CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 438
Osteoporosis Screening

A Report to the 2003-2004 California Legislature
February 9, 2004
Revised October 8, 2004

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HEALTH BENEFITS REVIEW PROGRAM

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 provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

A small analytic staff in the University of California's Office of the President supports a task force of faculty from several campuses of the University of California, as well as Loma Linda University, University of Southern California, and Stanford University, to complete each analysis within 60 days, 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 2003-2004 California State Legislature

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Osteoporosis Screening

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 438, a bill to mandate coverage of osteoporosis screening in postmenopausal women aged 50 to 64 years by public and private insurance plans regulated by the California Department of Insurance and Department of Managed Health Care, where screening is defined as the identification of the risk of osteoporotic fractures among postmenopausal women without a previous diagnosis of osteoporosis or in whom a specific risk factor for osteoporosis has been identified. In response to a request from the California Assembly Committee on Health on May 19, 2003, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127660, et seq., of the *California Health and Safety Code*.

Wade Aubry, MD, Ed Yelin, PhD, and Harold Luft, PhD, all of the University of California, San Francisco (UCSF), coordinated the preparation of this report and prepared the medical effectiveness section. Darren Schulte, MD, MPP, of UCSF technical assistance with the literature review and clinical expertise for the medical effectiveness section. Gerald Kominski, PhD, Miriam Laugesen, PhD, and Nadereh Pourat, PhD, all of the University of California, Los Angeles, prepared the cost impact section. Helen Halpin, PhD, and Sara McMenamin, PhD, both of the University of California, Berkeley, prepared the public health impact section. Robert Cosway, FSA, MAAA, and Jay Ripps, FSA, MAAA, both of Milliman USA, provided actuarial analysis. Other contributors include Patricia Franks and Noelle Lee, both of UCSF, and Michael E. Gluck, PhD, of CHBRP staff. Catherine Nancarrow of the University of California Office of the President provided editorial guidance on early drafts of this report, and Cherie Dee Wilkerson, freelance editor, copy edited the report. In addition, a balanced subcommittee of CHBRP's National Advisory Council (see final pages of this report), reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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Michael E. Gluck, PhD
Director

Revision:
October 8, 2004: Added a standard preface and appendix to appear in all CHBRP reports, identifying individual contributions to the analysis.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 438

Assembly Bill 438 proposes to require coverage of osteoporosis screening in postmenopausal women aged 50-64 years by public and private insurance plans regulated by the California Department of Insurance and Department of Managed Health Care, where screening is defined as the identification of the risk of osteoporotic fractures among postmenopausal women without a previous diagnosis of osteoporosis or in whom a specific risk factor for osteoporosis has been identified. The California Health Benefits Review Program has been asked by the California Legislature to conduct an evidence-based scientific review of the medical, financial, and public health aspects of such a mandate.

Osteoporosis is a major health concern in postmenopausal women and is characterized by low bone mass, increasing bone fragility, and a consequent susceptibility to fracture. It is estimated that approximately 50% of all postmenopausal women will suffer from a fracture due to osteoporosis during their lifetimes. In addition to age, risk factors for low bone density and fractures include smoking, family history of hip fracture, low body weight, and lack of estrogen replacement use.

Currently, universal screening for osteoporosis is a statutory benefit of the Medicare program for postmenopausal women aged 65 years and older. In California, approximately 30% of women aged 50 – 64 years have had a screening test for osteoporosis, and 35% of women in this same age group have been diagnosed with bone loss or osteoporosis.

I. MEDICAL EFFECTIVENESS

- Of the studies reviewed, there were none that directly assessed whether osteoporosis screening is effective in reducing fractures.

- Indirect evidence from observational studies indicates that:

    - Age, family history of fracture, concurrent chronic disease or disability, smoking, heavy alcohol use, oophorectomy (surgical menopause) before age 45 years, and number of children (greater than five) are associated with fracture.
    - Women with osteoporosis based on bone mineral testing by dual energy X-ray absorptiometry or quantitative ultrasound have a 4-fold risk of fracture compared with women with normal bone mineral density.
    - Bisphosphonates, which are non-estrogen based medications, have been shown in controlled trials to reduce the rate of fractures; however, few studies have been done among women younger than 65 years.

- There is almost universal agreement among relevant health care organizations based on prior systematic reviews that postmenopausal women aged 65 years and older should be screened for osteoporosis, but very little support exists in the literature or through recommendations of national health care organizations and specialty societies for general screening of younger postmenopausal women ages 50 to 64 years in the absence of identifiable risk factors.

II. UTILIZATION, COST, AND COVERAGE IMPACTS

- Expanding mandated coverage for osteoporosis screening to women between 50 and 64 years who are privately insured is likely to increase the utilization of screening services from 8% to around 30% among the female population aged 50-64 years, based on experience in Medicare and on other factors described in the main body of the report, below. A small increase (around 1%) in utilization of treatment services may also occur if screening increases, once new cases are identified.

- Total health expenditures (including premiums and out-of-pocket spending) among the privately insured would increase by less than 0.1% per month.

III. PUBLIC HEALTH IMPACTS

- The public health impact of a mandate to provide coverage for osteoporosis screening would be relatively small. Screening for osteoporosis and subsequent treatment for those women found to have low bone mineral density prevents hip fractures in 0.03% of women screened and prevents vertebral fractures in 0.1% of women aged 50-64 who are screened, on the assumption that more of them will seek effective treatment. Thus, the number of women aged 50-64 years needed to screen to prevent one fracture is large, approximately 700.

IV. CONCLUSION

- Published scientific evidence and recommendations based on the deliberation of consensus development panels do not support a universal osteoporosis screening strategy for postmenopausal women aged 50-64 years without identifiable risk factors, symptoms, or a previous vertebral fracture.

- Total health expenditures among the privately insured would be likely to increase by less than 0.1% per month. The public health impact of a mandate to provide coverage for osteoporosis screening for women 50-64 years would be small.

INTRODUCTION

Pursuant to Assembly Bill 1996, enacted in 2002, the California Health Benefits Review Program has been asked by the Legislature to conduct an evidence-based scientific review of the medical, financial, and public health aspects of imposing a mandate that osteoporosis screening for postmenopausal women in California aged 50 through 64 years be covered by public and private insurance plans regulated by the Department of Insurance and Department of Managed Health Care (Assembly Bill 438, introduced by Assembly Member Lieber on February 14, 2003). Currently, universal screening for osteoporosis is a statutory benefit of the Medicare program for postmenopausal women aged 65 years and older.

Approximately 30% of women between the ages of 50 and 64 years, or 694,000 women in California, report that they have had a test for osteoporosis. Thirty-five percent of women between the ages of 50 and 64 years say that they have been diagnosed with bone loss, osteopenia (reduced bone mass), or osteoporosis (UCLA, 2001). Rates of screening are somewhat higher for women who are between the ages of 65 and 69 years. In 2001, about 40% of women in this age group in California reported having had a bone density test; 60% said they had not had a bone density test (UCLA, 2001). A higher proportion (46%) of women in this age group than in the 50-64 year age group reports that they have been diagnosed with bone loss, osteopenia, or osteoporosis. Nationwide, around 33% of female Medicare enrollees 65 years of age and older report having had a bone mass or bone density measurement test, and 23% of women in this same group have been told that they have osteoporosis by their physician (Adler and Shatto, 2002). This review of the medical effectiveness and the financial and public health impacts of this legislation is based on applicable scientific literature and established recommendations and guidelines.

I. MEDICAL EFFECTIVENESS

Osteoporosis is characterized by low bone mass, increasing bone fragility, and a consequent susceptibility to fracture (Consensus Development Conference, 1993). According to the World Health Organization (WHO), osteoporosis is clinically diagnosed by either having a bone mineral density (BMD) at the spine, waist, or hip that is 2.5 standard deviations (SD) or more below the mean BMD for healthy young adult women, or by having had a fracture in the absence of trauma (Kanis, 1994). Based on survey and census data, it is estimated that 21% of postmenopausal white women, 16% of postmenopausal Hispanic women, and 10% of African-American women in the United States have osteoporosis (AACE, 2001). Bone density, however, is only one factor that influences fracture risk associated with osteoporosis. Because of changes in bone architecture and quality, as well as from other factors not related to osteoporosis, such as increased gait instability, older women have a higher fracture rate than younger women with similar BMD (Heaney, 1998). In addition to age, risk factors for low bone density and fractures include smoking, family history of hip fracture, low body weight (under 70 kg), and lack of estrogen replacement use (Lydick et al., 1998; Cadarette et al., 2000; Kanis, 2002).

Osteoporosis is a major health concern among postmenopausal women. It is estimated that about 40% of all postmenopausal women will suffer from a fracture due to osteoporosis during their

lifetime (Melton et al., 1992). A 50-year-old white woman has a 16% lifetime risk of developing a hip fracture and a 32% risk of developing a vertebral fracture (Sayegh et al., 2002). Among patients with a hip fracture, about 15% will die within one year due to complications from the fracture.

The fractures that occur as a result of osteoporosis are a common cause of disability; along with treatment and attendant complications, they contribute greatly to overall medical care costs. National health care costs for osteoporotic fractures in 1995 were estimated to be $13.8 billion (Cummings and Melton, 2002), which includes 432,000 hospital admissions, 180,000 nursing home admissions, and about 2.5 million physician visits (NOF, 1999). These costs are expected to rise exponentially given our growing elderly population and the increasing risk of fracture with age.

With newer, non-estrogen-based medications available for osteoporosis treatment, it is important to identify postmenopausal women who are at the greatest fracture risk and can benefit from medication. Many health care organizations, including the U.S. Preventive Services Task Force (USPSTF) (Nelson et al., 2002a), the National Osteoporosis Foundation (NOF, 1999), the American College of Obstetricians and Gynecologists (ACOG, 2002), and the American Association of Clinical Endocrinologists (AACE, 2001), recommend bone mineral testing for all women aged 65 years or older. Screening for osteoporosis among women aged 50 to 64 years is recommended by these organizations only for women with one or more specific risk factors for low BMD; however, there is no consensus as to *which* risk factors to include.

To assess whether screening for osteoporosis actually reduces fracture rates among postmenopausal women, randomized controlled trials (RCTs) are needed to demonstrate efficacy in the most rigorous fashion. Current guidelines are established by relying on evidence from the literature that address four relevant questions: (1) what are the risk factors that accurately predict low bone density; (2) what is the accuracy of current bone densitometry; (3) what is the relation of low bone density to fracture risk; and (4) what is the effectiveness of current treatments with respect to osteoporotic fracture reduction. For each question there is a body of applicable observational and cohort trials, along with their respective assumptions and biases.

