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An Analysis of California Assembly Bill 2185: Mandating Coverage of Pediatric Asthma Self-Management Training and Education

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Objective. To summarize for the California Legislature the evidence on the medical effectiveness of pediatric asthma self-management training and education (PASMTE), including the use of peak flow meters, spacers, and nebulizers and the impact that mandated coverage of these services and devices under Assembly Bill (AB) 2185 would have on total health care expenditures, monthly premiums, health services utilization, and the public's health.

Medical Effectiveness Findings. The review of the literature finds that PASMTE is medically effective and has favorable effects on the health of children with symptomatic asthma, as well as reduces asthma-related emergency room visits and hospitalizations. There was inadequate evidence to assess the effectiveness of the three medical devices independently of PASMTE.

Cost and Utilization Findings. One-hundred percent of children in health maintenance organization (HMO) plans in California are already covered for PASMTE, with fewer having coverage for the specific medical devices. However, despite full coverage of PASMTE in HMOs, these services are underutilized. We expect that the enactment of AB 2185 would increase utilization of PASMTE among children who are currently covered by 10 percent as a result of increased awareness of current coverage by all HMOs and increased awareness of the importance of these services. We estimate that this increased utilization by children who are already covered may result in a total statewide premiums increase of $170,000 or 0.006 percent, equal to one to two cents per member per month (PMPM).

Public Health Findings. It is estimated that the public health impact of the mandate, as a result of new utilization of PASMTE by 10 percent of children who are already covered, would reduce the number of school days missed because of asthma per year by 158,000; the number of children reporting restricted activity days by 6,020; the number of emergency department visits by 350; and the number of hospitalizations by 1,105.

Legislative Action. AB 2185 passed the legislature after being amended six times. The bill as it was signed into law did not mandate coverage for PASMTE, as all HMOs in California presently reported covering these services. However, the bill retained the

mandate for coverage of the three medical devices, as their coverage was not as universal across health plans.

Key Words. Health insurance, health policy, pediatrics, asthma, disease management, health education, politics, health maintenance organizations

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In February 2004, the California State Assembly introduced Assembly Bill (AB) 2185 that would require health service plans regulated and licensed by the California Department of Managed Care, as provided in the Knox–Keene Health Care Services Plan Act of 1975 (Knox–Keene), to cover self-management training and education for treating pediatric asthma, including the coverage of three medical devices (peak flow meters, nebulizers, and spacers). The proposed mandate applies to all insured children (ages 0–17 years) with symptomatic asthma who are enrolled in a Knox–Keene licensed health maintenance organization (HMO) or a point-of-service (POS) plan that covers outpatient prescription drugs. It does not apply to children in preferred provider organization (PPO) plans, or to children enrolled in self-funded employer plans, as they are exempt from states mandates by ERISA.

Asthma is a chronic inflammatory disease of the airways that is the most common chronic condition in childhood, affecting approximately 4.8 million children in the United States (CDC 1996). Childhood asthma that is poorly managed may result in acute episodes, often requiring emergency department visits and hospitalizations. This paper describes the available evidence regarding the effect of pediatric asthma self-management training and education (PASMTE) and the use of peak flow meters (PFM), nebulizers, and spacers on asthma-related health outcomes and health services utilization for children with symptomatic asthma in the state of California. In addition, this paper estimates changes in utilization of health services and devices following passage of the bill and the resulting impact of changes in utilization on total health care costs and monthly HMO premiums in the state, as well as the estimated

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public health impact of mandating these benefits. Finally, this paper concludes with a legislative update on the status of AB 2185.

Review of Medical Effectiveness Literature

For the review of the literature on medical effectiveness of PASMTE, trials were identified from the MEDLINE (1983 to October 2003) and Cochrane databases, including the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials (CENTRAL). The search was limited to English language abstracts and to studies involving children ages 0–17 years. Only trials conducted in the United States were reviewed, because (1) "usual care" differs substantially across nations, and (2) expectations and support for school attendance, as well as health care use vary substantially. The review included the following types of studies: clinical trials, controlled clinical trials, randomized-controlled trials, meta-analyses, and systematic reviews. Trials that included adults with asthma were excluded unless data were presented separately for children. Because of the difficulty of distinguishing between educational and self-management interventions, any trial that included an educational or self-management component was reviewed. The scope of the literature search included effects of self-management training and education 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. In addition, the review of the scientific research on the medical effectiveness of PFMs in monitoring pediatric asthma and the medical effectiveness of nebulizers and spacers as delivery devices for asthma medications for children were reviewed. At least two reviewers screened the title and abstract of each citation identified to determine eligibility for inclusion. Full-text articles were obtained and reviewers reapplied the initial eligibility criteria (Luft et al. 2006).

