CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 2185
Childhood Asthma Management

A Report to the 2003-2004 California Legislature
April 14, 2004
Revised October 8, 2004

CHBRP 04-09

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 2185, a bill to mandate that all health care service plans regulated and licensed by the California Department of Managed Care that provide an outpatient prescription drug benefit also cover self-management training and education as well as three medical devices (peak flow meters, nebulizers, and spacers) for children with asthma. In response to a request from the California Assembly Committee on Health on March 4, 2004, 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, Inc., provided actuarial analysis. Other contributors include Patricia Franks and Noelle Lee, both of UCSF, and Susan Philip, MPP, of CHBRP staff. Katrina Mather, freelance editor, copy edited this report. In addition, a balanced subcommittee of CHBRP's National Advisory Council (see final pages of this report), reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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Michael E. Gluck, PhD
Director

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 2185

Assembly Bill 2185 would require that all health care service plans regulated and licensed by the California Department of Managed Care that provide an outpatient prescription drug benefit also cover self-management training and education as well as three medical devices (peak flow meters, nebulizers, and spacers) for children with asthma. Asthma is a chronic inflammatory disease of the airways that affects approximately 350,000 children enrolled in California health plans that are licensed by Knox-Keene[*] and that cover outpatient prescription drugs. 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 and the use of peak flow meters, nebulizers, and spacers on asthma-related public health and health services utilization outcomes for children with symptomatic asthma as well as the effect of covering 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 related trials published since 1998 as well as from clinical trials conducted on the effectiveness of the three mandated medical devices (peak flow meters, nebulizers, and spacers) find the following:

- The asthma programs in these trials 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 in 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, 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 of self-management interventions were found on the number of physician visits for children with asthma.

- A review of the clinical trials specifically conducted on the effectiveness of the three mandated medical devices found there is inadequate evidence to determine the

[*] 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.

effectiveness of using spacers in children. The findings indicate there is no evidence that spacers are more efficacious than correctly used metered-dose inhalers (MDIs) alone. However, national guidelines recommend the use of spacers for children who have difficulties in using standard MDIs. Evidence from controlled trials demonstrates clinical equivalence for using nebulizers compared with using spacers with MDIs. However, the national guidelines recommend the use of nebulizers for patients of any age who cannot use an MDI with a spacer or a spacer and face mask. This analysis could not determine the clinical efficacy of peak flow meters themselves, as such meters will not have any clinical benefit when divorced from asthma self-management training and education.

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 medical devices.

- 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. Patient education materials (98%), prescription asthma medications (92%), group health education (91%), spacers and nebulizers (94%), and peak flow meters (75%) are also extensively covered.

- The greatest changes in utilization resulting from the mandate would be in increased use of pediatric self-management training and education programs and decreases in asthma-related emergency room visits and hospitalizations. Utilization of asthma self-management training and education and associated medical devices is estimated 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 evidence from the medical effectiveness review suggests that the mandate could reduce mean hospitalizations by 30% and mean emergency room visits by 26% for children with symptomatic asthma.

- The mandate would have a small impact on commercial HMO and POS costs. Total net expenditures (including total premiums and out-of-pocket costs) would increase by 0.007% in both the large- and small-group markets and the individual market. The savings associated with reduced emergency room and hospital utilization is estimated to offset total expenditures by 0.002% (approximately 22% 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 a 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 would 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 that 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 including training on the use of medical devices 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 these programs could result in up to 18,500 fewer days of school missed each month due to asthma. In addition, the evidence suggests that the mandate could reduce the percentage of children with restricted-activity days by up to 25%, or for approximately 6,200 children.

- Self-management programs could reduce acute episodes of childhood asthma. Based on the evidence, the analysis estimates there could be up to approximately 360 fewer asthma-related emergency department visits and 115 fewer asthma-related hospitalizations each year as a result of the mandate. Other estimated 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 would increase knowledge about asthma and its management for both children and their caregivers and would lead to improvements in the lives of children with symptomatic asthma and of 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 NAEPP guidelines are a set of consensus recommendations and are not evidence-based. The goals of asthma management as described by the NAEPP include 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 self-management training and education.

Assembly Bill (AB) 2185 would require that all health care service plan contracts that cover outpatient prescription drugs must also cover self-management training and education for treating pediatric asthma as well as three medical devices (peak flow meters, nebulizers, and spacers).

The proposed mandate would apply to all insured children (aged 0-17 years) with symptomatic asthma who are enrolled in a health maintenance organization (HMO) or point-of-service plan

(POS) plan licensed by Knox-Keene in California that covers outpatient prescription drugs. Combining data from the 2001 California Health Interview Survey (CHIS, 2001 data) with estimates from commercial databases maintained by Milliman USA, the mandate is estimated to cover approximately 350,000 children with symptomatic asthma in California who are enrolled in plans licensed by Knox-Keene.

The California Legislature has asked the California Health Benefits Review Program (CHBRP) to describe the available evidence regarding the effect of self-management training and education and the use of peak flow meters, nebulizers, and spacers on public health, health care costs, and the health of children with asthma.

A previous CHBRP report on AB 1549, introduced in the first year of the 2003-2004 session of the California Legislature, was delivered to the Legislature in February 2004. AB 2185 is similar to AB 1549 in its mandate for coverage of pediatric asthma self-management training and education, but it differs in three important ways. First, AB 2185 does not mandate coverage for prescription and over-the-counter medications for the treatment of pediatric asthma. Second, AB 2185 mandates coverage for three medical devices: peak flow meters, nebulizers, and spacers. Third, AB 2185 does not apply to all Knox-Keene–licensed full-service health plans, but applies only to those plans that cover outpatient prescription drugs. These differences between AB 2185 and AB 1549 influence both the number of children with asthma who would be affected by the mandate as well as the impact on health care expenditures and the public's health.

I. MEDICAL EFFECTIVENESS

The results of the review of the scientific research on the medical effectiveness of pediatric asthma 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 self-management interventions, any trial in which the intervention included an educational or self-management 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 to 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.

In addition, a review of the scientific research on the medical effectiveness of peak flow meters in monitoring pediatric asthma and the medical effectiveness of nebulizers and spacers as delivery devices for asthma medications for children was conducted.

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": few relevant findings, such that it is difficult to discern a pattern

A 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 complete list of all of the trials reviewed can be found in the References.

Self-Management Training and Education

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 (Krishna et al., 2003; Bonner et al., 2002; 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 self-management 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; Homer et al., 2000; LeBaron et al., 1985; Whitman et al., 1985); 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) that 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 other trials 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 included in the meta-analysis found statistically significant and favorable effects only for preschool children with severe asthma (Whitman et al., 1985), indicating reduced asthma severity following self-management 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 that were conducted in the United States (Evans et al., 1987; LeBaron et al., 1985; Whitman et al., 1985; Fireman et al., 1981) 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 preschool children but not school-aged 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 toward weak or no effect 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 meta-analysis included one trial conducted in the United States (Christiansen et al., 1997) that found that pediatric asthma self-management training and education improved PEFR by a statistically significant amount. One post–meta-analysis trial was identified that also found 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

Of the two U.S. trials reviewed that addressed nocturnal asthma, 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 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 a 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 meta-analysis, which included seven U.S. trials, found that the interventions had a statistically significant effect in reducing school absences (Christiansen et al., 1997; Persaud et al., 1996; Wilson et al., 1996; Perrin et al., 1992; Evans et al., 1987; Rubin et al., 1986; Fireman et al., 1981). 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., 2002) 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 trial also 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 (Christiansen et al., 1997; Shields et al., 1990; Alexander et al., 1988; Clark et al., 1986; Rubin et al., 1986; Lewis et al., 1984; Fireman et al., 1981). 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., 2001; 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 relevant 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. trial (2003), 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 postintervention rate for both the intervention and control groups was 0.1.

