, outside the service area" (California Code of Regulations, Title 28, Division 1, Chapter 2, Article 3, § 1300.51). Insurers regulated under the California Insurance Code also currently face requirements to maintain an adequate "number of professional providers, and license classifications of such providers, in

<sup>&</sup>lt;sup>7</sup> Office of Assemblyman Paul Koretz, AB 1185 Access to Chiropractic Treatment Act of 2005 Fact Sheet, April 5, 2005

relationship to the projected demands for services covered under the group policy or plan." The California Department of Insurance (CDI) is required to "consider the nature of the specialty in determining the adequacy of professional providers." (Insurance Code 10133.5.(b)2)

If more extensive requirements related to the number of contracting chiropractors are established, definitions of these different standards would be needed for implementation purposes. If that is the case, it is possible that a larger number of plans and insurers, including the subcontracting specialty plans, would need to substantially enlarge their provider networks and that changes would need to be more extensive.

### Background

The chiropractic profession has over 65,000 practitioners nationwide and over 12,000 in California. People commonly see chiropractors for complaints related to headaches, injuries, neck pain, back pain, arthritis, and strains. Although chiropractors also report treating or advising on a range of other conditions (including allergies, high blood pressure, obesity, and asthma), treatment of musculoskeletal disorders such as back pain and neck pain accounts for the majority of chiropractic visits. Chiropractors also report counseling their patients in lifestyle topics such as diet and exercise.

Spinal manipulation therapy (SMT) to treat musculoskeletal disorders is one of the main techniques used by chiropractors. This technique is also used by other kinds of health care professionals, such as physical therapists and osteopaths. It involves two primary clinical interventions, mobilization and manipulation. "Mobilization is a joint movement performed by the practitioner within the patient's joint's normal range (the range achieved under the patient's own volition), or physiologic space. Manipulation is the movement of the patient's joint by the practitioner beyond its range, or into the paraphysiologic space of the joint. Through joint mobilization and manipulation, the chiropractor works to restore the patient's proper spinal and musculoskeletal alignment" (Briggance, 2003).

#### Chiropractic Legislative Activity in California

Chiropractic first became a licensed profession in California in 1922, when the Chiropractic Initiative Act of California was passed by California voters. It created a board of examiners, vested with the responsibility to govern the chiropractic profession in California; outlined the educational requirements for a doctor of chiropractic license; and currently serves as the basis for all chiropractic regulation in the state.

In 1942, legislation was passed to include chiropractic services in the Workers Compensation Act. California Senate Bill 228 (2004), which was chaptered into law and took effect on January 1, 2004, limits an employee to no more than 24 chiropractic visits per industrial injury. Under this law, those employees eligible to designate their physician have the option to choose a chiropractor as their PCP if the chiropractor has treated the employee in the past and has their medical records.

A chiropractic benefit was also added for inclusion in the Medi-Cal program in 1965. Medi-Cal currently provides chiropractic benefits only for manual manipulation of the spine. Visits to chiropractors are combined with visits for many other types of services up to a maximum of two per month.

#### Chiropractic Legislative Activity in Other States

Approximately 43 states and the District of Columbia mandate some level of access to chiropractic services, at least for fee-for-service group insurance policies. In addition, three states, New Jersey, Washington, and Wisconsin, require that chiropractic services be offered as a benefit for purchase.

#### Chiropractic Activity at the Federal Level

Chiropractic services are covered by Medicare; however, services are limited to treatment by means of manual manipulation of the spine. No other diagnostic or therapeutic services are covered. In April 2005, the Centers for Medicare & Medicaid Services (CMS) started a two-year demonstration to expand the array of chiropractic services offered to Medicare Part B enrollees to those services chiropractors are currently licensed to perform under their respective state laws. CMS will hire an independent evaluator to assess the cost impact, utilization, and beneficiary satisfaction under the demonstration.<sup>8</sup>

There are three bills currently in the 109th U.S. Congress that would mandate chiropractic benefits for military personnel and veterans. Two bills would require the Department of Defense (DOD) to provide chiropractic services for current enrollees (HR 1594) and retirees and dependents (HR 999) covered under TriCare, the DOD's managed health care program. HR 917 would include chiropractic services as a benefit for veterans.

<sup>&</sup>lt;sup>8</sup> <u>http://www.cms.hhs.gov/media/press/release.asp?Counter=1417</u> accessed May 2, 2005

#### I. MEDICAL EFFECTIVENESS

#### **Results from the Literature Review**

The results of the review of the scientific literature on the medical effectiveness of chiropractic care for musculoskeletal disorders are organized into the following major categories of outcomes:

- Pain relief;
- Objective signs, e.g., physical exams and adverse events;
- Quality of life;
- Functional status, e.g., activities of daily living (ADL) and work status;
- Health care utilization and costs, e.g., use of medical services (including drugs) and patient satisfaction.

As can be seen in Table B-2, a great majority of these studies focus on pain relief, [a major issue for patients with musculoskeletal disorders]

Studies on the effectiveness of chiropractic care for musculoskeletal disorders were identified from PubMed, the Cochrane Collaboration, the Index to Chiropractic Literature, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Manual, Alternative, and Natural Therapy Index System (MANTIS) for the period from January 1995 through May 2005, yielding 280 references. The literature search includes randomized controlled trials, clinical trials, meta-analyses, case reports, case-control studies, and systematic reviews. The present analysis relies upon 23 meta-analyses and systematic reviews to assess the impact of chiropractic services for musculoskeletal disorders, supplemented by 2 case-control studies on serious adverse events and a recently published randomized controlled trial on the cost of chiropractic care.

A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure can be found in Appendix A: Literature Review Methods. Summary tables with detailed findings and evidence from the literature can be found in Appendix B: Summary of Published Studies on the Effectiveness of Chiropractic Services.

#### Methodological Limitations<sup>9</sup>

The literature to assess the medical effectiveness of chiropractic services had several methodological limitations. Trials that assessed the impact of manual therapies (e.g., manipulation and mobilization) often lacked the ability to use a placebo control, such as sham manipulation. Even when sham manipulation is done, it is difficult to administer, and effective blinding of manual therapy trials is, therefore, often impossible. In addition, there is a dearth of trials that compared the range of chiropractic services with that of allopathic providers (e.g.,

<sup>&</sup>lt;sup>9</sup> A comprehensive review of the methodological limitations of each study included in this review can be found in Table B-2b.

medical doctors) or physical therapists in a way that more accurately reflects the mix of clinical interventions utilized by each practitioner.

In terms of trial inclusion and exclusion criteria, many of the studies included in this review did not explicitly exclude work-related injuries. AB 1185 does not apply to such workers' compensation cases. However, this review may reflect the inclusion of data from this patient population.

Many of the studies which examined the effectiveness of SMT also included a mix of providers delivering SMT, such as chiropractors, physical therapists, and medical doctors. It is difficult then to synthesize the data on the effectiveness of SMT when provided exclusively by chiropractors.

The absence of diagnoses using the International Classification of Diseases, 9th Revision (ICD-9) codes in identifying and selecting patients with similar musculoskeletal disorders also created a methodological limitation in the majority of studies included in this review. Researchers grouped subjects into broad categories of complaints, such as low back pain (chronic and/or acute) or neck pain (for additional examples, see Table 5). The dearth of studies using ICD-9 codes limits the homogeneity of study samples and, consequently, the strength of subsequent statistical analyses.

Methodological limitations were also apparent in the outcomes measured by individual trials. Patient pain measurements, including the instruments used to assess pre- and postintervention pain levels, varied by trial, which hindered pooling of trial data and statistical analysis. Trials also assessed outcomes at several different time points (e.g., immediately postintervention, at two weeks, and at six months). Outcome data varied depending on the time point used. In one randomized controlled trial (Bronfort et al., 2004), patients receiving manipulation therapy experienced an immediate improvement in pain versus the control group, but after two weeks, that difference disappeared. For consistency, this review compares the data from the last outcome assessment point in each trial. Further, the relationship between pain symptom relief and such objectively measurable signs as range of motion has not been established in the literature, limiting the importance of the studies of objective signs.

Finally, the studies included in this review did not explicitly measure quality of life, defined as the assessment of a patient's physical and psychological or emotional well-being, across multiple trials. The absence of systematic reviews or meta-analyses that aggregate trial data using standardized instruments to measure quality of life (e.g., the 36-Item Short-Form Health Survey [SF-36]), makes it difficult to gauge the comprehensive effects of chiropractic care on study participants.

These methodological limitations notwithstanding,CHBRP's review includes only evidence from studies that meet its usual standards of scientific rigor. Appendix A describes CHBRP's methodology for reviewing the literature on medical effectiveness in detail, and Appendix B lists the studies included in the review and summarizes their results.

#### Pain Relief<sup>10</sup>

Seventeen publications, three of which are meta-analyses, presented evidence on the impact of chiropractic services on pain associated with musculoskeletal disorders (Assendelft et al., 2005; Astin and Ernst, 2002; Baldwin et al., 2001; Bronfort et al., 2001; Bronfort et al., 2004; Cooperstein et al., 2001; Ernst, 2003; Ferreira et al., 2002; Ferreira et al., 2003; Furlan et al., 2002; Gross, Kay, Hondras et al., 2002; Gross et al., 2004; Hagen et al., 2005; Heymans et al., 2005; Hurwitz et al., 1996; Koes et al., 1996; Lenssinck et al., 2004). Forty-nine studies, included in these publications, compared the effects of spinal manipulation therapy (SMT) with drug therapy (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] and analgesics). In all but 5 of these studies, patients receiving SMT reported an improvement in pain that was equal to (11 studies) or greater than (33 studies) that of the comparison group. Twenty studies compared SMT with physical therapy, with all but two studies reflecting improvements in pain after SMT that were equal to or better than the comparison group. Of the 23 studies that compared SMT with a sham treatment (14 studies) or placebo (9 studies), 16 studies reported greater improvements in pain after SMT. An additional 25 studies assessed pain after treatment with SMT compared with a variety of other therapies, including general practitioner care (3 studies), exercise (7 studies), rest (6 studies) and massage (9 studies). Only 2 of these studies reported unfavorable pain outcomes after SMT.

Overall, the evidence indicates a pattern toward favorable outcomes for chiropractic services, including SMT, with respect to symptom relief of musculoskeletal disorders.

#### **Objective Signs**

As defined by the Chiropractic Initiative Act, chiropractors can use radiographic equipment for the purpose of diagnosis. There is some evidence of uncertainty in this method of diagnosis, based upon a 1986 study by Frymoyer et al. that demonstrated low levels of interobserver reliability among chiropractors evaluating radiographic images. The study also concluded that radiographic images are of little value in determining back pain among patients.

In terms of effect on treatment outcomes, eight publications, including six systematic reviews and two case-control studies, presented information on the impact of chiropractic services for musculoskeletal disorders on objective clinical signs such as physical examination results (e.g., strength, range of motion, extension/flexion, straight-leg raise angle, and pelvic measurements) or adverse effects (Bronfort et al., 2001; Cooperstein et al., 2001; Furlan et al., 2002; Hagen et al., 2005; Heymans et al., 2005; Hurwitz et al., 1996; Rothwell et al., 2001; Smith et al., 2003). Five studies compared the effects of SMT with drug therapy, with four of these studies reporting favorable results for SMT compared with the drug therapy (i.e., increased range of motion and decreased side effects). Twelve additional studies reported on the effect of SMT versus massage

<sup>&</sup>lt;sup>10</sup> In most of the prior reviews done under CHBRP since the passage of AB 1996, the studies which subsume an analysis of pain relief do so under the more general rubric of "symptom relief." However, in our review of the studies on chiropractic services, nearly all refer to pain relief as the major symptom-related outcome.

(three studies), back school<sup>11</sup> (three studies), exercise (three studies), no treatment (one study), and bed rest (two studies). All but one study in this group reported improvements in objective clinical signs after SMT that were greater than or equal to the comparison group.

A review of two case-control studies indicated an association between SMT and rare adverse events such as vertebrobasilar accident (VBA) or stroke. These studies report a higher incidence of VBA or stroke among young patients (under 45 years old) who were treated with chiropractic care within the past week or month. However, it is difficult to infer a causal relationship between chiropractic manipulation and serious adverse events because of the lack of randomization in these studies.

Thus, overall, the evidence suggests that chiropractic services, including SMT, have a pattern toward favorable effect on objective signs. Also, some studies indicate that there may be an association between SMT and VBA or stroke in patients below age 45 years, although on this issue there have been no randomized clinical trials, the study design which produces the most solid form of medical evidence, to examine this.

### **Functional Status**

Thirteen publications, including three meta-analyses, reported data on the impact of chiropractic services for musculoskeletal disorders on functional status, e.g., ADLs and work status (Assendelft et al., 2005; Astin and Ernst, 2002; Baldwin et al., 2001; Bronfort et al., 2001; Bronfort et al., 2004; Cooperstein et al., 2001; Ernst, 2003; Ferreira et al., 2002; Ferreira et al., 2003; Furlan et al., 2002; Gross et al., 2002; Hagen et al., 2005; Heymans et al., 2005). All 16 of the randomized controlled trials comparing SMT to sham (7 studies) or placebo (9 studies) interventions reported favorable functional outcomes, such as a decrease in disability or reduction in sick leave. Five studies comparing SMT with general practitioner care unanimously reported greater improvements in functional status after SMT. When compared with drug therapy, SMT resulted in functional improvements that were equal to (one study) or greater than (four studies) that of the comparison group.

Overall, the evidence indicates a pattern toward favorable effect of chiropractic services, including SMT, on a patient's performance of ADLs and their ability return to work.

#### Health Care Utilization, Costs, and Patient Satisfaction

Eight publications, including seven systematic reviews and one recent randomized controlled trial, presented information on the impact of chiropractic services for musculoskeletal disorders on health care utilization and costs, e.g., use of medical services (including drugs) and patient satisfaction (Astin and Ernst, 2002; Baldwin et al., 2001; Bronfort et al., 2001; Cooperstein et al., 2001; Ernst, 2003; Furlan et al., 2002; Gross, Kay, Hondras et al., 2002; Kominski et al., 2005). Six studies observed drug use (e.g., over-the-counter analgesics) in patients receiving SMT versus other treatments (e.g., exercise, physical therapy, and massage). Three of these studies

<sup>&</sup>lt;sup>11</sup> "Back school" is a treatment method that combines education and exercise in a group setting (Heymans et al., 2005).

reported a decrease in drug use among subjects receiving SMT that was greater than that of the comparison group, whereas the other three studies reported no difference between the groups. The studies do not provide sufficient evidence as to whether increased use of chiropractic services would be accompanied by decreased use of physical therapy.