A recent meta-analysis (Wolf et al. 2003) 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. In updating these findings, we identified 16 additional trials published between 1998 and 2003. Of the primary trials selected, the results of randomized-clinical trials were given more weight than nonrandomized trials (as the latter may be subject to bias).

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

(1) Favorable: findings are uniformly favorable, many or all are statistically significant; (2) pattern toward favorable: findings are 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; difficult to discern a pattern.

Meta-analyses and randomized-controlled trials were used to estimate the mean effects for specific outcomes. Where possible, we reviewed the original studies referenced in the meta-analyses and summarized the results in the natural units. For those trials where outcomes were reported in natural units, weighted averages for each outcome measure were computed without confidence intervals. For outcomes where there was more than one trial, we estimated a weighted average percentage change, using the sample size for each trial and the estimated proportionate change expected in the experimental group (Luft et al. 2006).

Medical Effectiveness of Pediatric Self-Management Training and Education

The components of pediatric asthma management may include the following: medications for the treatment of asthma; outpatient asthma visits every 1–6 months (depending on severity); asthma education for children and parents (individual or group classes); peak airflow meter measurement at home (patients require a PFM for self-monitoring); spirometry testing (measurement of the air entering and leaving the lungs) 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 3–5 years); annual influenza vaccinations; and treatment of upper respiratory symptoms (rhinitis/sinusitis) and gastroesophageal reflux (which can create heartburn or more serious problems) (NAEPP 2003).

The results of the review of the scientific research on the medical effectiveness of PASMTE are organized into five major effects: health outcomes, knowledge and self-efficacy, disability, health services utilization, and quality of life. Table 1 summarizes the findings of all of the trials reviewed for each

Table 1: Summary of Evidence on the Effectiveness of Pediatric Asthma Self-Management Training and Education (PASMTE)

Outcome Measures	*# of Trials*	*Direction of Effect (Mean Percent Change)*	*Evidence Score*
Health Effects			
Days of asthma symptoms	5	Decrease	Favorable
Symptom-free days	2	Increase	Favorable
Symptom scores	3	Decrease	Favorable
PEFR	2	Increase	Favorable
Nocturnal asthma	3	Decrease	Favorable
Asthma severity	10	Decrease	Pattern toward favorable
Self-Efficacy and Knowledge			
Self-efficacy of children	9	Increase	Favorable
Child's knowledge	13	Increase	Favorable
Caregiver's knowledge	2	Increase	Pattern toward favorable
Disability Effects			
School absences—mean days	8	Decrease (−44%)	Favorable
Restricted activity days	1	Decrease (−25%)	Favorable
School absences—% children absent	2	Decrease (−43%)	Pattern toward favorable
Health Services Utilization			
Emergency department use	13	Decrease (−26%)	Favorable
Mean hospitalizations	9	Decrease (−30%)	Favorable
Use of medications (inhaled coticosteroids, cromolyn)	3	Increase in Rx Decrease in Dose	Favorable
Acute/urgent MD visits	5	Decrease	Pattern toward favorable
Quality-of-Life			
Child's quality-of-life	4	Increase	Favorable
Caregiver's quality-of-life	1	Increase	Pattern toward favorable

PEFR, peak expiratory flow rate.

outcome, including the number of trials reviewed, the observed direction of the effect of PASMTE, the estimated mean effect where this could be assessed, and a summary of the evidence. Only those outcomes for which the summary of the evidence found a favorable or a pattern towards favorable effects are reported. The full citations for the literature review are included in an electronic appendix.