Overall, the evidence suggests 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 (Krishna et al., 2003; Bonner et al., 2002; Lukacs 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., 2003; Brown et al., 2002; Homer et al., 2000) 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., 2003; 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, 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.

Quality-of-life effects

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 self-management training and education intervention (Perrin et al., 1992; Evans et al., 1987; Fireman et al., 1981). 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 self-management 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 1-3 years). The evidence suggests a pattern toward a

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

Medical Devices

This section reviews the scientific evidence for the effectiveness of three medical devices (spacers, nebulizers, and peak flow meters) in treating and managing pediatric asthma. The methods used for the literature review are described in Appendix A. In addition, tables listing and summarizing the findings from each of the trials reviewed are presented in Appendix B. The outcomes that were reviewed include physiological measures of lung function (forced expiratory volume in one second [FEV1], peak expiratory flow, and forced expiratory flow [FEF] 25%-75%), health care utilization (unscheduled medical visits and hospital admissions), and public health impact (missed days of school). FEV1 is defined as the volume of air expired in the first second of maximal expiration after a maximal inspiration. PEFR is the maximum flow at the outset of forced expiration, which is reduced in proportion to the severity of airway obstruction. FEF 25% to 75% is the forced expiratory flow in the middle half of an expiration and also indicates any obstruction in the airways.

Many of the trials reviewed had small sample sizes. Three of the four clinical trials on spacers, for example, had fewer than 35 participants. Because of the small sample sizes, even if one device was truly more effective than another, it might not be possible to detect a statistically significant difference in effectiveness. The trials assessed many types of metered-dose inhalers (MDIs), spacers, nebulizers, and medications, making it more difficult to quantify any overall change in outcome measures. Sometimes meta-analysis is used to combine results of many different small trials, but because of the differences in the devices and medications used and the outcomes measured across trials, a meta-analysis was not possible for this report. Given these constraints on quantifying the effectiveness of these devices, this analysis reviews the evidence qualitatively.

Furthermore, because almost all of the trials were conducted in a controlled setting where a health care professional delivered the medication using one of the devices, children and their parents using self-administered devices may not experience the same level of health benefits on their own. Thus, the efficacy of the devices identified in the trials would likely decrease for children using MDIs with spacers or nebulizers at home.

Finally, the effectiveness of asthma medication delivery devices and peak flow meters cannot be separated from pediatric asthma self-management training and education. A child and parent who are given a spacer device without instruction will not be able to use it properly. Similarly, a young child and parent given a peak flow meter will not understand the meaning of the peak flow readings without training and education. According to the American Academy of Allergy, Asthma and Immunology, “For all devices, education and training of patients, and family or professional caregivers who administer these medications to patients, for the proper and effective use of these devices is an essential component of inhalation therapy. It is so important, in fact, that proper inhalation technique should be constantly ensured, demonstrated at routine physician visits, for example, with re-education and re-training as necessary” (AAAAI, 2003).

Description of devices

The standard asthma medication delivery system is the MDI. The MDI is a small, pressurized can that contains aerosol medicine. Spacers, if needed, are used in conjunction with an MDI. A spacer device is a tube attached to the inhaler, which acts as a reservoir to hold the medication that is sprayed by the inhaler. Spacer devices remove the need for coordination between actuation of an MDI and inhalation. The spacer reduces the velocity of the aerosol, so that a larger proportion of the particles can be inhaled and deposited in the lungs. Spacer volumes and shapes vary; for instance, volumes of spacers range from 170 mL to 750 mL. Consequently, effects on physiological function vary as these devices vary.

A nebulizer is a medical device that delivers liquid medication to the recipient's airways in the form of a mist. Nebulizer compressors use air or oxygen under pressure to force air through tubing into a medicine cup filled with liquid medicine. The force of the air breaks the liquid into tiny mistlike particles that can be inhaled deeply into the airways. Nebulizers have three main parts: a cup that holds the medication; a mouthpiece or mask attached to a T-shaped part; and a thin plastic tube that connects the mouthpiece to the compressor. There are home and hospital models of nebulizers, as well as portable units (Health A to Z, 2003). Nebulizers tend to be easy for the patient to use and require only the usual inspiration and expiration through the connection to the nebulizer.

Peak flow meters (PFMs) are plastic handheld devices used for home monitoring of lung function as part of a comprehensive asthma self-management plan. PFMs measure the peak expiratory flow (the patient's ability to push air out of his or her lungs). These devices help patients and doctors monitor and manage asthma. For example, readings from the PFM can help the patient implement an action plan and change the doses of medications as needed. Most peak flow readings fall into three zones: green, yellow, and red. A reading in the red zone indicates a significant drop in peak flow rate and signals a medical alert where immediate action needs to be taken.

Effectiveness of spacers

The review of the literature suggests that there is inadequate evidence to determine the effectiveness of the use of spacers in children with asthma. This does not mean that spacers are ineffective. Rather, the evidence from literature is not of sufficient quality to draw conclusions about the effectiveness of these devices. In the published trials, when comparing the change in outcome after initiation of spacers to baseline measurements, the effectiveness of spacers was favorable. The spacers were also more effective when compared with a placebo. However, the evidence with respect to a comparison of MDIs with spacers versus MDIs alone is more complex and turns on the specific outcome measures.

Four randomized clinical trials of MDIs with spacers versus MDIs alone were reviewed. In two trials (Cunningham and Crain, 1994; Pedersen, 1983), MDIs with spacers were found to result in statistically significantly better results than MDIs used alone. Cunningham and Crain found in a trial of 84 participants that children who used spacers had statistically significantly earlier resolution of wheezing and coughing after asthma attacks and statistically significantly fewer school days missed at two and four months. However, at six months, there were no statistically significant differences. Also, at six months, there were no statistically significant differences in the number of unscheduled medical visits or hospitalizations. Pedersen found that MDIs with spacers produced statistically significantly more improvement in FEV1 than did MDIs alone in a

trial of 20 subjects.

There was evidence for equivalence between the use of MDIs alone and MDIs with spacers in two trials. In one trial with 16 participants, there was no statistically significant difference between the bronchodilator effects of MDIs alone and MDIs with spacers (Rachelefsky et al., 1986). In a paper by Becker and colleagues (1985), the results for FEV1 were statistically significant and not favorable for MDIs with spacers versus MDIs alone, but the authors noted that the measurements for FEV1 for the two groups were statistically significantly different at baseline, potentially explaining the result. However, when the authors measured the percent change of FEV1 from baseline to postintervention, MDIs with spacers had nonstatistically significant favorable results. Becker et al. also found that only four out of the 34 participants used the devices without any errors.

Based on the review of these four trials, there is inadequate evidence to determine the effectiveness of spacer use for children with asthma. These findings suggest that, although there is no evidence that adding a spacer to an MDI improves drug delivery or efficacy, compared with a correctly used MDI alone, spacers may enable more effective administration of medication for children who cannot coordinate actuation and inhalation using an MDI.

The NAEPP, which is administered by the National Heart, Lung, and Blood Institute, recommends the use of spacers for asthma patients older than four years. The NAEPP states that spacers are "recommended for all patients on medium-to-high doses of inhaled corticosteroids" (NAEPP, 1997). The larger-volume spacers (>600 cc) may increase medication delivery to the lungs compared with MDIs alone in patients with poor MDI technique. Spacers decrease oropharyngeal deposition and will reduce potential system absorption of inhaled corticosteroid preparations that have higher oral bioavailability. Another guideline included in a database used by clinicians states that the addition of a spacer corrects for poor MDI technique in most patients and allows faster resolution of symptoms in children with acute asthma (UpToDate, 2004).[1] The guideline recommends the use of a spacer for all patients in whom proper breath and actuation coordination is difficult and whenever an inhaled corticosteroid is being administered via an MDI.