There is almost universal agreement that postmenopausal women aged 65 years and older should be screened for osteoporosis, but very little support exists in the literature for screening younger postmenopausal women. The clinical value of screening this group in the absence of RCTs could be inferred based on demonstrating that osteoporosis and fracture risk is age-dependent, that bone densitometry and the use of other risk factors can accurately estimate short-term fracture risk, and that treatment for postmenopausal women with osteoporosis and low BMD can reduce their subsequent fracture risk by a substantial amount. As with the recent controversy over estrogen use, conclusions based on such a chain of logic may be proven incorrect should a rigorous randomized trial show otherwise. This review, however, relies on the current state of scientific evidence. Most trials involve older, more homogenous cohorts of postmenopausal women, cohorts that are not necessarily representative of the diverse California population. The patient population in most previous risk and treatment studies was disproportionately composed of white women, which limits the ability to estimate how screening may affect different ethnic and racial groups more common in California.

Methods

The relevant studies in the literature were identified in part through multiple literature searches of MEDLINE and the Cochrane databases in the period from 1982 through August 2003, as well as reference lists from systematic reviews, health care organization guidelines, reviews, and recommendations, and discussions with experts. Screening was defined as identifying the risk of future osteoporotic fractures among postmenopausal women (a) without a previous diagnosis of osteoporosis or (b) in whom no specific risk factor for osteoporosis had been identified. Only English-language studies were included in this review.

Studies were identified that addressed screening of postmenopausal women between the ages of 50 and 64 years. Search terms, inclusions, and exclusions are listed as follows:

MEDLINE search terms used (1982-August 2003)
"osteoporosis screening"
"bone mineral density" AND screening
" bone density" AND "hip fractures"
osteoporosis AND screening
osteoporosis, postmenopausal [MeSH] AND screening
osteoporosis [MeSH] AND mass screening [MeSH]
osteoporosis AND mass screening [MeSH] AND evaluation studies [MeSH]
osteoporosis AND diagnosis [MeSH]
effective* AND osteoporosis AND mass screening [MeSH]
osteoporosis AND prevent* AND screening [MeSH]
osteoporosis AND treatment

The search included meta-analyses, RCTs, non-randomized clinical trials, practice guidelines, and reviews. Systematic reviews published in the last five years were given precedence over earlier reviews. Non-English language publications and studies among men were excluded.

In addition to screening trials, articles that addressed one or more of the following were selected: risk factor prediction; bone radiography, especially with regard to bone density; and treatment efficacy. Studies were excluded if patients had secondary causes of osteoporosis, such as endocrine disorders (e.g., hyperthyroidism, hyperparathyroidism) or chronic steroid use. At least two reviewers read each study to determine its eligibility for inclusion in this report based on these criteria.

Appendix A lists technologies for osteoporosis screening, physician visit and management services associated with osteoporosis, and FDA-approved treatments for this condition. Appendix B summarizes the literature from meta-analyses and review articles about risk factors for fracture, effectiveness of treatments on BMD and rates of fracture, and adherence to treatment.

Evidence

Screening Studies**.** Of the studies reviewed, none directly addressed whether osteoporosis screening is effective in reducing fracture rates. Given the absence of RCTs to determine the effectiveness of screening in reducing fractures from osteoporosis, current guidelines and recommendations have relied on evidence from the peer-reviewed scientific literature concerning the following: (1) the age-related prevalence of osteoporosis; (2) the accuracy of BMD testing and bone fracture prediction; and (3) fracture rate reduction from use of the available pharmacologic treatments. Screening aims to identify those women who are likely to have osteoporosis with a high risk of fracture that could potentially be reduced with pharmacologic treatment, but in whom either the condition had not previously been diagnosed or no specific risk factor had been identified. Support for population screening for postmenopausal women aged 50 through 64 years would require evidence showing age-related increases in both osteoporosis and fracture rates, accurate short-term fracture risk estimates from BMD testing, and significant reduction of fracture rates among women with low BMD who undergo available treatment (Nelson et al., 2002a).

Fracture Epidemiology. In postmenopausal women, fractures that occur at the proximal femur (hip), vertebrae (spine), and distal forearm (wrist) are regarded as most often associated with osteoporosis (Cummings and Melton, 2002). In particular, hip fractures are most strongly related to low BMD; such fractures are the most expensive to repair surgically and result in hospital admissions and prolonged recovery periods. The strong association between age and the increase in the incidence of hip fractures for women in most of the world is due to a combination of decreased BMD and an increased risk of falls. Based on a study of women in the U.S. between 1970 and 1985, the incidence of hip fracture among women aged 50 years or older increased at 0.5 % per year (Gullberg et al., 1997). It is estimated that about 90% of hip fractures occur as a result of a fall from 3 feet or less (Youm et al., 1999). The annual risk of falling increases from 20% in middle-aged women to about 50% in women aged 85 years or older (Winner at al, 1989). With lower BMD, elderly women have less bone strength with which to counter the trauma from a fall.

Vertebral fractures, although not necessarily associated with falls, also increase with age among postmenopausal women. Compared with men of similar age, women in the US and Europe have a 2- to 3-fold greater incidence of vertebral fracture after age 50 years (Cummings and Melton, 2002). In a Minnesota population study, the prevalence of vertebral fractures increased from 5% among women aged 50 to 54 years to 13% among women aged 65 to 69 years (Ross et al., 1995). Fractures of the spine can occur with daily activities such as bending or lifting, and these fractures often escape clinical diagnosis. A history of fractures, however, is one of the strongest determinants of developing future fractures.

Risk Factors. Many studies attempt to uncover associations among specific risk factors, low BMD, and subsequent fractures (Nelson et al., 2002a). These risk factors are important in that they can augment BMD testing to predict future fracture risk in a postmenopausal woman. Screening and radiological testing are helpful in identifying women at highest risk of suffering an osteoporotic fracture. As previously stated, practice guidelines differ greatly as to which

factors are incorporated when deciding whether to screen postmenopausal women ages 50 to 64 years. Conditions known to cause secondary osteoporosis, such as endocrine disorders or kidney disease, chronic steroid use, or malnutrition, were not considered in evaluating the published literature.

The U.S. Preventive Services Task Force reviewed eight observational studies of risk factors and various fractures among populations of women in which at least half were aged 64 years or younger (Nelson et al., 2002a). Factors found to have a statistically significant association with fracture include: age, family history of fracture, concurrent chronic disease (e.g., diabetes) or disability, smoking, heavy alcohol use, oophorectomy (surgical menopause) before age 45 years, and having had more than five children (Table 1).

The differences among these guidelines occur primarily over whether to include specific medication use, caffeine intake, calcium intake, and various factors that influence lifetime estrogen exposure (e.g., age of menarche, age of menopause, and number of pregnancies).

One Canadian study (Cadarette et al., 2001), which compared five clinical decision rules for BMD testing among women aged 45 years or older, found that the Simple Calculated Osteoporosis Risk Estimation (SCORE) (Lydick et al., 1998) and Osteoporosis Risk Assessment Instrument (ORAI) (Cadarette et al., 2000) performed the best in terms of accurately predicting low BMD. The SCORE rule uses age, ethnicity, estrogen use, rheumatoid arthritis, and fracture history to identify women with a femoral neck BMD that is worse than 2 SD *below* the established mean. Osteoporosis is diagnosed when a woman has a femoral neck (hip) BMD that is worse than 2.5 SD below the mean. In comparison, the ORAI uses age, weight, and current lack of hormone replacement therapy (HRT) use to identify women with a hip or lumbar spine (lower vertebrae) BMD that is worse than 2.5 SD below the established mean. As described in these two studies, the SCORE decision rule has a sensitivity of 99.6% and a specificity of 17.9%[1] compared with the ORAI decision rule, which has a sensitivity of 97.5% and a specificity of 27.8%.

Both of these clinical decision rules suffer from relatively high false-positive rates among those without osteoporosis (82% and 72%, respectively). That is, they incorrectly labeled a woman as having low BMD when in fact she did not. The false-negative rate, however, was low in both of these studies. The value of these guidelines is not necessarily to diagnose osteoporosis, but rather to identify those high-risk younger postmenopausal women who should undergo BMD testing**.** Thus, if one were to screen women based only on applying these risk-factor scores, one would very rarely miss offering a test to someone whose BMD was in the range of being termed osteoporosis.

BMD measurement. In the absence of an established vertebral fracture, the clinical diagnosis of osteoporosis is made by measurement of BMD. Other features of osteoporosis, such as bone architecture deterioration, contribute to fracture risk, but these features cannot be measured by convenient or conventional means. Several technologies possess the ability to measure BMD, including single and dual X-ray absorptiomery (DEXA), ultrasound, and quantitative computed

[1] Sensitivity is the percentage of true positives who are correctly classified as being positive. Specificity is the percentage of true negatives who are correctly classified as being negative.

tomography (QCT). However, DEXA is the most widely used test and is considered the "gold standard" for the diagnosis of osteoporosis. Further discussion of technologies currently in use to measure BMD can be found in Appendix C.

Treatment. Studies that evaluated Food and Drug Administration (FDA)-approved initial treatments for osteoporosis to prevent fractures were reviewed. These include bisphosphonates (0alendronate, risedronate), selective estrogen receptor modulators (raloxifene), estrogen, and calcitonin. Another FDA-approved agent, recombinant human parathyroid hormone (PTH 1-34, teriparatide), is not widely used for initial therapy for newly diagnosed postmenopausal women, but rather for second-line therapy; therefore, it is not reviewed in this report. Given recent RCTs that show estrogen to have deleterious short-term cardiovascular side effects and a higher breast cancer risk, among other known side effects such as venous thromboembolism (Cauley et al., 2003), many clinicians are no longer prescribing HRT for the prevention of fractures in postmenopausal women with osteoporosis. The FDA recommends that approved non-estrogen treatments should be carefully considered as a first-line treatment rather than using HRT (National Osteoporosis Foundation, 1999). Although the FDA has approved many agents, results from recent meta-analyses indicate that alendronate and risedronate are the most effective medications for reducing the incidence of non-vertebral fractures. One meta-analysis found that alendronate reduced the risk for vertebral fractures and non-vertebral fractures by 48% and 49%, respectively (Cranney et al., 2002d). Appendix D includes detailed descriptions of FDA-approved treatments and results of relevant studies.

Screening Strategies

In the absence of any clinical trials that estimate the efficacy of osteoporosis screening in postmenopausal women to reduce fractures, the USPSTF (Nelson et al., 2002a) constructed a hypothetical model that incorporated data from the literature on age-adjusted osteoporosis prevalence, accuracy of bone densitometry, subsequent risk of osteoporotic fracture, and treatment benefits (Table 2)

The model assumed that treatment with bisphosphonates would reduce vertebral fractures by 50% and hip fractures by 37%. Based on results from many RCTs, they assumed that about 70% of patients adhered to the medication regimen. Age-related prevalence was calculated from observational data (Melton et al., 1992) at 5-year intervals. The screening population assumed for each 5-year age cohort was 10,000 women.

