

Analysis of Assembly Bill 1549 Childhood Asthma Management

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



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.

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A Report to the 2003-2004 California State Legislature

An Analysis of Assembly Bill 1549 Childhood Asthma Management

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California Health Benefits Review Program 1111 Franklin Street, 11th Floor Oakland, CA 94607 Tel: 510-287-3878 Fax: 510-987-9715 www.chbrp.org

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 1549, a bill to mandate that all health care service plans regulated and licensed by the California Department of Managed Care provide coverage for over-the-counter and prescription asthma medications and associated pediatric asthma outpatient self-management training and education. 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*.

Helen Halpin, PhD, and Sara McMenamin, PhD, of the University of California, Berkeley, coordinated the preparation of this report and prepared the public health impact section. Ed Yelin, PhD, Wade Aubry, MD, and Harold Luft, PhD, all of the University of California, San Francisco (UCSF), prepared the medical effectiveness section. Mark Eisner, MD, MPH, of UCSF provided technical assistance with the literature review and clinical expertise for the medical effectiveness section. Jerry Kominski, PhD, Miriam Laugesen, PhD, and Nadereh Pourat, PhD, all of the University of California, Los Angeles, prepared the cost 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 Katrina Mather, freelance editor, served as copy editor. 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:

California Health Benefits Review Program 1111 Franklin Street, 11th Floor Oakland, CA 94607 Tel: 510-287-3878 Fax: 510-987-9715 www.chbrp.org

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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

EXE	CUTIVE SUMMARY	. 3
INTI	RODUCTION	. 6
I.	MEDICAL EFFECTIVENESS	. 7
II.	UTILIZATION, COST, AND COVERAGE IMPACTS	14
	Present Baseline Cost and Coverage	14
	Impacts of Mandated Coverage	16
III.	PUBLIC HEALTH IMPACTS	18
	Present Baseline Health Outcomes	18
	Impact of the Proposed Mandate on Public Health	19
TAB	SLES	22
APP	ENDICES	26
REF	ERENCES	47





EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 1549

Assembly Bill 1549 would require that all health care services plans regulated and licensed by the California Department of Managed Care provide coverage for over-the-counter (OTC) and prescription asthma medications and associated pediatric asthma outpatient self-management training and education. Asthma is a chronic inflammatory disease of the airways that affects approximately 380,000 children in health plans in California that are licensed by Knox-Keene¹. Childhood asthma that is poorly managed may result in acute episodes, which can cause missed days of school, restricted activity, emergency room visits, and hospitalizations.

The California Legislature has asked the California Health Benefits Review Program to describe the available evidence regarding the effect of self-management training and education on asthma-related public health and health services utilization outcomes for children with symptomatic asthma, as well as the effect of these services on overall health care costs.

I. Medical Effectiveness

A review of evidence from a recent meta-analysis on pediatric asthma self-management training and education and the trials published since 1998 find the following:

- The asthma programs in these studies had favorable effects on a variety of health outcomes for children with symptomatic asthma. In particular, self-management training and education for children with symptomatic asthma has statistically significant effects in reducing the mean number of days of school absences; the percentage of children with asthma experiencing any restricted-activity days; mean number of nights of nocturnal asthma; days of asthma symptoms; and symptom scores, as well as increasing the number of symptom-free days; self-efficacy; and child and select caregiver knowledge about asthma and its management.
- The literature suggests that self-management interventions have favorable effects in reducing asthma-related emergency room visits and hospitalizations. Health service utilization outcomes for children with symptomatic asthma show a pattern toward favorable effects, including an estimated 26% reduction in mean asthma-related emergency room visits and a 30% reduction in the mean number of asthma-related hospitalizations. No clinically meaningful effects were found on the number of physician visits for children with asthma.

II. Utilization, Cost, and Coverage Impacts

The cost analysis indicates that nearly all children enrolled in health maintenance organizations (HMOs) in California are covered for asthma self-management training and education as well as other asthma-related health services, medications, and devices.

¹ Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.



- Nearly all commercially insured children in HMOs are covered for asthma-related inpatient care, ambulatory care, emergency department visits, asthma self-management and training, and individual health education. Prescription asthma medications (92%), equipment and devices (94%), patient education materials (98%), and group health education (91%) are also extensively covered. Nonprescription (OTC) asthma drugs are covered for 45% of children in HMOs.
- The greatest changes in utilization resulting from the mandate will be in increased use of pediatric self-management training and education programs, and use of OTC drugs, as well as decreases in asthma-related emergency room visits and hospitalizations. The mandate will have an impact on utilization of asthma-related services. Overall, utilization of services mandated under the legislation will increase by 4% for asthmatic children enrolled in HMO and point-of-service (POS) plans. In addition, the utilization of asthma self-management training and education is expected to increase by approximately 10 percentage points (from 54% to 64%) for children already covered as a result of increased awareness of the benefit resulting from the mandate. The use of OTC drugs for pediatric asthma is also expected to increase by approximately 10 percentage points. The evidence from the medical effectiveness review suggests that the mandate will reduce mean hospitalizations by 30% and mean emergency room visits by 26% for children with symptomatic asthma.
- The mandate will have a small impact on commercial HMO and POS costs. Total expenditures (including total premiums and out-of-pocket costs) will increase by 0.02% in both the large- and small-group markets and the individual market. The new costs associated with increased utilization of self-management training and education and OTC drugs are estimated to increase total expenditures by .022%. However, the savings associated with reduced emergency room and hospital utilization is estimated to offset total expenditures by .002% (approximately 10% of the increase is offset by savings). The analysis suggests that the mandate will increase the administrative expenses of health plans in proportion to the increase in health care costs.

III. Public Health Impacts

Public health impacts are based on the review of the evidence on medical effectiveness outcomes and the estimation that 10% of children with asthma who are presently covered will newly use these services following the mandate. *All estimates represent an upper bound;* it is unlikely that the effects demonstrated in trials will be duplicated at the same level in the population as a result of the mandate because the trials were conducted in tightly controlled circumstances, which do not necessarily represent how care is provided in the general population. In addition, there could be variations from insurer to insurer that could affect actual health outcomes. Hence, assuming 10 percent more covered children with asthma use these services, and that the actual new services adopted to meet the mandate are as effective in actual use as the clinical trials reviewed suggest, the analysis indicates pediatric asthma self-management training and education programs will have the following effects:

• These programs could reduce restrictions on the physical activities of children with symptomatic asthma. Based on the evidence, it is estimated that up to 20,000 fewer days of



school will be missed each month due to asthma, or 179,000 fewer days will be missed each year. In addition, the evidence suggests that the mandate will reduce the percentage of children with restricted-activity days by up to 25%, or for approximately 6,800 children.

- Self-management programs could reduce acute episodes of childhood asthma. Based on the evidence, the analysis estimates there will be up to approximately 400 fewer asthma-related emergency department visits and 130 fewer asthma-related hospitalizations as a result of the mandate. Other likely health outcomes suggested by the literature include an overall reduction in asthma severity for children, fewer days of asthma symptoms, more symptom-free days, fewer nights of nocturnal asthma, and improvement in lung function as measured by peak expiratory flow rates.
- The evidence suggests the mandate will increase knowledge about asthma and its management for both children and their caregivers and will lead to improvements in the lives of children with symptomatic asthma and the caregivers of young children (aged 1-3 years) with asthma.

If fewer additional covered children newly receive services as a result of the mandate, or if the actual interventions are less effective than what was observed in clinical trials, the public health benefits of this mandate would be less pronounced than estimated.



INTRODUCTION

Asthma is a chronic inflammatory disease of the airways, which disproportionately affects children in the United States. It is the most common chronic condition in childhood and is estimated to affect approximately 4.8 million children across the nation (CDC, 1996). Childhood asthma that is poorly managed may result in acute episodes, often requiring emergency department visits and hospitalizations. The components of pediatric asthma management include the following: medications for the treatment of asthma; outpatient asthma visits every 1 to 6 months (depending on severity); asthma education for children and parents (individual or group classes); peak airflow meter measurement at home (patients require a peak flow meter for self-monitoring); spirometry (measurement of the air entering and leaving the lungs) testing by a physician during outpatient visits; home environmental screening by a health care provider (for allergens, tobacco, pollutants, and irritants); nurse managers for high-risk patients; referral to an asthma specialist as necessary; allergen immunotherapy (typically lasts 3 to 5 years), annual influenza vaccinations; and treatment of upper respiratory symptoms (rhinitis/sinusitis) and gastroesophageal reflux (which can create heartburn or more serious problems).

The National Heart, Lung and Blood Institute's National Asthma Education and Prevention Program (NAEPP) convened an expert panel in 1997 to create guidelines for the diagnosis and management of asthma (NAEPP 1997). The goals of asthma management are described as preventing chronic or troublesome symptoms; maintaining near "normal" pulmonary function; maintaining normal activity levels; preventing recurrent exacerbations of asthma; minimizing the need for emergency department visits or hospitalizations; providing optimal pharmacotherapy with the least amount of adverse effects; and meeting patient and family expectations of and satisfaction with asthma care. The panel emphasized the importance of self-management; it recommended that health care providers systematically teach and review asthma management and control with their patients. A review of the literature on monitoring and management of asthma in the 1997 NAEPP guidelines included studies published through 1995 and was limited to trials conducted on adults with asthma. No evidence was reviewed or conclusions drawn about the effectiveness of asthma self-management education and training in children in those guidelines. In the 2002 update of the guidelines (NAEPP 2003), the expert panel continued to conclude that asthma self-monitoring is important to the effective management of asthma, especially for people with moderate or severe asthma. However, the 2002 update focused primarily on the relative effectiveness of different medications for treating asthma in children and an updated review of the effects of action plans and self-monitoring for adults with asthma. The 2002 update presented no summary of the evidence of the effectiveness of pediatric selfmanagement training and education.

Assembly Bill 1549 (AB 1549) would require that all health care services plans regulated and licensed by the California Department of Managed Care, as provided in the Knox-Keene Health Care Services Plan Act of 1975, provide coverage for prescription and over-the-counter (OTC) medications to treat pediatric asthma and for associated training and education. The bill does not specify the medications to be covered, but rather calls for the convening of a work group to develop a universal drug and device formulary that would include asthma medications available without a prescription. The analyses that follow assume that all prescription asthma-related drugs



presently covered by health maintenance organizations (HMOs) will continue to be covered following the mandate and that coverage of OTC medications will increase.