Effectiveness of nebulizers

To determine the effectiveness of nebulizers in children with asthma, trials that compared nebulizers to MDIs with spacers were reviewed. In one meta-analysis and one systematic review, MDIs used with spacers were found to be equivalent to nebulizers. In the meta-analysis, health care utilization outcomes were analyzed for 1,076 children included in trials conducted in emergency rooms and community settings (Cates et al., 2003). The relative risk of hospital admission was 0.65 for children using MDIs with spacers versus nebulizers. Peak flow and FEV1 results were similar for children using MDIs with spacers and children using nebulizers. The authors concluded that spacers used with MDIs produced outcomes that were at least equivalent to those achieved with nebulizers, and that MDIs used with spacers may have some advantages, as mentioned above, compared with nebulizers for children with acute asthma. In the systematic review (Brocklebank et al., 2001), the trials demonstrated no evidence of clinical improvement in lung function using nebulizers compared with other inhaler devices. The authors

[1] UpToDate is an electronic continuing-education textbook.

conclude there is no evidence that nebulizers are more effective than other medication delivery devices.

In eight randomized controlled trials, spacers used with MDIs were found to be as effective as nebulizers (Rao and Rizvi, 2002; Leversha et al., 2000; Ploin et al., 2000; Dewar et al., 1999; Schuh et al., 1999; Wildhaber et al., 1999; Batra et al., 1997; Chou et al., 1995). Dewar et al. (1999) found a nonstatistically significant pattern that children treated with MDIs with spacers in the emergency department had a shorter median hospital stay and a lower readmission rate than did children who were given medication via a nebulizer. In a ninth trial, peak expiratory flow was greater for children who used a nebulizer than for children who used an MDI with spacer (Robertson et al., 1998). Based on the nine trials reviewed, there is no clear or consistent evidence that treatment with nebulizers is more effective in improving clinical outcomes than MDIs with spacers. These trials, however, have inadequate statistical power to demonstrate clinical equivalence (i.e., they cannot exclude a clinical benefit of nebulizers).

The 1997 NAEPP guidelines state that nebulizers are less dependent on patient coordination or cooperation and recommend their use for children aged 2 years and younger and patients of any age who cannot use an MDI with spacer or a face mask and spacer. “Nebulized therapy is more effective in patients who are unable to coordinate inhalation of medication from an MDI because of their age, agitation, or severity of the exacerbation.” Nebulizers are the delivery method of choice for cromolyn in children and for high-dose beta2-agonists and anticholinergics in moderate-to-severe exacerbations in all patients. The NAEPP Expert Panel also recommends that children aged between 3 and 5 years begin therapy using an MDI with spacer, but if the desired therapeutic effects are not achieved, the children may require a nebulizer or an MDI with spacer/holding chamber and a face mask. Although the evidence suggests nebulizers have not been found to be more effective than MDIs with spacers, nebulizers may be the only option for some children.

Effectiveness of peak flow meters

Because PFMs are monitoring devices (not treatments or medication delivery systems), the clinical efficacy of peak flow meters by themselves cannot be determined. The literature search on PFMs excluded any trials that also included self-management training and education, as those trials were included in the section on self-management training and education. This left one randomized controlled trial that investigated lung function measured by spirometry compared with PFMs. This trial determined that none of the PFMs detected all episodes of clinically important deterioration in lung function and that the absolute values of peak expiratory flow reported with PFMs were inaccurate (Sly et al., 1994). However, this trial is now 10 years old and other more recent trials have been published that examine the effectiveness of PFMs, but those were done in conjunction with self-management training and education.

In order for PFMs to be effective, children must be given self-management education and action plans in conjunction with their PFMs. Children and their caregivers who are given a PFM without instruction would not know how to use it to manage their asthma. Although this analysis does not examine the effectiveness of symptom-based action plans versus peak flow–based action plans, a systematic review of the literature including children and adults conducted by the NAEPP concluded, “Evidence neither supports nor refutes the benefits of written action plans

based on peak flow monitoring compared to symptom-based plans in improving health care utilization, symptoms, or lung function. It is the opinion of the Expert Panel that peak flow monitoring for patients with moderate or severe persistent asthma should be considered (NAEPP, 2002)."

II. UTILIZATION, COST, AND COVERAGE IMPACTS

Present Baseline Cost and Coverage

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

The mandated services under AB 2185 include pediatric asthma self-mangement training and education and three medical devices (peak flow meters, nebulizers, and spacers). In estimating the impact of the bill on costs, utilization, and premiums, the services 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; and medical devices (peak flow meters, nebulizers, and spacers). 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, approximately 10% of children aged 0 to 17 years enrolled in Knox-Keene health plans have symptomatic asthma. However, approximately 12% of those children do not have coverage for outpatient prescription drugs and would not be affected by AB 2185. This analysis assumes similar costs and rates of utilization for children covered under group and individual insurance due to a lack of specific utilization data for each category. Using data from CHIS and commercial databases maintained by Milliman USA, the analysis finds that approximately 350,000 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 markets 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)
- 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)

- $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.

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%), group health education (91%), spacers (94%), nebulizers (94%), and PFMs (75%) are also extensively covered.

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%. Alternatively, children enrolled in large-group HMO plans are covered at a range of 90% to 100%, with the exception of PFMs (73%). Finally, children enrolled in small-group HMO plans are covered at a range of 91% to 100% for examined asthma services.

Public demand for coverage (Section 3(j))
The high rates of coverage for pediatric asthma services, as presented in the preceding section, indicate that asthma services are widely available to children in commercial HMO plans in California. Therefore, the evidence suggests there would be little unmet demand for these services, except among people who may be restricted by provider-referral or health plan-approval requirements.

Impacts of Mandated Coverage
How will changes in coverage related to the mandate affect the benefit of the newly covered service and the per-unit cost? (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).

How will utilization change as a result of the mandate? (Section 3(b))
Based on current rates of coverage for pediatric asthma services in California, the area most open to potential increases in use is self-management training and education programs. Even though education and training are now widely covered (90% to 100%), utilization of these programs is estimated to 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 data). 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. 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 may be reduced by 30% and the mean number of emergency room visits may be reduced by 26%. The evidence from the literature review on medical effectiveness also suggests that there would be no impact on outpatient visits for those 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.*

To what extent does the mandate affect administrative and other expenses? (Section 3(c))
The mandate is expected to increase the administrative expenses for health plans but not disproportionately to the increase in health care costs (see the following section). An increase in asthma treatment and education claims may increase claims administration costs. Plans would 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 C).

Impact of the mandate on total health care costs (Section 3(d))
Total net expenditures (including total premiums and out-of-pocket expenditures) are estimated to increase by approximately 0.007%. The impact varies among the large- and small-group and individual markets (Table 2). The estimated impact on total net expenditures in the HMO large-group market is 0.006% and in the small-group and individual markets is 0.009%. This would be 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 are estimated to increase total expenditures by 0.009%, however, the savings associated with reduced emergency room and hospital utilization is estimated to be a reduction in total expenditures of 0.002% (approximately 22% of the increase is offset).

The estimated impact of AB 2185 on total expenditures is $240,000 less than the estimated impact of AB 1549. In addition, the estimated impact of AB 2185 on insured premiums is 0.042% lower than that estimated for AB 1549 (Table 3).

Costs or savings for each category of insurer resulting from the benefit mandate (Section 3(e))
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 AB 2185.

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

The majority of asthma services currently provided to children enrolled in commercial HMO and POS plans in California are covered. After the mandate, these costs will continue to be borne by HMOs and PPOs in the small- and large-group and individual markets.

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

The mandated benefit would 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, there is no evidence that the mandate would impact net cost or availability of asthma services.

III. PUBLIC HEALTH IMPACTS

Present Baseline Health Outcomes

In California, 14% of insured children aged 1 to 17 years have ever been diagnosed with asthma (CHIS, 2001 data). 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 data). 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 data). Children who experience asthma symptoms are more likely to miss school due to poor health compared with children without asthma (Table 4).

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 5). 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 6). 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 data).

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 are the following: school absences (mean number of days missed), percentage of children with asthma reporting restricted-activity days, emergency department visits, and hospitalizations (Table 7).