Health Outcomes. The review of the literature on PASMTE showed favorable effects for five health outcomes including the number of days of asthma symptoms (Fireman et al. 1981; Evans et al. 1987; Bonner et al. 2002; Yoos

et al. 2002; Krishna et al. 2003), symptom-free days (Wilson et al. 1996; Brown et al. 2002), symptom scores (subjective measures of how much a patient is bothered by symptoms or how often a patient experiences asthma symptoms) (Christiansen et al. 1997; Bartholomew et al. 2000; Brown et al. 2002), peak expiratory flow rate (a measure of lung function as the maximum rate of airflow that can be achieved during a sudden forced expiration from a position of full inspiration) (Christiansen et al. 1999; Guendelman et al. 2002), and nocturnal asthma (Wilson et al. 1996; Georgiou et al. 2003; Krishna et al. 2003). In addition, the evidence on the effect of PASMTE on asthma severity showed a pattern toward favorable effects (LeBaron et al. 1985; Whitman et al. 1985; Perrin et al. 1992; Wilson et al. 1996; Bartholomew et al. 2000; Homer et al. 2000; Harish et al. 2001; Yoos et al. 2002; Georgiou et al. 2003; Huss et al. 2003).

Knowledge and Self-Efficacy. The effects of PASMTE were assessed on the child's and care-giver's knowledge of asthma and its management, as well as its effects on self-efficacy. Self-efficacy is measured as a belief in one's capabilities to organize and execute the sources of action required to manage asthma (Bandura 1994). A favorable effect was observed in the child's knowledge (Parcel et al. 1980; LeBaron et al. 1985; Whitman et al. 1985; Rubin et al. 1986; Perrin et al. 1992; Christiansen et al. 1997; Bartholomew et al. 2000; Shegog et al. 2001) and a pattern toward favorable effects was observed for knowledge of caregivers of children with asthma (Persuad et al. 1996; Krishna et al. 2003). In addition, PASMTE was found to have favorable effects on self-efficacy (Parcel et al. 1980; Kubly et al. 1984; LeBaron et al. 1985; Whitman et al. 1985; Rubin et al. 1986; Evans et al 1987; Bartholomew et al. 2000; Shegog et al. 2001; Bonner et al. 2002).

Disability Days. The review of the literature on PASMTE showed favorable effects in reducing school absences measured as the mean number of days children with asthma were absent from school (Fireman et al. 1981; Rubin et al. 1986; Evans et al. 1987; Perrin et al. 1992; Persaud et al. 1996; Wilson et al. 1996; Christiansen et al. 1997; Krishna et al. 2003). In addition, one trial found favorable effects on reducing the number of restricted activity days children with asthma experience (Guendelman et al. 2002). The review of the literature on the proportion of children with asthma who reported any school absences following PASMTE found a pattern toward favorable effects (Guendelman et al. 2002; Georgiou et al. 2003).

Health Services Utilization. The three utilization measures that were classified as having favorable effects include emergency department utilization measured as the mean number of emergency room visits for children with asthma (Fireman et al. 1981; Lewis et al. 1984; Clark et al. 1986; Rubin et al. 1986; Alexander et al. 1988; Shields et al. 1990; Christiansen et al. 1997; Greineder et al. 1999; Harish et al. 2000; Homer et al. 2000; Kelly et al. 2000; Krishna et al. 2003), hospitalizations (Fireman et al. 1981; Lewis et al. 1984; Clark et al. 1986; Christiansen et al. 1997; Greineder et al. 1999; Bartholomew et al. 2000; Kelly et al. 2000), and utilization rates for asthma medications such as inhaled corticosteroids (cromolyn) (Bonner et al. 2002; Lukacs et al. 2002; Krishna et al. 2003). In addition, a pattern toward weak or no effect was found for the effect of PASMTE on acute and urgent physician visits (Evans et al. 1987; Homer et al. 2000; Krishna et al. 2000; Brown et al. 2002; Lukacs et al. 2002).

Quality of life. The World Health Organization defines health-related 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." The review found that evidence on quality-of-life effects in children could be classified as favorable (Fireman et al. 1980; Evans et al. 1987; Perrin et al. 1992; Georgiou et al. 2003), while the effects on caregivers could be classified as a pattern toward favorable (Brown et al. 2002).

Medical Effectiveness of Medical Devices

Description of Medical Devices

The standard asthma medication delivery system is the metered dose inhaler (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 range from 170 to 750 mL and shapes vary. Consequently, the effects on physiological function vary with the size of these devices.

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 cup filled with liquid medicine. The force of the air breaks the liquid into tiny mist-like 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 plastic tube that connects the mouthpiece to the compressor. There are home and hospital nebulizers, as well as portable units (Health A to Z 2003). Nebulizers are easy for the patient to use and require only the usual inspiration and expiration through the connection to the nebulizer.