The proposed mandate would apply to all insured children (aged 0-17 years) with symptomatic asthma who are enrolled in an HMO licensed by Knox-Keene or point-of-service (POS) plan in California. Combining data from the California Health Interview Survey (CHIS, 2001) with estimates from commercial databases maintained by Milliman USA, the mandate is estimated to cover approximately 380,000 children with symptomatic asthma in California who are enrolled in plans licensed by Knox-Keene. A stated goal of the mandate is to "enable pediatric asthma patients and their families to gain an understanding of the disease process and the daily management of asthma in order to avoid frequent hospitalizations and complications" (AB 1549). The bill requires that affected health plans cover "asthma outpatient self-management training and education necessary to enable an enrollee to properly use medications and devices." The bill also requires that "additional pediatric asthma outpatient self-management training and education the direction or prescription of those services by the enrollee's participating physician" (AB1549).

This report describes the available evidence regarding the effects of asthma medication and associated self-management training and education on asthma-related health and health services utilization outcomes for children, as well as the effects on overall health care costs in California.

I. MEDICAL EFFECTIVENESS

The results of the review of the scientific research on the medical effectiveness of pediatric asthma medications and self-management training and education are organized into five kinds of effects: health effects, intermediate effects, disability effects, health services utilization effects, and quality-of-life effects. Due to the difficulty of distinguishing between educational and selfmanagement interventions, any trial in which the intervention included an educational or selfmanagement component was reviewed. The scope of the literature search included effects of self-management education and training interventions for children with asthma, benefits of written self-management action plans, effectiveness of peak airflow-based written action plans, and results of monitoring interventions and behavioral-enhancement interventions. Several trials also used computer-assisted instructional games and Internet-enabled, interactive multimedia asthma education tools. The search was limited to English abstracts and to children, defined as subjects aged 0-18 years. The review included clinical trials, controlled clinical trials, randomized controlled trials, meta-analyses, and systematic reviews. Trials that included any adults with asthma were excluded. One meta-analysis (Wolf et al., 2003) was identified that reviewed the literature on the effectiveness of pediatric asthma self-management training and education published through 1998. All other trials that were reviewed were published subsequent to the meta-analysis, from 1998 through 2003.

To evaluate the evidence for each outcome measure, the following grading system was used:

(1) Favorable: findings are uniformly favorable, many or all are statistically significant



(2) Strong pattern toward favorable: findings are generally favorable, but many are not statistically significant

(3) Ambiguous/mixed evidence: some significantly favorable, and some significantly unfavorable findings

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

(5) Unfavorable: statistical evidence of no effect in the literature with sufficient statistical power to make this assessment

(6) Insufficient evidence to make a "call": very few relevant findings, such that it is difficult to discern a pattern

A detailed description of the methods used to conduct the medical effectiveness review and summary tables with the detailed findings can be found in Appendices A and B. A brief description of the types of intervention and location of each trial can be found in Appendix C. A complete list of all of the trials reviewed can be found in the References.

Health Effects

Days of Asthma Symptoms

Although the meta-analysis (Wolf et al., 2003) did not examine days of asthma symptoms as an outcome measure, four trials conducted subsequent to the meta-analysis (Bonner et al., 2002; Krishna et al., 2003; Yoos et al., 2002; Evans et al., 1987) found statistically significant reductions in the number of days of asthma symptoms for children participating in a pediatric asthma self-management training and education intervention. Another trial (Fireman et al., 1981) found a nonstatistically significant decrease in days with wheezes and coughs for the intervention group compared with the control group. The evidence suggests that pediatric asthma self-management training and education interventions have favorable effects in reducing the number of days of asthma symptoms that children with asthma experience.

Symptom-Free Days

Two randomized controlled trials examined the effect of pediatric asthma self-management training and education on the number of symptom-free days children with asthma report (Brown et al., 2002; Wilson et al., 1996). In both trials, the number of symptom-free days increased in the intervention groups and the changes were statistically significant. The evidence suggests that self-management training and education has favorable effects in increasing the number of symptom-free days for children with asthma.

Symptom Scores

Symptom scores are a subjective measurement of how much a patient is bothered by symptoms or how often a patient experiences asthma symptoms. Two trials (Brown et al., 2002; Christiansen et al., 1997) demonstrated a statistically significant effect of asthma selfmanagement training and education on improving symptom scores for children with asthma. Another trial (Bartholomew et al., 2000) demonstrated a nonstatistically significant but positive effect. The evidence suggests that self-management training and education has favorable effects on improving symptom scores for children with asthma.



Asthma Severity

Asthma severity is often defined subjectively and is not measured in a standard way. The measures of asthma severity in the trials that were reviewed ranged from characterizations of days of asthma as being mild, moderate, or severe (Huss et al., 2003; LeBaron et al., 1985; Whitman et al., 1985; Homer et al., 2000); using National Institutes of Health criteria to define severity (Homer et al., 2000); the degree to which a child was bothered by symptoms (Wilson et al., 1996); and functional measures, such as functional status measures (Bartholomew et al., 2000) and the ability of children with asthma to perform their chores (Perrin et al., 1992). Despite the differing definitions, the meta-analysis included three trials conducted in the United States (Wilson et al., 1996; LeBaron et al., 1985; Whitman et al., 1985) and found overall that asthma severity decreased in children who had received pediatric self-management training and education, but the findings were not statistically significant. Two trials published after the metaanalysis found statistically significant effects (Homer et al., 2000; Perrin et al., 1992); two trials found favorable but nonstatistically significant effects (Yoos et al., 2002; Bartholomew et al., 2000); one trial found statistically significant and favorable effects only for preschool children with severe asthma (Whitman et al., 1985), indicating reduced asthma severity following selfmanagement training and education; and one study that was not a randomized trial found statistically significant effects showing reduced severity (Georgiou et al., 2003). The evidence suggests that the effectiveness of pediatric asthma self-management training and education interventions demonstrates a pattern toward favorable in reducing asthma severity in children.

Exacerbations

"Exacerbations" are defined in trials as asthma attacks or episodes of asthma. The meta-analysis found a nonstatistically significant effect of self-management education and training on reducing the mean number of exacerbations experienced by children with asthma. Four of the five trials included in the meta-analysis were conducted in the United States (Evans et al., 1987; Fireman et al., 1981; Whitman et al., 1985; LeBaron et al., 1985) and found that the intervention reduced the mean number of exacerbations, but the results were statistically significant in only two of the trials (Evans et al., 1987; Fireman et al., 1981); statistically significant in only two of the trials (Evans et al., 1987; Fireman et al., 1981); statistically significant in preschool children but not school-age children in one trial (Whitman et al., 1985); and nonstatistically significant in one trial (LeBaron et al., 1985). No more recent, similarly constructed U.S. trials published after the meta-analysis were identified. Accordingly, the evidence suggests that the effectiveness of pediatric asthma self-management training and education interventions shows a pattern of weak or no effects in reducing the mean number of exacerbations for children with symptomatic asthma.

PEFR

Peak expiratory flow rate (PEFR) measures lung function as the maximum rate of airflow that can be achieved during a sudden forced expiration from a position of full inspiration. The metaanalysis, which included one trial conducted in the United States (Christiansen et al., 1999), found that pediatric asthma self-management training and education improved PEFR by a statistically significant amount. One trial published after the meta-analysis was identified also found that the effects of pediatric asthma self-management and education improved PEFR by a statistically significant amount (Guendelman et al., 2002). The evidence suggests that pediatric asthma self-management training and education interventions show a favorable effect on improving PEFR.



Nocturnal Asthma

For the two U.S. trials reviewed, one trial in the meta-analysis (Wilson et al., 1996) and one more recent trial (Krishna et al., 2003), the intervention groups that received pediatric asthma self-management training and education experienced, on average, fewer nights of nocturnal asthma compared with the control groups. This finding was confirmed in another recent study that was not a randomized clinical trial (Georgiou et al., 2003). Thus, the evidence suggests that pediatric asthma self-management training and education has a favorable effect in reducing the mean number of nights with nocturnal asthma for children.

Intermediate Effects

Self-Efficacy

Self-efficacy is defined in the meta-analysis as "the belief in one's capabilities to organize and execute the sources of action required to manage prospective situations." The meta-analysis included measures of coping scores and health locus of control scales (a metric of how much control people feel they have over their health) and found that asthma self-management training and education statistically significantly increases self-efficacy of children with asthma. In two trials published after the meta-analysis (Bonner et al., 2002; Shegog et al., 2001), the authors also found statistically significant increases in the self-efficacy of children with asthma following self-management training and education. Overall, the evidence shows a favorable effect of asthma self-management training and education on increasing children's self-efficacy in managing their asthma.

Knowledge—Children with Asthma

Five of the U.S. trials that were included in the meta-analysis demonstrated that children with asthma who received self-management training and education experienced statistically significant improvements in their knowledge of asthma and its management (Christiansen et al., 1997; Rubin et al., 1986; LeBaron et al., 1985; Whitman et al., 1985; Parcel et al., 1980). One U.S. trial included in the meta-analysis (Persaud et al., 1996) found a nonsignificant effect on increasing children's knowledge and another trial found no effect (Lewis et al., 1984). An additional three trials published since the meta-analysis also found statistically significant increases in children's knowledge of their asthma following pediatric asthma self-management training and education (Krishna et al., 2003; Bonner et al., 2002; Homer et al., 2000), and three recent trials found nonsignificant effects on increasing children's knowledge (Shegog et al., 2001; Bartholomew et al., 2000; Perrin et al., 1992). Although the tests used to measure asthma knowledge were unique to each trial, the findings suggest a favorable effect of asthma self-management training and education in increasing children's knowledge of their condition.

Knowledge—Caregiver

Some asthma self-management training and education interventions include providing educational material to caregivers. Two trials measured caregivers' knowledge and found that their knowledge about asthma and its management increased as a result of their participation in the intervention. One trial (Krishna et al., 2003) found a statistically significant increase in caregiver knowledge; however, another trial (Persaud et al., 1996) found a nonstatistically significant increase. The evidence suggests a pattern toward favorable effects of pediatric asthma



self-management training and education on increasing caregiver knowledge about their child's asthma and its management.

Disability Effects

School Absences

A total of 16 trials measured the effect of pediatric asthma self-management training and education on the mean number of days children with asthma are absent from school. The metaanalysis, which included seven U.S. trials, found that the interventions had a statistically significant effect in reducing school absences (Fireman et al., 1981; Christiansen et al., 1997; Persaud et al., 1996; Wilson et al., 1996; Perrin et al., 1992; Evans et al., 1987; Rubin et al., 1986). One additional trial (Krishna et al., 2003) published after the meta-analysis also found a statistically significant effect in reducing school absences following the intervention. This evidence suggests that pediatric asthma self-management training and education has favorable effects on reducing the mean number of days children with asthma are absent from school.