The baseline data (Table 4) 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 data). This translates to a total of 420,000 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 data). 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 utilization of self-management training and education (from 54% to 64%) is estimated for children presently covered for these services as a result of increased demand created by 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 use these services at the same rate (54%) as children who presently have coverage. The remainder of this section discusses the potential impact of the proposed mandate on selected health outcomes based on the medical effectiveness literature presented in section I. A summary of the findings is presented in Table 7. 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. The estimated impact of AB 2185 on measures of public health is less than the estimated impact of AB 1549 (see Table 8 for a full comparison of CHBRP's analyses of the two bills). The estimated impact of AB 2185 is discussed below.

<u>School absences</u>

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 data). 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 the 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 18,000 days of missed school each month due to asthma, or approximately 166,000 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 the effect that would be 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 to some extent because of their asthma (CHIS, 2001 data): 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 would newly use the self-management training and education following the mandate, approximately 6,200 fewer children would 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 would be approximately 360 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 would be approximately 115 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 public 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 PEFR. 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 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

Table 1. Premandate: Coverage of Pediatric Asthma Services for Children Enrolled in Health Maintenance Organizations by Market, California, 2004

	Total (%)	Large Group (%)	Small Group (%)	Individual (%)
Prescription drugs	92	92	88	84
Disease management	100	100	100	100
Self-management training	100	100	100	100
Group health education	91	90	93	98
Individual health education	100	100	100	100
Patient education material	98	98	98	99
Medical devices	94	94	96	100
Spacers	94	93	96	100
Nebulizers	94	94	96	100
Peak flow meters	75	73	91	100
Inpatient care	100	100	100	100
Ambulatory care	100	100	100	100
Emergency department	100	100	100	100

Source: California Health Benefits Review Program, 2004. 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 of California, Blue Cross of California, CIGNA, Health Net, Kaiser Permanente, and PacifiCare).

Table 2. Postmandate Impacts of AB 2185 on Per Member Per Month Costs and Total Expenditures, California, Calendar Year 2004

	Large Group		Small Group			
	HMO	**POS**	**HMO**	**POS**	**Individual**	**Total**
PMPM Impact of Mandate						
A. Insured Premiums						
Average Portion of Premium Paid by Employer	$0.012	$0.011	$0.016	$0.017	$0.000	$130,000
Average Portion of Premium Paid by Employee	$0.003	$0.004	$0.006	$0.005	$0.017	$50,000
Total Premium	$0.015	$0.015	$0.022	$0.022	$0.017	$190,000
B. Covered Benefits Paid by Member (Deductibles, Copays, etc.)	$0.001	$0.001	$0.001	$0.002	$0.003	$10,000
C. Total Cost of Covered Benefits	$0.016	$0.016	$0.023	$0.023	$0.020	$200,000
D. Benefits Not Covered	-$0.001	-$0.001	-$0.002	-$0.002	-$0.001	$20,000
E. Total Expenditures	$0.014	$0.014	$0.021	$0.021	$0.021	$180,000
Percentage Impact of Mandate						
A. Insured Premiums	0.007%	0.006%	0.010%	0.009%	0.009%	0.008%
E. Total Expenditures	0.006%	0.005%	0.009%	0.008%	0.009%	0.007%

Source: California Health Benefits Review Program, 2004 (see Appendix C for detailed data sources).
Key: HMO=health maintenance organization; PMPM=per member per month; POS=point-of-service.

Table 3. Postmandate Impacts on Per Member Per Month Costs and Total Expenditures, California, Calendar Year 2004: Comparing AB 1549 with AB 2185

	AB 1549 Total	AB 2185 Total	Difference
Per Member Per Month Impact of Mandate			
A. Insured Premiums			
Total Premium	$1,130,000	$190,000	-$940,000
Average Portion of Premium Paid by Employer	$840,000	$130,000	-$710,000
Average Portion of Premium Paid by Employee	$290,000	$50,000	-$240,000
Total Premium	$1,130,000	$190,000	-$940,000
B. Covered Benefits Paid by Member (Deductibles, Copays, etc.)	$50,000	$10,000	-$40,000
C. Total Cost of Covered Benefits	$1,180,000	$200,000	-$980,000
D. Benefits Not Covered	-$760,000	-$20,000	-$740,000
E. Total Expenditures	$420,000	$180,000	-$240,000
Percentage Impact of Mandate			
A. Insured Premiums	0.05%	0.008%	-0.042%
E. Total Expenditures	0.02%	0.007%	-0.013%

Source: California Health Benefits Review Program, 2004 (see Appendix C for detailed data sources).

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

Days Missed	Symptomatic Asthma (%)	95% Confidence Interval	No Asthma (%)	95% Confidence 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	

Source: CHIS, 2001 data.
Note: "Symptomatic asthma" is defined as having experienced asthma symptoms in the last year.

Table 5. Symptomatic Asthma Prevalence in Children Aged 1 to 17 Years with Health Insurance Coverage by Sex, California, 2001

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

Source: CHIS, 2001 data.
Note: "Symptomatic asthma" is defined as having experienced asthma symptoms in the last year.

Table 6. Symptomatic Asthma Prevalence in Children Aged 1 to 17 Years with Health Insurance Coverage by Race/Ethnicity, California, 2001

Race/Ethnicity	% Children	95% Confidence 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: CHIS, 2001 data.
Note: "Symptomatic asthma" is defined as having experienced asthma symptoms in the last year.

Table 7. Postmandate: Health Outcomes Related to Asthma Management in Children in Health Maintenance Organizations and Point-of-Service Plans, California, Estimates for Calendar Year 2004

Public Health Measure	Baseline Rates	Change Based on Effectiveness Review*	Change as a Result of AB 2185
School absences	1.2 mean days/month	–44%	-18,500 days/ month
Restricted activity days	71% of children	–25%	-6,200 children
Emergency room visits	0.04 mean visits/child	–26%	-360 visits
Hospitalizations	0.01 mean hospitalizations/patient	–30%	-115 hospitalizations

Sources: California Health Benefits Review Program, 2004. School absences and restricted activity are from direct analysis of CHIS, 2001 data; emergency room visits and hospitalizations are based on estimates provided by Milliman USA.
Note: Estimates of the number of asthmatic children in California were obtained from Milliman USA and are restricted to children in health maintenance organizations and point-of-service plans. The estimates presented in this report include children who have had symptomatic asthma in the last year, as demonstrated by any asthma-related hospital, outpatient, or emergency room use with an ICD-9 code of 493 or use of any prescription asthma medication. The number of children to whom AB 1549 applied was 379,916. The number of children to whom AB 2185 applies is 349,523.
*It is estimated that 10 percent of children with asthma who are presently covered will newly use the benefit following the mandate.

Table 8. Postmandate: Public Health Impacts of AB 1549 and AB 2185, Estimates for Calendar Year 2004

Public Health Measure	Change Based on Effectiveness Evidence	Change as a Result of AB 1549* (number)	Change as a Result of AB 2185* (number)	Difference (number)
School absences (mean days/month)	-44%	-19,900 days/month	-18,500 days/month	1,400
Restricted-activity days (% of children)	-25%	-6,800 children	-6,200 children	400
Emergency department visits (mean visits/child)	-26%	-400 visits	-360 visits	40
Hospitalizations (mean hospitalizations/child)	-30%	-130 hospitalizations	-115 hospitalizations	15

Source: California Health Benefits Review Program, 2004.

Note: Estimates of the number of children with symptomatic asthma in California were obtained from Milliman USA and are restricted to children in health maintenance organizations and point-of-service plans. The estimates presented in this report include children who have had symptomatic asthma in the last year, as demonstrated by any asthma-related hospital, outpatient, or emergency department use with an ICD-9 code of 493 or use of any prescription asthma medication. The number of children to whom AB 1549 applied was 379, 916. The number of children to whom AB 2185 applies is 349,923.