In measuring patient satisfaction, six studies compared chiropractic treatment with general practitioner care, massage, exercise, or physical therapy. Five of these studies reported no difference in patient satisfaction after treatment with either the intervention or comparison groups. Only one study, comparing SMT with massage therapy, reported an increase in patient satisfaction after SMT.

The cost of chiropractic services versus general medical care was evaluated in five studies. Two studies reported that chiropractic services were associated with reduced costs. Two other studies presented data that indicated a greater cost of care for chiropractic services, although one of these studies did not include the cost of medications in their assessment of general medical services. One study showed no difference in cost between the two forms of treatment.

Thus, overall, there is ambiguous or mixed evidence that chiropractic care results in lowered use of drugs, improved patient satisfaction, or lower costs than other treatments.

#### Conclusions

A review of the evidence of the medical effectiveness of chiropractic services for musculoskeletal disorders reveals a pattern toward a favorable effect of chiropractic treatments and, more specifically, SMT on symptom relief, objective signs, and functional status. There is ambiguous or mixed evidence that chiropractic care results in lowered use of drugs, improved patient satisfaction, or lower costs of care than other treatments. However, the methodological limitations of the individual studies, systematic reviews, and meta-analyses outlined above indicate that the state of the literature is not sufficient to draw definitive conclusions on any of the outcomes with which this report is concerned.

It is also important to balance the findings in the studies examined against the methodological rigor with which the studies were conducted. CHBRP has established a preferred hierarchy of articles used in the effectiveness review, giving most weight to those meta-analyses and studies that have met the standards to merit inclusion in a Cochrane Review. Inclusion of a study in a Cochrane Review generally indicates a high level of attention to underlying research protocols and design issues.<sup>12</sup> Results from studies that met the methodological criteria to be included in a Cochrane Review (Assendelft et al., 2005; Hagen et al., 2005; Heymans et al., 2005) indicate that chiropractic services were often no more effective than comparator treatments such as analgesics, bed rest, back school, physical therapy, or exercise. However, when these studies are balanced against the findings of all studies, an appropriate interpretation of the literature is that the effectiveness of chiropractic services remains uncertain.

<sup>&</sup>lt;sup>12</sup> Cochrane reviews are published by the Cochrane Collaboration, an international nonprofit organization dedicated to disseminating systematic reviews of healthcare interventions. For further information on how CHBRP weighs evidence for the medical effectiveness review, please see http://chbrp.org/documents/medeffect\_paper.pdf.

# II. UTILIZATION, COST, AND COVERAGE IMPACTS

#### **Present Baseline Cost and Coverage**

#### Current coverage of the mandated benefit (3(i))

An estimated 20,485,000 people are covered by plans or insurers affected by this health insurance mandate. Of these, CHBRP estimates that 73% or 15,021,000 enrollees have coverage for chiropractic services, and around 27% or 5,464,000 enrollees do not have coverage for chiropractic services. Table 2 shows the distribution of enrollees in different plans by their insurance coverage. Coverage of chiropractic services is highest in employer-sponsored preferred provider organization (PPO) plans.

CHBRP compared current coverage levels of chiropractic services with those that would be required under AB 1185, which specifically mandates direct access to chiropractic services, or access without a referral from a primary care physician (PCP). This comparison showed that there are three types of coverage: (1) enrollees who have chiropractic coverage *and* direct access to chiropractors, (2) enrollees who have chiropractic coverage, but need a PCP referral, and (3) enrollees without chiropractic coverage. Currently, 68% of the affected population has coverage for chiropractics services with direct access. Approximately 32% of the market does not have coverage that meets the requirements of AB 1185: 5% have coverage but require a primary care referral, and 27% have no coverage.

#### Private health plans and insurers in California

CHBRP surveyed the seven largest full-service health care plans in California about coverage provided for chiropractic services. Of those seven, five responded to the survey. The results of this survey suggest that people who are privately insured generally have one of the three types of coverage mentioned above: coverage with a primary care referral required, coverage that allows direct access without a referral, or no coverage of chiropractic services. Of the five plans that responded, only one plan said they required a PCP referral for the portion of their membership that had coverage under their basic benefit. The remaining four indicated that, for the portion of their membership that had chiropractic coverage a referral was not required.

For plans that provide coverage, survey responses indicated that coverage is provided either as part of the basic benefit package or as an optional benefit ("rider") to purchase. Health plans and insurers typically provide this service by contracting with a "carve-out" company that specializes in chiropractic services.<sup>13</sup>

Privately insured individuals with chiropractic coverage generally have benefit limits, including a maximum number of annual visits. In addition, cost-sharing requirements may differ from the

<sup>&</sup>lt;sup>13</sup> "Carve-outs" in this case are specialty health plans licensed as Knox-Keene plans that would subcontract with full-service health care plans or with insurers regulated under the Insurance Code. CHBRP surveyed three of the largest chiropractic specialty plans regarding utilization information and obtained responses from two. This is discussed in the utilization section to follow.

cost-sharing for other medical services (e.g., use of differential copayments or annual dollar benefit limits).

#### Publicly financed enrollments in managed care plans

Public monies fund the insurance for health benefit plans offered by the California Public Employees' Retirement System (CalPERS), Healthy Families, and Medi-Cal.

CalPERS: Only health maintenance organizations (HMO), which cover 75% of the CalPERS population, are subject to the mandate. Other plans, which cover the remaining 25% of the CalPERS population, are self-insured and not subject to the mandate.<sup>14</sup> Almost half (49%) of all enrollees in CalPERS HMOs have coverage for chiropractic benefits, and just over half (51%) do not have coverage for these services. If enrollees are covered, they typically have coverage for up to 20 visits per year without a PCP referral. Most of the remaining CalPERS HMO members who are not covered for chiropractic services can access chiropractic services through an arrangement with a specialty chiropractic health plan. Members pay discounted rates for their visit.

Medi-Cal Managed Care: Medi-Cal managed care plans cover services provided by chiropractors. Services are limited to treatment of the spine by means of manual manipulation. Enrollees may access services directly without a PCP referral. The diagnosis must show sprain, strain, or dislocation of the spine or neck.

Although there is no PCP referral requirement, coverage is subject to benefit limits which are different than those found in the private market. Visits are limited to two per month for any of the following services: chiropractic, psychology, physical therapy, occupational therapy, speech pathology and audiological services, podiatry, acupuncture, and prayer or spiritual healing. For example, if an enrollee has one occupational therapy visit and one physical therapy visit, totaling two visits, treatment by a chiropractor would not be covered. CHBRP assumed that the current MediCal chiropractic benefits would meet the requirements of the mandate.

Healthy Families<sup>15</sup>: 68% of Healthy Families enrollees currently have coverage for the benefit, 32% do not have coverage. Of the 26 Healthy Families health care plans, 19 plans provide chiropractic services as an optional benefit; 7 plans do not offer it as a benefit.<sup>16</sup> For those plans that do provide chiropractic services, patients do not require a PCP referral. Enrollees pay a \$5 copayment and treatment is limited to 20 visits per year.

<sup>&</sup>lt;sup>14</sup> Of the 1.04 million enrollees in CalPERS-sponsored health benefit plans, 795,000 members are enrolled in HMO and the remaining estimated 200,000 are enrolled in self-insured PPO plans.

<sup>&</sup>lt;sup>15</sup> The Managed Risk Medical Insurance Board (MRMIB) awards contracts for the delivery of health, dental, and vision plan services to health plans and insurers to provide health, dental, and vision coverage to children who do not have insurance and do not qualify for free Medi-Cal. Families pay premiums of \$4–\$15 per child per month (maximum of \$45 per family) to participate in the program.

<sup>&</sup>lt;sup>16</sup> CHBRP assumes that the optional benefits offered by these plans in contract year 2004–2005 are equivalent to the coverage required under AB 1185, and that plans that do not currently provide the benefit would need to adopt similar provisions.

#### Current utilization levels and costs of the mandated benefit (Section 3(h))

CHBRP used several data sources to estimate the unit price and utilization of chiropractic services: Milliman Health Cost Guidelines, a survey of California large private insurers discussed above, a survey of chiropractic "carve-out" companies, and data from the Agency for Healthcare Research and Quality 2002 Medical Expenditure Panel Survey Western sample. The Milliman Health Cost Guidelines consists of an insurance claims database of over 7 million lives. (For more information on the methods and data sources used by CHBRP to conduct our cost impact analysis, please consult www.chbrp.org.)

#### Unit price

- The average cost per chiropractic visit is estimated to be \$36 for those enrollees who have coverage for chiropractic services. This amount includes any patient copayment.
- The average cost per chiropractic visit is estimated to be \$60 for those enrollees who do not have coverage for chiropractic services that pay out of pocket.

These estimates were based on insurers' billed and actual allowed charges. Billed charges represent the price of a visit prior to discounting and are used here as an estimate of the usual charge a patient would pay if the patient had no chiropractic insurance coverage. In this case, the charge is \$60. The allowed charge is the amount that insurers and members pay chiropractors for each visit (\$36), and it reflects health plans' and insurers' negotiated discounts with chiropractors.

#### Utilization

Currently, the average annual utilization of chiropractic services is 363 visits per 1,000 enrollees This average is for the total population affected by the mandate across all types of health plans. Table 3 shows the baseline utilization by plan type and the expected effects of AB 1185 on utilization across different chiropractic coverage categories.

Average chiropractic utilization varies according to differences in:

- coverage of chiropractic services, shown in Table 3 and 4;
- whether a primary care referral is required, shown in Table 3 and 4;
- the size of the copayment, shown in Table 4;
- o plan type, shown in Table 4.

Coverage is the most important determinant of utilization. Utilization of chiropractic services by coverage category varies as follows:

(a) People covered for chiropractic services with direct access (no primary care referral required):

The average utilization of people with coverage for chiropractic services is 452 visits per year per 1,000 members, or an average of 0.452 visits per person.

(b) People with coverage for chiropractic services that are required to obtain a primary care referral to access services:

Enrollees who are covered for chiropractic services only after receiving a PCP referral use an average of 300 visits per 1,000 members, or an average of 0.30 visits per person.

(c) People without coverage for chiropractic services:

The average number of chiropractic visits made by people enrolled in commercial plans without coverage for chiropractic services is estimated to be 146 per 1,000 members, or an average of 0.146 visits per person.

(d) Enrollment in Publicly Financed Plans:

Among CalPERS, current utilization by enrollees in CalPERS HMOs was estimated to be the same as other large-group HMOs, as show in Table 4.

Utilization rates for Medi-Cal managed care and Healthy Families enrollees differ from rates for commercial health plans due to the different age/gender makeup of their members. CHBRP did not perform an extensive analysis of current Medi-Cal managed care utilization because the mandate is not expected to affect Medi-Cal managed care costs given that chiropractic services are currently covered for Medi-Cal enrollees.

Utilization estimates for Medi-Cal managed care members younger than age 65 years were based on the observed employer-based rates, adjusted to reflect the differences in the adult/child mix between Medi-Cal and insured populations. The utilization rate is 420 per 1,000 members per year, as shown in Table 4.

For Medi-Cal members over 65 years of age utilization was based on chiropractic utilization for Medicare-eligible members using the Milliman Health Cost Guidelines. The average rate of utilization for Medi-Cal members over 65 is 420 visits per 1,000 members per year, as shown in Table 4. Utilization rates were estimated separately for the two populations (enrollees under age 65 and enrollees over age 65), however, the analysis produced identical results.

Healthy Families' utilization is estimated to be substantially lower than other plans because Healthy Families enrollees are mostly children, with lower chiropractic utilization in general. Healthy Families' enrollees with chiropractic coverage have a utilization rate of 160 per 1,000 members. Healthy Families' enrollees without chiropractic coverage made 47 visits per year for every 1,000 members, as shown in Table 4.

The extent to which costs resulting from lack of coverage are shifted to other payers, including both public and private entities. (Section 3(f))

A lack of coverage for chiropractic services would increase the out-of-pocket payments made by individuals who pay for chiropractic services on their own. Approximately 27% of the insured population does not have coverage for these benefits. Out-of-pocket expenditures for chiropractic services not currently covered by insurance are approximately of \$47,957,000 per year.

#### Public demand for coverage (Section 3(j))

Based on criteria specified under AB 1996 (2002), CHBRP is to report on the extent to which collective bargaining agents negotiate for coverage and the extent to which self-insured plans currently have coverage for the benefits specified under the proposed mandate. Currently, California's largest public self-insured plan, the CalPERS' preferred provider organization (PPO) plans, cover a limited number of visits (either 15 or 20 visits per calendar year) for both acupuncture and chiropractic benefits. Coinsurance varies from 10%–40% depending on whether subscribers use providers within or outside the PPO network. 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. Local unions would need to be surveyed individually to determine whether any engage in negotiations at such detail,.<sup>17</sup>

#### **Impacts of Mandated Coverage**

How would changes in coverage related to the mandate affect the benefit of the newly covered service and the per-unit cost? (Section 3(a))

#### Benefit of the newly covered service

CHBRP estimates no effect on the average clinical benefit of the service because the population that will gain coverage and, therefore, have increased access is assumed to have the same demographic and health characteristics as those who already have coverage. The population that would gain coverage as well as the population that already has coverage but will gain direct access are assumed to have the same health status and age characteristics as those people who already have coverage for direct access to chiropractic services. That is, those without coverage now are not assumed to lack coverage because they differ in systematic ways in demographic and health characteristics from those who have coverage. *Unit Cost* 

Because neither supply nor demand pressures would be expected to change after implementation of the mandate, CHBRP would expect no additional price pressures and, therefore, no change in the per-unit cost of a visit.

CHBRP assumes that plans and insurers would continue to negotiate similar reimbursement rates with chiropractors and would continue to use carve-out arrangements to manage utilization. Therefore there should be no expected increase in the per-unit cost of a visit.

#### Impact on other Health Care Costs

CHBRP considered whether increased coverage and use of chiropractic services would cause a decrease in other covered health care utilization and costs. No decrease in health care costs is estimated. Chiropractic coverage is not estimated to result in cost savings (and premium reductions) for health plans and insurers. There are two reasons for this conclusion: (1) previous

<sup>&</sup>lt;sup>17</sup> Personal communication with SEIU and California Labor Federation on February 8, 2005, and June 1, 2005

market behavior of insurers; and (2) analysis of existing evidence was inconclusive on potential cost offsets of other health care costs.