The model found that as the prevalence of osteoporosis and subsequent fractures increased, the number of women needed to be screened to prevent one fracture decreased.

The model predicted that among a cohort of 30,000 women between the ages of 50 and 65 years, only 8 hip fractures and 34 vertebral fractures would be prevented through osteoporosis screening and treatment. (This implies that screening in this age range averts hip fractures in about 0.03% and vertebral fractures in about 0.1% of the women screened.) In contrast, among 30,000 women between ages 65 and 79 years, about 133 hip fractures and 269 vertebral fractures would be prevented. This large difference is explained by age-related prevalence and the higher

fracture risk with old age due to other non-osteoporosis related factors such poor vision and gait instability. Nearly 1,900 women between the ages of 60 and 64 years would need to be screened to prevent one hip fracture, compared with only about 730 women between ages 65 to 69 years and about 250 women between the ages of 70 and 74 years.

Because universal osteoporosis screening appeared to yield fewer benefits in the cohort of younger postmenopausal women, the USPSTF did a sensitivity analysis to study how effective screening might be for those women at higher risk for osteoporosis and fracture. High risk was defined as having one or more factors that earlier studies (Lydick et al., 1998; Cadarette et al., 2000; Weinstein et al., 1999) identified as most strongly associated with low bone density, namely low body weight (<70 kg), and lack of HRT use.

Given the presence of these risk factors, this group of younger postmenopausal women would be expected to have a greater prevalence of osteoporosis with an increased fracture risk. A cohort of postmenopausal women aged 60 to 64 years with at least one risk factor was calculated to have nearly double the number of preventable fractures relative to their baseline counterparts (9 hip fractures vs. 5 hip fractures). If osteoporosis screening included only those postmenopausal women aged 60 to 64 years with at least one risk factor, only about 1,100 women would need to be screened to prevent one hip fracture rather than 1,850 women, as with a universal screening protocol.

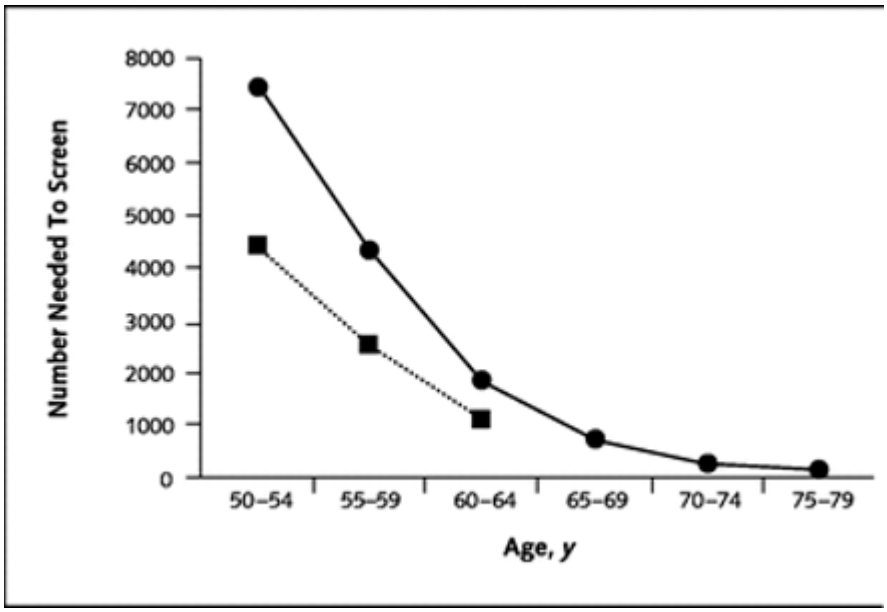

Figure 1. Number needed to screen to prevent one hip fracture in 5 years. The dotted line indicates women with at least one risk factor; the solid line indicates women without risk factors. Source: Nelson et al., 2002a for the U.S. Preventive Services Task Force, p. 537.

Summary of Effectiveness

Screening strategies based on age are somewhat supported by observational and cross-sectional data, which show an age-related increase in both osteoporosis and fracture prevalence. In

particular, a postmenopausal woman over the age of 50 years has a 2- to 3-fold higher risk of fracture compared with younger women, with her risk increasing at about 1% per year. However, prior to age 65, in the absence of other risk factors, the chances of fracture are still relatively low. It should be pointed out that although there is a marked increase in the years immediately prior to age 65, there is an even larger increase after age 65. By selecting for low weight, lack of estrogen replacement use, and perhaps other factors, younger postmenopausal women at higher risk of fracture can be identified for screening. Because these risk factors are associated with a lower BMD, their use improves the efficacy of screening.

Many studies indicate that low BMD is closely associated with an increased risk of fracture. Among the technologies used to measure bone density, the DEXA scan is the best validated in terms of predicting future fracture, and is now considered the "gold standard" for the diagnosis of osteoporosis. For women with low BMD, bisphosphonates lower fracture risk by about 45% to 50%--an amount greater than any other available treatment.

As shown in a screening model by the USPSTF, the benefits of osteoporosis screening for high-risk postmenopausal women aged 60 to 64 years approach those seen in the cohort aged 65 to 69 years with respect to the number of women needed to screen to prevent one hip fracture. Controversy remains as to which risk factors, other than age, to include in a screening strategy targeted to high-risk women. This is particularly important given that the scientific literature does not support universal osteoporosis screening for postmenopausal women aged 50 to 65 years. Further validation studies are needed to develop exactly which set of factors best predict low bone density and the subsequent risk of fracture.

II. UTILIZATION, COST, AND COVERAGE IMPACTS

Present Baseline Cost and Coverage

1. Current utilization levels and costs of the mandated benefit (Section 3(h))
Approximately 8% of women between the ages of 50 and 64 years are screened for osteoporosis every year, based on estimates of utilization from the over-65 age group. Because osteoporosis is slow to develop, most women do not need to be tested every year. Approximately 33% of women with private insurance between 50 and 64 years of age in California report that they have had a bone density test. Eleven percent of privately insured women between the ages of 50 and 64 report that they have been diagnosed with bone loss, osteopenia, or osteoporosis (UCLA 2001).

Based on data obtained from Milliman USA, the estimated average 2004 cost for a screening test using DEXA in California will be $173. Costs for screening by ultrasound would be less. The annual cost of treatment of osteoporosis for a newly diagnosed patient with osteoporosis is estimated at $100 for physician services and $1,200 for prescription drugs--approximately $1,300 in total.

2. Current coverage of the mandated benefit (Section 3(i))

Seventy-six percent of women between the ages of 50 and 64 years have private health insurance. Around 67% of women in this age group (1.57 million) are covered by employment-based coverage, and about 9% (207,000) have individual insurance policies.

California presently mandates coverage of services related to diagnosis, treatment, and appropriate management of osteoporosis (Health and Safety Code 1367.67 and Insurance Code 10123.185). Services may include all FDA-approved technologies, including BMD measurement technologies considered medically appropriate. In addition, Medicare has also explicitly covered screening for osteoporosis since 1998 for women who are defined as being at risk for the condition. As a result, most women with the greatest risk of developing osteoporosis, those aged 65 years and over, have this benefit.

To estimate the number of women who presently have the level of coverage that would be extended to all women after the proposed mandate, data from insurers and surveys of women in this group were used (see Table 3). A survey of the largest health maintenance organizations (HMOs) and insurers in California was conducted. Based on that survey, only a small proportion of women aged between 50 and 64 years *without specific risk factors* have private insurance coverage for osteoporosis screening services. All insurers, however, appear to cover BMD tests if there are indications of elevated risk factors for osteoporosis.

Assumptions were made about coverage that were based on the prevalence of osteoporosis (how many women have this condition in the 50-64 year age group). Survey data cited earlier show that, of the age group 50-64 years, 11% of the privately insured (i.e., not all women in this age group) report having been told they have either bone loss, osteopenia or osteoporosis (UCLA 2001). Bone loss or osteopenia are risk factors for the future development of osteoporosis. Women with any of these three conditions represent a group that is already "covered" by virtue of existing mandated diagnosis and treatment. The mandate already in existence means that insurers are likely to cover the cost of osteoporosis testing for these women who have risk factors for the condition or have symptoms of the condition.

The group of women who have already been diagnosed (11% of the age group) would therefore be less affected by the mandate covering screening of women older than age 50 years than women without any risk factors or existing diagnoses. Women in this latter category represent the other 89% of the population. This does not mean that all of the women in this latter group are free of osteoporosis; as noted previously, the condition can be slow to progress with few, if any, symptoms in this age group, and only 33% of women overall have been screened.

The survey showed that few plans automatically offer screening of their enrollees in the same way that insurers routinely cover mammography for women. Based on the assumptions and the survey data, an estimated 89% of privately insured women between 50 and 64 years of age are not presently covered in California for osteoporosis screening. The other 11% of women are not covered for routine screening, but by virtue of existing law and their existing diagnoses, they have a level of coverage that would be minimally affected by the mandate. This is a conservative estimate because an additional group of women with osteoporosis risk factures, but

no knowledge of bone loss, would qualify for coverage under existing health plan medical policies on BMD testing.

3. Public demand for health care coverage (Section 3(j))
There is no evidence available of significant demand for mandated coverage in California of osteoporosis screening for females aged 50 years and above. That is, few private plans cover routine screening in the absence of risk factors.

Impacts of Mandated Coverage

4. How will changes in coverage related to the mandate affect the benefit of the newly covered service and the per-unit cost (Section 3(a))
The per-unit cost of osteoporosis screening is unlikely to change as a result of the mandate. If, however, the proportion of women screened who are younger and healthier increases as a result of the mandate, the average benefit of screening may decrease further. This result may occur in part because more women who do not need to be screened will ask for screening or will be encouraged by their physician to receive treatment.

5. How will utilization change as a result of the mandate (Section 3(b))
Mandating coverage for screening of osteoporosis is likely to result in increased utilization of screening services. Approximately 8% of women aged 50 to 64 years are screened in a year. This estimate is based on Medicare data and Milliman USA analysis of claims data from private insurers for women 50 to 64 years of age. Overall, the frequency of screening would increase from approximately 8% to approximately 30% for women aged 50-64 years, an almost 4-fold increase. Utilization may increase more or less than this point estimate, with a lower-bound estimate of an increase to 10%, and an upper bound estimate of 50% (assuming growth to approximate the use of other screening procedures, such as mammography). Demand from patients for the service is likely to increase among those currently covered if patients become aware of the mandate, because they may view the mandate as providing a new benefit. Providers may also induce greater demand for the service if the restrictions on coverage are relaxed, especially with the availability of office-based technologies for screening. Among those women who already have coverage, we estimate a post-mandate 22% increase in screening.