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 the lungs). These devices help patients and doctors monitor and manage asthma. For example, readings from a PFM can help the patient implement an action plan and change medication doses as needed. Most peak flow readings fall into three zones—green, yellow, or red. A reading in the red zone indicates a significant drop in peak flow rate and signals a medical alert where immediate action is needed.

Literature Review on Medical Devices for Pediatric Asthma Management

The outcomes reviewed on the effectiveness of medical devices for children with asthma included physiological measures of lung function (forced expiratory volume in one second [FEV_1], peak expiratory flow [PEF], and forced expiratory flow [FEF]), health care utilization (unscheduled medical visits and hospital admissions), and public health impact (missed days of school). FEV_1 is the volume of air expired in the first second of maximal expiration after a maximal inspiration. PEF rate is the rate of maximum flow at the outset of forced expiration, which is reduced in proportion to the severity of airway obstruction. FEF 25–75 percent is the FEF in the middle half of an expiration and indicates any obstruction in the airways.

Many of the trials on medical devices reviewed had small sample sizes. Meta-analysis could not be used to combine results of small trials because of differences in the devices and medications used and the outcomes measured across trials. Thus, 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 effects on their own.

Finally, the effectiveness of asthma medication delivery devices and PFMs could not be separated from the effects from PASMTE. A child and parent who are given a spacer device without instruction would not be able to use it properly. According to the American Academy of Allergy, Asthma, and Immunology (2000), "For all devices, training and education 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." The results of the review of the medical effectiveness of medical devices for asthma management are organized around the three specific medical devices: spacers, nebulizers, and PFMs.

Effectiveness of Spacers. The evidence from literature is not of sufficient quality to draw conclusions about the effectiveness of spacers in children with asthma (Pedersen 1983; Becker et al. 1985; Rachelefsky et al. 1986; Cunningham and Crain 1994). 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 against a placebo. However, the evidence with respect to a comparison of MDIs with spacers versus MDIs alone depends on the specific outcome measures; thus, the conclusion is that there is inadequate evidence to assess the effectiveness of these devices independent of PASMTE.

Effectiveness of Nebulizers. Trials that compared nebulizers to MDIs with spacers were reviewed (Chou et al. 1995; Batra et al. 1997; Dewar et al. 1999; Schuh et al. 1999; Wildhaber et al. 1999; Leversha et al. 2000; Ploin et al. 2000; Brocklebank et al. 2001; Rao and Rizvi 2002; Cates et al. 2003). However, there is no clear or consistent evidence that treatment with nebulizers is more effective in improving clinical outcomes than MDIs with spacers. The literature was classified as showing a pattern toward no effect/weak evidence. The trials had inadequate statistical power to demonstrate clinical equivalence and cannot exclude a clinical benefit of nebulizers.

Effectiveness of PFMs. Because PFMs are monitoring devices (not treatments or medication delivery systems), and are generally used in conjunction with

patient education in asthma self-management, the clinical efficacy of PFMs by themselves cannot be determined. Therefore, the literature on the use of PFMs on their own was classified as insufficient evidence.

UTILIZATION, COST, AND COVERAGE IMPACTS

Baseline Utilization and Cost. The mandated services under AB 2185 include PASMTE and three medical devices (PFMs, nebulizers, and spacers). In estimating the impact of the proposed mandate on costs, utilization, and premiums, the relevant 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 the three medical devices. Health services utilization associated with poor management of childhood asthma includes emergency department visits and inpatient hospital stays.

For the utilization and cost analysis, children with symptomatic asthma were defined as having had at least one of the following events in the last year: one prescription asthma medication, one asthma-related emergency department visit, one asthma-related hospitalization, one asthma-related outpatient visit, or to have used asthma-related devices and tests. Under these criteria, about 10.1 percent of children aged 0–17 years enrolled in HMOs in California have symptomatic asthma. However, approximately 12 percent of these children do not have coverage for outpatient prescription drugs and thus would not be affected by AB 2185. This analysis assumes similar costs and rates of utilization for children covered under group and individual insurance because of lack of data on specific utilization rates for each market.