Two additional trials included in the review measured the proportion of children with asthma who reported any school absences following self-management training and education. The Georgiou et al. (2003) study demonstrated a statistically significant reduction of 48% in the proportion of children with asthma who missed school in the past six weeks. However, the study design was an uncontrolled, longitudinal survey and thus prone to more biases than a randomized controlled trial. The trial by Guendelman et al. (2002) found a nonsignificant reduction in the proportion of children reporting school absences. The evidence suggests that self-management training and education shows a pattern toward favorable effects in reducing the proportion of children with asthma who report any school absences.

Restricted-Activity Days

One recent U.S. trial (Guendelman et al., 2003) reported a statistically significant effect of decreasing the proportion of children with asthma who reported any restricted-activity days following pediatric asthma self-management training and education. This evidence shows a favorable effect of pediatric asthma self-management training and education on reducing the mean number of restricted-activity days for children with asthma.

Health Services Utilization Effects

Emergency Department Utilization

The meta-analysis included seven trials conducted in the United States measuring the effects of self-management training and education on the mean number of emergency room visits for children with asthma (Alexander et al., 1988; Clark et al., 1986; Rubin et al., 1986; Lewis et al., 1984; Fireman et al., 1981; Christiansen et al., 1997; Shields et al., 1990). The meta-analysis concluded that children with asthma who received the self-management training and education experienced a statistically significant reduction in the mean number of emergency department visits. Five subsequent trials (Krishna et al., 2003; Harish et al., 2000; Homer et al., 2000; Kelly et al.; 2000, Greineder et al., 1999) also found that pediatric asthma self-management training and education reduced emergency department visits by a statistically significant amount, and another recent trial found a nonsignificant reduction in emergency department visits (Bartholomew et al., 2000). The evidence suggests that pediatric asthma self-management training and education interventions show favorable effects in reducing the mean number of



asthma-related visits to the emergency department for children with asthma. The overall effect, based on the published U.S. trials, is an estimated 26% reduction in the mean number of emergency department visits for children with asthma.

Hospitalization

The meta-analysis, which included four U.S. trials, found that the self-management training and education intervention had a nonsignificant effect in reducing the mean number of hospital admissions for pediatric asthma patients (Christiansen et al., 1997; Clark et al., 1986; Lewis et al., 1984; Fireman et al., 1981). Among the trials published after the meta-analysis, two trials (Bartholomew et al., 2000; Greineder et al., 1999) found that the intervention reduced the mean number of hospitalizations for children with asthma by a statistically significant amount. Another study (Kelly et al., 2000), which was not a randomized trial (and hence could be subject to biased results), also found that the intervention reduced the mean number of hospitalizations for children with asthma by a statistically significant amount. All trials included in the review showed that the intervention had the effect of reducing the mean number of hospitalizations for children with asthma following the intervention, except the Krishna et al. (2003) trial, which found no effect in the intervention group. For several reasons, the impact of pediatric asthma self-management training and education on hospitalization is estimated excluding the Krishna (2003) trial. Both the intervention and control groups in the Krishna trial received asthma education, which may explain the statistically significant decrease in hospitalizations for the control group. In addition, the average number of hospitalizations in the intervention group was low (0.1) and much lower than the average number of hospitalizations for the control group (0.6). The post-intervention rate for both the intervention and control groups was 0.1.

Overall, the evidence suggests that there is a pattern toward favorable effects on reducing the mean number of asthma-related hospitalizations for children with asthma following asthma self-management training and education interventions. Based on the evidence, the effect is estimated to be a 30% reduction in mean hospitalizations.

Use of Medications: Inhaled Corticosteroids, Cromolyn, Nedocromil

Three trials conducted in the United States measured medication use as an outcome of pediatric asthma self-management training and education (Lukacs et al., 2002; Krishna et al., 2003; Bonner et al., 2002). These trials examined the effects on use of long-term-control asthma medicines, such as inhaled steroids, cromolyn, and nedocromil, which help to prevent and control asthma flares. Taken together, the trials indicate a favorable effect on the use of controller medications following pediatric asthma self-management training interventions. However, the trials were sufficiently different in the medications that were included that no point estimate could be made on the use of these medications.

Acute and Urgent Physician Visits Versus Routine Visits

The meta-analysis summarizing the effect of pediatric asthma self-management training and education on physician visits measured total "general practitioner" or "primary care" visits, which were defined to include both routine as well as urgent ambulatory visits to a general practitioner, family physician, pediatrician, or other related health care provider. The meta-analysis found that the interventions showed a nonsignificant decrease in office visits, but only one trial in the meta-analysis was conducted in the United States (Evans et al., 1987). To develop



a clearer picture of the evidence, the trials were divided into those that measured urgent or unscheduled doctor visits from trials that did not distinguish the type of physician visits.

Three trials published since the meta-analysis (Krishna et al., 2000; Homer et al., 2000; Brown et al., 2002) demonstrated a statistically significant reduction in the number of urgent or unscheduled visits for the intervention group receiving pediatric asthma self-management training and education, however, the differences in the mean number of visits between the control and experimental groups following the intervention did not vary to the extent that they were clinically meaningful. One additional study (Lukacs et al., 2002) that was not a randomized trial found that the intervention group had a nonsignificant increase in acute asthma visits to a family practitioner following hospital discharge. Two of the largest trials (Krishna et al., 2000; Homer et al., 2000) found that the mean number of urgent care or unscheduled doctor visits in the intervention groups decreased by a smaller amount than the decrease in the control groups. So that although the intervention reduced unscheduled doctor visits in the intervention group, the decline was less than that observed in the control group, and the differences in the rates of unscheduled visits postintervention between the intervention and control groups were so small as to not be meaningful. Only one U.S. trial did not describe the type of doctor visit, and it found a nonsignificant decrease in the number of overall visits (Shields et al., 1990).

The evidence suggests that pediatric asthma self-management training and education shows a weak pattern toward a decrease in the number of acute and urgent doctor visits or in total physician visits for children.

<u>Quality-of-Life Effects</u> Quality of Life—Child

According to the American Thoracic Society, quality of life is "an individual's satisfaction or happiness with life in domains he or she considers important." The World Health Organization defines quality of life as an "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." In the four studies reviewed, a standardized measurement for quality of life was not used. However, three trials found that quality of life for children with asthma improved by a statistically significant amount for those who participated in the asthma selfmanagement training and education intervention (Evans et al., 1987; Fireman et al., 1980; Perrin et al., 1992). One study published after the meta-analysis found a statistically significant improvement for children who participated in the asthma self-management training and education intervention, but this study was not a randomized trial (Georgiou et al., 2003). Therefore, the evidence suggests that self-management training and education has a favorable effect on the quality of life of children with asthma.

Quality of Life—Caregiver

Only one trial conducted in the United States assessed the impact of pediatric asthma selfmanagement training and education on the quality of life of the caregivers of children with asthma (Brown et al., 2002). This trial found a statistically significant increase in the caregiver's quality of life for caregivers whose asthmatic child had participated in a self-management training and education intervention, however, the effect was statistically significant only for caregivers of younger children (aged 1 to 3 years). The evidence suggests a pattern toward



favorable effects of asthma self-management training and education on improving caregiver quality of life.

Summary Conclusions on Medical Effectiveness

Based on a comprehensive review of the scientific literature on the medical effectiveness of pediatric asthma self-management training and education, the evidence suggests that such interventions have favorable effects on a variety of health, intermediate, and disability outcomes, health services utilization measures, and quality of life. In most of the trials reviewed, however, it was not possible to distinguish between the effects of self-management training separately from education. Accordingly, the review was unable to identify what specific components of pediatric asthma self-management training and education are responsible for statistically significant effects.

The evidence suggests that self-management training and education for children with asthma has the following favorable effects: reduction in the proportion of children with any restrictedactivity days, symptom scores, mean number of days of school absences, days of asthma symptoms, number of nights children experience asthma symptoms, and mean number of asthma-related emergency department visits. The evidence also suggests that self-management training and education has favorable effects on increasing the self-efficacy of children to manage their asthma, child and caregiver knowledge of asthma and its management, and the number of symptom-free days for children with asthma. Outcomes where the evidence suggests a pattern toward favorable effects include a reduction in mean number of asthma exacerbations, asthma severity, percent of children with school absences, and mean number of hospitalizations. Additional outcomes where the evidence suggests a pattern toward favorable effects include improvements in child quality of life, caregiver quality of life (for caregivers of children aged 1 to 3 years), and lung function (PEFR). Outcomes for which there was mixed evidence and no conclusions could be reached based on the evidence include the proportion of subjects with restricted activity, and proportion of children with any emergency department visits. Outcome measures where the evidence found a pattern toward no effect or weak effects include forced expiratory volume (a measure of lung function), the proportion of subjects with nocturnal asthma, and proportion of subjects with exacerbations. The proportion of patients with any asthma-related hospitalizations was the only outcome for which the intervention was found to have no effect. In conclusion, the evidence suggests that educational and self-management training interventions for pediatric patients with asthma are effective in improving specified health outcomes and reducing the mean number of emergency department visits and mean number of hospitalizations.

II. UTILIZATION, COST, AND COVERAGE IMPACTS

Present Baseline Cost and Coverage

1. <u>Current utilization levels and costs of the mandated benefit (Section 3(h))</u>

The mandated services under AB 1549 include "coverage for medications to treat pediatric asthma and for associated training and education." Asthma medications and associated training and education are defined to include physician visits; laboratory and radiology diagnostic tests;



patient and parent self-management training and education on a group or individual basis; devices (e.g., peak flow meters and nebulizers); immunizations and immunotherapy; and prescription and OTC drugs. Long-term-control prescription asthma medications that are presently covered include inhaled corticosteroids, cromolyn sodium and nedocromil, leukotriene modifiers, methylxanthines, and long-acting inhaled beta-2 agonists. Quick-relief prescription asthma medications that are currently covered include short-acting beta 2-agonists, anticholinergics (ipratropium bromide), and systemic corticosteroids. OTC medications used by children with asthma include Claritin, nonprescription antihistamines or decongestants (e.g., Actifed, Benadryl, Contact, Sudafed, Tavist), nonprescription breathing sprays (e.g., Bronkaid, Primatene), and nonprescription nasal sprays (e.g., Afrin, Ortivin, Vicks Sinex). Health services utilization associated with poor management of childhood asthma includes emergency department care and inpatient hospital stays.

For the utilization and cost analysis, children with symptomatic asthma were defined as having had at least one of the following events in the last year: one prescription asthma medication, one asthma-related emergency department visit, one asthma-related hospitalization, one asthma-related outpatient visit, or to have used asthma-related devices and tests.