Given the increased utilization of screening services, the number of women who are diagnosed with osteoporosis would be expected to increase by slightly less than 1% in the group between ages 50 and 64 years. Of this newly diagnosed group of women (the 1% of the population in this age group), about two thirds (0. 67% of the total population) will seek treatment for osteoporosis. Increased detection would therefore result in some increased utilization of physician services and prescription drugs.

6. To what extent does the mandate affect administrative and other expenses (Section 3(c))
This mandate will likely increase the administrative expenses for health plans, but not disproportionately to the increase in health care costs. Claims administration costs may go up slightly due to an increase in screening claims, although many screening services may be billed as "diagnostic" and may, therefore, not be *additional* claims that would not have occurred in the

absence of this mandate. Plans will have to modify their insurance contracts and member materials, and may have to re-contract with providers to define reimbursement for these services. Health care plans include a component for administration and profit in their premiums. In estimating the impact of this mandate on premiums, we have assumed that health plans will apply their existing administration and profit loads to the marginal increase in health care costs produced by the mandate (see Table 4).

7. Impact of mandate on total health care costs (Section 3(d))

Small cost increases would result from increased utilization of screening and increases in the utilization of treatment by women newly diagnosed with osteoporosis. The cost estimates assume the treatment that results from the new screening will cause a reduction in the number of fractures and that the added cost of treatment that results from screening is approximately offset by the decrease in the cost of treating the fractures that were avoided. Total estimated expenditures (including premiums and out-of-pocket spending) would increase by less than one fifth of 1% (0.1%) for all privately insured individuals (see Table 5).

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

Cost increases and savings as a result of the mandate are likely to be similar for insurers and health care service plans in the individual and group markets. The cost of providing mandated screening services does not vary substantially by insurer type, and treatment service costs across insurers are assumed to be the same. Table 5 shows the range of increases in premiums per member per month, which translates to 0.09% in the small-group market (i.e., firms with less than 50 employees) with fee-for-service policies to 0.15% for employees in the large-firm market with HMO coverage.

The cost model assumes a uniform increase in utilization of between 10% and 50% across all plans. Utilization differences across plan types may exist at present, however, and so the effect of the mandate on utilization could be slightly larger for insurers that have more stringent review of health plan requests BMD testing at the present time.

9. Current costs borne by payers (both public and private entities) in the absence of the mandated benefit (Section 3(f))

Because the detection of osteoporosis is expected to increase by less than 1% after the mandate, it is unlikely to change any underlying distribution of costs that may presently be borne by public and private payers.

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

No significant impact on overall access and health service availability is expected, given the small increase expected in premiums.

III. PUBLIC HEALTH IMPACTS

Present Baseline Osteoporosis Health Outcomes

Incidence

In California, 33% of privately insured women between the ages of 50 and 64 years have had a BMD test. Approximately one third (34.0%) of these women have been diagnosed with a bone condition such as bone loss, osteopenia, or osteoporosis (Tables 6 and 7). This translates into an overall prevalence rate of 10.9% for being diagnosed with a bone condition (Table 8). An analysis by race/ethnicity shows that Hispanic women (16.4%) and African-American women (16.5%) are significantly less likely to be screened for osteoporosis compared with other racial/ethnic groups, whereas white women are significantly more likely to be screened (36.7%). Of the women screened with a bone density test, there were no significant differences by race/ethnicity in the rates at which they were diagnosed with a bone condition.

Osteoporosis-Related Trauma and Hospitalizations

Women with osteoporosis are at a greater risk for bone fractures. In California in 2002, 2% of women aged 55-64 years with health insurance who had been diagnosed with osteoporosis reported breaking a bone as a result of a fall in the last 12 months (UCLA, 2001). This rate did not vary significantly among women of differing races or ethnicities. In addition, 10,693 hospital discharges among women aged 45-64 years in 1998 and one death were attributable to osteoporosis.

Impact of the Proposed Mandate on the Public's Health

There is little evidence that screening for osteoporosis in the absence of risk factors is effective in diagnosing osteoporosis. The number of women between the ages of 50 and 64 years needed to screen to prevent one fracture is very large; for example, screening for osteoporosis prevents hip fractures in 0.03% of women and prevents vertebral factures in 0.1% of women aged 50-64 years. Therefore, the potential benefit of this mandate on the public's health is relatively small.

Currently in California, 1.2 million privately insured women aged 50-64 years are not covered for osteoporosis screening (Table 9). Assuming 30% of these women would be screened for osteoporosis once the mandate went into effect (based on experience in Medicare and on other factors described in the cost and utilization section), an additional 360,000 women would undergo osteoporosis screening. This post-mandate change would translate into preventing approximately 96 women from having a hip fracture and 408 women from developing vertebral fractures, some of which would be asymptomatic.

Table 1. Risk Factors for Fractures in Women 50-65 Years of Age

Risk Factor	Relative Risk for Fracture (95% CI)
Age	
Per 2 y	1.11 (1.01-1.21)
Per 5 y	1.94 (1.55-2.42)
Body mass index	
Per increase of 10 kg/m^2	0.58 (0.36-0.92)
≥25.6 kg/m^2	Wrist, 0.7 (0.5-0.9); ankle, 1.6 (1.0-2.4)
≥28.6 kg/m^2	Wrist, 0.5 (0.4-0.7); ankle, 2.0 (1.3-3.1)
Low	1.1 (1.0-1.2)
Height (per 0.1 m)	1.58 (1.18-2.12)
Mother with fracture	1.27 (1.16-1.40)
Grandmother with hip fracture	3.70 (1.55-8.85)
Hormone replacement therapy	
Current use	0.82 (0.74-0.91)
Per 5 y of use	0.5 (0.2-0.9)
>2 y of use	0.44 (0.22-0.89)
Long history of use	0.70 (0.50-0.96)
African American ethnicity	0.54 (0.41-0.72)
Diabetes mellitus	9.17 (3.38-24.92)
Chronic conditions	1.3 (1.1-1.5)
Disability pension	3.79 (2.15-6.68)
Long-term work disability	1.3 (1.1-1.6)
Self-rated health (fair or poor)	1.79 (1.52-2.11)
Moderate daily physical activity	0.61 (0.37-0.99)
Alcohol	
≥100 g/wk	1.70 (1.08-2.67)
Regular use	1.4 (1.3-4.4)
1 to 6 drinks/wk	0.85 (0.75-0.96)
Smoking	
Current	1.5 (1.3-1.5); 1.14 (1.00-1.30)
Former	1.09 (1.00-1.19)
≥11 cigarettes/day	3.0 (1.9-4.6)
Unmarried	2.16 (1.28-3.64)
College education or higher	1.26 (1.16-1.38)
Age at menopause	0.94 (0.88-0.99)
Time since menopause	
10-19 y	1.18 (1.01-1.38)
20-29 y	1.31 (1.12-1.54)
30 y	1.51 (1.26-1.81)
Oophorectomy before age 45	3.64 (1.01-13.04)
≥ 5 children	2.5 (1.1-6.7)

Source: Nelson et al., 2002a for the U.S. Preventive Services Task Force.

Table 2. Screening for Osteoporosis in 10,000 Postmenopausal Women

	Without Risk Factors for Osteoporosis			With ≥1 Risk Factors*
	Aged 50-54 years	Aged 55-59 years	Aged 60-64 years	Aged 60-64
Prevalence of Osteoporosis	0.0305	0.0445	0.065	
RR for hip fracture w/treatment	0.63	0.63	0.63	
RR for vertebral fracture w/treatment	0.52	0.52	0.52	
Adherence for treatment	0.7	0.7	0.7	
Identified as high risk (osteoporotic)	305	445	650	
Hip fractures prevented	1	2	5	9
NNS to prevent 1 hip fracture	7446	4338	1856	1092
NNT to prevent 1 hip fracture	227	193	121	72
Vertebral fractures prevented	5	7	22	
NNS to prevent 1 vertebral fracture	1952	1338	458	
NNT to prevent 1 vertebral fracture	60	60	30	

Source: Nelson 2002 for the U.S. Preventive Services Task Force.

Notes:
NNS = # needed to screen for benefit, NNT= # needed to treat
Estimates for assumptions include age-specific prevalence rates for osteoporosis and probabilities of fractures; relative risk of 0.63 for hip fractures and 0.52 for vertebral fractures with treatment; treatment adherence of 0.7.
* RR of risk factor = 1.7 (age, low weight/BMI, no HRT)

Table 3. Baseline / Pre Mandate Per Member Per Month Cost For Calendar Year 2004

	Large Group				Small Group				Individual	
	HMO (4)	PPO	POS	FFS	HMO	PPO	POS	FFS		**Total**
Population Currently Covered under 65 (3)	5,692,000	1,538,000	1,433,000	54,000	2,325,000	1,103,000	775,000	40,000	1,602,000	14,562,000
Baseline per-member per-month (PMPM) Costs (1)										
Total Premium	$218.00	$314.73	$251.73	$319.70	$225.89	$317.75	$246.57	$331.59	$188.19	$3,484,370,000
Average Portion of Premium Paid by Employer	$169.13	$256.17	$185.92	$276.33	$168.18	$269.65	$194.56	$276.96	$0.00	$2,488,310,000
Average Portion of Premium Paid by Employee	$48.87	$58.56	$65.80	$43.37	$57.71	$48.11	$52.01	$54.63	$188.19	$996,060,000
Total Premium	$218.00	$314.73	$251.73	$319.70	$225.89	$317.75	$246.57	$331.59	$188.19	$3,484,370,000
B. Covered Benefits Paid by Member (Deductibles, copays, etc)	$7.72	$42.52	$15.92	$70.54	$11.53	$47.21	$19.26	$77.26	$32.93	$285,630,000
C. Total Cost of Covered Benefits	$225.72	$357.25	$267.64	$390.24	$237.42	$364.96	$265.83	$408.85	$221.12	$3,770,010,000
D. Benefits Not Covered (2)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
E. Total Expenditures	$225.72	$357.25	$267.64	$390.24	$237.42	$364.96	$265.83	$408.85	$221.12	$3,770,010,000

Source: California Health Benefits Review Program, 2003 (see Appendix E for data sources).

Notes

(1) All values include all health care benefits, except "Benefits not Covered" which includes only benefits covered by the mandate.

(2) Cost of mandate benefits only. We assume no non-covered osteoporosis screening is being performed and paid for directly by the member.

(3) Excludes individuals working for firms that self-insure their employees.