*It is estimated that 10 percent of children with asthma who presently have coverage will newly use the benefit following the mandate.

APPENDIX A
Literature Review Methods

Asthma Self-Management Training and Education

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 to 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 and self-management interventions, any trial in which the intervention included an 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 those 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.

Medical Devices

The literature search focused on the effectiveness of spacers, nebulizers, and peak flow meters. The search was limited to English abstracts and to children, defined as subjects aged 0 to 18 years. The MEDLINE database and Cochrane Library were initially searched for trials published from 1994 to 2004, using a combination of Medical Subject Headings (MeSH) and text words aimed at locating meta-analyses, systematic reviews, individual randomized controlled trials, and clinical practice guidelines.

Trials that included adults were excluded, as were trials with a trial design that did not adequately assess one of the aforementioned devices. For example, numerous trials returned from the literature search compared dry powder inhalers with spacer devices used with metered-dose inhalers (MDIs). However, those trials were excluded because dry powder inhalers use a different delivery system than MDIs. This analysis also excluded "wheezy infants" (children younger than 2 years), because a clinical diagnosis of asthma cannot be definitively made at that age; wheezing may be due to diseases and factors other than asthma.

The first literature search returned few trials that measured the effectiveness of spacers. In particular, there were no trials that compared the effectiveness of spacers used with MDIs versus MDIs alone. Consequently, the original search criteria for spacer devices was expanded to include trials published in the past 20 years in children aged 2 to 18 years and to include review articles.

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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 Medical Effectiveness Findings

Pediatric Asthma Self-Management and Training

A tabular list of interventions informing the findings on the effectiveness of pediatric self-management training and education interventions appears below. Full bibliographic information can be found in the list of references at the end of this report. Studies marked with an * indicate inclusion in the meta-analysis (Wolf et al., 2003).

Citation	Intervention vs. Comparison Group	Characteristics	Location
Georgiou et al., 2003	Education and management (w/peak flow meter) vs. (no control)	Pediatric asthmatic members and caregivers of UnitedHealthcare (national health care organization)	Multiple states within the United States
Huss et al., 2003	Education and computer-based instructional asthma game vs. education	Inner-city children	Baltimore
Krishna et al., 2003	Internet-enabled, interactive, multimedia asthma education and conventional education, management (w/action plan) vs. conventional education, management (w/action plan)	Participants were children who visited a pediatric pulmonary clinic	Missouri
Bonner et al., 2002	Education and management (diary, peak flow meter) vs. usual care	Almost 85% of families received Medicaid or had no insurance, urban families	New York
Brown et al., 2002	Education vs. usual care	More than 80% received Medicaid (84% in intervention group)	Metro Atlanta
Burkhart et al., 2002	Behavioral enhancement, education, management (peak flow meter) vs. education, management (peak flow meter)	Predominantly Caucasian, middle-income families	West Virginia
Guendelman et al., 2002	Education and management w/Health Buddy vs. asthma diary	Intervention 92% public, 8% private. Control group 93% public, 6% private	Oakland, CA

Citation	Intervention vs. Comparison Group	Characteristics	Location
Lukacs et al., 2002	Education, management (written action plan) vs. usual care	Kaiser Permanente members.	Colorado
Yoos et al., 2002	Education, management (symptoms) vs. education, management (w/peak expiratory flow rate monitoring)	Recruited from diverse primary care settings	New York
Burkhart et al., 2001	Behavioral strategies, education, management (peak flow) vs. education, management (peak flow)	Predominantly middle-to-high-income families	West Virginia
Harish et al., 2001	Asthma clinic (w/education, action plan) vs. usual care	Low-income, inner-city population	New York (Bronx)
Shegog et al., 2001	Computer-assisted instruction game designed to teach self-management vs. conventional education	Recruited from clinics and schools in a large urban area	Texas
Bartholomew et al., 2000	Computer-assisted instructional game (self-management education) vs. usual care	Total sample, 6.8% health maintenance organization, 6.8% Medicare, 48.3% Medicaid, 6.8% self-pay, 31.4% none	Inner-city Texas
Homer et al., 2000	Educational computer game (designed to teach management) vs. written education	13.3% total sample had private insurance	Urban youth in Boston
Kelly et al., 2000	Education in clinic and management (w/written action plan) vs. usual care	All children were covered by Medicaid	Norfolk, VA

Citation	Intervention vs. Comparison Group	Characteristics	Location
Greineder et al., 1999	Education, management (action plan), follow-up vs. education, management	Selected from urban health centers of Harvard Pilgrim Health Care (health maintenance organization)	New England
Christiansen et al., 1997*	Education, management vs. usual care	Inner-city	San Diego
Persaud et al., 1996*	Education, management vs. usual care	69% Medicaid -	Galveston, TX
Wilson et al., 1996*	Education, management vs. usual care	Mothers were relatively well-educated (52% graduated from college), 10.7% minority	St. Paul, MN
Perrin et al., 1992	Education and stress management program vs. usual care	Predominantly white, middle-to-upper-class	Boston
Shields et al., 1990*	Education vs. usual care	Drawn from urban health maintenance organization	Chicago
Alexander et al., 1988*	Education, management vs. usual care	No consistent source for asthma management other than emergency room (primarily low-income)	Tennessee
Evans et al., 1987*	School-based education, management vs. usual care	Low-income (71% received Medicaid or other public assistance)	New York City
Clark et al., 1986*	Education, management vs. usual care	Low-income urban children	New York City
Rubin et al., 1986*	Educational asthma computer game vs. 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
LeBaron et al., 1985*	Education vs. usual care	Patients at private pediatric allergy practices; low-to-middle-income or higher	San Antonio, TX

Citation	Intervention vs. Comparison Group	Characteristics	Location
Rakos et al., 1985*	Education, management vs. usual care	N/A	Cleveland, Ohio
Whitman et al., 1985*	Education, management vs. usual care	School-aged, preschool (no control); referred by private physicians	Utah
Kubly and McClellan, 1984*	Education, management vs. usual care	Mostly Anglo American, median family income $20,000- $30,000	Southwestern United States
Lewis et al., 1984*	Education, management vs. usual care	Patients of the Southern California Permanente Medical Group	Los Angeles
Fireman et al., 1981*	Education, management vs. usual care	Selected from pediatric allergist's office and Allergy Clinic of Children's Hospital	Pittsburgh, PA
Parcel et al., 1980*	School-based education vs. usual care	Mostly African American, low-middle to lower socioeconomic status	Galveston, TX

In the tables below, results are categorized as "favorable" (fav) for the intervention or "not favorable" (not fav). Results could be statistically significant (Sig, meaning unlikely to have occurred just by chance -- P value <0.05) or not statistically significant (NS), meaning that the results could have been obtained by chance more than one 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. As above, studies marked with an * indicate inclusion in the meta-analysis (Wolf et al., 2003). A key covering all the tables is as follows: ED=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[3].

School absences (% patients)—pattern toward favorable

Trial	Results	Categorization
Meta-analysis (1 trial)	OR 0.78 [0.36, 1.66]	NS, fav
Estimated impact from U.S. trials	43% reduction	

[3] Standardized mean difference is the difference between two means divided by an estimate of the within-group standard deviation. When an outcome (such as pain) is measured in a variety of ways across studies (using different scales), it may not be possible directly to compare or combine study results in a systematic review. By expressing the effects as a standardized value, the results can be combined since they have no units.