Under these criteria, about 10.1% of children aged 0 to 17 years enrolled in health plans in California licensed by Knox-Keene have symptomatic asthma. This analysis assumes similar costs and rates of utilization for children covered under group and individual insurance due to lack of data on specific utilization data for each category. Using data from CHIS and commercially available databases from Milliman USA, the analysis finds that approximately 380,000 children in California have symptomatic asthma, are insured through job-based or individual/family policies, and are enrolled in underwritten HMO and POS plans.

Based on data from Milliman USA, the current utilization rates, costs per service, and per member per month (PMPM) costs for children with symptomatic asthma in the group and individual insurance market are approximately as follows:

- ➤ 3,000 prescriptions per 1,000 members per year
- > 300 asthma-related equipment and devices per 1,000 members per year
- 536 sessions of asthma training and education per 1,000 members per year (individual, group, and patient education materials)
- ➢ 3,000 OTC drugs per 1,000 members per year
- ➤ 1.8 office visits per patient per year
- > 0.011 inpatient days per patient per year
- > 0.4 emergency room visits per patient per year
- ⋟ \$57 cost per prescription
- ⋟ \$50 cost per equipment and devices
- \$80 cost per education and training session (individual, group, and patient education materials)
- ▶ \$10 cost per OTC drug
- ▶ \$7.03 PMPM cost per ambulatory visit
- ▶ \$3.70 PMPM cost per inpatient stay
- ➢ \$1.88 PMPM cost per emergency room visit



These estimates are based on actual claims data from commercial plans. Less than half of HMOs cover OTC asthma drugs for children, and they are often not tracked in claims data at the same level of detail as prescription drugs and other health care services. As a result, the utilization and unit costs for OTC drugs are rough estimates.

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

Coverage of pediatric asthma services in commercial HMO plans in California is relatively extensive (Table 1). It appears that all (100%) of commercially insured children in HMOs are covered for asthma-related inpatient care, ambulatory care, and emergency department visits. On average, asthma self-management training (100%), individual health education (100%), patient education materials (98%), and group health education (91%) are also extensively covered. Equipment and devices are generally covered for 94% of children in commercial HMOs, although peak flow meters are covered least frequently (75%). OTC asthma drugs are covered for 45% of children in commercial HMOs.

Some differences in coverage exist by group and individual plans. Overall, children enrolled in individual/family HMO plans have the highest rate of coverage for all examined asthma services at a range of 98% to 100%, with the exception of OTC asthma drugs (79%) and prescription asthma medications (84%). Alternatively, children enrolled in large-group HMO plans are covered at a range of 90.3% to 100%, with the exception of peak flow meters (73%) and OTC asthma drugs (42%). Finally, children enrolled in small-group HMO plans are covered at a range of 91% to 100%, with the exception of OTC asthma drugs (59%) and prescription asthma medications (88%).

3. <u>Public demand for coverage (Section 3(j))</u>

The high rates of coverage for pediatric asthma services, as presented in the preceding section, indicate that asthma services (with the exception of OTC drugs) are widely available to children in commercial HMO plans in California. Therefore, the evidence suggests there will be little unmet demand for these services, except among those who may be restricted by provider referral or health plan approval requirements. Because of the prevalence of children with symptomatic asthma in California (10.6%), the public demand for coverage of OTC asthma drugs in commercially insured HMO enrollees is estimated to be high.

Impacts of Mandated Coverage

4. <u>How will changes in coverage related to the mandate affect the benefit of the newly covered</u> service and the per-unit cost? (Section 3(a))

No effect on per-unit cost of the benefit or the service is expected, because this legislation does not propose an increase in the number of children who have health insurance coverage, but rather mandates a change in the types of services available to children with coverage (see below).



5. <u>How will utilization change as a result of the mandate? (Section 3(b))</u>

Based on current rates of coverage for pediatric asthma services in California, the areas most open to potential increases in use are self-management training and education programs and OTC drugs. Even though education and training are now widely covered (90% to 100%), utilization of these programs will increase due to the increased awareness of the benefits following the mandate. A current utilization rate of approximately 54% for pediatric asthma self-management training and education for all children with symptomatic asthma enrolled in HMOs and POS plans is based on statewide public health data (CHIS, 2001). Utilization of pediatric asthma self-management training and education services for these members is estimated to increase by 10 percentage points (to 64%) following the mandate. The use of OTC drugs for pediatric asthma is also estimated to increase by approximately 10 percentage points. For children who currently lack coverage for asthma-related services, a 54% utilization rate for these programs is estimated.

Based on the review of the medical effectiveness of pediatric asthma self-management training and education programs, the evidence suggests that, following the mandate, the mean number of inpatient hospitalizations for children with symptomatic asthma will be reduced by 26% and the mean number of emergency room visits will be reduced by 30%. The evidence from the literature review on medical effectiveness also suggests that there will be no impact on outpatient visits for these children. The effects identified in the literature review, on which the above utilization estimations were made, were observed as part of trials and therefore may not be achieved at the same levels when implemented in a population, because the trials were conducted under tightly controlled circumstances. Thus, *all estimates of effects of the mandate on health services utilization should be viewed as upper bounds*.

6. <u>To what extent does the mandate affect administrative and other expenses? (Section 3(c))</u> The mandate is expected to increase the administrative expenses for health plans, but not disproportionately to the increase in health care costs (see Item 7, below). An increase in asthma treatment and education claims may increase claims administration costs. The required coverage of OTC drugs may increase the number of small claims that the carriers have to process and may require them to establish new systems for their coverage. Plans will have to modify their insurance contracts and member materials and may have to contract with new providers that specialize in asthma education.

Health care plans include a component for administration and profit in their premiums, which may be sufficient for covering increased administrative costs (see Appendix D).

7. <u>Impact of the mandate on total health care costs (Section 3(d))</u>

Total expenditures (including total premiums and out-of-pocket expenditures) will increase by an estimated 0.02% in the large- and small-group as well as individual markets (Table 2). This is the net effect of the mandate on costs, factoring in both the new costs associated with new utilization of services, as well as the estimated cost savings resulting from reduced asthma-related emergency room visits and hospitalizations. The new costs associated with increased utilization of self-management training and education and OTC drugs is estimated to increase total



expenditures by 0.022%, however, the savings associated with reduced emergency room and hospital utilization is estimated to be a reduction in total expenditures of 0.002% (approximately 10% of the increase is offset).

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

Based on the evidence of medical effectiveness, inpatient and emergency department costs are expected to decrease by approximately 30% and 26%, respectively. Physician visit costs are not expected to change. However, no impact is expected on rates of coverage as a consequence of this mandate.

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

The majority of asthma services currently provided to children enrolled in commercial HMO and POS plans in California are covered. The current coverage rate for OTC asthma drugs is 45%. In addition, \$0.09 PMPM are paid out-of-pocket by the enrollees for OTC asthma drugs (Table 2). After the mandate, these costs will be borne by HMOs and PPOs in the large, small, and individual markets.

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

The mandated benefit will increase access to asthma-related services for children with asthma who are currently insured but do not have coverage for the mandated services. Given the size of the population affected, expected reductions in utilization of inpatient and emergency department services, and a 10 percentage-point increase in use of education and training and OTC drug use, there is no evidence that the mandate will impact net cost or availability of asthma services.

III. PUBLIC HEALTH IMPACTS

Present Baseline Health Outcomes

In California, 14% of insured children aged 1-17 years have ever been diagnosed with asthma (CHIS, 2001). However, nearly one-quarter of insured children diagnosed with asthma did not experience any symptoms in the past year. This means that approximately 10% of insured children in California have symptomatic asthma (i.e., asthma for which they experienced symptoms in the past year) (CHIS, 2001). Of those children with symptomatic asthma, almost two-thirds report they take medicine for their asthma, and almost half report they have asthma symptoms at least once a month (CHIS, 2001). Children who experience asthma symptoms are more likely to miss school due to poor health compared with children without asthma (Table 3).

An analysis by gender and race/ethnicity finds that boys are more likely than girls to have symptomatic asthma by a statistically significant amount (12% vs. 9%) (Table 4). In addition,



African American children are statistically significantly more likely to have symptomatic asthma (17%) compared with children of all other racial/ethnic groups, and Latino children are the least likely to have symptomatic asthma (8%) (Table 5). A survey of adolescents (aged 12-17 years) in California found that half of adolescents with asthma report that a doctor explained to them how to recognize asthma attacks (51%) or how to avoid the things that make their asthma worse (53%) (CHIS, 2001).

Although a review of the medical evidence suggests there are many categories of public health outcomes associated with pediatric asthma self-management training and education programs, there were only four public health outcomes for which quantitative estimates of the effects of the mandate could be made due to lack of population-based baseline data for California's children on many of the outcomes. The four public health outcomes for which quantitative estimates were made include the following: school absences (mean number of days missed), percentage of children with asthma reporting restricted-activity days, emergency department visits, and hospitalizations (Table 6).

The baseline data (Table 3) suggest that adolescents in California with symptomatic asthma missed an average of 1.2 days of school in the last four weeks, and of the 40% who missed any school, an average of 2.9 days of school were missed (CHIS, 2001). This translates into a total of 456,000 days of school missed among children with symptomatic asthma prior to the mandate because of asthma and other reasons. Seventy-one percent of children with symptomatic asthma with health insurance reported that they experienced restricted physical activity due to their asthma prior to the mandate (CHIS, 2001). In terms of health care utilization, 1% of children with asthma were hospitalized because of their disease in the past year, and 3% had emergency department visits due to asthma symptoms.

Impact of the Proposed Mandate on Public Health

Although nearly all children in California with symptomatic asthma currently have coverage for self-management training and education, a 10 percentage-point increase in the provision of selfmanagement training and education (from 54% to 64%) is estimated for children presently covered for these services as a result of increased demand, media attention, and activity from advocacy organizations following the mandate. (This percentage increase in utilization was determined by the consensus of an expert panel and represents expert opinion; the actual change in utilization of the benefit as a result of the mandate may be higher or lower than this assumption.) Children with symptomatic asthma enrolled in commercial HMOs, who are not presently covered for self-management education and training, are estimated to utilize these services at the same rates as children who presently have coverage (54%). The remainder of this section discusses the potential impact of the proposed mandate on selected health outcomes based on the effectiveness literature presented in section I. A summary of the findings is presented in Table 6. For all of the public health outcomes, the effects identified in the literature review, which were observed as part of trials, may not be achieved at the same levels when implemented in a population, because the trials were conducted in tightly controlled circumstances that do not necessarily represent how care is provided in the real world. In addition, there could be variations from insurer to insurer that could affect actual health



outcomes. Thus, *all estimates of effects of the mandate on the public's health should be viewed as upper bounds*. If fewer additional covered children newly receive services as a result of the mandate, or if the actual interventions are less effective than what was observed in clinical trials, the public health benefits of this mandate would be less.