Using data from the 2001 California Health Interview Survey (CHIS) and commercially available databases from Milliman USA (Milliman USA 2003), the analysis found that approximately 337,000 children in California have symptomatic asthma, are insured through the individual or group markets, are enrolled in an underwritten Knox–Keene licensed plans, and have outpatient prescription drug coverage.

We further estimated the current baseline utilization rates, costs per service, and costs per member per month (PMPM) for children with symptomatic asthma in the group and individual insurance markets. For every 1,000 covered children with asthma, there are 3,000 prescriptions, 300 asthma-related equipment and devices, and 536 sessions of asthma training and education. In addition there are 1.8 office visits, 0.011 inpatient days, and

0.4 emergency room visits per pediatric asthma patient per year. The costs are estimated to be $57 per prescription, $50 per device, and $80 per training and education session (individual, group, and patient education materials), while the PMPM costs are estimated at $7.03 PMPM per ambulatory visit, $3.70 PMPM per inpatient stay, and $1.88 PMPM per emergency room visit.

Baseline Coverage. Based on a survey of the eight largest commercial HMOs operating in California at the time of the study, we found that coverage of pediatric asthma services in commercial HMOs in California is extensive. All commercial HMOs cover pediatric asthma-related inpatient care, ambulatory care, and emergency department visits for 100 percent of enrolled children. In addition, asthma self-management training (100 percent), individual health education (100 percent), patient education materials (98 percent), group health education (91 percent), and spacers (94 percent), nebulizers (94 percent), and PFMs (75 percent) are also widely covered for children. Thus, the mandate will have no impact on the coverage of PASMTE but will increase coverage for the medical devices to 100 percent of children in HMOs.

Impact of Mandate on Utilization. Even though asthma self-management training and individual health education are covered by 100 percent of HMOs in California, utilization of these services by children with asthma remains low at 54 percent. It is not clear why utilization is so low. It may be because families and providers are not aware of the coverage or that physicians are not aware of the effectiveness of these services. We expect the passage of the bill to create new demand. PASMTE is already covered 100 percent, but passage of the bill will increase awareness of three things: (1) that PASMTE services are covered by all HMOs, (2) that all HMOs will now cover the medical devices, which require training and education for their proper use, and (3) that these services are very effective in reducing adverse events for children with asthma. The bill, in effect, informs people of the existing coverage, the new coverage of the devices, and the effectiveness of the services. It is assumed that this increased awareness will stimulate new utilization. The current rate at which children receive training and education is approximately 54 percent for all children with symptomatic asthma enrolled in HMOs and POS plans (CHIS 2003). Utilization of PASMTE services for enrolled children is estimated to increase by 10 percentage points (to 64 percent) in the year following the mandate. This projected increase in

the utilization of PASMTE is based on the expected increased demand as a result of increased awareness of patient families and providers through media attention and the activities of advocacy organizations following the enactment of the bill. 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 bills passage may be higher or lower than this assumption. All estimates are made for just 1 year following adoption of the mandate, and only point estimates are provided to the legislature, even thought there is uncertainty associated with all estimates. It is our experience that trying to communicate uncertainty about estimates by using ranges or confidence intervals actually creates more confusion than clarity, because of many legislators' unfamiliarity with statistics.

The review of the medical effectiveness of PASMTE programs suggests that, following enactment of the mandate, the assumed increase in utilization of the services by 10 percent of currently covered children will result in a mean reduction in the number of inpatient hospitalizations for children with symptomatic asthma by 30 percent and the mean number of emergency room visits would be reduced by 26 percent. The evidence from the literature review on medical effectiveness also suggests that there would be little to no impact on outpatient visits. The effects on hospitalizations and emergency room visits identified in the literature review 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 health services utilization impacts should be viewed as upper bounds.

Impact on Administrative and Other Expenses. The mandate is expected to increase the administrative expenses for health plans, but not disproportionately to the increase in health care costs. An increase in PASMTE claims may increase administration costs, as plans would have to modify their insurance contracts and member materials and may have to contract with new providers specializing in asthma education. Health plans include a component for administration and profit in their premiums, which may be sufficient for covering increased administrative costs. No effect on per-unit cost of 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.