Trial	Results	Categorization
Guendelman 2002	42.8% reduction in percent of children who missed school in past 6 weeks in the int group compared with controls	NS, fav
Georgiou 2003 (non-RCT)	36%→23% (missed 1 or more days in past month)	Sig, fav

School absences (mean days)—favorable

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

Restricted activity (% children with asthma)—favorable

Trial	Results	Categorization
Estimated impact from U.S. trials	25% proportionate reduction	
Guendelman 2002	Int pre 66.7%→post 32.3%, control pre 72.1%→post 46.7%	Sig, fav

Emergency department visits (mean)—strong pattern toward favorable

Trial	Results	Categorization
Meta-analysis (12 trials)	SMD –0.21 [–0.33, –0.09]	Sig, fav
Estimated impact from U.S. trials	26% reduction	

Trial	Results	Categorization
Krishna 2003	Int pre 2.0→post 0.1, control pre 1.2→post 0.6	Sig, fav—both groups
Harish 2001	Mean number of ED visits per patient/month: Int post 0.101, control post 0.326	Sig, fav
Homer 2000	Mean/year: Int pre 2.14→post 0.86, control pre 2.24→post 0.73	Sig, fav for both groups; NS between groups
Kelly 2000 (non-RCT)	Mean/year: Intervention pre 3.6→post 1.7, control pre 3.5→post 2.3. Control RR 1.4	Sig, fav
Greineder 1999	Int pre 1.55→post 0.41, control pre 1.57→post 0.96	Sig, fav for both groups; Sig, fav between groups
Alexander 1988*	Int pre 2.6→post 0.6, control pre 2.5→post 2.4	Sig, fav
Bartholomew 2000	Int pre 2.0→post 1.3, control pre 1.9→post 1.2; effect size 0.03	NS, fav
Clark 1986*	Int pre 1.72→post 1.18, control pre 2.49→post 2.34	NS, fav
Rubin 1986*	Acute visits due to asthma: Int pre 5.2→post 2.4, control pre 5.6→post 4.9	NS, fav
Lewis 1984*	Int pre 3.68→post 2.30, control pre 3.04→post 3.71	NS, fav
Fireman 1981*	Int post 0.08, control post 1.00	NS, fav
Christiansen 1997*	Mean per subject year: Int post 0.304, control post 0.197	NS, not fav
Shields 1990*	Int post 0.54, control post 0.38	NS, not fav

Hospitalizations (mean—pattern toward favorable)

Trial	Results	Categorization
Meta-analysis (8 trials)	SMD –0.08 [–0.21, 0.05]	NS, fav
Estimated impact from U.S. trials	30% reduction	
Bartholomew 2000	Mean/year: Int pre 0.7→post 0.4, control pre 0.6→post 0.5; effect size=–0.14	Sig, fav
Kelly 2000 (non-RCT)	Int pre 0.6→post 0.2, control pre 0.53→post 0.48; control RR 2.4	Sig, fav
Greineder 1999	Int pre 0.86→post 0.14, control pre 1.00→post 0.57	Sig, fav for both groups; Sig, fav

Trial	Results	Categorization
		between groups
Krishna 2003	Int pre 0.1→post 0.1, control pre 0.6→post 0.1	Sig, fav—control group; No effect for int
Harish 2001	Int post 0.37, control post 0.42	NS, fav
Christiansen 1997*	Mean per subject-year: Int post 0.027, control post 0.254	NS, fav
Clark 1986*	Int pre 0.11→post 0.09, control pre 0.21→post 0.17	NS, fav
Lewis 1984*	Child/year: Int post 0.27, control post 0.60	NS, fav
Fireman 1981*	Int post 0, control post 0.31	NS, fav

Physician visits—weak effect

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

Trial	Results	Categorization
		treatment given)
Not distinguished as to type of visit		
Meta-analysis (6 trials)	SMD –0.15 [–0.31, 0.01]	NS, not fav
Rubin 1986	Int mean 2.80, control mean 4.5	NS, not fav
Shields 1990*	Mean office visits—int post 1.63, control post 1.86	NS, fav

Medications: inhaled corticosteroids, cromolyn, nedocromil

Trial	Results	Categorization
Lukacs 2002 (non-RCT)	Int group received more than 1 dispensing of inhaled corticosteroid compared with controls; RR 1.41	Sig, fav
Krishna 2003	Daily dose of inhaled corticosteroids: Int pre 353.09→post 433.51 µg, control pre 350.53→post 753.88	Sig, fav between groups; fav for int
Bonner 2002	Prescribed inhaled corticosteroids: Int pre 54%→post 70%, control pre 44%→post 38%. Prescribed cromolyn: Int pre 26%→post 24%, control pre 36%→post 36%	Corticosteroids-Sig, fav for int; cromolyn—NS, fav

Forced expiratory volume1—weak evidence toward favorable

Trial	Results	Categorization
Meta-analysis (1 trial)	SMD 0.46 [0.08, 0.84]	Sig, fav
Yoos 2002	Spirometry (FEV1% predicted mean) 1) pre 88→post 90 2) pre 87→post 94 3) pre 83→post 88	NS, fav

Days of asthma symptoms—favorable

Trial	Results	Categorization
Krishna 2003	Int pre104.5→post 23.9, control pre 97.8→post 48.2	Sig, fav—both groups

Trial	Results	Categorization
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→post 2.87 2) pre 2.87→post 2.00 3) pre 3.19→post 2.68	Sig, fav for group 2 (PEFR vs. symptoms); NS, fav for group 3
Evans 1987*	Annual days w/asthma symptoms: Int pre 31.9→post 18.1, control pre 28.3→post 30.3	Sig, fav
Fireman 1981*	Average # of wheezing days/patient/month: Int post 3.1, control post 4.6	NS, fav

Nights of nocturnal asthma—favorable

Trial	Results	Categorization
Meta-analysis (3 trials)	SMD –0.34 [–0.62, –0.05]	Sig, fav
Georgiou 2003 (non-RCT)	Symptoms improved 5.8 (scale 0-100)	Sig, fav
Krishna 2003	Nights of sleep disturbance: Inte pre 64.7→post 15.2, control pre 62.0→post 17.1	Sig, fav—both groups
Wilson 1996*	Parental nights of sleep interruption/week: Int pre 0.6→post 1.3, control pre 0.8→post 2.6	Sig, not fav compared with baseline; fav compared with controls

Peak expiratory flow rate—pattern toward favorable

Trial	Results	Categorization
Meta-analysis (3 trials)	SMD 0.53 [0.19, 0.86]	Sig, fav
Guendelman 2002	Peak expiratory flow in yellow or red zone – OR –0.43	Sig, fav
Christiansen 1997*	Int pre 261.04→post 331.37, control pre 272→post 313.53	NS, fav

Exacerbations (mean)—pattern toward favorable

Trial	Results	Categorization
Meta-analysis (5 trials)	SMD –0.21 [–0.43, 0.01]	NS, fav

Trial	Results	Categorization
Evans 1987*	Average annual # episodes: Int pre 10.6→post 9.0, control pre 10.1→post 11.8 Average duration of episodes (days): Int pre 2.77→post 1.87, control pre 2.85→post 2.40	Sig, fav; Sig, fav
Fireman 1981*	Average # of attacks/patient/month: Int post 1.5, control post 5.0	Sig, fav
Whitman 1985*	Preschool children: Int pre 10.10→post 5.14. School-aged children: Int 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): Int pre 9.13→post 8.87, control pre 8.31→post 8.75	NS, not fav

Asthma severity—pattern toward favorable

Trial	Result	Categorization
Meta-analysis (4 trials)	SMD –0.15 [–0.43, 0.12]	NS, fav
Georgiou 2003 (non-RCT)	Int pre 66.9%–post 75.3% moderate asthma	Sig, fav
Homer 2000	Severity based on National Institutes of Health criteria, 0=mild, 2=severe: Int pre 1.11→post 0.94, control pre 1.05→post 0.78	Sig, fav for both groups; NS between groups
Perrin 1992	Functional measures: Daily chores (#/week): Int pre 15.3→post 19.5, control pre 17.2→post 17.6 Time playing with friends (hours/week): Int pre 8.1→post 11.1, control pre 10.2→post 11.5 After-school activities (#/week): Int pre 3.4→post 4.5, control pre 5.7→post 4.7	Chores: Sig, fav; Other measures: NS, fav
Harish 2001	Severe asthma: Int pre 26.5%→post 35.0%, control pre 19.8%→post 16.18%	Sig, not fav
Huss 2003	Patients w/moderate or severe asthma: Int pre 26/56→post 19/56, control pre 17/45→post 9/45	NS, fav
Yoos 2002	Mean scores: Group 1) pre 1.7→post 1.56 Group 2) pre 1.85→post 1.49 Group 3) pre 1.76 →post 1.50	NS, fav