School Absences

Forty percent of children with symptomatic asthma (151,200 children) missed school in the past month due to illness, with a reported 1.2 days of school missed per month per asthmatic child (CHIS, 2001). The evidence suggests that pediatric asthma self-management training and education leads, on average, to a reduction in the number of school days missed by asthmatic children (44% reduction estimated for 10% of children who newly receive asthma self-management services following the mandate). The analysis based on this evidence suggests a total reduction of approximately 19,900 days of missed school each month due to asthma, or approximately 180,000 fewer days of missed school per year, assuming a 9-month school year. However, the effect observed in the trials may not be as great as that experienced in the population as a result of a mandate, and therefore the above estimates should be considered an upper bound.

Restricted-Activity Days

More than 70% of children with symptomatic asthma report that their physical activity is limited because of their asthma (CHIS, 2001): 43% report that their physical activity is rarely limited due to asthma, 22% report that their physical activity is sometimes limited due to asthma, and 6% report that their physical activity is limited either most of the time or always due to asthma. The evidence suggests that pediatric asthma self-management training and education leads to a 25% reduction in the percentage of children reporting that their physical activity is limited due to asthma. Based on the evidence, the analysis suggests that for the 10% of children with asthma who will newly use the benefit following the mandate, approximately 6,800 fewer children will report that their physical activity is limited due to asthma. However, the estimated effect observed in randomized trials may not be as great as that experienced in the population as a result of the mandate, and therefore this estimate should be considered an upper bound.

Emergency Department Visits

Approximately 3% of asthmatic children visit the emergency department each year (11,400 children), for a total of approximately 15,200 asthma-related emergency room visits per year (Milliman USA, 2003). The evidence suggests that pediatric asthma self-management training and education leads, on average, to a decrease in the mean number of emergency department visits (26% reduction for the 10% of children who will newly use the benefit). Based on this evidence, the analysis suggests that there will be approximately 400 fewer emergency department visits for asthmatic children. However, the effects observed in randomized trials may not be as great as those experienced in the population as a result of the mandate, and therefore this estimate should be considered an upper bound.

Hospitalizations

An estimated 1% of children with asthma are hospitalized each year for asthma-related conditions (calculated using claims data from Milliman USA, 2003). The evidence suggests that pediatric asthma self-management training and education leads, on average, to a 30% reduction



in the mean number of asthma-related hospitalizations. Based on this evidence, there will be approximately 130 fewer hospitalizations for asthma-related conditions among children with symptomatic asthma. However, the effects observed in randomized trials may not be as great as those experienced in the population as a result of the mandate, and therefore this estimate should be considered an upper bound.

Other Significant Pubic Health Effects

A review of the literature on the effectiveness of pediatric asthma self-management and education identified other outcomes, however, quantitative estimates of the impact on children in California with symptomatic asthma could not be made because baseline data were not available. These outcomes include an overall reduction in asthma severity for children, fewer days of asthma symptoms, more symptom-free days, reduced nocturnal asthma, and improvement in lung function as measured by peak expiratory flow rates. In addition, literature on the impact of pediatric self-management training and education suggests that children and, in some cases, their caregivers report an increase in their quality of their life and increased knowledge about asthma and its management. Finally, evidence suggests that children who have had asthma self-management training and education perceive they are more capable of organizing and executing the actions required to manage their asthma.

TABLES

	Total	Large Group	Small Group	Individual Market
Prescription Drugs	91.7%	92.4%	88.1%	83.8%
Over-the-counter Drugs	44.9	41.7	58.6	79.3
Disease Management	100.0	100.0	100.0	100.0
Self management training	100.0	100.0	100.0	100.0
Group health education	90.9	90.3	92.8	97.7
Individual health education	100.0	100.0	100.0	100.0
Patient education material	98.0	97.9	98.3	99.4
Devices	94.0	93.7	96.5	100.0
Aerosol devices	90.8	90.4	93.6	100.0
Space holding chambers	93.8	93.4	96.5	100.0
Nebulizers	94.0	93.7	96.5	100.0
Peak flow meters	75.0	72.8	90.7	100.0
Inpatient Care	100.0	100.0	100.0	100.0
Ambulatory Care	100.0	100.0	100.0	100.0
Emergency Department	100.0	100.0	100.0	100.0

Table 1. Prior to Mandate: Coverage of Asthma Pediatric Services for Children Enrolled inHMOs by Market, California, 2003

Source: These coverage data were provided by actuaries in the seven largest health maintenance organizations (HMOs) operating in California for the children enrolled in HMO plans (Aetna, Blue Shield HMO, CaliforniaCare, CIGNA, Health Net, Kaiser, and PacifiCare). California Health Benefits Review Program, 2003.

	Large Group	Small (Group			
	НМО	POS	НМО	POS	Individual	Total
PMPM \$ Impact of Mandate						
A. Insured Premiums						
Total Premium	\$0.12	\$0.12	\$0.08	\$0.07	\$0.06	\$1,130,000
Average Portion of Premium Paid						
by Employer	\$0.09	\$0.09	\$0.06	\$0.06	\$0.00	\$840,000
Average Portion of Premium Paid						
by Employee	\$0.03	\$0.03	\$0.02	\$0.02	\$0.06	\$290,000
Total Premium	\$0.12	\$0.12	\$0.08	\$0.07	\$0.06	\$1,130,000
B. Covered Benefits Paid by						
Member (Deductibles, Copays,						
etc.)	\$0.00	\$0.01	\$0.00	\$0.01	\$0.01	\$60,000
C. Total Cost of Covered						
Benefits	\$0.12	\$0.13	\$0.08	\$0.08	\$0.07	\$1,180,000
D. Benefits Not Covered	-\$0.09	-\$0.09	-\$0.04	-\$0.04	-\$0.03	(\$760,000)
E. Total Expenditures	\$0.04	\$0.04	\$0.04	\$0.04	\$0.04	\$430,000
Percentage Impact of Mandate On						
E. Total Expenditures	0.02%	0.01%	0.02%	0.01%	0.02%	0.02%

Table 2. Post-mandate Impacts on Per Member Per Month (PMPM) Cost and Total Expenses,California, Calendar Year 2004

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

		95% 95%			
	Symptomatic	Confidence	No Asthma	Confidence	
Days Missed	Asthma (%)	Interval	(%)	Interval	
Missed 0 Days	60.2	54.7 - 65.7	68.2	66.1-70.2	
Missed 1 Day	13.7	9.9 – 17.6	11.5	10.1-12.8	
Missed 2 Days	10.9	7.6 - 14.1	9.0	7.8-10.2	
Missed 3+ Days	15.3		11.2		

Table 3. Prior to Mandate: Number of School Days Missed (in the Past 4 Weeks) Due to Health,Adolescents Aged 12-17 Years with Health Insurance Coverage, California, 2001

Source: California Health Interview Survey, 2001

Note: Symptomatic asthma is defined as having experienced asthma symptoms in the last year.

Table 4. Symptomatic Asthma Prevalence in Children Aged 1-17	
Years with Health Insurance Coverage by Gender, California, 200	1

		95% Confidence
Gender	%	Interval
Female	8.7	7.9-9.6
Male	12.3	11.3-13.4
Overall	10.6	9.9-11.3

Source: California Health Interview Survey, 2001

Note: Symptomatic asthma is defined as having experienced asthma symptoms in the last year.

Table 5. Symptomatic Asthma Prevalence in Children Aged
1-17 Years with Health Insurance Coverage by Race/Ethnicity,
California, 2001

		95% Confidence
Race/Ethnicity	% Children	Interval
Latino	7.7	6.7-8.8
Asian	9.0	7.0-11.1
African American	17.3	13.8-20.1
White	11.6	10.6-12.5
Overall	10.6	9.9-11.3

Source: California Health Interview Survey, 2001

Note: Symptomatic asthma is defined as having experienced asthma symptoms in the last year.

Maintenance Organizations and Font-or-Service Frans, Camornia						
		Change				
		(Based on	Change as a Result of			
Baseline		Effectiveness	Mandate			
Rates	Baseline *	Review)				
			-19,900 absent school			
1.2	45,590 days/months	-44%	days/months			
			- 6,800 children with			
71%	26,900 children	u -25%	restricted days			
0.04	1,520 visits	s -26%	-400 ER visits			
0.01	420 hospitalizations	-30%	-130 hospitalizations			
	Baseline Rates 1.2 71% 0.04	Baseline Rates Baseline * 1.2 45,590 days/months 71% 26,900 children 0.04 1,520 visits	Baseline RatesChange (Based on Effectiveness Review)1.245,590 days/months-44%71%26,900 children-25%0.041,520 visits-26%			

Table 6. Post-mandate: Health Outcomes Related to Asthma Management in Children in Health

 Maintenance Organizations and Point-of-Service Plans, California

Sources: School absences and restricted activity are from the California Health Interview Survey, 2001; emergency room (ER) visits and hospitalizations are based on estimates provided by Milliman USA. *Notes:* Estimates of the number of asthmatic children in California were obtained from Milliman USA and are restricted to children in health maintenance organizations (HMOs) and point-of-service (POS) plans only. The estimates presented in this report include children who have had symptomatic asthma in the last year, as demonstrated by any use of asthma-related hospital, outpatient, or ER use with an ICD-9 code of 493 or use of any prescription asthma medication. The n (total number of children) for the table is 379,916. *It is estimated that 10 percent of children with asthma who are presently covered will newly use the benefit following the mandate.



APPENDIX A Literature Review Methods

Trials were identified from the MEDLINE (1983 – October 2003) and Cochrane databases, including the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials (CENTRAL). The scope of the literature search included effects of self-management education interventions for children with asthma, benefits of written self-management action plans, and effectiveness of peak flow–based written action plans. The search was limited to English abstracts and to children, defined as subjects aged 0-18 years. The review included clinical trials, controlled clinical trials, randomized controlled trials, meta-analyses, and systematic reviews. Trials that included any adults with asthma were excluded. Due to the difficulty of distinguishing between educational or self-management component was reviewed. At least two reviewers screened the title and abstract of each citation returned by the literature search to determine eligibility for inclusion. Full text articles were obtained and reviewers reapplied the initial eligibility criteria.

Through the literature search, a recent meta-analysis published in the Cochrane Database of Systematic Reviews was identified. The meta-analysis, titled "Educational Interventions for Asthma in Children," included 32 trials published between 1980 and 1998. Meta-analysis can be defined as a "quantitative statistical analysis that is applied to separate but similar experiments of different and usually independent researchers and that involves pooling the data and using the pooled data to test the effectiveness of the results" (Merriam-Webster). Results from the meta-analysis were given substantial weight in the decision-making process about the effectiveness of asthma education or self-management because the authors of the meta-analysis applied rigorous methodological criteria prior to the inclusion of each article.