Impact on Total Health Care Costs. Total expenditures (including total premiums and out-of-pocket expenditures) would increase by an estimated $170,000 or 0.006 percent. The impact varies in the large and small group as well as individual markets (Table 2). The impact on total expenditures in the HMO large group and individual markets is estimated to be 0.005 percent while the impact in the HMO small group market is estimated to be 0.007 percent. This is the net effect of the mandate on costs, factoring in both the new costs associated with new utilization of services, as well as the estimated cost savings resulting from reduced asthma-related emergency room visits and hospitalizations (estimated as 0.002 or 25 percent of the increase). After the mandate, the overall cost increase would be borne by HMOs and PPOs in the large, small, and individual markets. The total premium increase of $170,000 would amount to approximately one to two cents PMPM.

Public Health Impacts

Present Baseline Health Outcomes

In California, 14 percent of insured children aged 1–17 years have ever been diagnosed with asthma (CHIS 2003). However, nearly one-quarter of these children did not experience any symptoms in the past year. This means that approximately 10 percent of insured children in California have symptomatic asthma (i.e., asthma for which they experienced symptoms in the past year) (CHIS 2003). Of those children with symptomatic asthma, almost two-thirds report they take medicine for their asthma, and almost half report they experience asthma symptoms at least once a month (CHIS 2003). Children who experience asthma symptoms are more likely to miss school and be restricted in their activities compared with children without asthma.

Although a review of the medical evidence suggests there are many categories of public health outcomes associated with PASMTE programs, there were only four public health outcomes for which quantitative estimates of the effects of the mandate could be made because of lack of population-based baseline data for California's children (McMenamin 2006). The four public health outcomes for which quantitative estimates could be made include mean number of days of school missed, percentage of children with asthma reporting restricted-activity days, and mean number of emergency department visits and hospitalizations.

Table 2: Postmandate Impacts of AB 2185 on per Member per Month (PMPM) Cost and Total Expenses, California, Calendar Year 2004

	Large Group		*Small Group*			
	HMO	*POS*	*HMO*	*POS*	*Individual*	*Total*
PMPM $ Impact of Mandate						
Insured Premiums						
Total premium	$0.013	$0.012	$0.019	$0.0018	$0.008	$170,000
Average portion of premium paid by employer	$0.010	$0.009	$0.014	$0.014	$0.000	$130,000
Average portion of premium paid by employee	$0.003	$0.003	$0.005	$0.004	$0.008	$50,000
Covered benefits paid by member (deductibles, copays, etc.)	$0.0001	$0.001	$0.001	$0.0012	$0.0013	$10,000
Total cost of covered benefits	$0.0136	$0.0136	$0.0203	$0.0203	$0.0102	$180,000
Benefits not covered	−$0.001	−$0.001	−$0.002	−$0.002	−$0.0001	($20,000)
Total expenditures	$0.0124	$0.0124	$0.0182	$0.0182	$0.0102	$170,000
Percentage Impact of Mandate on						
Insured premium	0.0067%	0.0056%	0.0081%	0.0079%	0.0049%	0.0068%
Total expenditures	0.0056%	0.0055%	0.0079%	0.0078%	0.0059%	0.0067%

Source: California Health Benefits Review Program (2003).

The baseline data suggest that adolescents in California with symptomatic asthma missed an average of 1.2 days of school in the last month, and, of the 40 percent who missed any school, an average of 2.9 days of school were missed per month (CHIS 2003). This translates into approximately 400,000 days of school missed among California children with symptomatic asthma. Before the mandate, 71 percent of children with symptomatic asthma with health insurance reported that they experienced restricted physical activity because of their asthma (CHIS 2003). In terms of health care utilization, 1 percent of children with asthma were hospitalized because of their disease in the past year, and 3 percent had emergency department visits because of asthma symptoms (Milliman USA 2003). Half of adolescents (aged 12–17 years) with asthma in California report that a doctor explained to them how to recognize asthma attacks (51 percent) or how to avoid the things that make their asthma worse (54 percent) (CHIS 2003).

Impact of the Proposed Mandate on Public Health

Although all California children with symptomatic asthma who are enrolled in HMOs currently have coverage for PASMTE, a 10 percentage point increase in the utilization of PASMTE services (from 54 to 64 percent) is estimated following the bill's enactment for these presently covered children. For all of the public health outcomes assessed, the effects identified in the literature review from clinical trials may not be achieved at the same levels when implemented in the 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 the effects of the mandate on the public's health should be viewed as upper bounds. If fewer additional covered children newly receive services as a result of the mandate, or if the actual interventions are less effective than what was observed in clinical trials, the public health benefits of this mandate would be less.