**Previous market behavior of insurers:** The impact of the legislation on health premiums depends on the assumptions that insurers make regarding the impact of increased chiropractic coverage on future health care costs. Milliman's experience with conducting actuarial estimates for insurance carriers throughout the United States suggests that carriers tend to estimate increased premiums based on the expected costs of newly covered chiropractic services, with no offset for reductions in other health care costs. Although these reductions are possible, carriers would likely be conservative about making this assumption, in part because of the inconclusive evidence in the literature.

**Existing evidence on cost offsets:** Studies that estimate whether chiropractic care results in an offsetting reduction in other health care costs are inconclusive. As discussed earlier, eight studies were analyzed that considered the impact of chiropractic services for musculoskeletal disorders on health care utilization and costs, e.g., use of medical services (including drugs) and patient satisfaction (Astin and Ernst, 2002; Baldwin et al., 2001; Bronfort et al., 2001; Cooperstein et al., 2001; Ernst, 2003; Furlan et al., 2002; Gross, Kay, Hondras, et al., 2002; Kominski et al., 2005). The state of the literature is not sufficient to draw definitive conclusions on the impact of chiropractic care on cost and utilization of other health care services.

Six additional studies were also analyzed but not considered for inclusion in the Medical Effectiveness section (either because they did not focus on health outcomes or because they did not meet the selection criteria of the medical effectiveness analysis<sup>18</sup>), (Legorreta et al., 2004; Metz et al., 2004; Nelson et al., 2005; Shekelle, Rogers, and Newhouse, 1996; Stano et al., 2002; Stano and Smith, 1996). These studies either focused on the health care costs of people treated by chiropractors, or the health characteristics or health care costs of people with chiropractic coverage.

#### Treatment expenditures

Observational studies that compared the health care or treatment expenditures of people with chiropractic insurance coverage with the expenditures of people without chiropractic coverage were found to be inconclusive. For example, one study found that patients who received chiropractic care had \$91 in higher costs (Stano et al. 2002). Another study, which measured episodes differently, showed reduced costs when a chiropractor rather than a medical provider first treated the patient (Stano and Smith 1996)). However, the design of both studies was not able to address unobserved differences between the two groups, such as insurance characteristics (acknowledged by Stano and Smith, 1996), or whether the patient was enrolled in a managed care plan (Stano et al. 2002). The methodological limitations of the literature on the cost effects of chiropractic treatment conform to the analysis of literature in the Medical Effectiveness section.

<sup>&</sup>lt;sup>18</sup> For example, observational studies are excluded from the effectiveness analysis. See Appendix A for additional details on how the literature review was conducted and how articles are selected for the Medical Effectiveness analysis.

#### Costs for people with chiropractic coverage

A second group of studies (Legorreta et al. 2004; Metz et al. 2004; Nelson et al. 2005) compares the characteristics of people with and without chiropractic coverage; however, these studies do not consistently measure total health care costs, and they have methodological weaknesses. For example, Legoreta et al (2004) found lower health care expenditures for people with coverage for chiropractic services, in the order of a 12% annual cost decrease, but this study failed to control for selection bias in terms of peoples' insurance choices or the firms that select chiropractic coverage. Failure to control for selection bias is not an insignificant factor because research indicates that individuals with chiropractic coverage tend to be healthier and younger than those without coverage (Metz et al. 2004; Nelson et al. 2005).

Another study (Shekelle, Rogers, and Newhouse 1996) addressed the selection effects inherent in Legorreta's study design by randomizing participants to different insurance plans, but the researchers did not measure total health care costs of treatment. However, the researchers did demonstrate that people's use of chiropractic services was highly price sensitive: enrollees with free medical and chiropractor visits used chiropractors more frequently than those with 95% coinsurance for chiropractic coverage (Shekelle, Rogers, and Newhouse 1996). People who had to pay 95% of the cost of chiropractic care but paid nothing for medical care had lower utilization rates for *both* medical doctors and chiropractors.

In conclusion, research on the characteristics of people with chiropractic coverage generally shows that this group has lower costs and is healthier. However, this literature cannot demonstrate that chiropractic coverage reduces costs. With the exception of (Shekelle, Rogers, and Newhouse 1996), the studies cited do not control for selection bias in terms of peoples' insurance choices or whether people who work for employers that provide chiropractic coverage to their employees vary from those employees who work for firms that do not cover it. The studies are based on observational data, rather than randomized treatment or insurance status. Chiropractic coverage is acknowledged as encouraging healthier people to enroll in those plans (Nelson et al. 2005). In other words, people who select health insurance plans with chiropractic coverage are different from those who do not, making it more difficult to explain lower health care costs or healthier enrollees as being caused by chiropractic care, or as a result of an unobserved or observed difference between the two groups.

Prospective studies that randomize participants to different care represent the strongest research design for measuring the cost effect of chiropractic care. Of the few studies that randomize participants, (Kominski et al. 2005) showed an increase in treatment costs.

#### Substitution and Complementary Effects

CHBRP considered substitution and complementary effects for services, such as physical therapy. A substitution effect would occur if new mandated coverage of a service decreases utilization of a similar covered service, by shifting those patients to the mandated provider. These effects may occur for some services; however, it is not possible to specify the nature of the effect or the services that would be substituted by chiropractic care. A complementary effect

increases the use of services that are commonly used in conjunction or in addition to the use of the mandated service. The only service that was considered as a complementary service was radiology. Although there is some utilization of radiology by chiropractors, these costs are included in the cost estimates.

#### How would utilization change as a result of the mandate? (Section 3(b))

Averaged across all plan types and baseline levels of coverage, utilization of chiropractic services is estimated to increase from 363 to 464 visits per 1,000 enrollees. However, the impact would be likely to vary across plan types. Discussed below are the utilization patterns across different groups, and the supporting rationale.

Baseline utilization rates were discussed in Section 3 (h). To calculate how utilization could change after implementation of the mandate, CHBRP considered likely market behavior and theories of demand for health care, and made the following assumptions:

- A primary care referral requirement tends to reduce utilization.
- After the implementation of mandates in general, plans and insurers would apply similar utilization limits and copayments as a way to manage utilization. This assumption is based on an assessment of current market conditions and experience in other services in which coverage has expanded.
- Higher copayments for chiropractic services tend to reduce demand for the service, and coverage of services will lower the cost of care for those enrollees without coverage. Demand for chiropractic care is particularly responsive to changes in the level of cost sharing (Shekelle, Rogers, and Newhouse, 1996). Access to free chiropractic care among HMO enrollees in one randomized control trial of insurance status increased chiropractic use nine-fold, whereas access to free medical care decreased fee-for-service chiropractic care by 80% (Shekelle, Rogers, and Newhouse, 1996).
- The population that is not receiving any chiropractic coverage is similar to the population receiving coverage within each plan type (managed care or preferred provider, for example). This means that if there are two HMOs, one offering coverage for chiropractic care and one not, both have similar populations in terms of average age and health status.
- Nevertheless, differences in utilization would exist *across plan types*, because of the design of benefits and underlying population characteristics that choose particular types of insurance. For example, an HMO in the private market would have different utilization patterns from a PPO, and utilization would be different in an HMO Medi-Cal 65+ plan. These differences would persist even after a mandate because the population in the plans remains unchanged.

Based on these assumptions, the general impact of increased coverage would affect groups differently according to baseline coverage levels. If implemented, the utilization effects of AB 1185 if can be summarized as follows:

• Enrollees who currently have chiropractic coverage without a referral are not expected to change their utilization rate if AB 1185 is implemented.

• Enrollees who do not have coverage at the present time or enrollees who need a referral to receive covered services would increase their utilization to levels that equal the utilization rates of enrollees within the same plan types that currently have coverage.

Table 3 shows the baseline utilization by plan type and the expected effects of AB 1185 on utilization across different chiropractic coverage categories.

#### For Enrollees Who Have Coverage for Chiropractic Services with Direct Access

Enrollees who have coverage for chiropractic services without a PCP referral would be expected to have the same utilization after the mandate is implemented. At present, the average utilization is estimated at 452 chiropractic visits per year per 1,000 members among those with coverage, as shown in Table 3. After implementation, the utilization rate is expected to remain at 452 visits per 1,000 enrollees. Table 4 shows the estimated effect of AB 1185 by plan type for this group. As discussed in Section 3(h), utilization varies by plan type due to different copayments and benefit structures. For example, as shown in Table 4, the estimated current utilization for covered members is 506 chiropractic visits per year per 1,000 HMO members, and 435 chiropractic visits per year per 1,000 HMO members, and 435 chiropractic visits per year per 1,000 HMO members, and 435 chiropractic visits per year per 1,000 HMO members, and 435 chiropractic visits per year per 1,000 HMO members, and 435 chiropractic visits per year per 1,000 HMO members, and 435 chiropractic visits per year per 1,000 PPO members. Member demographics also drive different utilization patterns in Medi-Cal managed care and Healthy Families. Healthy Families' enrollees have a much lower utilization rate than enrollees in other plans, with a utilization rate of 160 per 1,000 members.

All other enrollees, enrollees who do not have direct access, or do not have chiropractic coverage are expected to increase their utilization if AB 1185 is implemented, as shown in Table 3. Among this second group of enrollees, the baseline average utilization rate for enrollees who have coverage, but not direct access, premandate is expected to change from 300 visits per 1,000 members to 506 visits per 1,000 members. Among enrollees who presently have no coverage, utilization is expected to increase from 146 visits per 1,000 enrollees to 487 visits per 1,000 enrollees.

Table 4 shows the effects of the mandate across the different baseline or current coverage categories, and shows why the average utilization rate postmandate would increase. A larger proportion of those who are not presently covered for chiropractic are HMO members, so the average utilization rate across all plans is estimated to increase slightly as a result of plan membership mix. In other words, a disproportionate number of newly covered members are enrolled in HMO plans, and enrollees in HMO plans have higher utilization rates.

#### To what extent does the mandate affect administrative and other expenses? (Section 3i)

Administrative costs would increase in proportion to the rise in premiums as a result of this mandate. This mandate would be likely to increase the administrative expenses for health plans, but this increase is expected to be in proportion to the increase in health care costs. Health plans and insurers include a component for administration and profit when they project premiums. The estimated impact of this mandate on premiums includes the assumption that plans and insurers would be likely to apply their existing administration and profit loads to the marginal increase in health care costs produced by the mandate. In other words, plans would be likely to assume that

the marginal increase in health care costs is mirrored by a proportional increase in their administrative costs and expected profits. Therefore, the administrative costs *as a proportion of the premium* would not change.

AB 1185, for example, would require health plans and insurers to communicate to members and enrollees the names and contact information of chiropractors included in their networks. Updating and disseminating provider directories would be an administrative cost. In addition, to meet AB 1185's requirement to provide members and enrollees with "meaningful access to chiropractors," health plan and insurers would (1) need to conduct a network analysis to determine whether their current contracts with chiropractors would meet the access requirement and make the associated contractual changes, and (2) make associated changes referral policies and procedures to allow members to self-refer in instances where prior authorization would be required.

Some health plans and insurers may implement this mandate for newly covered members by subcontracting with a specialty carve-out company to provide chiropractic services. Typically the carve-out company agrees to provide all chiropractic services to the health plan members in exchange for a fixed monthly premium. Although subcontracting arrangements could be expected to add additional administrative cost, it is not uncommon for carve-out companies to incur lower total costs through more effective medical management and different provider reimbursement arrangements. For this reason, CHBRP assumes that these arrangements would be covered by the proportional increase in administrative costs and expected profits.

#### Impact of the mandate on total health care costs (Section 3(d))

Total health care costs are expected to increase by \$71,577,000 dollars, an increase of 0.119%. These health care costs changes are shown in Table 6.

#### Costs or savings for each category of insurer resulting from the benefit mandate (Section 3(e))

AB 1185 would be likely to lead to changes in total annual expenditures for each major category of payer by the following amounts and percentages (see Table 1):

Total private employer premiums are projected to increase by a total of \$53,187,000 per year, an increase of 0.150%. Individuals who pay for a share of their employer-based insurance and individuals paying CalPERS and Healthy Families premiums would be likely to pay a total of \$19,372,000 in additional premiums, an increase of 0.189%. Premium expenditure on individually purchased insurance are projected to increase by a total of \$10,041,000, an increase of 0.263%. CalPERS' employer costs are projected to increase by a total of \$5,272,000 per year or by 0.238%.

Medi-Cal already covers direct access to chiropractic services; therefore costs would be likely to remain the same. CHBRP estimates no additional utilization and no additional costs for Medi-Cal managed care because coverage of chiropractic services appears to meet the requirements of

AB 1185. The Department of Health Services (DHS) and the Department of Managed Health Care may respond to AB 1185 by altering their benefit structure required under Medi-Cal managed care, in which case, the estimated cost would be different.

For Healthy Families, CHBRP assumes the coverage under the optional benefit meets the requirements of AB 1185 and that plans that do not currently provide the benefit would need to adopt similar provisions. Healthy Families state expenditures would likely increase by a total of \$993,000 per year, an increase of 0.231%.

Copayments associated with chiropractic care would be likely to increase by a total of \$30,669,000, an increase of 0.752%. Other out-of-pocket costs for chiropractic care presently not covered by insurance would be expected to decrease from a total of \$47,957,000 to \$0, a decrease of 100%.

In the cost analysis, CHBRP assumed that plans that currently provide coverage with specified benefit limits for chiropractic services would not need to change their chiropractic benefit provision to comply with the mandate.

#### Impact on access and health service availability (Section 3(g))

As mentioned, AB 1185 would require that health plans and insurers contract with a sufficient number of chiropractors to provide "meaningful access to chiropractic services." As discussed in the Introduction of this analysis, to become compliant with AB 1185, plans and insurers would need to not only contract with a sufficient number of chiropractors, but also conduct a network analysis to determine that the geographical distance and travel time to contracted specialty providers would meet the standard of meaningful access. The extent of changes needed in plans' provider networks is dependent on the access standards currently applied and the extent to which the California Departments of Managed Health Care and Insurance expand on these access requirements as a result of AB 1185. Changes in access to chiropractic services would depend on how "meaningful" access is defined and enforced by the regulatory agencies and whether that results in changes to the current supply and distribution of chiropractors throughout the plans' and insurers' geographic service areas.

Increases in premiums can discourage purchase of insurance by individuals and employers, and this can limit access to health care. Average annual premiums across the insured population (see Table 6) are expected to increase as a result of AB 1185 by approximately 0.159%. However, the increase in premiums brought about by AB 1185 is not of the magnitude that is expected to significantly impact the purchase of insurance for most employers, employees, and individual purchasers.