To arrive at a consensus on the medical effectiveness of an educational intervention for children with asthma, a table was created for each outcome measure, such as number of school days absent or mean number of hospitalizations. However, due to a lack of sufficient evidence, the effectiveness of various components of educational self-management programs could not be determined, nor was it possible to determine that a specific intervention program was better than another.

Results from the meta-analysis and from each additional trial were organized into a table specific to each outcome. The outcomes tables were organized into three categories: outcomes with a health or health care impact, including the impact on quality of life and health care utilization; physiological outcomes, such as measures of lung function that are thought to affect a measurable health or health care impact; and process measures that should show a response if the intervention is "working" as it is expected to work, such as measures of respondents' knowledge of self-management behaviors.² In the third column of each table, the statistical significance of

² Especially for interventions in which it is difficult to have a "blinded placebo" control group that did not know whether they were receiving the intervention under study, it is possible that there is a "Hawthorne effect" in which merely being in the experiment produces results that are unrelated to the actual intervention. Thus, one might have a series of studies that show better asthma outcomes for children given the extra attention of an educational



the result was indicated in addition to whether the evidence demonstrates a medically favorable effect on the outcome. Of the primary trials selected, the results of randomized, clinical trials were given more weight than nonrandomized trials (because the latter may be subject to biased results). Only trials conducted in the United States were included in the review, because (1) "usual care" differs substantially across nations, and (2) expectations and support for school attendance, as well as health care use vary substantially. In the tables, the results of the meta-analysis are presented first, followed by the individual U.S. trials published subsequent to the meta-analysis.

Trials fell into two broad groupings. The first involved before and after comparisons of intervention and control groups, reporting four sets of measures. The second grouping provided "after" measures for intervention and control groups, implicitly assuming that the "before" values were the same because of adequate randomization and large samples. Results in individual trials are sometimes reported in "natural units," such as percent with a hospital stay or number of visits per year. Meta-analyses often combine the results of many trials and transform them into "unitless" measures, such as odds ratio or standardized mean differences and calculate the confidence intervals around these measures. Without detailed information for each of the trials included in the meta-analyses, it is impossible to reverse these calculations to get natural units. Thus, weighted averages were computed for the outcome measures without confidence intervals. In addition, the problem of heterogeneity of the interventions was recognized.

intervention relative to those without such an additional program. However, if the knowledge of the two groups of children is no different, it may be the extra attention that results in the improved outcomes.



APPENDIX B Summary of Findings on Effectiveness of Pediatric Asthma Self-Management and Training

In the tables below, results are categorized as being "favorable" (fav) for the intervention or "not favorable" (not fav). Results could be statistically significant (Sig) (meaning unlikely to have occurred just by chance) or not statistically significant (Ns), meaning that these results could have been obtained by chance more than 1 time in 20 even if there was no true difference. Based on the contents of these tables, the effectiveness of the education and self-management training interventions was evaluated and assigned one of five grades for each outcome: (1) favorable, (2) pattern toward favorable, (3) mixed evidence, (4) pattern toward no effect/weak evidence, and (5) unfavorable/no effect. ED indicates emergency department; FEV₁, forced expiratory volume (a measure of lung function); int, intervention; OR, odds ratio; PEFR, peak expiratory flow rate; RCT, randomized controlled trial; RR, relative risk; SMD, standardized mean differences.

** Trial was included in the meta-analysis (Wolf et al., 2003)

Meta-analysis (1 trial)	OR 0.78 [0.36, 1.66]	Ns, fav
Estimated impact	43% reduction	
from U.S. trials		
Guendelman 2002	42.8% reduction in percent who missed school in	Ns, fav
	past 6 weeks in the intervention group compared	
	with controls	
Georgiou 2003 (non-	$36\% \rightarrow 23\%$ (missed 1 or more days in past	Sig, fav
RCT)	month)	

School Absences (% patients) – pattern toward favorable

Meta-analysis (16 trials)	SMD -0.14 [-0.23, -0.04]	Sig, fav
Estimated impact	44% reduction	
from U.S. trials		
Krishna 2003	Intervention: pre 7.9 \rightarrow post 1.4, control: pre 6.4	Sig, fav
	\rightarrow post 5.4	
Fireman 1981**	Mean intervention post 0.5, control post 4.6	Sig, fav
Christiansen 1997**	Mean intervention post 2.39, control post 2.98	Ns, fav
Persaud 1996**	Intervention post 6.4, control post 7.6	Ns, fav
Wilson 1996**	Sick days in 1 month – intervention pre 1.0 \rightarrow post	Ns, fav
	0.8, control pre 0.7 \rightarrow post 1.4	
Perrin 1992**	No/month - intervention pre 0.73 \rightarrow post 0.24,	Ns, fav
	control pre 0.14 \rightarrow post 0.22	
Evans 1987**	Absences/year: intervention pre 21.3 \rightarrow post 19.4,	Ns, fav
	control pre 20.8 \rightarrow post 19.7	
Rubin 1986**	Intervention pre 13.0 \rightarrow post 14.1, control pre 17.0	Ns, fav
	\rightarrow post 18.6	

School Absences (mean days) – favorable



Restricted Activity (% children with asthma) – favorable

Estimated impact from U.S. trials	25% proportionate reduction	
Guendelman 2002	Intervention pre 66.7% \rightarrow post 32.3%, control pre 72.1% \rightarrow post 46.7%	Sig, fav

Emergency Department Visits (mean) – strong pattern toward favorable

Meta-analysis (12	SMD -0.21 [-0.33, -0.09]	Sig, fav
	[-0.21 [-0.35, -0.09]]	51g, 1av
trials)		
Estimated impact	26% reduction	
from U.S. trials		
Krishna 2003	Intervention pre 2.0 \rightarrow post 0.1, control pre 1.2 \rightarrow	Sig, fav – both
	post 0.6	groups
Harish 2001	Mean number of ED visits per patient/month:	Sig, fav
	Intervention post 0.101, control post 0.326	
Homer 2000	Mean/year: Intervention pre 2.14 \rightarrow 0.86, control	Sig, fav for both
	pre 2.24 \rightarrow post 0.73	groups. Ns between
		groups
Kelly 2000 (non-	Mean/year: Intervention pre 3.6 \rightarrow post 1.7,	Sig, fav
RCT)	control pre 3.5 \rightarrow post 2.3. Control RR 1.4.	0,
Greineder 1999	Intervention pre 1.55 \rightarrow post 0.41, control pre 1.57	Sig, fav for both
	\rightarrow post 0.96	groups. Sig, fav
	- P	between groups
Alexander 1988**	Intervention pre 2.6 \rightarrow post 0.6, control pre 2.5 \rightarrow	Sig, fav
	post 2.4	
Bartholomew 2000	Intervention pre 2.0 \rightarrow post 1.3, control pre 1.9 \rightarrow	Ns, fav
	post 1.2, effect size 0.03	
Clark 1986**	Intervention pre 1.72 \rightarrow post 1.18, control pre 2.49	Ns, fav
	\rightarrow post 2.34	, ,
Rubin 1986**	Acute visits due to asthma: Intervention pre 5.2 \rightarrow	Ns, fav
	post 2.4, control pre 5.6 \rightarrow post 4.9	
Lewis 1984**	Intervention pre 3.68 \rightarrow post 2.30, control pre 3.04	Ns, fav
	\rightarrow post 3.71	, ,
Fireman 1981**	Intervention post 0.08, control post 1.00	Ns, fav
Christiansen 1997**	Mean per subject year: Intervention post 0.304,	Ns, not fav
	control post 0.197	
Shields 1990**	Intervention post 0.54, control post 0.38	Ns, not fav

Hospitalizations (mean) – pattern toward favorable

Meta-analysis (8	SMD -0.08 [-0.21, 0.05]	Ns, fav
trials)		
Estimated impact	30% reduction	
from U.S. trials		
Bartholomew 2000	Mean/year: Intervention pre $0.7 \rightarrow$ post 0.4, control	Sig, fav
	pre 0.6 \rightarrow post 0.5. Effect size = -0.14	



Kelly 2000 (non- RCT)	Intervention pre 0.6 \rightarrow post 0.2, control pre 0.53 \rightarrow post 0.48, control RR 2.4	Sig, fav
Greineder 1999	Intervention pre 0.86 \rightarrow post 0.14, control pre 1.00 \rightarrow post 0.57	Sig, fav for both groups. Sig, fav between groups
Krishna 2003	Intervention pre 0.1 \rightarrow post 0.1, control pre 0.6 \rightarrow post 0.1.	Sig, fav – control group. No effect for int
Harish 2001	Intervention post 0.37, control post 0.42	Ns, fav
Christiansen 1997**	Mean per subject-year: Intervention post 0.027, control post 0.254	Ns, fav
Clark 1986**	Intervention pre 0.11 \rightarrow post 0.09, control pre 0.21 \rightarrow post 0.17	Ns, fav
Lewis 1984**	Child/year: Intervention post 0.27, control post 0.60	Ns, fav
Fireman 1981**	Intervention post 0, control post 0.31	Ns, fav

Physician Visits - weak effect

Physician Visits – wea		1
Estimated impact	No substantive effect	
from U.S. trials		
Urgent/unscheduled		
visits		
Krishna 2003	Urgent visits to physician: Intervention pre 6.6 \rightarrow	Sig, fav for both
	post 0.8, control pre 6.4 \rightarrow post 0.6	groups
		No substantive
		difference between
		groups
Brown 2002	Acute asthma care: Intervention pre 5.04 \rightarrow post	Sig, fav (acute
	2.71, control pre 4.52 \rightarrow post 2.80	asthma, regardless
		of site)
Homer 2000	Mean acute office visits: Intervention pre $0.91 \rightarrow$	Sig, fav for both
	post 0.93, control pre 0.96 \rightarrow post 0.77	groups.
		Ns, not fav
		between groups
Evans 1987**	Episodes requiring a visit to a physician:	Ns, fav
	Intervention pre 4.3 \rightarrow post 3.6, control pre 3.8 \rightarrow	No substantive
	post 3.3	difference between
	-	groups
Lukacs 2002 (non-	1 or more acute outpatient visit RR 1.16 [0.70,	Ns, not fav – acute
RCT)	1.84]	asthma outpatient
		visit (w/nebulized
		beta-agonist
		treatment given)



Not distinguished as to type of visit		
Meta-analysis (6 trials)	SMD -0.15 [-0.31, 0.01]	Ns, not fav
Rubin	Intervention mean 2.80, control mean 4.5	Ns, not fav
Shields 1990**	Mean office visits – intervention post 1.63, control post 1.86	Ns, fav