School Absences. Forty percent of children with symptomatic asthma who would be affected by the mandate (135,000 children) missed school in the past month because of illness, with a reported average of 1.2 days of school missed per month per asthmatic child (CHIS 2003). The evidence suggests that PASMTE leads, on average, to a reduction of 44 percent in the number of school days missed by asthmatic children. Based on our assumption that 10 percent of children with symptomatic asthma will newly receive asthma

self-management services, the bill may result in a reduction of approximately 17,600 days of missed school each month because of asthma, or approximately 158,000 fewer days per year, assuming a 9-month school year.

Restricted-Activity Days. More than 70 percent of children with symptomatic asthma report that their physical activity is limited because of their asthma (CHIS 2003). The evidence suggests that PASMTE leads to a 25 percent reduction in the percentage of children reporting restrictive activity because of asthma. The analysis suggests that for the 10 percent of already covered children with asthma who would newly use the services following the bill's passage, approximately 6,020 fewer children would report limitations in physical activity because of asthma.

Emergency Department Visits. The mean number of annual asthma-related emergency department visits per child with symptomatic asthma is 0.04 per year (Milliman USA 2003). This translates into 13,485 asthma-related emergency department visits per year in California for children with symptomatic asthma who would be affected by the mandate. The evidence suggests that PASMTE leads, on average, to a decrease in the mean number of emergency department visits of 26 percent. Thus, for the 10 percent of already covered children who would newly use the services following passage of the bill, the analysis suggests that there would be approximately 350 fewer asthma-related emergency department visits per year.

Hospitalizations. An estimated 1 percent of children with asthma or 3,370 children in California who would be affected by the mandate are hospitalized each year for asthma-related conditions (Milliman USA 2003). The evidence suggests that PASMTE leads, on average, to a 30 percent reduction in the mean number of asthma-related hospitalizations. Based on this evidence, for the 10 percent of already covered children who will newly use PASMTE services following the bill's passage, there would be approximately 1,105 fewer hospitalizations for asthma-related conditions among children with symptomatic asthma.

Other Significant Pubic Health Effects. A review of the literature on the effectiveness of PASMTE identified other health 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 measured by PEF. In addition, literature on the impact of PASMTE suggests that children and, in some cases, their caregivers report an increase in the quality of their life and increased knowledge about asthma and its management. Finally, evidence suggests that children who have had PASMTE perceive they are more capable of organizing and executing the actions required to manage their asthma.

Legislative Action

The CHBRP analysis of SB 2185 found that all children insured by HMOs and POS plans in California have coverage for PASMTE, but fewer children are currently covered for the three mandated medical devices, particularly PFMs (75 percent). The review of the medical effectiveness literature found that PASMTE produces favorable health status, health services utilization, and quality of life outcomes for children with symptomatic asthma. However, little evidence was found on the effects of PFMs, spacers, and nebulizers independent of training and education on how to use them properly. The impact of the proposed mandate on health care costs in California was estimated to increase utilization of already covered PASMTE services, as well as increased use of newly covered medical devices. The total health care expenditures are estimated to increase by only $170,000 and increase the average cost of the HMO premium by one to two cents PMPM. The estimated public health impacts in the first year following the mandate include 1,105 fewer asthma-related hospitalizations, 350 fewer asthma-related emergency department visits, 6,020 fewer children with asthma experiencing restricted activity days, and 158,000 fewer days missed from school.

The final CHBRP report analyzing AB 2185 was submitted to the legislature on April 14, 2004. Several interest groups testified at committee hearings subsequently held on the bill and most submitted written documentation for their support or opposition to the proposed mandate. Groups supporting the bill included the American Lung Association, the Asthma and Allergy Foundation of America, the California School Nurses Organization, Health Access California, the Latino Issues Forum, the Gray Panthers, California School Employees, and the American Academy of Pediatrics. The positions of these groups supported the coverage of the medical devices. They argued that PFMs were one of the basic tools that all asthmatic children need to monitor their asthma, and that spacers and nebulizers enable children to properly administer their asthma medications. The American Lung Association also

supported the bill based on their position that training and education in asthma self-management by children helps "reduce asthma attacks, severity of attacks, and helps children live full, quality lives."