## **III. PUBLIC HEALTH IMPACTS**

#### **Present Baseline Health Outcomes**

Chiropractic therapies are used to treat a variety of musculoskeletal disorders such as neck pain, back pain, strains, and other injuries. The underlying prevalence of these injuries and disorders in the population, with the exception of back pain, is unknown. Therefore, in this report, utilization data are presented in lieu of data on the underlying prevalence of specific musculoskeletal disorders treated with chiropractic care.

National and regional estimates on the annual use of chiropractic services vary from 4% to 11% (Table 7). The California Health Interview Survey finds that approximately 4% of insured adults ages 18–64 years in California reported having a chiropractic visit in 2001 (CHIS, 2001). In addition, a breakdown of this utilization rate by insurance status indicates that those with privately purchased insurance had the highest utilization rates of chiropractic care (5%) followed by those with employer-sponsored coverage (4%) and those with Medicaid coverage (2%). The 2002 MEPS survey (MEPS, 2002) of household medical expenditures found that 4% of insured, non-elderly persons in the United States had an expense for chiropractic care in 2002. According to the 1999 and 2002 National Health Interview Surveys (Barnes et al. 2004, Ni et al. 2002), 20% of the adult population had used chiropractic therapy in their lifetime and approximately 8% had used it in the past 12 months. Another national telephone survey in 1997 found that 11% of respondents had used chiropractic care in the last 12 months (Eisenberg et al, 1998).

The majority of the chiropractic care is for musculoskeletal disorders, such as back and neck pain. Based on an analysis of insurance claims data provided by Milliman, as shown in Table 8, approximately 44% of injuries or disorders that result in chiropractic care are located in the back, 35% are in the neck, and 21% are in other locations. Shekelle et al. (1995) found that chiropractors were the main provider for 40% of back-pain episodes.

Back pain is a relatively common condition; however, measures of prevalence vary according to the definition and the population (Woolf and Pfleger, 2003). Table 9 details the prevalence of back pain per 100,000 persons under 65 years in the United States and shows that prevalence increases with age. The prevalence rates range from 1% in the youngest age group (15- to 24-year-olds) to 10% in the oldest age group (55- to 64-year-olds).

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

It is estimated that as a result of this mandate, approximately 5.5 million Californians would gain insurance coverage for chiropractic services. Assuming an increase in utilization of chiropractic services from 2.4% of this population premandate to 7.0% of this population postmandate, this would translate into approximately 250,000 more people using at least one chiropractic service as a result of the mandate. The literature review on the effectiveness of chiropractic care suggests that AB 1185 could have positive impacts on public health, such as increased pain relief,

increases in objective measures of health status such as range of motion, strength, or flexibility, and increased functional status.

Although it is possible that these 250,000 newly covered people could have an increase in health status as defined above, because of the methodological limitations of the literature such as trial design issues, inconsistent inclusion or exclusion criteria across studies, and inconsistency in the measurements of outcomes across studies, it is not possible to quantify the overall effect of chiropractic care or to quantify the overall impact on public health.

#### Impact on Community Health Where Gender and Racial Disparities Exist (Section 1B)

In terms of general chiropractic services utilization, a number of studies have found that females use between 57% and 62% of total chiropractic care (Briggance, 2003; Cherkin et al., 2002; Coulter et al., 2002). Higher use among women is not surprising considering that females use more health care services overall, even after controlling for health status and socio-demographic factors (Bertakis et al., 2000). In addition, females report a slightly higher rate of back pain compared with males (Table 9). Compared with males, females also have more restricted activity days and bed days due to back pain (WHO, 2003).

Chiropractic patients are predominantly White (but not of Latino background), with minority groups less likely to receive chiropractic services (Cherkin et al., 2002; Hawk and Long, 1999). Among insured adults in California, it was reported that Whites used chiropractic services more than twice as often as Latinos, Asians, or Blacks (Table 10). Additionally, Shekelle et al. (1995) found that Whites were more likely to choose a chiropractor for the treatment of back pain.

Although no research was found to report racial differences in the prevalence of back-pain diagnoses, there is some evidence regarding racial disparities in the medical treatment for back pain that suggests non–Whites receive less care for back pain. Mort et al. (1994) found that Blacks had lower age- and sex-adjusted rates of lumbar disc procedures. In another study in North Carolina, researchers found treatment differences between Black and White low back-pain patients: Blacks who saw chiropractors received more services than Whites whereas the reverse was true when seeing medical doctors (Carey and Garrett, 2003). Taylor et al. (2005) examined the interaction of gender and race with regards to physician treatment for low back pain and found that non–White females were significantly less likely to have surgery offered compared with White males.

Although there are differences by gender and race/ethnicity in the utilization rates of chiropractic care, it is not possible to estimate the impact of AB 1185 on access to chiropractic care or health outcomes for specific gender or racial and ethnic groups, due to insufficient evidence.

# Reduction of Premature Death and the Economic Loss Associated with Disease (Section $1\mathrm{C})$

The health outcomes related to the use of chiropractic care are primarily the reduction of pain symptoms and improved quality of life. No research was identified that examined the relationship between chiropractic care and a reduction in premature death.

There are substantial productivity costs associated with the disorders that chiropractors treat. Murt et al. (1986) estimated that musculoskeletal disorders accounted for 13% of restricted activity days, 9% of bed disability days and 11% of all work-loss days in 1980. Yelin et al. (2003) estimated that the indirect costs (based on lower employment rates and earnings losses among the employed) associated with musculoskeletal disorders in the United States in 1997 were approximately \$104 billion.

Looking specifically at back-pain costs in the United Kingdom, Maniadakis and Gray (2000) found that a majority of the total costs were those associated with informal care and production losses<sup>19</sup>. In the United States, Guo et al. (1999) found that in 1988 the prevalence of lost-workday back pain among workers was 4.6% and a total of 102 million workdays were lost as a result of back pain. According to estimates from the National Health Interview Survey, in 1996 there were 284,491,000 restricted activity days and 53,545,000 bed days in the United States due to back pain/injury (WHO, 2003).

No information was identified on lost productivity due to non–work-related disorders; however, there is literature that suggests that work-related back injury accounts for significant losses in productivity. California's work injury and illness statistics indicate an injury and illness rate of 5.6 cases per 100 full-time employees in the private sector in 2002. Sprain and strains remain the most common type of work injury, accounting for about 39% of days-away-from-work cases in the private sector. The back is the most frequently injured body part, accounting for almost one out of every four days-away-from-work cases in the private sector (CHSWC, 2005).

There is evidence of significant economic loss associated with musculoskeletal disorders such as back pain, and there is also evidence that chiropractic care may result in improvement in health outcomes. Although AB 1185 has the potential to reduce the economic loss associated with musculoskeletal disorders, there is insufficient evidence to conclude that AB 1185 would result in reductions in this economic loss.

<sup>&</sup>lt;sup>19</sup> These findings, however, would likely be different for California due to differences in direct medical costs in the United States and the United Kingdom.

## **TABLES**

Table 2. Current Coverage fo	r Chiropractic Services, In	ncluding Coverage with Re	ferral Requirements, California 2005.

		Large G	roup		Small Group					Individual Public					
	НМО	РРО	POS	FFS	НМО	PPO	POS	FFS	НМО	PPO	CalPERS	Medi-Cal HMO Over 65	Medi-Cal HMO Other	Healthy Families	
Population in plans subject to the mandate	7,400,000	3,220,000	457,0000	19,000	1,498,000	875,000	454,000	4,000	887,000	1,065,000	795,000	354,000	2,846,000	611,000	20,485,000
Covered enrollees who have direct access to chiropractic services	56%	100%	56%	100%	20%	87%	20%	87%	62%	65%	49%	100%	100%	68%	68%
Covered enrollees with primary care referral requirement	11%	0%	11%	0%	6%	0%	6%	0%	0%	0%	0%	0%	0%	0%	5%
Members without coverage	33%	0%	33%	0%	74%	13%	74%	13%	38%	35%	51%	0%	0%	32%	27%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Source: California Health Benefits Review Program, 2005

*Note:* AB 1185 mandates direct access to Chiropractic services. *Key:* FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization. CalPERS = California Public Employees' Retirement System.

Visits per 1,000 Enrollees in Each Category	Premandate	Postmandate	Change	Percentage Change
All enrollees	363	464	101	27.8%
Enrollees with chiropractic coverage and direct access (no provider referral required)	452	452	0	0.0%
Enrollees with chiropractic coverage with primary care referral required*	300	506	206	68.7%
Enrollees without chiropractic coverage	146	487	341	233.0%

## Table 3. Pre- and Postmandate Utilization of Chiropractic Services, by Type of Chiropractic Coverage, 2005

Source: California Health Benefits Review Program, 2005.

*Note:* This is an average of the number of visits per 1,000 members regardless of whether those members have used chiropractic services and those that do not in a given year. AB 1185 requires members to have access to chiropractic care without PCP referral. Primary care referral refers to baseline only.

## Table 4. Utilization Pre- and Postmandate Per 1,000 Members

		Large Gi	roup			Small G	oup		Individ	lual		Pul	blic		
Visits per 1,000 members and copayments	НМО	РРО	POS	FFS	НМО	РРО	POS	FFS	НМО	РРО	CalPERS	Medi-Cal HMO Over 65	Medi-Cal HMO Other	Healthy Families	Composite
Average copayment	\$10	\$20	\$10	\$20	\$10	\$20	\$10	\$20	\$10	\$20	\$10	\$0	\$0	\$5	
Premandate utilization (visits per 1,000) composite	365	435	365	435	230	398	230	364	371	335	325	420	420	124	363
Enrollees with coverage (no PCP referral required)	506	435	506	435	506	435	506	435	506	435	506	420	420	160	452
Enrollees with coverage (PCP referral required)	300	NA	300	NA	300	NA	300	NA	NA	NA	NA	NA	NA	NA	300
Enrollees without coverage	150	NA	150	NA	150	150	150	150	150	150	150	NA	NA	47	146
Postmandate utilization (visits per 1,000) composite	506	435	506	435	506	435	506	435	506	435	506	420	420	160	464
Enrollees previously covered before AB 1185 (no PCP referral)	506	435	506	435	506	435	506	435	506	435	506	420	420	160	452
Enrollees previously covered (PCP referral required)	506	435	506	435	506	435	506	435	506	435	506	420	420	160	506
Enrollees previously without coverage	506	435	506	435	506	435	506	435	506	435	506	420	420	160	487

Source: California Health Benefits Review Program, 2005.

*Note:* This is an average of the number of visits per 1,000 members regardless of whether those members have used chiropractic services in a given year. *Key:* FFS = fee for service; HMO = health maintenance organization; PCP = Primary Care Provider; POS = point of service; PPO = preferred provider organization. CalPERS = California Public Employees' Retirement System.

		Large G	roup			Small G	roup		Indivi	dual		Pı	ublic		
Population	<b>HMO</b> 7,400,000	<b>PPO</b> 3,220,000	<b>POS</b> 457,000	<b>FFS</b> 19,000	<b>HMO</b> 1,498,000	<b>PPO</b> 875,000	<b>POS</b> 454,000	<b>FFS</b> 4,000	HMO 887,000	<b>PPO</b> 1,065,000	CalPERS HMO 795,000	Medi-Cal HMO Over 65 354,000	<b>Medi-Cal</b> <b>HMO</b> <b>Other</b> 2,846,000	Healthy Families 611,000	<b>Total Annual</b> 20,485,000
Percentage of enrollees covered for chiropractic care	67%	100%	67%	100%	26%	87%	26%	73%	62%	65%	49%	100%	100%	68%	67%
Average portion of premium paid by employer	\$187.97	\$283.90	\$234.95	\$240.59	\$161.28	\$234.40	\$180.93	\$181.88	\$0.00	\$0.00	\$231.96	\$235.05	\$86.12	\$58.68	\$41,942,845,000
Average portion of premium paid by employee	\$50.45	\$57.87	\$51.96	\$63.25	\$83.36	\$73.27	\$94.91	\$37.09	\$214.23	\$120.38	\$44.18	\$0.00	\$0.00	\$6.32	\$14,088,704,000
Total premium	\$238.42	\$341.77	\$286.90	\$303.83	\$244.64	\$307.67	\$275.84	\$218.97	\$214.23	\$120.38	\$276.14	\$235.05	\$86.12	\$65.00	\$56,031,549,000
Covered benefits paid by member (deductibles, copayments, etc)	\$8.44	\$46.18	\$18.14	\$67.04	\$12.49	\$45.71	\$21.55	\$51.02	\$13.04	\$28.09	\$9.78	\$0.00	\$0.00	\$1.77	\$4,077,377,000
Benefits not covered <sup>2</sup>	\$0.25	\$0.00	\$0.25	\$0.00	\$0.56	\$0.10	\$0.56	\$0.10	\$0.29	\$0.26	\$0.38	\$0.00	\$0.00	\$0.08	\$47,957,000
Total Expenditures	\$247.12	\$387.95	\$305.29	\$370.87	\$257.69	\$353.48	\$297.95	\$270.08	\$227.56	\$148.73	\$286.30	\$235.05	\$86.12	\$66.84	\$60,156,882,000

## **Table 5.** Baseline (Premandate) Per Member Per Month<sup>1</sup> Premium and Expenditures, California, Calendar Year 2005.

Source: California Health Benefits Review Program, 2005.

*Note* The population includes individuals and dependents in California who have private insurance (group and individual) or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families.

All population figures include enrollees aged 0-64 years, except the Medi-Cal population, which includes dually eligible Medicare/Medi-Cal recipients of all ages.

Employees and their dependents that receive their coverage from self-insured firms are excluded because these plans are not subject to mandates.

(1) This represents what all individuals in a plan pay to cover the cost of this service. It represents the total expenditures per service multiplied by the quantity utilized, divided by the number of members in each plan, divided by 12 months.

(2) All values include all health care benefits, except expenditures by individuals on the mandated benefit.

*Key*: FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization. CalPERS = California Public Employees' Retirement System.