Medications: Inhaled Corticosteroids, Cromolyn, Nedocromil

Lukacs 2002 (non-	Intervention group received more than 1	Sig, fav
RCT)	dispensing of inhaled corticosteroid compared with	
	controls: RR 1.41	
Krishna 2003	Daily dose of inhaled corticosteroids: Intervention	Sig, fav btw groups
	pre 353.09 \rightarrow post 433.51 ug, control pre 350.53 \rightarrow	(fav for int)
	post 753.88	
Bonner 2002	Prescribed inhaled corticosteroids: Intervention pre	Corticosteroids- Sig,
	54% \rightarrow post 70%, control pre 44% \rightarrow post 38%.	fav for int
	50% increase. Prescribed cromolyn: Intervention	Cromolyn – Ns, fav
	pre 26% \rightarrow post 24%, control pre 36% \rightarrow post	
	36%	

FEV₁ – weak evidence toward favorable

Meta-analysis (1 trial)	SMD 0.46 [0.08, 0.84]	Sig, fav
Yoos 2002	Spirometry (FEV ₁ % predicted mean) 1) pre 88 \rightarrow post 90 2) pre 87 \rightarrow post 94 3) pre 83 \rightarrow post 88	Ns, fav

Days of Asthma Symptoms - favorable

Krishna 2003	Intervention pre104.5 \rightarrow post 23.9, control pre 97.8 \rightarrow post 48.2	Sig, fav – both groups
Bonner 2002	Symptom persistence – effect size 0.71	Sig, fav
Yoos 2002	Mean # days/week of symptoms, baseline and in 3 months: 1) pre 2.83 \rightarrow post 2.87, 2) pre 2.87 \rightarrow post 2.00 3) pre 3.19 \rightarrow post 2.68	Sig, fav for group 2 (PEFR vs. symptoms). Ns, fav for group 3
Evans 1987**	Annual days w/ asthma symptoms: Intervention pre 31.9 \rightarrow post 18.1, control pre 28.3 \rightarrow post 30.3	Sig, fav
Fireman 1981**	Average # of wheezing days/patient/month: Intervention post 3.1, control post 4.6	Ns, fav

Nights of Nocturnal Asthma – favorable

Meta-analysis (3	SMD -0.34 [-0.62, -0.05]	Sig, fav
trials)		
Georgiou 2003 (non-	Symptoms improved 5.8 (scale 0-100)	Sig, fav
RCT)		_
Krishna 2003	Nights of sleep disturbance: Intervention pre 64.7	Sig, fav – both



	\rightarrow post 15.2, control pre 62.0 \rightarrow post 17.1	groups
Wilson 1996**	Parental nights of sleep interruption/week:	Sig, not fav
	Intervention pre 0.6 \rightarrow post 1.3, control pre 0.8 \rightarrow	compared to
	post 2.6	baseline, fav
		compared to
		controls

Peak Expiratory Flow Rate – pattern toward favorable

Meta-analysis (3	SMD 0.53 [0.19, 0.86]	Sig, fav
trials)		
Guendelman 2002	PEF in yellow or red zone – OR – 0.43	Sig, fav
Christiansen 1997**	Intervention pre 261.04 \rightarrow post 331.37, control pre	Ns, fav
	$272 \rightarrow \text{post } 313.53$	

Exacerbations (mean) – pattern toward favorable

Meta-analysis (5 trials)	SMD -0.21 [-0.43, 0.01]	Ns, fav
Evans 1987**	 Average annual # episodes: Intervention pre 10.6 → post 9.0, control pre 10.1 → post 11.8 Average duration of episodes (days): Intervention pre 2.77 → post 1.87, control pre 2.85 → post 2.40 	Sig, fav. Sig, fav
Fireman 1981**	Average # of attacks/patient/month: Intervention post 1.5, control post 5	Sig, fav
Whitman 1985**	Preschool children: Intervention post 10.10 → post 5.14. School-age children: Intervention pre 11.05 → post 6.26, control pre 7.84 → post 4.47	Pre-school – Sig, fav School-age – Ns, fav (int). Sig, fav (control)
LeBaron 1985**	Frequency of attacks (0=constant, 10=none): Intervention pre 9.13 → post 8.87, control pre 8.31 → post 8.75	Ns, not fav

Asthma Severity – pattern toward favorable

notimia octomy pa		
Meta-analysis (4	SMD -0.15 [-0.43, 0.12]	Ns, fav
trials)		
Georgiou 2003 (non-	Intervention pre 66.9% \rightarrow post 75.3% moderate	Sig, fav
RCT)	asthma	
Homer 2000	Severity based on NIH criteria, 0=mild, 2=severe:	Sig, fav for both
	Intervention pre 1.11 \rightarrow post 0.94, control pre 1.05	groups. Ns between
	\rightarrow post 0.78,	groups
Perrin 1992	Functional measures: Daily chores (no/week):	Chores sig, fav.
	Intervention pre 15.3 \rightarrow post 19.5, control pre 17.2	Other measures- ns,
	\rightarrow post 17.6	fav
	Time playing with friends (hr/wk): Intervention pre	
	8.1 \rightarrow post 11.1, control pre 10.2 \rightarrow post 11.5	



		,
	After-school activities (no/wk): Intervention pre	
	$3.4 \rightarrow \text{post 4.5, control pre 5.7} \rightarrow \text{post 4.7}$	
Harish 2001	Severe asthma: Intervention pre $26.5\% \rightarrow \text{post}$	Sig, not fav
	35.0%, control pre 19.8% \rightarrow post 16.18%	
Huss 2003	Patients w/moderate or severe asthma:	Ns, fav
	Intervention pre $26/56 \rightarrow \text{post } 19/56$, control pre	
	17/45 → post 9/45	
Yoos 2002	Mean scores: group 1) pre 1.7 \rightarrow post 1.56, group	Ns, fav
	2) pre 1.85 \rightarrow post 1.49, group 3) pre \rightarrow post 1.50	
Bartholomew 2000	Functional status: Intervention pre 138.0 \rightarrow post	Ns, fav
	139.6, control pre 136.5 \rightarrow post 137.3, effect size =	
	0.16	
Wilson 1996**	Degree to which child was bothered by symptoms:	Ns, fav
	Intervention pre 2.7 \rightarrow post 2.3, control pre 2.6 \rightarrow	
	post 2.3	
LeBaron 1985**	Asthma severity (0=severe, 10=none):	Ns, fav
	Intervention pre 8.6 \rightarrow post 8.87, control pre 6.81	
	\rightarrow post 8.81	
Whitman 1985**	Preschool children (Intervention): Days of no	Preschool kids – no
	asthma: pre 69.37 \rightarrow post 69.62. Days of mild	asthma ns, fav. Mild
	asthma: pre 18.67 \rightarrow post 17.62. Days of moderate	asthma – ns, fav.
	asthma: pre 5.52 \rightarrow post 5.10. Days of severe	Moderate asthma –
	asthma: pre 1.76 \rightarrow post 0.81	ns, fav. Severe
	School-age children: days of no asthma:	asthma –sig, fav.
	Intervention pre 68.26 \rightarrow post 70.56, control pre	
	$63.74 \rightarrow \text{post } 72.21$. Days of mild asthma:	School-age children
	1 5	– no asthma ns, fav.
	Intervention pre 16.53 \rightarrow post 13.59, control pre	Mild asthma ns, fav.
	$13.74 \rightarrow \text{post } 12.95$. Days of moderate asthma:	Moderate asthma ns,
	Intervention pre 7.21 \rightarrow post 6.00, control pre	fav. Severe asthma
	$9.05 \rightarrow \text{post } 7.79$. Days of severe asthma:	–ns, not fav.
	Intervention pre 0.79 \rightarrow post 1.84, control pre 1.26	
	\rightarrow post 0.63	

Symptom-Free Days - favorable

Brown 2002	Intervention pre 42 \rightarrow post 101, control pre 33 \rightarrow	Sig, fav for younger
	post 91	children, not for
		older children
Wilson 1996**	In 2 weeks: Intervention pre 8.5 \rightarrow post 10.2,	Sig, fav. Sig, fav
	control pre 11.9 \rightarrow post 9.3. For 1 month:	
	Intervention pre 20.2 \rightarrow post 22.2, control pre 24.6	
	\rightarrow post 20.8	

Symptom Scores - favorable

Brown 2002	(Scale: 1=not bothered, 7=extremely bothered):	Sig, fav for younger,
	Intervention pre 2.50 \rightarrow post 1.63, control pre 2.47	no treatment effect
	\rightarrow post 1.74. Effect size 13%-15%	for older children

Christiansen 1997**	Mean: Intervention post 2.87, control post 4.36	Sig, fav
Bartholomew 2000	Intervention pre 60.4 \rightarrow post 65.8, control pre 60.3	Ns, fav
	\rightarrow post 64.9. Effect size 0.10	

Quality of Life – Child – pattern toward favorable

Georgiou 2003 (non-	Scale 0-100: graph provided, no data available	Sig, fav
RCT)		
Perrin 1992	Child Behavior Checklist:	Sig, fav
	total problems score: Intervention pre 60.8 \rightarrow post	
	54.4, control pre 57.7 \rightarrow post 55.0	
Evans 1987**	Positive feelings about asthma (% change):	Sig, fav
	Intervention 6%, control -4%	
Fireman 1980**	Illness anxiety: Intervention pre 8.4 \rightarrow post 7.4,	Sig, fav
	control pre 9.1 \rightarrow post 9.2	

Quality of Life –Caregiver – pattern toward favorable

Brown 2002	Scale 1-2, 1= never bothered: Intervention pre 1.77	Sig, fav for younger
	\rightarrow 1.35, control pre 1.83 \rightarrow post 1.50. Effect size	children
	13-18% for younger children	Ns for older
		children

Self-Efficacy - favorable

Sell-Efficacy - lavoia		
Meta-analysis (6 trials)	SMD 0.36 [0.15, 0.57]	Fav
Bonner 2002	Intervention 41% increase, control 9% increase. Effect size 1.28	Sig, fav
Shegog 2001	F=4.45	Sig, fav
Evans 1987**	Self-efficacy index (% change): Intervention 3%, control 0%	Sig, fav
Rubin 1986**	Asthma Behavioral Assessment (child total score): Intervention post 54.1, control post 57.8	Sig, fav
Whitman 1985**	Skills (self-care) difference between control and intervention groups after 3 months = 11.84	Sig, fav
Kubly 1984**	Children's Health Locus of Control - F=4.29	Sig, fav.
	Self-Care Activity Questionnaire for Asthmatic children - F=1.25	Ns, fav
Parcel 1980**	Health locus of control: Intervention pre 29.0 \rightarrow post 30.2, control pre 27.1 \rightarrow post 27.5	Sig, fav
Bartholomew 2000	Intervention pre 74.3 \rightarrow post 75.3, control pre 72.0 \rightarrow post 73.6, effect size = 0.06	Ns, fav
LeBaron 1985**	Overall control of asthma (0=very poor, 10=excellent) Intervention pre 6.23 \rightarrow post 6.93, control pre 6.50 \rightarrow post 6.91	Ns, fav