(4) Health Maintenance Organization (HMO), Preferred Provider Organization (PPO), Point-of-Service (POS), and Fee-for-Service (FFS) plans

Table 4. Estimated Per Member Per Month Premium and Total Costs after Mandate for Calendar Year 2004

A. Insured Premiums	Large Group				Small Group				Individual	
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS		**Total**
Total Premium	$218.32	$315.03	$252.05	$319.98	$226.23	$318.07	$246.90	$331.88	$188.52	$3,489,110,000
Average Portion of Premium Paid by Employer	$169.38	$256.41	$186.16	$276.57	$168.44	$269.91	$194.82	$277.20	$0.00	$2,491,580,000
Average Portion of Premium Paid by Employee	$48.94	$58.61	$65.89	$43.41	$57.79	$48.15	$52.08	$54.68	$188.52	$997,530,000
Total Premium	$218.32	$315.03	$252.05	$319.98	$226.23	$318.07	$246.90	$331.88	$188.52	$3,489,110,000
B. Covered Benefits Paid by Member (Deductibles, copays, etc)	$7.73	$42.57	$15.94	$70.60	$11.55	$47.26	$19.29	$77.32	$32.99	$286,000,000
C. Total Cost of Covered Benefits	$226.05	$357.59	$267.98	$390.58	$237.78	$365.32	$266.19	$409.20	$221.51	$3,775,110,000
D. Benefits Not Covered (2)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	0
E. Total Expenditures	$226.05	$357.59	$267.98	$390.58	$237.78	$365.32	$266.19	$409.20	$221.51	$3,775,110,000

Source: California Health Benefits Review Program, 2003 (see Appendix E for data sources).

Notes

(1) All values include all healthcare benefits, except "Benefits not Covered" which includes only benefits covered by the mandate.
(2) Cost of mandate benefits only. We assume no non-covered osteoporosis screening is being performed and paid for directly by the member.

Table 5. Post-Mandate: Additional Costs on a Per Member Per Month Basis

PMPM $ Impact of Mandate	Large Group				Small Group				Individual	
A. Insured Premiums	**HMO**	**PPO**	**POS**	**FFS**	**HMO**	**PPO**	**POS**	**FFS**		**Total**
Total Premium	$0.33	$0.30	$0.32	$0.28	$0.34	$0.31	$0.33	$0.29	$0.33	$4,740,000
Average Portion of Premium Paid by Employer	$0.25	$0.24	$0.24	$0.24	$0.25	$0.26	$0.26	$0.24	$0.00	$3,270,000
Average Portion of Premium Paid by Employee	$0.07	$0.06	$0.08	$0.04	$0.09	$0.05	$0.07	$0.05	$0.33	$1,470,000
Total Premium	$0.33	$0.30	$0.32	$0.28	$0.34	$0.31	$0.33	$0.29	$0.33	$4,740,000
B. Covered Benefits Paid by Member (Deductibles, copays, etc)	$0.01	$0.04	$0.02	$0.06	$0.02	$0.05	$0.03	$0.07	$0.06	$370,000
C. Total Cost of Covered Benefits	$0.34	$0.34	$0.34	$0.34	$0.36	$0.36	$0.36	$0.35	$0.39	$5,110,000
D. Benefits Not Covered (2)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
E. Total Expenditures	$0.34	$0.34	$0.34	$0.34	$0.36	$0.36	$0.36	$0.35	$0.39	$5,110,000
Percentage Impact of Mandate										
A. Insured Premiums	0.15%	0.10%	0.13%	0.09%	0.15%	0.10%	0.14%	0.09%	0.18%	0.14%
E. Total Expenditures	0.15%	0.10%	0.13%	0.09%	0.15%	0.10%	0.14%	0.09%	0.18%	0.14%

Source: California Health Benefits Review Program, 2003 (see Appendix E for data sources).

Notes

(1) All values include all healthcare benefits, except "Benefits not Covered" which includes only benefits covered by the mandate.

(2) Cost of mandate benefits only. We assume no non-covered osteoporosis screening is being performed and paid for directly by the member.

Table 6. Prevalence of osteoporosis screening in women aged 50-64 years with health insurance coverage, by race/ethnicity, 2001.

Race/Ethnicity	%	95% Confidence Interval	Number screened with bone density test
White	36.7	35.0 – 38.4	523,000
Asian	29.1	23.5 – 34.8	54,000
African-American	16.5	11.8 – 21.2	24,000
Hispanic	16.4	12.4 – 20.5	38,000
Overall	32.0	30.5 – 33.4	654,000

Source: California Health Interview Survey, 2001 (UCLA, 2001).

Note: Survey item was "Have you ever had a bone density test (a test to determine bone loss)?

Table 7. Diagnosed bone condition in those screened, women aged 50-64 years with health insurance coverage by race/ethnicity, 2001.

Race/Ethnicity	% of Total Insured	95% Confidence Interval	Number screened with bone density test
Asian	37.7	26.2 – 49.1	20,000
White	34.7	31.9 – 37.4	180,000
African-American	29.1	13.3 – 44.8	7,000
Hispanic	23.0	12.8 – 33.2	9,000
Overall	34.0	31.5 – 36.6	221,000

Source: California Health Interview Survey, 2001 (UCLA, 2001)

Note: Denominator is insured women ages 50-64 years who have had a bone density test. Survey item was "Have you ever been told by a doctor that you had bone loss, osteopenia, or osteoporosis?"

Table 8. Diagnosed bone condition, women aged 50-64 years with health insurance coverage by race/ethnicity, 2001.

Race/Ethnicity	% of Total Insured
White	12.7
Asian	11.0
African-American	4.8
Hispanic	3.8
Overall	10.9

Source: Calculated using data in Tables 1and 2 from the California Health Interview Survey, 2001 (UCLA, 2001). Note: Denominator is all insured women ages 50-64.

Table 9. Calculated Public Health Impact of Legislation

Newly Covered (#)	1.2 million
Rate of screening among newly covered	30%
Newly screened (#)	360,000
Number of Hip Fractures prevented (Screened/3750)	96
Number of Vertebral Fractures prevented (Screened/882)	408

Notes: The number of newly covered (i.e. those covered for osteoporosis screening after passage of the legislation) is derived from surveys of the largest 7 health plans in California regarding coverage for osteoporosis screening in this population. The assumption is that 70% of older women are screened, based on a 70% treatment adherence rate assumed in the USPSTF report "Screening for Postmenopausal Osteoporosis" (Nelson et al., 2002a). The number of hip and vertebral fractures prevented was calculated using information from the USPSTF report that indicated that 30,000 women aged 50-64 years needed to be screened to prevent 8 hip fractures (3750 screened to prevent 1 facture) and 34 vertebral fractures (882 screened to prevent 1 facture).

Appendix A
Osteoporosis Screening Services

Technologies for Osteoporosis Screening

1. Radiographic Absorptiometry (RA, also called photodensitometry) – CPT code 76078
2. Quantitative Computed Tomography (QCT) – CPT codes 76070, 76071
3. Single Photon Absorptiometry (SPA)
4. Dual Photon Absorptiometry (DPA)
5. Single X-Ray Absorptiometry (SXA)
6. Dual Energy X-Ray Absorptiometry (DEXA or DXA) – CPT code 76075, 76076
7. Quantitative Ultrasound (QUS) – CPT code 76977

Note: technologies are listed in the order they were developed. RA is an older technology that is rarely used. QCT is higher in radiation exposure. SPA and DPA have been supplanted by SXA and DEXA. DEXA is considered to be the gold standard. Costs differ depending on whether the axial or peripheral skeleton (or both) is measured. CPT refers to Current Procedural Terminology, a registered trademark of the American Medical Association.

Physician Visits for Evaluation and Management Services (E & M CPT codes)

1. 99201 through 99205 – initial outpatient visit, new patient
2. 99211 through 99215 – subsequent outpatient visit, established patient
3. 99241 through 99245 – outpatient consultation
4. 99301 through 99303 – comprehensive skilled nursing facility (SNF) assessment, new or established
5. 99311 through 99313 – subsequent SNF assessment, new or established

Note: inpatient services are expected to be negligible or minimal.

Treatments (FDA Approved Pharmaceuticals)

1. Biphosphonates
    a. Alendronate (Fosamax): prevention (5 mg qday or 35 mg qweek) and treatment (10 mg qday or 70 mg qweek)
    b. Risedronate (Actonel): prevention and treatment (5 mg qd or 35 mg qw)
    c. Ibanronate (Boniva): prevention and treatment (2.5 mg qd) – approved by the FDA in May 2003
2. Salmon Calcitonin (Miacalcin): treatment (single intranasal spray of 200 IU qd)
3. Estrogen Therapy (ET) or Hormone Therapy (HT): prevention and treatment
    a. ET brand names include Climara, Estrace, Estraderm, Estratab, Ogen, Ortho-Est, Premarin, Vivelle, Alora
    b. Generic ET: conjugated estrogens, etradiol
    c. HT brand names include Activella, Femhrt, Premphase, Prempro
    d. Generic HT: medroxyprogesterone acetate
4. Raloxifene Hydrochloride (Evista): prevention and treatment (60 mg qd)
5. Teriparatide (Forteo), parathyroid hormone (PTH 1-34): treatment (2.5μg qd)

Appendix A (cont'd)
Osteoporosis Screening Services

Note: agents approved by the FDA for prevention and/or treatment of osteoporosis act by reducing bone resorption except for PTH, which has anabolic effects on bone.

Other Treatments
Calcium and vitamin D formulations, Fluoride, Etidronate (Didronel -- approved for Paget's Disease of Bone)

Appendix B
Risk Factors for Fracture, Effectiveness of Treatments on Bone Mineral Density and Rates of Fracture, and Adherence to Treatment: Results from Meta-analyses and Review Articles