Trial	Result	Categorization
Bartholomew 2000	Functional status: Int pre 138.0→post 139.6, control pre 136.5→post 137.3; effect size=0.16	NS, fav
Wilson 1996*	Degree to which child was bothered by symptoms: Int pre 2.7→post 2.3, control pre 2.6→post 2.3	NS, fav
LeBaron 1985*	Asthma severity (0=severe, 10=none): Int pre 8.6→post 8.87, control pre 6.81→post 8.81	NS, fav
Whitman 1985*	Preschool children (int): Days of no asthma: pre 69.37→post 69.62 Days of mild asthma: pre 18.67→post 17.62 Days of moderate asthma: pre 5.52→post 5.10 Days of severe asthma: pre 1.76→post 0.81 School-aged children: Days of no asthma: Int pre 68.26→post 70.56, control pre 63.74→post 72.21 Days of mild asthma: Int pre 16.53→post 13.59, control pre 13.74→post 12.95 Days of moderate asthma: Int pre 7.21→post 6.00, control pre 9.05→post 7.79 Days of severe asthma: Int pre 0.79→post 1.84, control pre 1.26→post 0.63	Preschool kids: No asthma—NS, fav; Mild asthma—NS, fav; Moderate asthma—NS, fav; Severe asthma—Sig, fav School-aged children: No asthma—NS, fav;Mild asthma—NS, fav; Moderate asthma—NS, fav; Severe asthma—NS, not fav

<u>Symptom-free days—favorable</u>

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

Symptom scores—favorable

Trial	Results	Categorization
Brown 2002	(Scale: 1=not bothered, 7=extremely bothered): Int pre 2.50→post 1.63, control pre 2.47→post 1.74. Effect size 13%-15%	Sig, fav for younger, no treatment effect for older children
Christiansen 1997*	Mean: Int post 2.87, control post 4.36	Sig, fav
Bartholomew 2000	Int pre 60.4→post 65.8, control pre 60.3→post 64.9. Effect size 0.10	NS, fav

Quality of life—child—pattern toward favorable

Trial	Results	Categorization
Georgiou 2003 (non-RCT)	Scale 0-100: graph provided, no data available	Sig, fav
Perrin 1992	Child Behavior Checklist: Total problems score: Int pre 60.8→post 54.4, control pre 57.7→post 55.0	Sig, fav
Evans 1987*	Positive feelings about asthma (% change): Int 6%, control –4%	Sig, fav
Fireman 1981*	Illness anxiety: Int pre 8.4→post 7.4, control pre 9.1→post 9.2	Sig, fav

Quality of life—caregiver—pattern toward favorable

Trial	Results	Categorization
Brown 2002	Scale 1-2, 1=never bothered: Int pre 1.77→ post 1.35, control pre 1.83→post 1.50. Effect size 13%-18% for younger children	Sig, fav for younger children; NS for older children

Self-efficacy—favorable

Trial	Results	Categorization
Meta-analysis (6 trials)	SMD 0.36 [0.15, 0.57]	Fav
Bonner 2002	Int 41% increase, control 9% increase. Effect size 1.28	Sig, fav
Shegog 2001	F (analysis of variance)=4.45	Sig, fav
Evans 1987*	Self-efficacy index (% change): Int 3%, control 0%	Sig, fav
Rubin 1986*	Asthma Behavioral Assessment (child total score): Int post 54.1, control post 57.8	Sig, fav
Whitman 1985*	Skills (self-care) difference between control and int groups after 3 months=11.84	Sig, fav

Trial	Results	Categorization
Kubly and McClellan 1984*	Children's Health Locus of Control—F=4.29 Self-Care Activity Questionnaire for Asthmatic Children—F=1.25	Sig, fav NS, fav
Parcel 1980*	Health locus of control: Int pre 29.0→post 30.2, control pre 27.1→ post 27.5	Sig, fav
Bartholomew 2000	Int pre 74.3→post 75.3, control pre 72.0→post 73.6; effect size=0.06	NS, fav
LeBaron 1985*	Overall control of asthma (0=very poor, 10=excellent): Intpre 6.23→post 6.93, control pre 6.50→post 6.91	NS, fav

Knowledge—child—favorable

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

Knowledge—caregiver—favorable

Trial	Results	Categorization
Krishna 2003	Intervention caregivers for children aged 0-6 years: pre 47.94→post 55.68. Caregivers for children 7-17: pre 49.95→post 55.38. Control caregivers for children 0-6: pre 48.41→post 52.30. For caregivers for children 7-17: pre 49.57→post 51.70	Sig, fav—all groups
Persaud 1996**	Change: Intervention 1.9, control 2.6	NS, fav

Spacers, Nebulizers, and Peak Flow Meters

A list of interventions informing the findings on the effectiveness of asthma devices for children appears below in tabular form. Full bibliographic information can be found in the list of references at the end of this report. Studies marked with an * indicate inclusion in the meta-analysis (Cates et al., 2003). Only clinical trials are listed below. A key for the table is as follows: ED=emergency department; MDI=metered-dose inhaler; RCT=randomized clinical trial.

Citation	Type of Trial	Intervention vs. Comparison Group	Characteristics	Location
Cunningham and Crain, 1994	RCT	MDI vs. MDI w/spacer	Children aged 3-10 years w/asthma receiving care in urban ED	Bronx, NY
Rachelefsky et al., 1986	RCT	MDI vs. MDI w/spacer	Children aged 5-12 years w/moderate asthma given inhaler instruction	Los Angeles
Becker et al., 1985	RCT	MDI vs. MDI w/spacer	Children aged 8-16 years w/ stable, chronic asthma	Canada
Pedersen, 1983	RCT	MDI vs. MDI w/spacer	Children, aged 6-12 years, w/exercise-induced asthma	Denmark
Rao and Rizvi, 2002	RCT	Nebulizer vs. MDI w/spacer	Asthmatic patients presented w/acute attack at ED	India
Leversha et al., 2000*	RCT	Nebulizer vs. MDI w/spacer	Children (aged 1-4 years) w/moderate and severe acute asthma treated at ED	New Zealand
Ploin et al., 2000*	RCT	Nebulizer vs. MDI w/spacer	Children aged 12-60 months w/acute recurrent wheezing, treated in ED	France
Dewar et al., 1999*	RCT	Nebulizer vs. MDI w/large-volume spacer	Children (older than 3 years) admitted to hospital w/acute asthma	United Kingdom
Schuh et al., 1999	RCT	Nebulizer vs. MDI w/spacer	Children aged 5-17 years w/asthma exacerbation who arrived at ED	Canada
Wildhaber et al., 1999	RCT	Nebulizer vs. MDI w/spacer	Children aged 2-9 years w/stable asthma	Australia
Robertson et al., 1998*	RCT	Jet nebulizer vs. MDI w/large-volume spacer	Children aged 4-12 years presenting to ED w/acute asthma	Australia
Batra et al., 1997*	RCT	Jet nebulizer vs. MDI w/spacer	Children aged 1-12 years with acute asthma exacerbation, treated in ED	India
Chou et al., 1995*	RCT	Nebulizer vs. MDI w/spacer	Children 2 years and older w/at least two episodes wheezing presenting to ED w/acute asthma exacerbation	Bronx, NY
Sly et al., 1994	RCT	Spirometry vs. 3 brands of peak flow meter	Children aged 11-17 years	Australia

In the tables below, results are categorized as "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 the results could have been obtained by chance more than one time in 20 even if there was no true difference. As above, studies marked with an * indicate inclusion in the meta-analysis (Cates et al., 2003). A key for the tables below is as follows: FEF=forced expiratory flow; FEV1=forced expiratory volume in one second; MDI=metered-dose inhaler; PEFR=peak expiratory flow rate; RR=relative risk.