Knowledge – Child – favorable

Krishna 2003	Intervention: aged 7-17 pre 43.11 \rightarrow post 53.12,	Sig, fav – both
	control: aged 7-17 pre 43.44 → post 47.51	groups
Bonner 2002	Effect size 1.09	Sig, fav
Homer 2000	Intervention pre 60 \rightarrow post 77, control pre 57 \rightarrow post 63	Sig, fav for both groups. Sig, fav
		between groups
Christiansen 1997**	Intervention pre 9.9 \rightarrow post 13.7, control pre 11.3 \rightarrow post 10.9	Sig, fav
Rubin 1986**	Change in % correct : Intervention 14.4, control 2.0	Sig, fav
LeBaron 1985**	Patient knowledge of cromolyn: Intervention pre 9.00 \rightarrow post 11.93, control pre 9.00 \rightarrow post 10.63	Sig, fav
Whitman 1985**	Intervention pre 5.63 \rightarrow post 8.47, control pre 5.68 \rightarrow post 6.42	Sig, fav
Parcel 1980**	Grades K-2: Intervention pre $13.07 \rightarrow \text{post } 14.62$, control pre $11.58 \rightarrow \text{post } 12.19$. Grades 3-5:	Sig, fav. Sig, fav.
	Intervention pre 14.19 \rightarrow post 15.96, control pre 13.95 \rightarrow post 14.10	
Shegog 2001	F for intervention pre and post = 37.87, but no between-group differences	Ns, fav
Bartholomew 2000	Intervention pre 13.7 \rightarrow post 16.4, control pre 4.0 \rightarrow post 15.8, effect size = 0.17	Ns, fav
Persaud 1996**	Change: Intervention 1.8, control 1.9	Ns, fav
Perrin 1992	Intervention pre 11.76 \rightarrow post 13.76	Ns, fav
Lewis 1984**	% correct: Intervention pre $66\% \rightarrow \text{post } 61\%$, control pre 74% $\rightarrow \text{post } 71\%$	Ns, no effect

Knowledge – Caregiver - favorable

8 8		
Krishna 2003	Intervention caregivers for children 0-6: pre 47.94	Sig, fav –all groups
	\rightarrow post 55.68. Caregivers for children 7-17: pre	
	49.95 \rightarrow post 55.38. Control caregivers for	
	children 0-6: pre 48.41 \rightarrow post 52.30. For	
	caregivers for children 7-17: pre 49.57 \rightarrow post	
	51.70	
Persaud 1996**	Change: Intervention 1.9, control 2.6	Ns, fav



APPENDIX C Summary of Interventions Reviewed

Author, Year, Intervention Versus Comparison Group, Characteristics (and Location) of Groups Studied ** Trial was included in the meta-analysis (Wolf et al., 2003)

- Georgiou 2003. Education and management (w/peak flow meter) versus (no control) pediatric asthmatic members and caregivers of UnitedHealthcare (national health care organization).
- 2) Huss 2003. Education and computer-based instructional asthma game v. education but participants were inner-city children in Baltimore, MD.
- Krishna 2003. Internet-enabled, interactive multimedia asthma education and conventional education, management (w/action plan) versus conventional education, management (w/action plan) – participants were children who visited pediatric pulmonary clinic in Missouri.
- Bonner 2002. Education and management (diary, peak flow meter) versus usual care almost 85% of families received Medicaid or had no insurance, urban families - New York.
- 5) Brown 2002. Education versus usual care over 80% received Medicaid (84% intervention group) in metro Atlanta.
- 6) Burkhart 2002. Behavioral enhancement, education, management (peak flow meter) versus education, management (peak flow meter) predominantly Caucasian, middle-income families in West Virginia.
- 7) Guendelman 2002. Education and management w/Health Buddy versus asthma diary intervention 92% public, 8% private. Control group 93% public, 6% private, conducted in Oakland, CA.
- 8) Lukacs 2002. Education, management (written action plan) versus usual care Kaiser Permanente Colorado members.
- 9) Yoos 2002. Education, management (symptoms) versus education, management (w/peak expiratory flow rate monitoring) – recruited from diverse primary care settings – New York.
- 10) Burkhart 2001. Behavioral strategies, education, management (peak flow) versus education, management (peak flow) – families predominantly middle to high incomes in West Virginia.
- 11) Harish 2001. Asthma clinic (w/education, action plan) versus usual care low-income, inner-city population in New York (Bronx).
- 12) Shegog 2001. Computer-assisted instruction game designed to teach self-management versus conventional education Texas.
- 13) Bartholomew 2001. Computer-assisted instructional game (self-management education) versus usual care total sample, 6.8% HMO, 6.8% Medicare, 48.3% Medicaid, 6.8% self-pay, 31.4% none inner-city Texas.
- 14) Homer 2000. Educational computer game (designed to teach management) versus written education 13.3% total sample had private insurance, urban youth in Boston.
- 15) Kelly 2000. Education in clinic and management (w/written action plan) versus usual care all children were covered by Medicaid Norfolk, VA.



- 16) Greneider 1999. Education, management (action plan), follow-up versus education, management – selected from urban health centers of Harvard Pilgrim Health Care (health maintenance organization) in New England.
- 17) Christiansen 1997.** Education, management versus usual care inner-city San Diego, CA.
- 18) Persaud 1996.** Education, management, versus usual care 69% Medicaid Galveston, TX.
- 19) Wilson 1996.** Education, management versus usual care St. Paul, MN.
- 20) Perrin 1992. Education and stress management program versus usual care predominantly white, middle- to upper-class, Boston, MA.
- 21) Shields 1990.** Education versus usual care drawn from urban health maintenance organization in Chicago.
- 22) Alexander 1988.** Education, management, versus usual care no consistent source for asthma management other than emergency room (primarily low income) Tennessee.
- 23) Evans 1987.** School-based education, management versus usual care low-income (71% received Medicaid or other public assistance) New York City.
- 24) Clark 1986.** Education, management versus usual care low-income urban children New York City.
- 25) Rubin 1986.** Educational asthma computer game versus brief verbal instructions children were patients at Yale-New Haven Hospital, Hospital of St. Raphael, Yale Health Plan (university-based health maintenance organization), Community Health Care Plan (private health maintenance organization), or private pediatrician's office. New Haven, CT.
- 26) LeBaron 1985.** Education versus usual care patients at private pediatric allergy practices in San Antonio, TX. Low- to middle-income or greater.
- 27) Rakos 1985.** Education, management versus usual care.
- 28) Whitman 1985.** Education, management versus usual care (school-age), preschool (no control) referred by private physicians Utah.
- 29) Kubly 1984.** Education, management versus usual care southwestern United States
- 30) Lewis 1984.** Education, management versus usual care patients of the Southern California Permanente Medical Group Los Angeles, CA.
- 31) Fireman 1981.** Education, management versus usual care selected from pediatric allergist's office practice and Allergy Clinic of Children's Hospital of Pittsburgh, PA.
- 32) Parcel 1980.** School-based education versus usual care Galveston, TX.

APPENDIX D 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
	U
	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 percentage change in premiums. These same percentage 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.

Large-Group HMO Large-Group PPO Large-Group POS Large-Group FFS Small-Group HMO Small-Group PPO Small-Group POS Small-Group FFS	Administrative/Profit Expenses as a Percent of Total Insured Premiums 15% 17% 16% 17% 20% 22% 21% 22%
Small-Group FFS Individual	22% 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 assumption underlie discussions in the Utilization, Cost, and Coverage Impact section of this report, specifically as it related to:

- Current coverage of pediatric services (see Table 1)
- Percentage of insured children in California with symptomatic asthma
- Current utilization rate and average costs for asthma treatment and education procedures
- Post-mandate utilization rate for asthma treatment and education procedures
- Reduction in other healthcare costs due to fewer inpatient days and emergency room visits for new children receiving treatment and education.

Children with "symptomatic asthma" are assumed to be those affected by the mandate.

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California Health Benefits Review Program Committees and Staff

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

Faculty Task Force

Helen Halpin, PhD, Vice Chair for Public Health Impacts, University of California, Berkeley Gerald Kominski, PhD, Vice Chair for Financial Impacts, University of California, Los Angeles

- Harold Luft, PhD, Vice Chair for Medical Effectiveness, University of California, San Francisco
- Wayne S. Dysinger, MD, MPH, Loma Linda University Medical Center

Theodore Ganiats, MD, University of California, San Diego

Sheldon Greenfield, MD, University of California, Irvine

Richard Kravitz, MD, University of California, Davis

Thomas MaCurdy, PhD, Stanford University

Thomas Valente, PhD, University of Southern California

Other Contributors

Wade Aubry, MD, University of California, San Francisco Patricia Franks, University of California, San Francisco Miriam Laugesen, PhD, University of California, Los Angeles Sara McMenamin, PhD, University of California, Berkeley Nadereh Pourat, PhD, University of California, Los Angeles Edward Yelin, PhD, University of California, San Francisco



National Advisory Council

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

John Bertko, FSA, MAAA, Vice President and Chief Actuary, Humana, Inc., Oakland, CA

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

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

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- Michael Pollard, JD, MPH, Consultant, Federal Policy and Regulation, Medco Health Solutions, Washington, DC
- Christopher Queram, Chief Executive Officer, Employer Health Care Alliance Cooperative, Madison, WI
- Richard Roberts, MD, JD, Professor of Family Medicine, University of Wisconsin-Madison, Madison, WI
- Frank Samuel, LLB, Science and Technology Advisor, Governor's Office, State of Ohio, Columbus, OH
- Roberto Tapia-Conyer, MD, MPH, MSc, Senior Professor, National University of Mexico, Cuauhtémoc, Mexico

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

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

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

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

CHBRP Staff

Michael E. Gluck, PhD, DirectorCalifornia Health Benefits Review
ProgramRebecca R. Paul, MPH, MA,
Manager/Principal Analyst1111 Franklin Street, 11th Floor
Oakland, CA 94607Susan Philip, MPP, Principal AnalystTel: 510-287-3878 Fax: 510-987-9715Jill Hedgepeth, Administrative Assistantinfo@chbrp.org

The California Health Benefits Review Program is administered by the Division of Health Affairs at the University of California Office of the President, Michael V. Drake, MD, Vice President.