Risk factors for fractures			**relative risk reduction/risk increase**	**average change**
low BMD				89% increase
BCOHTA 1997	1 SD decrease of BMD	RR 2.4 [1.9-3.0]	140% increase	
Melton 2003	1 SD decrease of BMD	RR 1.37 [1.05-1.70]	37% increase	
low BMD at hip				110% increase
Marshall et al., 1996	1 SD decrease of hip BMD	RR 2.6 [2.0-3.5]	160% increase	
BCOHTA 1997	1 SD decrease of hip BMD	RR 1.6 [1.4-1.8]	60% increase	
low BMD at spine				90% increase
Marshall et al., 1996	1 SD decrease of spine BMD	RR 2.3 [2.0-3.5]	130% increase	
BCOHTA 1997	1 SD decrease of spine BMD	RR 1.5 [1.4-1.7]	50% increase	
Age	Nelson 2001 - age per 5 years	RR 1.4 (1.2-1.6)	40% increase	54% increase
	Nelson 2001 - age per 5 years	RR 1.7 (1.4-2.0)	70% increase	
	Nelson 2001 - age per 5 years	RR 1.94 (1.55-2.42)	94% increase	
	Nelson 2002a - per 2 years	RR 1.11 [1.01-1.21]	11% increase	
low BMI	Espallargues 1999	RR 1.65 [1.57-1.73]	65% increase	38% increase
	Nelson 2001	RR 1.1 (1.0-1.2)	10% increase	
weight loss	Espallargues 1999	RR 1.98 [1.39-2.84]	98% increase	98% increase
alcohol	Espallargues 1999	RR 1.02 [0.94-1.11]	2% increase	116% increase
	Nelson 2001 - regular use	RR 1.4 (1.3-4.4)	40% increase	
	Nelson 2001 - daily alcohol	RR 5.41 (1.78-16.4)	441% increase	
	Nelson 2002a > 100 g/wk	RR 1.79 [1.08-2.67]	79% increase	
	Nelson 2002a - 1-6 drinks/week	RR 0.85 [0.75-0.96]	15% decrease	
smoking	Espallargues 1999 - smoking vs. nonsmokers	RR 1.33 [1.20-1.48]	33% increase	94% increase
	Nelson 2002a>11 cigarettes/day	RR 3.0 [1.9-4.6]	200% increase	
	Nelson 2002a current smoker	RR 1.5 [1.3-1.5]	50% increase	
history of hip	Nelson 2001	RR 1.8 (1.2-2.7)	80% increase	126%

fracture				increase
	Nelson 2002a	RR 1.27 [1.16-1.40]	27% increase	
	Nelson 2002a	RR 3.70 [1.55-8.85]	270% increase	
age at menopause	Nelson 2002a	RR 0.95 [0.88-0.99]	5% decrease	5% decrease
time since menopause	Nelson 2002a 10-19 years	RR 1.18 [1.01-1.38]	18% increase	18% increase
oophorectomy before age 45 years	Nelson 2002a	RR 3.64 [1.01-13.04]	264% increase	264% increase
Effects of Treatments on either BMD or fractures				
BMD				
hip				
Cranney 2002c	risedronate - 2.5 mg/more	WMD 2.75% [2.32, 3.17]		
Cranney 2002a	raloxifene	WMD 2.11% [1.68, 2.53]		
Cranney 2002b	calcitonin	WMD 3.80% [-0.32-7.91]		
Cranney 2002d	alendronate - 10 mg/more	WMD 5.60% [4.80-6.39]		
Papadimitropoulos 2002	vitamin D (hydroxylated)	WMD 2.56% [-7.80, 12.72]		
Shea 2002	calcium	WMD 1.64% [0.70-2.57]		
Wells 2002	HRT	WMD 4.12% [3.45-4.80]		
Guyatt 2002	Etidronate - 400 mg	WMD 2.35% [3.94-7.44]		
lumbar spine				
Cranney 2002c	risedronate - 2.5 mg/more	WMD 4.54% [4.12, 4.97]		
Cranney 2002a	raloxifene	WMD 2.51% [2.21, 2.82]		
Cranney 2002b	calcitonin	WMD 3.74% [2.04-5.43]		
Cranney 2002d	alendronate - 10 mg/more	WMD 7.48% [6.12-8.85]		
Papadimitropoulos 2002	vitamin D (hydroxylated) 1.0 µg	WMD 2.45% [1.47, 3.42]		
Shea 2002	calcium	WMD 1.66% [0.92-2.39]		
Wells 2002	HRT	WMD 6.76% [5.83-7.89]		
Guyatt 2002	Etidronate - 400 mg	WMD 4.06% [3.12-5.00]		
Fractures				
Hip (non-vertebral)				
Cranney 2002c	risedronate - 2.5 mg/more	RR 0.73 [0.61, 0.87]	27% decrease	
Cranney 2002a	raloxifene	RR 0.92 [0.79-1.07]	8% decrease	

Cranney 2002b	calcitonin	RR 0.52 [0.22-1.23]	48% decrease	
Cranney 2002d	alendronate - 10 mg/more	RR 0.51 [0.38-0.69]	49% decrease	50% decrease
Meunier 1999	Alendronate	RR 0.49	51% decrease	
Papadimitropoulos 2002	vitamin D	RR 0.77 [0.57-1.04]	23% decrease	
Shea 2002	calcium	RR 0.86 [0.43-1.72]	14% decrease	
Wells 2002	HRT	RR 0.87 [0.71-1.08]	13% decrease	24% decrease
Roussouw 2002	estrogen plus progestin (WHI)	RR 0.66 [0.45-0.98] - risk benefit high	34% decrease	
Guyatt 2002	Etidronate - 400 mg	RR 0.99 [0.69-1.42]	31% decrease	
Guyatt 2002	Fluoride	RR 1.46 [0.92-2.32]	46% increase	
Meunier 1999	vitamin D + calcium	RR 0.73	27% decrease	
Vertebral				
Cranney 2002c	risedronate - 2.5 mg/more	RR 0.64 [0.54, 0.77]	36% decrease	
Cranney 2002a	raloxifene	RR 0.60 [0.50-0.70]	40% decrease	
Cranney 2002b	calcitonin	RR 0.46 [0.25-0.87]	53% decrease	
Cranney 2002d	alendronate - 5 mg/more	RR 0.52 [0.43-0.65]	48% decrease	48% decrease
Meunier 1999	Alendronate	RR 0.53	47% decrease	
Papadimitropoulos 2002	vitamin D	RR 0.63 [0.45-0.88]	37% decrease	
Shea 2002	calcium	RR 0.77 [0.54-1.09]	23% decrease	
Wells 2002	HRT	RR 0.66 [0.41-1.07]	34% decrease	
Guyatt 2002	Etidronate - 400 mg	RR 0.63 [0.44-0.92]	37% decrease	
Guyatt 2002	Fluoride	RR 0.67 [0.38-1.19]	33% decrease	
Treatment Adherence				
Gill 2003	diagnosed osteoporosis	58.1% w/osteoporosis were taking prescription osteoporosis-related medications		
Steel 2003	low bone mass	5-year adherence to HRT of 61% was achieved		

Appendix C
Bone density measurement technologies

Single and Dual X-ray Absorptiometry (DEXA)
Both single and dual X-ray absorptiometry (DEXA) provide two-dimensional pictures of bone content. The BMD is calculated from the DEXA scan by dividing the measured mass by the area under study. Bone size has been shown to contribute to fracture risk (Kanis, 2002) and can also affect the derived BMD, as the value is a calculated rather than a direct density measurement. The diagnosis of osteoporosis can be erroneous when patients have had previous fractures or suffer from other bone diseases, including osteoarthritis, spinal scoliosis (curvature of the spine), or osteomalacia (defect in bone mineral formation from vitamin D deficiency).

DEXA scans can measure BMD at single sites, such as the spine, hip, forearm, heel, or finger, or over the entire skeleton. DEXA at the femoral neck (hip) is considered the gold standard radiologic technique to measure BMD, given that it has been the most studied test with which to predict fracture outcomes. The advantages of DEXA include a relatively low radiation exposure with a high precision and accuracy. A WHO report cited the accuracy of DEXA at the hip to be about 90% (WHO, 1994). It should be noted that, as with all diagnostic technologies, there is some variation in the diagnosis of osteoporosis in a given patient depending on the equipment manufacturer. This variation is estimated to be between 6% and 15 % (Nelson et al., 2002a).

A meta-analysis of 11 prospective cohort studies, which included women mostly in their late 60s or older, concluded that DEXA at the femoral neck predicted subsequent hip fracture better than measurements at other sites (Marshall et al., 1996). No data existed in the analysis, however, to predict fracture in postmenopausal women below age 65 years. In the composite analysis, for each standard deviation decrease in the hip BMD below the mean, the relative risk of hip fracture increased by 2.6, and the relative risk of suffering any fracture increased by 1.5. The BMD measured at the femoral neck proved to be the best predictor of future fracture risk, regardless of location (e.g., hip, forearm, or spine).

Based on these studies, using DEXA to measure BMD predicts hip fracture better than using serum cholesterol levels to predict coronary heart disease, and is similar to using diastolic blood pressure to predict risk of stroke (WHO, 1994; Marshall et al., 1996; Cooper and Aihie, 1994).

Ultrasound
Using quantitative ultrasound (QUS) technology—specifically, how the speed of sound is attenuated by skeletal bone— it is possible to determine both bone mass and structural organization. QUS is used at various peripheral skeleton sites, such as the heel, ankle, and patella (knee), in order to predict fracture risk. QUS is not used to clinically diagnose osteoporosis, given that current accepted guidelines are based only upon DEXA values.

QUS results have been shown to be a strong predictor of osteoporotic fractures (Gregg et al., 1997), and values obtained at the heel predict hip fracture risk as well as DEXA at the hip (Hans et al., 1996). For each standard deviation reduction in bone density, QUS measurements are associated with a 1.5- to 2-fold increase in fracture risk (Gluer et al., 1997). However, most QUS studies to date have enrolled only elderly women. None have sought to examine QUS exclusively in women aged 50 to 65 years. However, because QUS is a cheaper, faster, and

radiation-free alternative to other modalities that assess fracture risk, it is likely that more data will be gathered in younger postmenopausal women for validation purposes.

Computed Tomography
Quantitative computed tomography (QCT) has been used both at the spine and at the peripheral skeleton to determine bone density. Relative to other bone densitometry technologies, QCT is most useful in estimating cancellous bone density because it measures true bone volume rather than relying upon area-adjusted values, as with DEXA. Cancellous bone is spongy or honeycomb in structure, and it is often located at the ends of long bones, such as the tibia (ankle) or humerus (arm). This distinction is important because cancellous bone undergoes more rapid turnover and is therefore more responsive, in the short-term, to treatment than cortical bone. QCT can be used to monitor whether osteoporotic bone improves with medication. In addition, QCT avoids the measurement error associated with degenerative diseases, such as osteoarthritis, that occur at the spine with DEXA.

The main disadvantages of QCT include a relatively high radiation dose and lower accuracy and speed given that most machines are not dedicated densitometric machines.

Radiography
Before the advent of the newer diagnostic imaging, plain radiographs, often obtained for other indications, were used to diagnose osteoporosis, especially at the spine. In fact, many subclinical, atraumatic spinal fractures are still discovered in this manner. These particular fractures are known to be a strong predictor of future fractures. However, because plain film radiographs are associated with a high false-negative rate, and they have not been validated for predicting fracture risk, they are not useful for screening or diagnosis, aside from finding occult, or hidden, fractures.

Despite the myriad of techniques used to assess the mass, density, and architecture of bone, DEXA is the most widely used test; it is considered the “gold standard” for the diagnosis of osteoporosis. In a recent prospective cohort study, postmenopausal women aged 50 years and older without a previous diagnosis of osteoporosis were followed for one year, with baseline and one-year BMD measurements to evaluate the performance of peripheral bone density tests in predicting fracture (Siris et al., 2001). Tests were completed at the forearm and finger using DEXA and at the heel using QUS and single X-ray absorptiometry. After 12 months, those women diagnosed with osteoporosis based on initial BMD had a 4-fold higher rate of fracture compared with normal BMD. In addition, postmenopausal women with low BMD, but not osteoporosis, had twice the risk of fracture. Interestingly, those women diagnosed with osteoporosis based on DEXA had higher fracture risks than women tested with other modalities, suggesting that the DEXA may, indeed, be the best method from a public health perspective.