		Large G	roup			Small G	roup		Indivi	dual		Pu	blic		
	НМО	РРО	POS	FFS	НМО	РРО	POS	FFS	НМО	PPO	CalPERS HMO	Medi-Cal HMO Over 65	Medi-Cal HMO Other	Healthy Families	Total Annual
Population	7,400,000	3,220,000	457,000	19,000	1,498,000	875,000	454,000	4,000	887,000	1,065,000	795,000	354,000	2,846,000	611,000	20,485,000
Average portion of premium paid by Employer	\$0.3829	\$0.0000	\$0.4024	\$0.0000	\$0.6906	\$0.0736	\$0.6959	\$0.0803	\$0.0000	\$0.0000	\$0.5526	\$0.0000	\$0.0000	\$0.1354	\$59,451,433
Average portion of premium paid by Employee	\$0.1028	\$0.0000	\$0.0890	\$0.0000	\$0.3570	\$0.0230	\$0.3650	\$0.0164	\$0.5952	\$0.2900	\$0.1052	\$0.0000	\$0.0000	\$0.0146	\$29,412,870
Total premium	\$0.4856	\$0.0000	\$0.4914	\$0.0000	\$1.0476	\$0.0967	\$1.0609	\$0.0967	\$0.5952	\$0.2900	\$0.6578	\$0.0000	\$0.0000	\$0.1500	\$88,864,303
Covered benefits paid by member (Deductibles, copayments, etc.)	\$0.1588	\$0.0000	\$0.1588	\$0.0000	\$0.3223	\$0.0943	\$0.3223	\$0.0943	\$0.1602	\$0.2538	\$0.2151	\$0.0000	\$0.0000	\$0.0213	\$30,669,064
Benefits not covered <sup>2</sup>	-\$0.2475	\$0.0000	-\$0.2475	\$0.0000	-\$0.5550	-\$0.0975	-\$0.5550	-\$0.0975	-\$0.2850	-\$0.2625	-\$0.3825	\$0.0000	\$0.0000	-\$0.0757	-\$47,957,000
Total expenditures	\$0.3969	\$0.0000	\$0.4026	\$0.0000	\$0.8150	\$0.0934	\$0.8282	\$0.0934	\$0.4704	\$0.2813	\$0.4904	\$0.0000	\$0.0000	\$0.0956	\$71,576,693
Percentage impact of mandate															
Insured premiums	0.204%	0.000%	0.171%	0.000%	0.428%	0.031%	0.385%	0.044%	0.278%	0.241%	0.238%	0.000%	0.000%	0.231%	0.159%
Total expenditures	0.161%	0.000%	0.132%	0.000%	0.316%	0.026%	0.278%	0.035%	0.207%	0.189%	0.171%	0.000%	0.000%	0.143%	0.119%

Source: California Health Benefits Review Program, 2005.

*Note* The population includes individuals and dependents in California who have private insurance (group and individual) or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families.

All population figures include enrollees aged 0-64 years, except the Medi-Cal population, which includes dually eligible Medicare/Medi-Cal recipients of all ages.

Employees and their dependents that receive their coverage from self-insured firms are excluded because these plans are not subject to mandates.

(1) This represents what all individuals in a plan pay to cover the cost of this service. It represents the total expenditures per service multiplied by the quantity utilized, divided by the number of members in each plan, divided by 12 months.

(2) All values include all health care benefits, except expenditures by individuals on the mandated benefit.

*Key:* FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization. CalPERS = California Public Employees' Retirement System

Rate	Sample Population	Source
3.6%	Insured adults (18–64 yrs) in California	CHIS, 2001
4.1%	Insured non-elderly (<65 yrs) in U.S.	MEPS, 2002
7.5%	Adults (18+ yrs) in U.S.	NHIS, 2002
11.0%	Adults in U.S.	Eisenberg et al., 1998

Table 7: Population Estimates of Use of Chiropractic Services in Past Year

Sources: 2002 NHIS data as presented in Barnes et al., 2004, and Ni et al., 2002; 2002 Medical Expenditure Panel Survey (MEPS) data presented by the Agency for HealthCare Research and Quality http://www.meps.ahrq.gov/whatis.htm.

# **Table 8:** Summary of Chiropractic Claims by Location of Injury<br/>or Disorder, United States, 2002

Location of Injury or Disorder	Distribution
Back	44%
Neck	35%
Other	21%
Total	100%

Source: Analysis of commercial claims data by Milliman.

### **Table 9:** Prevalence of Back Pain by Age per 100,000 in the United States, 1996

	15–24	25–34	35–44	45–54	55–64
Females	1,549	2,380	3,185	10,177	11,483
Males	1,188	1,987	5,132	9,165	8,853
Total	1,364	2,184	4,151	9,682	10,233

Source: Calculated using data presented in the WHO Technical Report Series 919 (2003) based on the 1996 National Health Interview Survey and the US Census Population data for July 1, 1996 found at: <u>http://www.census.gov/popest/archives/1990s/nat-agesex.txt</u>

### Table 10: Rates of Chiropractic Visits by Race/Ethnicity

Race/Ethnicity	Estimate	95% Confidence Interval				
White	4.6%	4.3%-5.0%				
Latino	2.3%	1.8%-2.8%				
Asian	2.1%	1.5%-2.7%				
Black	1.6%	1.0%-2.1%				

Source: 2001 California Health Interview Survey. Insured Adults 18-64.

## APPENDIX A Literature Review Methods

Appendix A describes the literature search for studies that evaluate the medical effectiveness of chiropractic services. The outcomes identified in the literature search include *symptom relief*, *objective signs*, including physical exam results, side effects, and adverse events, *quality of life*, *functional status*, including activities of daily living (ADL) and work status, and *health care utilization and costs*, including the use of medical services (e.g., drugs) and patient satisfaction.

To "grade" the evidence for all outcome measures, the CHBRP effectiveness team uses a system<sup>20</sup> with the following categories:

1. Favorable (statistically significant effect): Findings are uniformly favorable, and many or all are statistically significant.

2. Pattern<sup>21</sup> toward favorable (but not statistically significant): Findings are generally favorable, but there may be none that are statistically significant.

3. Ambiguous/mixed evidence: Some findings are significantly favorable, and some findings with sufficient statistical power show no effect.

4. Pattern toward no effect/weak evidence: Studies generally find no effect, but this may be due to a lack of statistical power.

5. No effect: There is statistical evidence of no clinical effect in the literature with sufficient statistical power to make this assessment.

6. Unfavorable: No findings show a statistically significant benefit, and some show significant harms.

7. Insufficient evidence to make a "call": There are very few relevant findings, so it is difficult to discern a pattern.

For additional information on the literature review and underlying methodology, please refer to the CHBRP Web site, http://www.chbrp.org/documents/medeffect\_paper.pdf.

Studies of the effectiveness of the foregoing agents were identified from PubMed, the Cochrane Library, the Index to Chiropractic Literature (ICL), the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Manual, Alternative, and Natural Therapy Index System (MANTIS) from the period between January 1995 and May 2005. The search terms used to elicit studies relevant to the mandate, that is, those that were relevant to studies about chiropractic services, were as follows:

## Medical Subject Headings (MeSH) for PubMed and Cochrane

Chiropractic Chiropractic/economics/adverse effects/standards Manipulation, Chiropractic Manipulation, Chiropractic/adverse effects/economics/standards Manipulation, Spinal

<sup>&</sup>lt;sup>20</sup> The foregoing system was adapted from the system used by the U.S. Preventive Services Task Force, available at http://www.ahcpr.gov/clinic/3rduspstf/ratings.htm. The medical effectiveness team also considered guidelines from the Centers for Medicare & Medicaid Services, (available at http://www.cms.hhs.gov/mcac/8b1-i9.asp) and guidelines from the Blue Cross and Blue Shield Association (available at http://www.bcbs.com/tec/teccriteria.html).

<sup>&</sup>lt;sup>21</sup> In this instance, the word "trend" may be used synonymously with "pattern."

Manipulation, Spinal/adverse effects/standards **Risk Factors** Back Pain/therapy Back Low Back Pain/therapy Lower Back Hand Neck Pain/therapy Neck Shoulder Pain/therapy Shoulder Activities of Daily Living Death Paralysis Patient Satisfaction **Treatment Outcome** Humans **Comparative Study Evaluation Studies** Follow-Up Studies **Prospective Studies Retrospective Studies** Cost and Benefit Analysis Costs and Costs Analysis Delivery of Health Care/utilization Health Care Costs Head, Headache, Headache Disorders

### Keywords

Below is a list of keywords used in the search to retrieve newly published articles that haven't been indexed with MeSH terms, or because no MeSH terms are available.

Back pain Back Shoulder pain Shoulder Neck pain Neck Hand Chiropractic Spinal manipulation Chiropractic manipulation Pain intensity Pain relief Return to work Functional status Activities of daily living Opiate Narcotic 42

Health care utilization Cost\*<sup>22</sup> Cost benefit analysis Costs and costs analysis Delay\* Diagnosis Cancer Tumor Metastatic Metastasized Acute injur\* Complication\* Adverse effect\* Effective\* Efficacy Death Paraplegia Paralysis Patient satisfaction Treatment outcome Systematic review Randomized controlled trial\* Clinical trial\* Meta analysis Case\* Head Headache Headache disorders

### **CINAHL Search Terms**

Chiropractic Chiropractic/adverse effects/economics/evaluation/methods/standards/utilization Chiropractic Assessment Chiropractic Manipulation Chiropractic Manipulation/adverse effects/economics/evaluation/methods/ standards/utilization **Chiropractic Practice** Back Pain Neck Pain Shoulder Pain Hand Pain Systematic Review **Clinical Trial** Head Head Injuries

<sup>&</sup>lt;sup>22</sup> The asterisk (\*) indicates that the word has been truncated, meaning that the search retrieves all variations with the same root. For example, effect\* would retrieve effect, effects, effectiveness, effective, etc.

Headache Randomized Controlled Trial

## ICL Search Terms

Chiropractic Practice Manipulation Manipulation, Chiropractic Back Back Pain Hand Neck Neck Pain Shoulder Shoulder Shoulder Pain Treatment Outcome Activities of Daily Living

## MANTIS Search Terms

Chiropractic Manipulation, Chiropractic Manipulation, Spinal Back Pain Low Back Pain Hand Head Headache Headache Disorders Shoulder Pain Neck Pain Adverse Effects Death **Paralysis Treatment Outcome** Outcome Assessment (Health Care) Costs and Benefit Analysis Costs and Costs Analysis Delivery of Health Care Health Care Costs **Controlled Clinical Trials Randomized Controlled Trials** Meta Analysis Human

## MANTIS Keywords

Complication\* Effective\* Efficacy 44

## Systematic review

The types of publications included in the literature search were:

Randomized Controlled Trials Clinical Trials Meta-analyses Case Reports Case-Control Studies Systematic Reviews

The literature review resulted in 280 references. However, in CHBRP analyses, we rely on a hierarchy of study designs. In this hierarchy, meta-analyses and systematic reviews of randomized trials are given the greatest weight, followed by individual randomized trials and then by such other study designs as observational studies and case reports. Among the 280 references, there were 23 meta-analyses and systematic reviews of randomized trials (all of the randomized trials were also among the 280 articles). The present analysis relies upon 23 meta-analyses and systematic reviews to assess the impact of chiropractic services for musculoskeletal disorders, supplemented by two case-control studies on serious adverse events and a recently-published randomized controlled trial on the cost of chiropractic care. The complete articles for the 23 meta-analyses and systematic reviews and the 3 other relevant publications were retrieved and reviewed by at least two persons.

# APPENDIX B Summary of Published Studies on Effectiveness of Chiropractic Services

# Table B-1Summary of Published Studies on Effectiveness of Chiropractic Services for Musculoskeletal Disorders

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Aker et al., 1996	Meta-analysis of 29 RCTs <sup>23</sup>	Manual treatment vs. physical medicine vs. drug treatment vs. patient education	Patients with mechanical neck disorders (conditions causing neck pain with or without referral into the shoulder and upper arm)	United States, Europe
Assendelft et al., 2005	Meta-analysis of 39 RCTs	Spinal manipulative therapy (manipulation or mobilization) vs. sham therapy, general practitioner care, analgesics, physical therapy, exercises, or back school	Patients with low back pain (acute or chronic)	United States, Europe
Assendelft et al., 2003	Meta-analysis of 39 RCTs	Spinal manipulative therapy vs. sham therapy, conventional general practitioner care, analgesics, physical therapy, exercises, back school, and a collection of therapies (traction, corset, bed rest, home care, topical gel, no treatment, diathermy, and minimal massage)	Patients with low back pain, regardless of radiation pattern	United States, Europe
Astin and Ernst, 2002	Systematic review of 8 RCTs	Spinal manipulation vs. drug therapy, placebo, or palpation	Patients with headache disorders (migraine, tension, cervicogenic)	Unknown

<sup>&</sup>lt;sup>23</sup> Randomized controlled trials

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Baldwin et al., 2001	Literature review of 3 RCTs and 4 cohort studies	Chiropractic care vs. physiotherapy or medical care	Patients with occupational low back pain	Sweden, Australia, North America
Bronfort et al., 2004	Systematic review of 43 RCTs	Spinal manipulative therapy and mobilization vs. established efficacious treatment, commonly used therapy, or placebo (e.g., acupuncture, back school, bed rest, corset, diathermy, education advice, electrical modalities, exercise, heat, injections, massage and trigger point therapy, medication, no treatment, placebo, physical therapy, sham manipulation, and ultrasound)	Patients with acute and/or chronic back pain and patients with acute and/or chronic neck pain	United States, Europe
Bronfort et al., 2001	Systematic review of 9 RCTs	Spinal manipulation vs. placebo, drug therapy, deep friction with placebo, mobilization, palpation and rest, cold packs, or waiting list	Patients with chronic headaches	Unknown
Cherkin et al., 2003	Systematic review of 20 RCTs and meta-regression analysis of 26 RCTs	Acupuncture, massage, or spinal manipulation vs. sham therapies or conventional treatment (general practitioner care, physiotherapy, exercise, traction, and bed rest)	Patients with nonspecific back pain (acute and chronic)	Europe, Australia, United States
Cooperstein et al., 2001	Literature review of 143 studies (39 clinical trials, 2 meta-analyses, 15 cohort studies, 3 time series experimental design, and 81 case reports)	A variety of chiropractic procedures (e.g., manipulation, pelvic blocking, mobilization) vs. surgery, drug therapy, bed rest, physical therapy, and patient instruction	Primarily patients with low back pain (with or without buttock-leg pain or neurologic deficits). Also includes studies of patients with leg pain, herniated disks, sacroiliac dysfunction, posterior joint dysfunction, and spondylolisthesis	United States (multiple sites), New Zealand, Australia, Canada