Effectiveness of spacers (MDI v. MDI w/spacer)

Forced expiratory volume1

Trial	**Results**	**Categorization of Results**
Rachelefsky 1986	MDI alone: 34% increase from baseline, for spacer 30%	FEV1—NS, not fav for spacer
Becker 1985	MDI alone: pre 87.0 → post 100.4. Spacer pre 78.3 → post 89.7. Sig difference between groups at baseline. FEV1 increased to a maximum of 118% (MDI) to 119% (spacer) of baseline.	Sig, not fav for spacer (absolute value of FEV1) NS, fav for spacer (% change)
Pedersen 1983	Both treatments resulted in a significant increase in FEV1 as compared with placebo, but treatment with spacer produced significantly more improvement than did treatment w/MDI alone. No data provided—graph	Sig, fav for spacer

Forced expiratory flow, 25%-75%

Trial	**Results**	**Categorization of Results**
Rachelefsky 1986	MDI alone: 83% increase from baseline, for spacer 67%	FEF25%-75% -NS, not fav for spacer
Becker 1985	MDI alone: pre 46.0 → post 63.3. Spacer pre 38.3 → post 58.7. FEV1 increased to a maximum of 118% (MDI) to 119% (spacer) of baseline. FEF25%-75% increased to 159% (MDI) to 162% (spacer) of baseline.	Sig, not fav for spacer (absolute value of FEV1) NS, fav for spacer (% change)

Wheezing

Trial	**Results**	**Categorization of Results**
Cunningham 1994	At 2- and 4-month follow-up, spacer groups experienced significantly earlier resolution of wheezing (0 vs. 2). At 6 months, no sig difference.	At 2 and 4 months: Sig, fav for spacer At 6 months: NS, fav for spacer

Coughing

Trial	Results	Categorization of Results
Cunningham 1994	At 2- and 4-month follow-up, spacer groups experienced significantly earlier resolution of coughing after asthma attack (0 days vs. 3 days). At 6 months, no sig difference (0 vs. 2).	At 2 and 4 months: Sig, fav for spacer At 6 months: NS, fav for spacer

Median school days missed

Trial	Results	Categorization of Results
Cunningham 1994	At 2- and 4-month follow-up, spacer groups experienced significantly reduced number of school days missed after asthma attack (0 vs. 2). At 6 months, no sig difference.	At 2 and 4 months: Sig, fav for spacer At 6 months: NS, fav for spacer

Hospitalizations

Trial	Results	Categorization of Results
Cunningham 1994	No sig difference in number of hospitalizations. No data provided.	NS, no difference

Unscheduled medical visits

Trial	Results	Categorization of Results
Cunningham 1994	No sig difference in number of unscheduled medical visits. No data provided.	NS, no difference

<u>Nebulizers vs. spacers</u>

Forced expiratory volume1

Trial	Results	Categorization of Results
Rao 2002	In both groups, significant improvement occurred in mean FEV1.	NS, no difference
Schuh 1999	After 90 minutes, spacers had greater degree of improvement in % predicted FEV1.	NS, fav spacer
Batra 1997*	No outcomes specified; measures were comparable between the two groups.	NS, no difference

Peak expiratory flow

Trial	Results	Categorization of Results
Rao 2002	In both groups, significant improvement occurred in PEFR	NS, no difference
Robertson 1998*	Improvement in PEF at 60 min 57 L/min (nebulizer), 31.5 L/min (MDI). At 30 min,	Sig, not fav for spacer

Trial	Results	Categorization of Results
	PEF improved by 17% in spacer and 32% in nebulizer groups	
Chou 1995*	% predicted final PEFR—nebulizer 79%, spacer 76%	NS, not fav for spacer

Hospital admission

Trial	Results	Categorization of Results
Cates 2003 (meta-analysis)	Hospital admission: RR for spacer vs. nebulizer —0.65. Two studies in children did not report admissions but did report data on poor outcomes; when included, RR of admission or poor outcome is not sig different between spacer and nebulizer (RR 0.85).	Hospital admission: NS, fav for spacers
Leversha 2000*	Fewer children in spacer group required admission (33% spacer vs. 60% nebulizer).	Sig, fav for spacers
Ploin 2000*	10% patients hospitalized after treatment. Three patients from each group were hospitalized.	NS, no difference
Dewar 1999*	Readmission rate over 12-month follow-up: nebulizer 27.2%, spacer 13.8%	NS, fav for spacers
Chou 1995*	Admission rate (%): nebulizer 6.2%, spacer 5.6%	NS, fav for spacers

Hospital stay

Trial	Results	Categorization of Results
Dewar 1999*	Median hospital stay: nebulizers 40 hours, spacers 36.5 hours	NS, fav spacers

Dose deposition

Trial	Results	Categorization of Results
Wildhaber 1999	Mean (absolute dose) total lung deposition expressed as percentage of nebulized dose was 5.4% in younger children (<4 years) and 11.1% in older children (>4 years). MDI 5.4% in younger children and 9.5% in older children. Delivery rate per minute and total dose deposited were sig higher for nebulizer.	Sig, not fav for spacer

Wheezing

Trial	Results	Categorization of Results
Leversha 2000*	Change in wheeze, –0.93 spacer, –0.48 nebulizer. Mean difference 0.45.	Sig, fav for spacers

Peak flow meter

Peak expiratory flow

Trial	Results	Categorization of Results
Sly 1994—RCT	None of the mini flow meters detected all episodes of clinically important deterioration in lung function (6/19, 6/15, 6/18). All meters showed false-positive reductions in PEF. The relation between changes in lung function measured with spirometer and peak flow meter were poor. Absolute values of PEF obtained with mini flow meters are inaccurate.	N/A

APPENDIX C
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 plan models 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 plan model 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 plan models are designed to be a reasonable representation of the average plans offered in California today.

The plan models 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 plan models 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 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, In 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 HMO plan model 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 PPO plan model 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 POS plan model used for this analysis is assumed to be moderately managed with respect to in-network coverage and loosely managed for out-of-network coverage.

• **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 plan models:

Population younger than age 65 currently covered

The data for these analyses were obtained from multiple sources. The 2001 California Health Interview Survey (CHIS) 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, PPO, POS, and HMO. 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 nonworking 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 their health premium through monthly contributions. 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

The value of covered benefits paid by member 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:

Table D-1. Cost Sharing

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

Benefits not covered

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

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 premiums, 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.

Table D-2. Administrative/Profit Expenses

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

Cost Estimation Approach—Mandate Impact Methodology
Once the current baseline PMPM health care costs and premiums are determined, the next step is to estimate the increase in these PMPM costs and premiums due to the mandate.

Step 1: Estimate the change in health care costs covered by insurance
For services that are newly required by the mandate, the PMPM health care costs 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 Table D-1, above. 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 Table D-2, above.

The total of the increase in the health care and administrative/profit components of the 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 the 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 costs of these services that are not currently covered but are being paid for 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 noncovered 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 7: 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 Benefits 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 USA.

A variety of external data sources was used in preparing the cost estimates for this report. Although these data were reviewed for reasonableness, they were 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 the following:

- 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 would have a direct impact on the distribution of costs between the health plan and the insured person and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). The effects of such potential benefit changes in this analysis were not included.
- Adverse Selection. Theoretically, individuals or employer groups who had previously foregone insurance may elect to enroll in an insurance plan postmandate because they perceive 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 underlies analysis of the Utilization, Cost, and Coverage Impacts section of this report, specifically as related to the following:

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

Children with “symptomatic asthma” (defined as children having had experienced asthma symptoms in the past year) are assumed to be those affected by the mandate.

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

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

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

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