Groups opposing the bill included the California Chamber of Commerce, the National Federation of Independent Businesses, and the California Association of Physician Groups (CAPG). Based on their concern that AB 2185, along with other mandates that were being considered, would increase premiums that would lead to increased numbers of uninsured, the Chamber of Commerce called on the legislature to adopt a moratorium on all new benefit mandates. CAPG strongly opposed the PASMTE provisions of the bill because they would "set a dangerous precedent by mandating the practice of medicine" and that "legislative mandates dictating doctors' conduct undermines the doctor–patient relationship."

After CHBRP sent its report on AB 2185 to the legislature in April 2004, the bill was amended six times, twice in the State Assembly and four times in the State Senate. The bill as amended was approved by greater than two-thirds bipartisan majorities in the Assembly Health Committee (80 percent), Assembly Appropriations Committee (80 percent), on the Assembly Floor (69 percent), in the Senate Insurance Committee (78 percent), and on the Senate Floor (74 percent). The most significant change made to the bill was the deletion of the mandate to provide coverage for PASMTE, as the HMO plans in the state reported that 100 percent of children in affected plans already had coverage for these services. The bill, as it was enrolled and signed into law by the California Governor on September 23, 2004 mandates coverage only for the three medical devices (PFM, spacer, and nebulizer) to make them equally available to children across HMO and POS plans. The bill also states that "education for pediatric asthma, including education to enable an enrollee to properly use the devices, shall be consistent with current professional medical practice." The bill effectively assumes that the education and training in the use of these devices would be provided under the PASMTE services currently covered by the plans.

Even though the final bill did not include mandated coverage for PASMTE, but only for the three medical devices, the original CHBRP estimated impacts of the bill are not expected to change significantly. In our original analysis, we assumed that there would be no increase in coverage for PASMTE as a result of the mandate. Whether or not the final bill included a mandate for coverage of PASMTE, coverage will remain at 100 percent. The utilization impacts we estimated are a result of the new demand stimulated by the bill's passage, not by increasing coverage for PASMTE. Thus, regardless of

whether or not the bill includes PASMTE, we assume that utilization of PASMTE will increase along with the increased coverage for the devices and as a result of the increased awareness of full coverage and effectiveness. This is because the original estimated new utilization and costs associated with the bill's passage were not a function of any new coverage, but were a function of the expected impact of the bill's passage on increased patient and provider awareness of these covered services and their importance, resulting in a 10 percent increase in utilization. We anticipate that enactment of the bill mandating coverage only for medical devices will also stimulate new demand and increase utilization of these services by 10 percent of children with asthma who will benefit from their medical effectiveness, and will produce the estimated public health benefits.

What the legislation did not do was to address the question of the availability and accessibility of PASMTE, as well as the three medical devices, for children with symptomatic asthma in California who are not enrolled in HMO plans—those who are in PPO plans, Medicaid, the state's children's health insurance program (Healthy Families), and self-insured employer plans, as well as those who are uninsured. In fact, the mandate will affect fewer than half of the children in California with symptomatic asthma, including 389,000 who are in non-HMO/POS plans and 83,000 without any health insurance coverage (CHIS 2003). The bill targets those who already have relatively comprehensive coverage for pediatric asthma services. Thus, while the costs associated with the mandate are only pennies per month per enrollee and the health benefits are estimated to affect thousands of children, the mandate will do little overall to increase access to PASMTE and associated medical devices for the majority of children in California who suffer from asthma and are not enrolled in an HMO.

In addition, the utilization of PASMTE services is relatively low in California's HMO and POS plans, even though they are fully covered. Only about half of symptomatic children report receiving any training or education about the management of their asthma. While a mandated benefit may be expected to increase awareness of the availability of the services covered by HMO and POS plans, the key to increasing appropriate use of these services is more likely to come from holding health plans and health care providers accountable for the delivery of PASMTE to their patients with asthma (Casalino et al. 2003), and from more effectively educating patients, their families, and health care professionals about the health benefits of PASMTE in reducing asthma symptoms, related disability, and the adverse outcomes associated with pediatric asthma if it is not properly managed.

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SUPPLEMENTARY MATERIAL

The following supplementary material for this article is available online:

Literature Review of the Medical Efficacy of Pediatric Asthma Self-Management Training and Education, Nebulizers, Spacers, and Peak Flow Meters.