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Ernst, 2003	Systematic review of 4 RCTs	Spinal manipulation vs. mobilization or exercise therapy	Patients with non-traumatic neck pain	United States, Europe
Ferreira et al., 2003	Literature review and meta-analysis of 27 clinical trials	Spinal manipulative therapy vs. placebo therapy, no treatment, massage, short wave therapy, exercise, physiotherapy, or medical care	Patients with nonspecific back pain of less than 3 months' duration	Australia, United States, Europe
Ferreira et al., 2002	Systematic review and meta-analysis of 9 RCTs	Spinal manipulative therapy or manual therapy vs. placebo, NSAIDs <sup>24</sup> , shortwave diathermy, or physiotherapy	Patients with chronic low back pain	Australia, Egypt, Europe, United States,
Furlan et al., 2002	Systematic review of nine studies (8 RCTs)	Massage (hand or device) vs. sham treatment, manipulation, TENS <sup>25</sup> , corsets, exercise, relaxation therapy, acupuncture, and self-care education	Patients with acute, sub-acute, or chronic nonspecific low back pain	North America, Brazil, Europe
Gross et al., 2004	Systematic review of 33 RCTs	Manipulation and/or mobilization vs. placebo, control groups, or other treatments (wait list control, soft tissue treatments, high-technology exercise, drug therapy, or physiotherapy)	Acute, subacute, or chronic mechanical neck disorders (with or without headache)	Canada, Europe, United States
Gross, Kay, Hondras, et al., 2002	Systematic review of 20 RCTs	Manipulation or mobilization vs. manipulation plus mobilization, manipulation plus mobilization and massage, manipulation plus exercise, or multimodal therapy (e.g., physical medicine, mobilization, patient education, and analgesics)	Patients with neck disorders (with or without radicular findings or headache)	Europe, North America
Gross, Kay, Kennedy, et al., 2002	Systematic review of 28 review articles	Manipulation and/or mobilization vs. exercise, thermal modalities, patient education, collar, and combination therapies	Patients with mechanical neck disorders, neck disorders with headache of cervical origin, and neck disorders with radicular signs or symptoms	North America, Europe, Australia
Hagen et al., 2005	Systematic review of 11 RCTs	Bed rest vs. exercise, physiotherapy, drug therapy, manipulation, back school, or placebo	Patients with acute low back pain or sciatica	Unknown
Heymans, et al, 2005	Systematic review of 19 RCTs	Back school vs. placebo, wait list control, exercise, manipulation, myofascial therapy, or	Patients with nonspecific low back pain, ages 18–70 yrs	Unknown

 <sup>&</sup>lt;sup>24</sup> Non-steroidal anti-inflammatory drugs
 <sup>25</sup> Transcutaneous electrical nerve stimulation

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
		advice		
Hurwitz et al., 1996	Systematic review of 81 manipulation and mobilization studies (15 RCTs, 3 cohort, 15 case series, and 48 case reports)	Manipulation vs. mobilization vs. a variety of interventions (TENS, rest, analgesics, exercise, muscle relaxants, physical therapy, placebo, general practitioner care, massage, traction, ergonomic instruction)	Patients with neck pain (with and without arm pain, migraine, and tension headache) with varied prognoses (acute and chronic pain, traumatic and nontraumatic neck pain)	North America, Europe, Australia, and New Zealand
Koes et al., 1996	Systematic review of 36 RCTs	Spinal manipulation vs. other treatments (short- wave diathermy, massage, exercises, analgesics, placebo, physiotherapy, corset)	Patients with low back pain (acute and chronic)	Netherlands, England, United States, Egypt, New Zealand
Kominski et al., 2005	RCT	Chiropractic care vs. medical care, medical care plus physical therapy, and chiropractic care with a physical component	Patients with low back pain	United States
Lenssinck et al., 2004	Systematic review of 8 RCTs	Physiotherapy (massage, ultrasound, relaxation techniques, cryotherapy, parafango) and/or spinal manipulation vs. acupuncture, deep friction massage with mobilization, palpation, rest, or placebo	Patients with tension-type headache	North America, Europe
Oliphant, 2004	Systematic review of 8 review articles, 9 prospective/retrosp ective studies, and 2 surveys	Treatment with spinal manipulation vs. treatment with NSAIDS or surgery	Patients with lumbar disk herniations	Europe, North America
Rothwell et al., 2001	Case-control study of 582 patients	VBA patients vs. four control groups (age and sex matched) with no history of stroke	Patients with a history of VBA	Ontario, Canada
Smith et al., 2003	Case-control study of 151	Patients with cervical arterial dissection and ischemic stroke or TIA <sup>26</sup> vs. patients with other identified causes of stroke (age and sex matched)	Patients with cervical arterial dissection and ischemic stroke or TIA	California (two locations)

<sup>&</sup>lt;sup>26</sup> Transient ischemic attack

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Stevinson and Ernst, 2002	Systematic review of 5 prospective investigations, 45 case reports, and 3 retrospective surveys of neurologists	Spinal manipulation without side effects vs. spinal manipulation with side effect(s) and/or adverse events	Patients receiving spinal manipulation	Europe, United States (multiple sites), Ukraine

# Table B-2 Summary of Evidence of Effectiveness by Outcome for Chiropractic Services in Treatment of Musculoskeletal Disorders

## **Pain Relief**

Pattern toward favorable for comparisons between spinal manipulative therapy (SMT) and placebo/sham, medical, and/or physical therapy treatments.

Pain Relief		
Citation		Categorization of Results
	Results	(Significance, Direction)
Assendelft et al., 2005	Improvement in pain rating after SMT <sup>27</sup> (vs. sham) for acute low back pain (VAS <sup>28</sup> : 10-mm difference in pain)	3 studies: sig <sup>29</sup> , fav
	Improvement in pain rating after SMT (vs. sham) for chronic low back pain (VAS: 10-mm difference in pain [short-term], VAS: 19-mm difference in pain [long-term])	7 studies: sig, fav
Astin and Ernst,	Improvements in intensity of pain through manipulation by a chiropractor vs. sham, rest,	7 studies: 3 sig, fav
2002	soft tissue massage, and manipulation or mobilization by physician or physiotherapist	1 NS, fav
	No difference in pain between manipulation and control groups (sham, oral amitriptyline, and soft tissue therapy)	3 NS, neutral
Baldwin et al., 2001	No difference between groups in pain intensity	1 study: SNE <sup>30</sup> , neutral

<sup>&</sup>lt;sup>27</sup> Spinal manipulation therapy
<sup>28</sup> Visual analog scale
<sup>29</sup> For studies where the P-value was not given, significant outcomes are characterized by a P-value of less than 0.05 and nonsignificant outcomes by a P-value of greater than 0.05.
<sup>30</sup> Significance not evaluated

Pain Relief		
Bronfort et al., 2004	Reduction in pain after manipulation therapy for chronic low back pain	3 studies: 2 limited evidence, fav; 1 mod. evidence, neutral
	No difference in pain outcome between all groups for mixed (acute and chronic) back pain	5 studies: moderate evidence, neutral
	Reduction in pain after manipulation therapy for mixed back pain	3 studies: limited evidence, fav
	Increased pain after SMT for chronic neck pain	1 study: moderate evidence, not fav/neutral
	Decreased pain after SMT for mixed neck pain	3 studies: moderate evidence, fav
	Increased pain after SMT for mixed neck pain	1 study: limited evidence, not fav
	No difference between groups for mixed neck pain	1 study: moderate evidence, neutral
Bronfort et al., 2001	Increased headache pain after SMT vs. amitriptyline ( $P = 0.05$ )	1 study: not fav
Total of 5 studies with SMT performed	Decreased headache index score after SMT vs. amitriptyline("borderline statistical significance" <sup>31</sup> )	1 study: fav
by chiropractors	No difference in headache pain after SMT with massage (vs. massage with placebo)	1 study: SNE, neutral
	Decrease in headache hours (by 22% vs. massage with placebo) and intensity of headache (twice the reduction vs. massage with placebo)	1 study: SNE, fav
	Decreased pain, frequency, and duration of headache after chiropractic SMT vs. MD or $PT^{32}$ SMT ( $P > 0.05$ )	1 study: NS, fav

<sup>&</sup>lt;sup>31</sup> Bronfort et al., 2001
<sup>32</sup> Physical therapy
52

Pain Relief		
Cooperstein et al., 2001	Decrease in low back pain (VAS) after SMT vs. back education program	1 study: NS, fav
Total of 32 studies	Decrease in low back pain after SMT/MOB <sup>33</sup> plus steroid injections vs. conventional treatment ( $P = 0.015$ )	1 study: sig, fav
(excluded studies		
with no/unknown control group or	Decrease in radiating low back pain after SMT (vs. heat, massage, and exercise)	1 study: sig, fav
unclear outcome)	Decrease in low back pain and time to relief of symptoms after SMT (vs. microwave diathermy, isometric abdominal exercises, and ergonomic instruction)	1 study: sig, fav
	Decrease in distress related to low back pain after SMT (vs. sham)	1 study: NS, fav
	Decrease in low back pain after SMT plus prescription drug (vs. prescription drug alone)	1 study: sig, fav
	Decrease in low back pain (VAS) after SMT (vs. back school, ergonomic advice, back exercises, and postural exercises)	1 study: sig, fav
	Decrease in short-term low back pain after SMT (vs. massage)	1 study: NS, fav
	Increase in low back pain patients who are symptom-free after SMT (vs. bed rest, lumbar pillow, and analgesics)	1 study: NS, fav
	No difference in low back pain after SMT (vs. shortwave diathermy)	1 study: NS, neutral
	No difference in low back pain (VAS) after SMT (vs. detuned ultrasound, cold packs, and massage)	1 study: NS, neutral
	Increased low back pain (VAS, Oswestry <sup>34</sup> ) after SMT vs. back school	1 study: NS, not fav
Ernst, 2003	No difference in pain after SMT (vs. exercise, physiotherapy, or manipulation and exercise)	2 studies: NS, neutral
	Decrease in short-term pain after SMT (vs. mobilization)	1 study: sig, fav
Ferreira et al., 2003	Decrease in pain after SMT vs. placebo ( $-17$ on RMDQ <sup>35</sup> ; 95% CI <sup>36</sup> , $-26$ to $-8$ )	3 studies: SNE, fav

 <sup>&</sup>lt;sup>33</sup> Spinal mobilization
 <sup>34</sup> The Oswestry low back pain disability questionnaire
 <sup>35</sup> Roland-Morris Disability Questionnaire

Pain Relief		
Ferreira et al., 2002	Decrease in pain after SMT vs. placebo (VAS: 7 mm; 95% CI: 1 to 14)	2 studies: NS, fav
	Decrease in pain after SMT vs. NSAIDS <sup>37</sup> (VAS: 14 mm; 95% CI: -11 to 40)	2 studies: sig, fav
Furlan et al., 2002	No difference in pain after SMT (vs. massage)	2 studies: SNE, neutral
Gross et al., 2004	No difference in pain after SMT (vs. sham) for MNDs <sup>38</sup> (pooled SMD <sup>39</sup> –0.51: 95% CI: – 1.10 to –0.07)	2 studies: SNE, neutral
	No difference in pain after SMT vs. wait-list control, soft tissue treatments, exercise,	5 studies: SNE, neutral
	manipulation plus exercise, tenoxicam plus ranitidine, low-voltage electrical acupuncture, or physiotherapy	3 studies: SNE, neutral
	No difference in pain after SMT (vs. mobilization) for MNDs or neck disorders with headache with radicular findings	4 studies: SNE, neutral
	No difference in pain after mobilization (vs. cold pack, collar, TENS, acupuncture, and ultrasound)	2 studies: SNE, fav
	Decrease in pain after SMT plus mobilization vs. no treatment (pooled SMD –0.34; 95% CI: –0.71 to 0.03)	6 studies: SNE, neutral
	No difference in pain after SMT and/or mobilization (vs. no treatment, placebo, exercise, exercise/traction/massage, collar, galvanic current/ultrasound/UV light, massage/munaripack, SMT or mobilization plus heat or electric muscle stimulation, or	15 studies: strong evidence,
	<ul> <li>massage/traction/electrical stimulation/analgesics/education</li> <li>Decreased pain after SMT plus mobilization and exercise vs. wait-list control (pooled SMD -0.85 95% CI: -1.20 to -0.50, VAS: 23 to 27 mm) for chronic neck disorder with or</li> </ul>	fav
	without radicular findings and for subacute chronic neck disorder with headache No difference in pain after SMT plus mobilization and exercise (vs. exercise alone)	6 studies: SNE, neutral

 <sup>&</sup>lt;sup>36</sup> Confidence interval
 <sup>37</sup> Non-steroidal anti-inflammatory drugs
 <sup>38</sup> Mechanical neck disorders
 <sup>39</sup> Standardized mean difference

Pain Relief		
Gross, Kay,	No difference in pain after SMT plus galvanic current (vs. current alone, ultrasound, UV	1 study: SNE, neutral
Hondras, et al.,	light, munaripack, or massage)	
2002		
	No difference in pain after SMT vs. mobilization (SMD: -1.04; 95% CI: -1.46 to -0.61)	1 study: SNE, neutral
Excluded repetitive		
studies from Gross et	Increased pain after SMT vs. mobilization (RR <sup>40</sup> : 0.97; 95% CI: 0.47 to 2.03)	1 study: SNE, not fav
al., 2004		
	No difference in pain after mobilization vs. acupuncture (SMD: -0.33; CI 95%: -0.89 to	1 study: SNE, neutral
	0.23)	
		1 study: SNE, fav
	Decrease in pain after mobilization vs. ice (SMD: -1.06; 95% CI: -2.03 to -0.08)	
		1 study: SNE, neutral
	No difference in headache intensity after SMT/traction/education vs. exercise (SMD 0.00;	
	95% CI: -0.47 to 0.47)	
		1 study: SNE, neutral
	No difference in pain after SMT vs. massage or laser (SMD: -0.45; 95% CI: -0.99 to 0.10)	
		1 study: SNE, neutral
	No difference in pain after mobilization vs. control group (SMD: -0.45; 95% CI: -1.34 to	
	0.44) or TENS (SMD: 0.04; 95% CI: -0.83 to 0.92)	
Hagen et al., 2005	No difference in pain after SMT vs. bed rest for acute low back pain	1 study: SNE, neutral