Appendix D
Treatments for osteoporosis

Bisphosphonates

Bisphosphonates work as antiresorptive agents; that is, these drugs impair the normal process of bone breakdown that occurs in the remodeling process. This alteration favors net bone formation. The most well-studied bisphosphonate for fracture reduction in osteoporotic postmenopausal women is alendronate. In a recent large meta-analysis of 11 RCTs, including nearly 13,000 women with at least 1 year of follow-up, alendronate was found to reduce both vertebral and non-vertebral fractures (Cranney et al., 2002d). The pooled relative risk estimate from eight trials for vertebral fractures in women given 5 mg or more of alendronate per day was 0.52 (95% confidence interval 0.43-0.65), or a 48% decrease for fracture risk. For non-vertebral fractures, the relative risk in patients given 10 mg or more of alendronate was 0.51 (95% confidence interval, 0.38-0.69), or a 49% decrease in risk.

Based on this meta-analysis, women receiving alendronate were half as likely over the short-term to develop a fracture compared with those receiving placebo. This effect was seen for all types of fractures, even those not considered as typical osteoporotic fractures, as well as for women with BMD below the mean but not considered osteoporotic. The gain in bone density observed in these trials was seen disproportionately in cancellous bone, which has implications for the use of QCT to monitor treatment effects.

One problem with these alendronate findings from a screening program perspective is that the trials mostly enrolled women older than age 65 years (Adami et al., 1995; Black et al., 1996; Bone et al., 1997; Chestnut et al., 1995; Hosking et al., 1998; Liberman et al., 1995; McClung et al., 1998; Greenspan et al., 1995; Pols et al., 1999; Bonnick et al., 1998; Cummings et al., 1998), which limits their generalizability to women aged 50 through 64 years. Only 5 of 11 trials involved populations with a mean age below 65 years, and of these, only two trials (both prevention) had a population with a mean age younger than 60 years (Hosking et al., 1998; McClung et al., 1998). These two studies taken together showed overall benefit, which was statistically significant. In the larger trial, (n = 1,000), however, alendronate had no effect on vertebral fracture risk compared with placebo (Hosking et al., 1998). Most trials had exclusion criteria that ensured a cohort of relatively healthy women not already receiving HRT.

A large meta-analysis of 8 RCTs found that risedronate reduced both vertebral fractures (relative risk: 0.64 [95% confidence interval 0.54-0.77], a 32% decrease) and non-vertebral fractures (relative risk: 0.73 [95% confidence interval 0.61-0.87], a 27% decrease) with a daily dose of 2.5 mg or more (Cranney et al., 2002c). Even though the increase in bone density reported was greater in the spine, hip, and wrist with a daily dose of 5 mg, there was no appreciable additional reduction in fracture risk. These trials followed women for at least 6 months after treatment initiation.

The main side effects of bisphosphonates are gastrointestinal, primarily dyspepsia (upset stomach), which is seen in 5% to 25% of patients. In placebo-controlled trials, however, these complaints were generally not much higher than those reported in the placebo group.

Estrogen

Hormone replacement therapy has been widely used among postmenopausal women both to treat unwanted symptoms of menopause and to prevent certain chronic diseases such cardiovascular disease. The value of estrogen for prevention of coronary heart disease (CHD) has been refuted by recent RCTs (Hulley et al., 1998; WHII, 2002). In fact, current evidence shows that short-term risk of stroke and CHD is increased after initiation of HRT. Among its other effects in the body, estrogen prevents bone breakdown and promotes new bone growth, and has been shown in many cohort studies to reduce fractures in postmenopausal women at the spine (Maxim et al., 1995), hip (Cauley et al., 1995; Kiel et al., 1987; Hoidrup et al., 1999; Grodstein et al., 1999), and wrist (Hulley et al., 1998; Cauley et al., 1995). However, a meta-analysis of 22 trials of low-dose estrogen use among postmenopausal women for at least 1 year reported a 27% reduction in non-vertebral fractures (Torgeson and Bell-Syer, 1998), without any statistical difference seen in vertebral fractures. This finding was seen despite an improvement in bone density 2 years after therapy in the spine (6.8%), hip (4.8%), and wrist (3.4%).

The first RCT to study estrogen use in postmenopausal women, the Women's Health Initiative (WHI), found that there were 24% fewer total fractures and 34% fewer vertebral and non-vertebral fractures reported among the 8,500 women assigned to the HRT cohort (WHII, 2002). This finding agrees with similar results observed in non-randomized trials. Given significant harms uncovered by the WHI and other RCTs (Hulley et al., 1998) with respect to CHD, stroke, breast cancer, and venous blood clots, the overall harms associated with HRT use are now believed to outweigh the potential benefits of reducing osteoporotic fractures in most postmenopausal women (Nelson et al., 2002b).

Raloxifene

Selective estrogen receptor modulators mimic the benefits of estrogen to inhibit bone turnover and promote new bone growth. A meta-analysis of seven RCTs, which followed postmenopausal women for at least 1 year, found that raloxifene decreased vertebral fractures compared with placebo, but there was no difference with respect to non-vertebral fractures (Cranney et al., 2002a). All women in these trials were also taking calcium and vitamin D supplements.

Data from one large study within this meta-analysis, the Multiple Outcomes of Raloxifene Evaluation (MORE) Trial, found a reduction of vertebral fractures, with a relative risk of 0.60 (95% confidence interval 0.50-0.70), but there was no statistically significant reduction in non-vertebral fractures, despite an increase in bone density of 2% to 3% in the spine, hip, and wrist--sites of most osteoporotic fractures (Ettinger et al., 1999). These findings held true regardless of a dosage increase from 60 to 120 mg per day.

The side effects of raloxifene include hot flashes, leg cramps, and a 2- to 4-fold increase in risk for blood clots in the leg.

Calcitonin

Calcitonin is produced by cells in the thyroid gland and has a number of roles in regulating calcium and phosphate metabolism. One role is to suppress the resorption of bone that occurs in normal remodeling activities. Salmon calcitonin at intranasal weekly doses of 250 IU has been shown in a meta-analysis of several RCTs to reduce the incidence of vertebral fractures in postmenopausal women by about 50% (Cranney et al., 2002b). No difference was seen in the

pooled analysis when only non-vertebral fractures were studied. Of particular significance, calcitonin had a significant analgesic effect in women who used it after sustaining a vertebral fracture. This effect was shown to promote earlier ambulation and to contribute to less morbidity.

APPENDIX E
Cost Analysis and Estimates Used in This Report

Cost Estimation Approach – General Assumptions

The process of estimating the cost impact of a mandate involves developing assumptions regarding the current levels of health care coverage in place and then simulating the impact of the mandate on costs, premium levels, and benefit coverage. Four different "model" plans were selected: health maintenance organization (HMO), preferred provider organization (PPO), point-of-service (POS), and fee-for-service (FFS), along with three insured types (large group, small group, and individual) to represent typical insured plan benefits in California.

Coverage of mandated benefits in each model plan was estimated by surveying the seven largest California health insurers. Although this information is reflected in the modeling, each of these carriers offers a range of plan options, and it is impractical to summarize actual current coverage levels overall. Based on general knowledge of today's health insurance marketplace and information received from California insurers, the model plans are designed to be a reasonable representation of the average plans offered in California today.

The model plans used in the analysis are as follows:

- Large-Group HMO
- Large-Group PPO
- Large-Group POS
- Large-Group FFS
- Small-Group HMO
- Small-Group PPO
- Small-Group POS
- Small-Group FFS
- Individual (HMO and PPO)

The commercial market was divided into large-group (51 or more employees), small-group (2 to 50 employees), and individual coverage. Each of these markets is subject to different regulations and market forces.

Four model plans were selected, representing the four general plan types that are commonly available in today's market. These plan types vary in terms of the benefit structure, the limitations on choice of providers (i.e., physicians and hospitals), and the level of managed care restrictions imposed by the health insurer. Standard descriptions of these plan types are as follows:

- **HMO** – A health maintenance organization is a "closed-panel" plan that limits coverage to those providers in a designated panel (other than in emergency situations). The plan member is typically required to select one of the panel's primary care physicians, who serves as the referral point to specialty care. The primary care physician, by agreeing to participate in the HMO's network, agrees to abide by the utilization management requirements and the fee schedules or other reimbursement approaches specified by the HMO.

The HMO coverage is broader than fee-for-service coverage, meaning it has lower member cost sharing and includes certain preventive care services that are not generally covered under an FFS or PPO plan. The model HMO plan used in this analysis is assumed to be moderately managed in terms of the degree of managed care, meaning that the plan uses some management protocols and standards, with moderate conformity to such standards.

- **PPO** – A preferred provider organization uses a fee-for-service approach to paying providers. The plan designates a preferred network of providers; members must use providers in the network in order to receive the highest level of benefit coverage. If a member chooses to use a non-network provider, the services are covered but the member must pay a substantially greater level of cost sharing. The model PPO plan used in this analysis is assumed to be loosely managed with respect to all services.

- **POS** – A point-of-service plan has a closed panel that is similar to an HMO plan, but it also allows members to go outside the panel, subject to paying a significantly higher level of cost sharing. The level of coverage for "in-network" benefits, meaning services within the closed panel, is similar to HMO coverage and has the same primary care physician role. The model POS plan used for this analysis is assumed to be moderately managed with respect to in-network coverage and loosely managed for out-of-network coverage.

- **Fee-for-Service (FFS)** – The fee-for-service plan is a traditional indemnity plan with minimal focus on managed care (referred to as "loosely managed"). Members can seek care from the providers of their choice.

The following information was estimated for each of the model plans:

Population Younger Than Age 65 Currently Covered

The data for these analyses were obtained from multiple sources. The California Health Interview Survey (CHIS), 2001 was used to identify the demographic characteristics and estimate the insurance coverage of the population in the state. CHIS is a random telephone survey of more than 55,000 households that is conducted in multiple languages by the University of California at Los Angeles Center for Health Policy Research. CHIS is the first state-level survey of its kind to provide detailed information on demographics and health insurance coverage as well as health status and access to care, including representative samples of non–English-speaking populations. CHIS insurance coverage estimates were cross-validated with administrative or other data sources.