<sup>&</sup>lt;sup>40</sup> Relative risk

Pain Relief		
Heymans, et al, 2005	Increase in pain after SMT vs. back school for chronic and mixed back pain	1 study: SNE, not fav
	No difference in pain after SMT vs. back school for low back pain with radiating symptoms	1 study: SNE, neutral
Hurwitz et al., 1996	Decrease in pain (VAS) after Maitland mobilization/neck collar/mobilization advice vs. rest and analgesics	1 study: sig, fav
	Decrease in pain (VAS) after Maitland mobilization vs. cervical collar	1 study: sig, fav
	Decrease in pain after SMT vs. mobilization	1 study: NS, fav
	Increase in pressure pain threshold (neck) after SMT vs. mobilization, PT, placebo, GP <sup>41</sup> care, or muscle relaxants (combined VAS: 12.6 mm; 95% CI: –0.15 to 25.5)	3 studies: sig, fav
	Decrease in pain after mobilization/salicylate vs. salicylate/massage/traction/electrical stimulation and salicylate alone	1 study: sig, fav
	Decrease in pain after manual treatment (traction/mobilization/manipulation) vs. drug therapy and PT	1 study: NS, fav
	No difference in headache pain after SMT vs. cold packs	1 study: NS, neutral
	Decrease in short term pain after SMT vs. palpatory examination or rest	1 study: sig, fav
	Reduction in frequency and intensity of headaches after chiropractic manipulation vs. manipulation by physicians, physical therapists, or mobilization	1 study: sig, fav

<sup>&</sup>lt;sup>41</sup> General practitioner 56

Pain Relief		
Koes et al., 1996	Decrease in acute low back pain after SMT vs. physiotherapy or drug therapy	5 studies: SNE, fav
	Decrease in acute low back pain after SMT vs. physiotherapy or drug therapy (subgroup only)	3 studies: SNE, fav
	Increase in acute low back pain after SMT vs. physiotherapy or drug therapy	4 studies: SNE, not fav
	increase in acute four back pain arter Sivir vs. physiotherapy of artig incrupy	5 studies: SNE, fav
	Decrease in chronic low back pain after SMT vs. usual GP care, physiotherapy, back school, or drug therapy	
		2 studies: SNE, neutral
	No difference in chronic low back pain after SMT vs. usual GP care, physiotherapy, back school, or drug therapy	
	Decrease in subacute and chronic pain after SMT vs. physiotherapy, corset, exercise, heat,	8 studies: SNE, fav
	bed rest, back school, drug therapy, massage, or home care instructions	
	Decrease in subacute and chronic pain after SMT vs. physiotherapy, corset, exercise, heat,	1 study: SNE, fav
	bed rest, back school, drug therapy, massage, or home care instructions (subgroup only)	
	No difference in a bound of the size of the CMT and the second of the se	2 studies: SNE, neutral
	No difference in subacute and chronic pain after SMT vs. physiotherapy, corset, exercise, heat, bed rest, back school, drug therapy, massage, or home care instructions	
		7 studies: SNE, fav
	Decrease in pain after SMT vs. placebo	1 study: SNE, fav
	Decrease in pain after SMT vs. placebo (subgroup only)	
	No difference in nois often SMT ve alcoche	3 studies: SNE, neutral
Lenssinck et al.,	No difference in pain after SMT vs. placebo           Decrease in pain after SMT vs. rest or no treatment	1 study: sig, fav
2004	Decrease in pain arter Sivir vs. lest of no treatment	1 Study. Sig, 1av

# **Objective Signs**

Pattern towards favorable for comparisons between spinal manipulative therapy (SMT) and placebo/sham, medical, and/or physical therapy treatments.

Objective Signs		
Citation	Results	Categorization of Results (Significance, Direction)
Bronfort et al., 2001	Fewer side effects after SMT for headache (vs. amitriptyline)	2 studies, SNE, fav
Cooperstein et al., 2001	No difference in strength, extension, or flexion after SMT (vs. detuned ultrasound, cold packs, and massage)	1 study: NS, neutral
	No difference in physical outcomes after SMT (vs. massage, transcutaneous muscle stimulation, or corset)	1 study: NS, neutral
		1 study: NS, fav
	Improvements in pelvic measurements after SMT for low back pain (vs. training)	
		1 study: sig, fav
	Increase in ROM <sup>42</sup> for low back pain patients after SMT with codeine phosphate (vs. codeine phosphate alone)	
		1 study: sig, fav
	Improved biomechanic outcomes for low back pain patients after SMT (vs. back school)	
		1 study: sig, fav
	Improved ROM and SLR <sup>43</sup> angles for low back pain patients after mobilization (vs. shortwave diathermy, isometric exercises, and postural instruction)	
		1 study: sig, fav
	Decreased hamstring tension in low back pain patients after SMT (vs. asymptomatic patients receiving SMT)	
		1 study: NS, fav
	Increase in lumbar extension ROM after SMT (vs. microwave diathermy, abdominal exercises, and ergonomic instruction)	
		1 study: sig, fav
	Increase in strength after SMT (vs. moist heat and passive stretching)	
		1 study: NS, fav
	Decreased amplitude of surface EMG <sup>44</sup> during extension of lumbar erector spinae and elimination of spontaneous EMG activity after SMT vs. no treatment ( $P = 0.006$ )	

<sup>&</sup>lt;sup>42</sup> Range of motion 58

Objective Signs		
Furlan et al., 2002	No difference in physical strength, flexibility, ROM, or muscle fatigue after SMT (vs. massage)	2 studies: SNE, neutral
Hagen et al., 2005	No difference in physical exam after SMT vs. bed rest for acute low back pain	1 study: SNE, neutral
Heymans, et al, 2005	Decrease in spinal mobility after SMT vs. back school for chronic and mixed back pain	1 study: SNE, not fav
	No difference in spinal mobility after SMT vs. back school for low back pain with radiating symptoms	1 study: SNE, neutral
Hurwitz et al., 1996	Increase in lateral flexion movement after Maitland mobilization/collar/mobilization advice vs. rest and analgesics	1 study: SNE, fav
	Increase in cervical ROM after Maitland mobilization vs. cervical collar	1 study: SNE, fav
	No difference in cervical mobility after mobilization/salicylate vs. salicylate/massage/traction/electrical stimulation and salicylate alone	1 study: SNE, neutral
Rothwell et al., 2001	Association between VBA <sup>45</sup> and chiropractic treatment (patients <45 years old were 5 times more likely to have visited a chiropractor in the week before VBA; 95% CI from bootstrapping, 1.32 to 43.87; the rate ratio of the risk of VBA associated with chiropractic within one week of the reference date was 5.03 [ $P = 0.006$ ]) vs. control (individuals with no history of stroke).	1 study: NS, not fav
Smith et al., 2003	Association between vertebral artery dissection and chiropractic treatment (patients were more likely to have had SMT within 30 days of vertebral artery dissection, 14% vs. 3%, $P = 0.032$ ) vs. patients with other forms of stroke.	1 study: sig, not fav

 <sup>&</sup>lt;sup>43</sup> Straight leg raise
 <sup>44</sup> Electromyography
 <sup>45</sup> Vertebrobasilar accident

# **Functional Status**

Pattern towards favorable for comparisons between spinal manipulative therapy (SMT) and placebo/sham, medical, and/or physical therapy treatments.

<b>Functional Status</b>	Functional Status		
Citation	Results	Categorization of Results (Significance, Direction)	
Assendelft et al., 2005	Spinal manipulation (vs. sham) for acute low back function RMDQ: 2.8 mm	4 studies: NS, fav	
	Spinal manipulation (vs. sham) for chronic low back function RMDQ: 3.3 mm	2 studies: sig, fav	
Astin and Ernst, 2002	Reduction in disability by manipulated group	1 study: sig, fav	
	No difference in disability by manipulated group	1 study: NS, fav	
Baldwin et al., 2001	Improvement in functional status through chiropractic care (vs. physiotherapy)	1 study: SNE, fav	
	No difference in functional status	2 studies: SNE, neutral	
	No difference in disability status or days of work-related disability	1 study: SNE, neutral	
	Improved patient satisfaction with chiropractic	1 study: SNE, fav	
	Reduced work absence with chiropractic treatment (compared with medical care)	3 study: SNE, fav	

<b>Functional Status</b>		
Bronfort et al., 2004	Reduced disability after spinal manipulation for acute low back pain (vs. mobilization or detuned diathermy)	6 studies: moderate evidence, fav
	Improved recovery time after spinal manipulation for acute low back pain (vs. diathermy, exercise, and ergonomic instruction)	6 studies: limited evidence, fav
	Reduced disability after spinal manipulation for chronic low back pain (vs. sham, PT or home exercise, or exercise after disk surgery)	4 studies: limited evidence, fav
	No difference in disability between groups with mixed low back pain	
	Improved physical function after SMT/MOB for chronic neck pain (vs. GP management or PT)	4 studies: moderate evidence, neutral
		2 studies: moderate evidence, fav
Bronfort et al., 2001	Increase in general health status after SMT for headache (vs. amitriptyline)	1 study: SNE, fav
	Decreased disability after chiropractic SMT for headache (vs. MD or PT SMT)	1 study: SNE, fav

Functional Status		
Cooperstein et al., 2001	Improved activity tolerance after SMT (vs. back education program)	1 study: NS, fav
	Decrease in sick leave time after SMT (vs. conventional therapy)	1 study: NS, fav
	Decrease in sick leave time after SMT (vs. analgesia, rest, and advice)	1 study: sig, fav
	Decrease in sick leave time after SMT with sick leave (vs. sick leave alone)	1 study: NS, fav
	Improvement in recovery after SMT (vs. heat)	1 study: sig, fav
	No difference in disability scores (Oswestry) after SMT (vs. detuned ultrasounds, cold packs, and massage)	1 study: NS, neutral
	Decrease in disability (Oswestry) after SMT (vs. Williams flexion exercises)	1 study: sig, fav
	Decrease in disability (RMDQ, Oswestry) after SMT (vs. massage, corset, or transcutaneous muscular stimulation)	1 study: NS, fav
	Improved recovery time after SMT (vs. infrared lamp)	1 study: sig, fav
	Decrease in disability (Oswestry) after SMT (vs. McKenzie extension exercises)	1 study: sig, fav
	Short term improvement in ADLs after SMT (vs. massage)	1 study: NS, fav
	Decrease in disability and increase in rate of recovery after mobilization (vs. back school, ergonomic advice, back exercises, and postural exercises)	1 study: sig, fav
	No difference in recovery time after mobilization (vs. rest)	1 study: NS, neutral
Ernst, 2003	Decrease in disability after SMT vs. placebo (-5 RMDQ; 95% CI: -9 to -2)	3 studies: SNE, fav

Functional Status		
Ferreira et al., 2003	Decrease in disability after SMT vs. massage (0–100 scale,-17; 95% CI: -40 to 7)	9 studies: NS, fav
	Decrease in disability (Oswestry: -17; 95% CI: -29 to -4) and producing a complete recovery (RR reduction 0.11; 95% CI: 0.02 to 0.75) after SMT vs. shortwave diathermy	1 study: sig, fav
	Decrease in disability after SMT vs. exercise (0–100 scale: -22; 95% CI: -36 to -18)	1 study: NS, fav
	No difference in disability after chiropractic care (manipulation) vs. physiotherapy care (Maitland mobilization, manipulation, or both) (0–100 scale: –2; 95% CI: –4 to 1)	1 study: NS, neutral
Ferreira et al., 2002	Decrease in disability after SMT vs. NSAIDS (0-100 scale: 6; CI 95%: -1 to 12)	2 studies: NS, fav
Furlan et al., 2002	No difference in functional status or disability after SMT (vs. massage)	2 studies: SNE, neutral
Gross et al., 2004	No difference in function after SMT vs. wait-list control, soft tissue treatments, exercise,	5 studies: SNE, neutral
	manipulation plus exercise, tenoxicam plus ranitidine, low-voltage electrical acupuncture, or physiotherapy	
Gross, Kay,	No difference in function after mobilization vs. acupuncture (SMD: -0.16; 95% CI:-0.72 to	1 study: SNE, neutral
Hondras, et al., 2002	0.39)	1 study: SNE poutrol
2002	No difference in function after chiropractic treatment (SMT, traction, education) vs.	1 study: SNE, neutral
	physiotherapy (SMD: 0.00; 95% CI: -0.48 to 0.48) or exercise/education (SMD: -0.36;	
	95% CI: -0.84 to 0.12)	
Hagen et al., 2005	No difference in function after SMT vs. bed rest for acute low back pain	1 study: SNE, neutral
Heymans, et al, 2005	Decrease in function after SMT vs. back school for chronic and mixed back pain	1 study: SNE, not fav
	No difference in function after SMT vs. back school for low back pain with radiating symptoms	1 study: SNE, neutral

# Health Care Utilization/Costs and Patient Satisfaction

Ambiguous/mixed evidence for comparisons between spinal manipulative therapy (SMT) and placebo/sham, medical, and/or physical therapy treatments.

Health Care Utilization, Costs, and Patient Satisfaction		
Citation	Results	Categorization of Results (Significance, Direction)
Astin and Ernst, 2002	Decreased use of OTC <sup>46</sup> or analgesic drugs by manipulation patients	2 studies: sig, fav
Baldwin et al., 2001	Increased duration of treatment with chiropractic (vs. medical services)	1 study: SNE, not fav
	Decreased cost of care for chiropractic services (vs. medical services)	2 studies: SNE, fav
	Increased cost of care for chiropractic services (vs. medical services)	2 studies: SNE, not fav
	No difference in cost of care for chiropractic services (vs. medical services)	1 study: SNE, neutral
Bronfort et al., 2001	No difference in analgesic use after SMT with massage (vs. massage with placebo)	1 study: SNE, neutral
	Decreased OTC drug use after SMT (vs. amitriptyline)	1 study: SNE, fav
Cooperstein et al., 2001	Higher level of confidence in SMT treatment (vs. massage, TMS, or corset)	1 study: SNE, fav
Ernst, 2003	No difference in medication use after SMT (vs. exercise or physiotherapy)	1 study: SNE, neutral
Furlan et al., 2002	No difference in patient satisfaction after SMT vs. wait-list control, soft tissue treatments, exercise, manipulation plus exercise, tenoxicam plus ranitidine, low-voltage electrical acupuncture, or physiotherapy	5 studies: SNE, neutral
Gross, Kay, Hondras, et al., 2002	Increase in patient satisfaction after SMT plus galvanic current (vs. current alone, ultrasound, UV light, munaripack, or massage)	1 study: NS, fav
2002	No difference in patient satisfaction after chiropractic treatment (SMT, traction, education) vs. physiotherapy or exercise/education (SMD: 0.00; 95% CI: -0.48 to 0.48)	1 study: NS, neutral
Kominski et al., 2005	Increased cost of chiropractic care (51.9%, $P = 0.001$ ) vs. medical care	1 study: sig, not fav

<sup>&</sup>lt;sup>46</sup> Over the counter

# Table B-2bSummary of Study Methodology

Aker et al., 1996	Lack of evidence due to small number of trials. Significant adverse events not	Neutral <sup>47</sup>
	"well documented."	
Assendelft et al., 2005	Uneven quantity and quality of original studies.	Neutral
Assendelft et al., 2003	Uneven quantity and quality of studies.	Neutral
Astin and Ernst, 2002	Low methodological quality, small sample sizes, small number of trials.	No conclusion
Baldwin et al., 2001	Methodological deficiencies.	Neutral
Bronfort et al., 2004	Few high quality trials for subgroups of back pain (e.g., acute vs. chronic); most lack long-term follow up.	Favorable
Bronfort et al., 2001	Results "based on only a few trials of adequate methodological quality."	Favorable/neutral
		(depending on control group)
Cherkin et al., 2003	In general, the RCTs included are of poor quality.	Neutral
Cooperstein et al., 2001	Deficit in high quality clinical trials.	Favorable (with limits)
Ernst, 2003	Paucity of RCTs; those available are poorly designed.	Neutral
Ferreira et al., 2003	Results are limited by the methodological quality.	Favorable
Ferreira et al., 2002	Poor methodological quality.	Neutral
Furlan et al., 2002	Mixed methodological quality.	Favorable
Gross et al., 2004	42% of included trials are of "high quality."	Favorable
Gross, Kay, Hondras, et al., 2002	RCTs are small, with varied methodological quality.	Inconclusive
Gross, Kay, and Kennedy, 2002	Paucity of trials.	Neutral/favorable (depending on control group)
Hagen et al., 2005	Only 1 RCT included.	Not favorable
Heymans, et al, 2005	Low methodological quality.	Neutral
Hurwitz et al., 1996	Poor quality research.	Favorable
Koes et al., 1996	Variable methodological quality and limited number of trials.	No conclusion/neutral (depending on control group)
Kominski et al., 2005	Absence of pharmaceutical data may underestimate cost of medical care.	Not favorable
Lenssinck et al., 2004	Poor methodological quality of included studies and insufficient evidence.	No conclusion
Oliphant, 2004	Variable quality of included studies.	Favorable

<sup>&</sup>lt;sup>47</sup> "Neutral" is defined as a treatment with no clear benefit or one that is equally effective when compared to control groups.