To obtain estimates of the percentage of employees by size of firm and type of health plan, this analysis used the 2001 Health Research and Educational Trust (HRET) survey of California employers. Conducted annually for the Kaiser Family Foundation (KFF) of representative samples of small and large employers, these data provide estimates of numbers of employees working in such firms and their types of coverage. Coverage categories include conventional FFS, PPOs, POS, and HMOs. Furthermore, the HRET/KFF survey also provides information on whether each health plan is self-insured or underwritten. The latter two data points were used to complement CHIS data, because CHIS does not provide details on PPO and POS or self-insured coverage. The HRET/KFF survey also contains data on health insurance premium costs of

individual and family plans as well as the proportion of premiums that are paid by the employee and the firm for each type of health plan.

The percentages of workers with employment-based coverage obtained from CHIS data were inflated to reflect children and non-working individuals with this type of coverage. The final numbers of individuals with each type of coverage used in the analysis included only those covered under insured policies.

Baseline PMPM Costs – Insured Premiums

For large and small groups, the single and family premium rates from the HRET/KFF data were converted to per member per month (PMPM) rates by assuming 44% of covered employees had single coverage and 56% had family coverage. Employees with family coverage were assumed to have 2.21 dependents on average. These demographic assumptions were based on Milliman USA research.

For individual coverage, PMPM premium information was obtained through a survey of the largest insurers and HMOs in California.

The historical PMPM premium information discussed above was inflated by a rate of 12% per year to estimate premiums for calendar year 2004.

An actuarial cost model was constructed for each plan type, breaking down the observed premiums into administration costs and detailed health care service categories. The current utilization and average cost per service were estimated for each service category. The starting point for cost estimates in the analysis was the *Milliman Health Cost Guidelines* (HCGs), July 2003 edition. The HCGs are Milliman USA's proprietary information base that show how the components of per capita medical claim costs vary with benefit design, demographic composition, location, provider reimbursement arrangements, degree of managed care delivery, and other factors. In most instances, HCG cost assumptions are based on an evaluation of several data sources and are not specifically attributable to a single data source. The HCGs are used by Milliman USA client insurance companies, HMOs, and other organizations, primarily for pricing and evaluating health insurance products.

Adjustment factors from the HCGs were used to modify utilization and unit cost assumptions specifically for the state of California. The resulting cost estimates were then compared with the average premium rate information for the State of California from Milliman USA's *2003 HMO Intercompany Rate Survey* and to the premium rate survey discussed above to ensure the reasonableness of the estimates of the overall health care cost and premium levels.

Baseline PMPM Costs – Average Portion of Insured Premium Paid by Employer/Employee

Most employers require employees to pay a portion of the health premium through monthly contributions. The calendar year 2002 data from HRET/KFF 2002 included the average single and family monthly employee contribution rates. The residual between the total premium and the employee contribution rates was assumed to be the portion of the premium paid by the employer. Note that the employee costs in this value are just the monthly contribution rates; member cost sharing at the point of service is calculated separately.

Covered Benefits Paid by Member

This value varies by the plan type. Using the actuarial cost models described above, an estimate was made for the PMPM value of the deductibles and copays paid by plan members/insured as a percentage of total PMPM health care costs for each plan type:

	Member Cost Sharing As a Percent of Total Health Care Costs
Large-Group HMO	4%
Large-Group PPO	14%
Large-Group POS	7%
Large-Group FFS	21%
Small-Group HMO	6%
Small-Group PPO	16%
Small-Group POS	9%
Small-Group FFS	23%
Individual	20%

Benefits Not Covered

For each mandate, an estimate was made for the cost of services that are now being paid for directly by patients, exclusive of deductible and cost sharing, for benefits that would be covered by insurance under the mandate.

Administrative/Profit Component of Premiums

Estimates are expressed as the percent change in premiums. These same percent changes would also apply separately to the benefit costs and the administrative expenses of health insurers. It was estimated that insurers' administrative expenses would change proportionately to the underlying change in benefit costs, reflecting the expected impact on claims-processing costs, utilization management costs, and other administrative functions.

The following table contains the assumed administrative/profit component of premium, expressed as a percentage of total premiums. These assumptions are general, and may not reflect the assumptions used by any particular insured plan in California.

	Administrative/Profit Expenses as a Percent of Total Insured Premiums
Large-Group HMO	15%
Large-Group PPO	17%
Large-Group POS	16%
Large-Group FFS	17%
Small-Group HMO	20%
Small-Group PPO	22%
Small-Group POS	21%
Small-Group FFS	22%
Individual	30%

Cost Estimation Approach – Mandate Impact Methodology

Once the current baseline PMPM health care costs and premiums are determined, the next step is to estimate the increase in these PMPM costs and premiums due to the mandate.

Step 1: Estimate the change in health care costs covered by insurance

For services that are newly required by the mandate, the PMPM health care cost of these services that are already covered and being paid for under insurance plans was determined first. Note that these are the total costs for insured benefits, including the amounts paid by the insurer and amounts paid by the member through cost sharing. For a given plan type, this is calculated as follows:

(Percentage of members currently covered for the service), X
(Percentage of currently covered members expected to use the service in a year), X
(The cost per person who uses the service)

These costs are assumed to be included in the baseline costs estimated above.

Next is determined the cost of these mandated services covered under insurance plans after the mandate. For a given plan type, this is calculated as follows:

(Percentage of members covered for the service (assumed to be 100%)), X
(Percentage of current and newly covered members expected to use the service in a year), X
(The cost per person who uses the service)

The difference between the PMPM insured health care costs of newly mandated services before and after the mandate is the change in the *direct* health care costs covered by insurance.

In some cases, the increase in cost due to the newly covered services is offset by a decrease in the cost for other health care services.

The total change in health care costs covered by insurance is equal to the change in the *direct* health care costs covered by insurance less the value of the offset due to decreases in other health care costs.

Step 2: Allocate the change in health care costs covered by insurance between amounts paid by member cost sharing and amounts paid by the insurer

The portion of new health care costs that is paid by member cost sharing, "Covered Benefits Paid by Member," is estimated based on the above table, "Member Cost Sharing as a Percent of Total Health Care Costs." This is modified if the impact of the mandate is to modify the cost-sharing provisions as opposed to adding new covered benefits.

The portion of new health care costs not paid by member cost sharing is defined as the increase in the health care component of insured premiums.

Step 3: Estimate the change in insured premiums

The change in insured premiums is equal to the increase in the health care component of insured premiums, from Step 2, plus the increase in the administration and profit expense of the insurer. The administration and profit portion of the increase in insured premiums is based on the above table, "Administrative/Profit Expenses as a Percent of Total Insured Premiums."

The total of the increase in the health care and administrative/profit components of premium is added to the baseline PMPM premiums to estimate the PMPM premiums after the mandate.

Step 4: Allocate the change in health care premiums between amounts paid by the employer and amounts paid by the employee

The PMPM premium after the mandate is allocated between the portions paid by the employer and employee by assuming employers will continue to pay the same percentage of health care costs as before the mandate.

Step 5: Estimate the health care costs for newly mandated services that are currently paid by individuals due to lack of insurance coverage

For services that are newly required by the mandate, the PMPM health care cost of these services that are not currently covered but are being paid out of pocket by individuals is determined. For a given plan type, this is calculated as follows:

(Percentage of members currently not covered for the service), X
(Percentage of currently not-covered members expected to use the service in a year), X
(The cost per person who uses the service)

Step 6: Estimate the health care costs for newly mandated services that will be paid by individuals due to lack of insurance coverage after the mandate

This value is assumed to be zero.

Step 6: Estimate the impact on total expenditures for the insured population

The impact on total expenditures is equal to the total change in insured premiums, plus the change in the Covered Benefits Paid by Member, plus the change in the Benefits not Covered. Note that this amount is typically less than the impact on Insured Premiums, because some of the increase in Insured Premiums is offset by decreases in the Covered Benefits Paid by Member and Benefits not Covered. Also, the analysis assumes the estimated net change in actuarial costs translates fully into expenditure changes.

General Caveats and Assumptions

The California Health Benefit Review Program conducted the cost analysis presented in this report. 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, U.S.A.

A variety of external data sources was used in preparing the cost estimates for this report. Although this data was reviewed for reasonableness, it was used without independent audit. The *Milliman Health Cost Guidelines* were used extensively 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.

Unless otherwise noted in the report, the estimated net changes in actuarial costs are not the same as economic costs associated with the mandate because actuaries and economists define "costs" differently. While actuarial costs are net expenditures as just described, estimates of economic costs would typically include the value of the alternative uses of resources associated with the mandate.

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 already covered different from analysis assumptions
- Utilization of mandated services before and after the mandate different from analysis assumptions
- Assumptions used by health plans to price the mandated benefits different from analysis assumptions
- Random fluctuations in the utilization and cost of health care services

Additional assumptions that underlie the cost estimates presented here are as follows:

- Cost impacts are shown only for people with insurance.

- The projections do not include people covered under self-insurance employer plans, as 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 by unaffected by the mandate.

There are other variables that may affect costs but were not considered in the cost projections presented in this report. Such variables include, but are not limited to, the following:

- Population Shifts by Type of Health Insurance Coverage. If a mandate increases health insurance costs, then some employer groups or individuals may elect to drop their coverage. Employers may also switch to self-funding to avoid having to comply with the mandate.

- Changes in Benefit Plans. To help offset the premium increase resulting from a mandate, members or insured may elect to increase their overall plan deductibles or copayments. Such changes will 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). The effects of such potential benefit changes in its analysis were not included.

- Adverse Selection. Theoretically, individuals or employer groups who had previously foregone insurance may now elect to enroll in an insurance plan because they perceive that it is to their economic benefit to do so.

- Medical Management. Health plans may react to the mandate by tightening their medical management of the mandated benefit. This would tend to dampen cost estimates in the analysis. 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 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 provider practice patterns, the level of managed care, and possibly the underlying health status of the local commercial population. The average cost per service varies due to different underlying cost levels experienced by providers 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, the impact has been estimated on a statewide level.

Cost Estimation Approach - Mandate Impact Assumptions

The following assumptions underlie discussions in the Utilization, Cost, and Coverage Impact section of this report, specifically as it related to:

- Current coverage of osteoporosis screening
- Current utilization rate for osteoporosis screening procedures
- Post-mandate utilization rate for osteoporosis screening procedures
- Average Cost for screening procedures, per newly screened member
- The costs associated with this mandate include the treatment costs that would result from newly diagnosed patients.

About 1% of newly screened women aged 50-64 are assumed to be diagnosed with osteoporosis, and of these, 2/3 are assumed to seek treatment.

The annual cost for treatment, including physician visits and prescription drugs, is assumed to equal $1,300.

The costs associated with this mandate have been reduced by an estimate of the healthcare savings due to reduced fractures among newly treated osteoporosis patients. Each newly screened member is assumed to have a 0.13% lower probability of having a fracture. The average assumed cost to treat a fracture is $19,000.

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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 USA, to assist in assessing the financial impact of each benefit mandate bill. Milliman USA 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.

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