Rothwell et al., 2001	Rarity of VBAs, completeness of exposure data, and limitations in chiropractic	Not favorable
	billing diagnostic codes may contribute to study bias.	
Smith et al., 2003	Retrospective nature of the study may include recall bias.	Not favorable
Stevinson and Ernst, 2002	Poor data on serious adverse events.	No conclusion

## APPENDIX C Cost Impact Analysis: General Caveats and Assumptions

This appendix describes general 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/costimpact.html.

The cost analysis in this report was prepared by Milliman and University of California, Los Angeles, with the assistance of CHBRP staff. Per the provisions of AB 1996 (California Health and Safety Code, Section 127660, et seq.), the analysis includes input and data from an independent actuarial firm, Milliman. In preparing cost estimates, Milliman and UCLA relied on a variety of external data sources. The *Milliman Health Cost Guidelines* (HCG) were used to augment the specific data gathered for this mandate. The HCGs are updated annually and are widely used in the health insurance industry to estimate the impact of plan changes on health care costs. Although this data was reviewed for reasonableness, it was used without independent audit.

The expected costs in this report are not predictions of future costs. Instead, they 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 different from our assumptions;
- Utilization of mandated services before and after the mandate different from our assumptions;
- Random fluctuations in the utilization and cost of health care services.

Additional assumptions that underlie the cost estimates presented here are:

- Cost impacts are only shown for people with insurance;
- The projections do not include people covered under self-insurance employer plans because those employee benefit 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.

There are other variables that may affect costs, but which Milliman 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, enrollees 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). Milliman 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 our cost estimates. The dampening would be more

pronounced on the plan types that previously had the least effective medical management (i.e., FFS and 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 we modeled (HMO, PPO, POS, and FFS), there are variations in utilization and costs within California. One source of difference is geographic. Utilization 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, we have estimated the impact on a statewide level. The per-person costs represent an average cost, which may mask the variations in costs of chiropractic care. This is important to consider in the individually-purchased insurance markets,

and the expenditures on copayments.

## APPENDIX D

## Information Submitted by Outside Parties for Consideration for CHBRP Analysis

In accordance with its policy to analyze evidence submitted by outside parties during the first two weeks of each 60-day review of a proposed benefit mandate, CHBRP received the following submissions:

# Personal Communication, Kristine Shultz, Government Affairs Director, California Chiropractic Asssociation, May 26, 2005

Snapshot member survey of current chiropractic patients who have insurance coverage and whether their insurance covers chiropractic benefits, conducted April 2005.

### California Chiropractic Association, May 26, 2005

The following research abstracts were submitted for consideration:

Baldwin ML, Cote P, Frank JW, Johnson WG. (2001). Cost-effectiveness studies of medical and chiropractic care for occupational low back pain: a critical review of the literature. *The Spine Journal*. 1(2):138–147.

Cooper RA. (2001). Health care workforce for the twenty-first century: the impact of nonphysician clinicians. *Annual Review of Medicine*. 52:51–61.

Dagenais S, Haldeman S. (2002). Chiropractic. Primary Care. (2):419-437

Hee H, Whitecloud T 3rd, Myers L. (2004). The effect of previous low back surgery on general health status. *Spine* 29(17):1931–1937.

Horwitz AD, Hosek R, Boyle J, Cianciulli A, Glass J, Codario R. (1998). A new gatekeeper for back pain. *American Journal of Managed Care*. 4(4):576–579.

Jarvis KB, Phillips RB, Danielson C. (1997). Managed care preapproval and its effect on the cost of Utah worker compensation claims. *Journal of Manipulative and Physiological Therapeutics*. 20(6):372–376

Jarvis KB, Phillips RB, Morris EK. (1991). Cost per case comparison of back injury claims of chiropractic versus medical management for conditions with identical diagnostic codes. *Journal of Occupational Medicine*. 33(8):847–852

Legorreta AP, Metz RD, Nelson CF, Ray S, Chernicoff HO, Dinubile NA. (2004) Comparative analysis of individuals with and without chiropractic coverage. *Archives of Internal Medicine*. 164:1985–1992.

Manga P. (2000) Economic case for the integration of chiropractic services into the health care system. *Journal of Manipulative and Physiological Therapeutics*. (2):118-22.

Metz D, Nelson CF, LaBrot T, Pelletier KR. (2004). Chiropractic care: is it substitution care or add-on care in corporate medical plans? *Journal of Occupational and Environmental Medicine*. 46(8):847–855.

Sarnat R, Winterstein J. (2004). Clinical and cost outcomes of an integrative medicine IPA. *Journal of Manipulative and Physiologic Therapeutics*. 27:336–347.

Smith M, Stano M. (1997). Costs and recurrences of chiropractic and medical episodes of low-back care. *Journal of Manipulative and Physiological Therapeutics*. (1):5–12.

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Stano M, Ehrhart J, Allenburg TJ. (1992). The growing role of chiropractic in health care delivery. *Journal of American Health Policy*. 2(6):39–45.

Tuchin PJ, Bonello R. (1995). Preliminary findings of analysis of chiropractic utilization and cost in the workers' compensation system of New South Wales, Australia. *Journal of Manipulative and Physiological Therapeutics*. 18(8):503–511.

UK BEAM Trial Team. (2004). United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care. *BMJ*. 329(7479):1381.

CHBRP analyzes all evidence received during the initial public submission period according to its relevance to the proposed legislation and the program's usual methodological criteria. For more information about CHBRP's methods, to learn how to submit evidence relevant to an on-going mandate review, or to request email notification of new requests CHBRP receives from the California Legislature, please visit: http://www.chbrp.org.

## **APPENDIX E** Chiropractic Scope of Practice

## Taken from the "Laws and Regulations Relating to the Practice of Chiropractic" of the State of California Board of Chiropractic Examiners

## Article 1, Section §302. Practice of Chiropractic.

(a) Scope of Practice.

(1) A duly licensed chiropractor may manipulate and adjust the spinal column and other joints of the human body and in the process thereof a chiropractor may manipulate the muscle and connective tissue related thereto.

(2) As part of a course of chiropractic treatment, a duly licensed chiropractor may use all necessary mechanical, hygienic, and sanitary measures incident to the care of the body, including, but not limited to, air, cold, diet, exercise, heat, light, massage, physical culture, rest, ultrasound, water, and physical therapy techniques in the course of chiropractic manipulations and/or adjustments.

(3) Other than as explicitly set forth in section 10(b) of the Act, a duly licensed chiropractor may treat any condition, disease, or injury in any patient, including a pregnant woman, and may diagnose, so long as such treatment or diagnosis is done in a manner consistent with chiropractic methods and techniques and so long as such methods and treatment do not constitute the practice of medicine by exceeding the legal scope of chiropractic practice as set forth in this section.

(4) A chiropractic license issued in the State of California does not authorize the holder thereof:

(A) to practice surgery or to sever or penetrate tissues of human beings, including, but not limited to severing the umbilical cord;

- (B) to deliver a human child or practice obstetrics;
- (C) to practice dentistry;
- (D) to practice optometry;
- (E) to use any drug or medicine included in materia medica;
- (F) to use a lithotripter;
- (G) to use ultrasound on a fetus for either diagnostic or treatment purposes; or
- (H) to perform a mammography.

(5) A duly licensed chiropractor may employ the use of vitamins, food supplements, foods for special dietary use, or proprietary medicines, if the above substances are also included in section 4057 of the Business and Professions Code, so long as such substances are not included in materia medica as defined in section 13 of the Business and Professions Code. The use of such substances by a licensed chiropractor in the treatment of illness or injury must be within the scope of the practice of chiropractic as defined in section 7 of the Act.

(6) Except as specifically provided in section 302(a)(4), a duly licensed chiropractor may make use of X-ray and thermography equipment for the purposes of diagnosis but not for the purposes of treatment. A duly licensed chiropractor may make use of diagnostic ultrasound equipment for the purposes of neuromuscular skeletal diagnosis.

(7) A duly licensed chiropractor may only practice or attempt to practice or hold himself or herself out as practicing a system of chiropractic. A duly licensed chiropractor may also advertise the use of the modalities authorized by this section as a part of a course of chiropractic treatment, but is not required to use all of the diagnostic and treatment modalities set forth in this section. A chiropractor may not hold himself or herself out as being licensed as anything other than a chiropractor or as holding any other healing arts license or as practicing physical therapy or use the term "physical therapy" in advertising unless he or she holds another such license.

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

As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman, to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP's 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.

## **Faculty Task Force**

Helen Halpin, PhD, Vice Chair for Public Health Impacts, University of California, Berkeley
Gerald Kominski\*, PhD, Vice Chair for Financial Impacts, University of California, Los Angeles
Edward Yelin, PhD, Vice Chair for Medical Effectiveness (acting)

University of California, San Francisco

Harold Luft, PhD, Vice Chair for Medical Effectiveness, (on leave from CHBRP)

University of California, San Francisco

Wayne S. Dysinger, MD, MPH, Loma Linda University Medical Center
Theodore Ganiats, MD, University of California, San Diego
Sheldon Greenfield, MD, University of California, Irvine
Richard Kravitz, MD, University of California, Davis
Thomas MaCurdy, PhD, Stanford University

### **Other Contributors**

Wade Aubry, MD, University of California, San Francisco Nicole Bellows, MHSA, University of California, Berkeley Patricia Franks\*, BA, University of California, San Francisco Miriam Laugesen, PhD, University of California, Los Angeles Witney McKiernan, RN, University of California, San Francisco Sara McMenamin, PhD, University of California, Berkeley Nadereh Pourat, PhD, University of California, Los Angeles

\*Professor Kominski and Senior Research Associate Franks recused themselves from participation or review of this analysis

### National Advisory Council

Susan Dentzer, Health Correspondent, News Hour with Jim Lehrer, PBS, Alexandria, Virginia, Chair

John Bertko, FSA, MAAA, Vice President and Chief Actuary, Humana, Inc., Flagstaff, AZ

Deborah Chollet, PhD, Senior Fellow, Mathematica Policy Research, Washington, DC

Michael Connelly, JD, President and CEO, Catholic Healthcare Partners, Cincinnati, OH

Maureen Cotter, ASA, Founder, Maureen Cotter & Associates, Inc., Dearborn, MI

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

Joseph Ditre, JD, Executive Director, Consumers for Affordable Health Care, Augusta, ME

Jack Ebeler, MPA, President and CEO, Alliance of Community Health Plans, Washington, DC

Allen D. Feezor, Chief Planning Officer, University Health System of Eastern Carolina, Greenville, NC

Charles "Chip" Kahn, MPH, President and CEO, Federation of American Hospitals, Washington, DC

Lauren LeRoy, PhD, President and CEO, Grantmakers In Health, Washington, DC

Trudy Lieberman, Health Policy Editor, Consumers Union, Yonkers, NY

Devidas Menon, PhD, MHSA, Executive Director and CEO, Institute of Health Economics, Edmonton, AB

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

Michael Pollard, JD, M P H, Consultant, Federal Policy and Regulation, Medco Health Solutions, Washington, DC

Karen Pollitz, Project Director, Georgetown University Health Policy Institute, Washington, DC

Christopher Queram, Chief Executive Officer, Employer Health Care Alliance Cooperative, Madison, WI

Richard Roberts, MD, JD, Professor of Family Medicine, University of Wisconsin-Madison, Madison, WI

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

Roberto Tapia-Conyer, MD, MPH, MSc, Senior Professor, National University of Mexico, Cuauhtémoc, Mexico

Prentiss Taylor, MD, Vice President, Medical Affairs, Amerigroup, Chicago, IL

Reed V. Tuckson, MD, Senior Vice President, UnitedHealth Care, Minnetonka, MN

Judith Wagner, PhD, Scholar-in-Residence, Institute of Medicine, Washington, DC

Dale Whitney, Corporate Health and Welfare Manager, UPS, Atlanta, GA

Ronald A. Williams, President, Aetna, Inc., Hartford, CT

## **CHBRP** Staff

Michael E. Gluck, PhD, DirectorCalifornia Health Benefits Review ProgramSusan Philip, MPP, Assistant Director1111 Franklin Street, 11th FloorSharon CulpepperOakland, CA 94607Assistant to the Director and<br/>CHBRP Administrative AssistantTel: 510-287-3876 Fax: 510-987-9715Sachin Kumar, BA<br/>Analystinfo@chbrp.org www.chbrp.orgRobert O'Reilly, BSSachin Kumar, BS

Consultant

## Cynthia Robinson, MPP

Principal Analyst

The California Health Benefits Review Program is administered by the Division of Health Affairs at the University of California Office of the President, Cathryn L. Nation, MD, Acting Vice President.