CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Senate Bill 1508: Use of Propofol for Colonoscopies

A Report to the 2006–2007 California Legislature
April 8, 2006

CHBRP 06-05

Established in 2002 to implement the provisions of Assembly Bill 1996 (*California Health and Safety Code,* Section 127660, et seq.), the California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates. The statute defines a health insurance benefit mandate as a requirement that a health insurer and/or managed care health plan (1) permit covered individuals to receive health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

A small analytic staff in the University of California's Office of the President supports a task force of faculty from several campuses of the University of California, as well as Loma Linda University, the University of Southern California, and Stanford University, to complete each analysis within a 60-day period, usually before the Legislature begins formal consideration of a mandate bill. A certified, independent actuary helps estimate the financial impacts, and a strict conflict-of-interest policy ensures that the analyses are undertaken without financial or other interests that could bias the results. A National Advisory Council, made up of experts from outside the state of California and designed to provide balanced representation among groups with an interest in health insurance benefit mandates, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes sound scientific evidence relevant to the proposed mandate, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work though a small annual assessment of health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at CHBRP's Web site, www.chbrp.org.

A Report to the 2006–2007 California State Legislature

Analysis of Senate Bill 1508
Use of Propofol for Colonoscopies

April 8, 2006

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Senate Bill 1508, a bill that would require health care service plans and insurance policies to include coverage for propofol for colonoscopies. In response to a request from the California Senate Committee on Banking, Finance and Insurance on February 8, 2006, CHBRP undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127600, et seq., of the California Health and Safety Code.

Wade Aubry, MD, Janet Coffman, PhD, Patricia Franks, BA, Witney McKiernan, RN, Harold Luft, PhD, and Edward Yelin, PhD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Maurice S. Zwass, MD, provided technical assistance with the literature review and clinical expertise for the medical effectiveness analysis. Stephen L. Clancy, MLS, AHIP**,** of the University of California, Irvine, conducted the literature search. Helen Halpin, PhD, Sara McMenamin, PhD, Janine Santimauro, and Nicole Bellows, MHSA, of the University of California, Berkeley, prepared the public health impact analysis. Ying-Ying Meng, PhD, Meghan Cameron, MPH, and Gerald Kominski, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Robert Cosway, FSA, MAAA, of Milliman, provided actuarial analysis. Cynthia Robinson, MPP, of CHBRP staff prepared the background section and synthesized individual sections into a single report. Cherie Wilkerson, BA, provided editing services. In addition, a subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Theodore Ganiats, MD, of the University of Calfiornia, San Diego, 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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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 1508: Propofol for Colonoscopies

The California Legislature has asked the California Health Benefits Review Program to conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill 1508 (SB 1508). In response to a request from the California Senate Committee on Banking, Finance and Insurance on February 8, 2006, CHBRP undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127600, et seq., of the California Health and Safety Code.

SB 1508 would mandate that health care service plans licensed under the Knox-Keene Health Care Service Plan Act of 1975 and health insurance policies regulated under the California Insurance Code cover propofol, an anesthetic, for the purpose of colonoscopies. SB 1508 would not explicitly preclude a health plan or insurer from determining medical necessity, or conducting utilization review.

Colonoscopy is a procedure that allows complete examination of the large intestine. Although colonoscopies are most often used to diagnose or rule out colon cancer, colonoscopies are also frequently used to evaluate symptoms such as abdominal pain, rectal bleeding, and weight loss to diagnose other diseases. Colonoscopies can also be used for treatment.

In the United States, most colonoscopies are performed with the patient under moderate (conscious) sedation. A minority of colonoscopies are performed under "deep" sedation in which an anesthetic agent is used for sedation. Propofol is the most recently developed intravenous anesthetic and is rapidly replacing other types of anesthetics.

Based on discussions with the author's staff, the intent of this bill is to ensure physicians have the option to use deep sedation with propofol for those patients whose anxiety interferes with their willingness to undergo a colonoscopy or return for a subsequent screening exam.

I. Medical Effectiveness

The evidence base for assessing the medical effectiveness of propofol includes studies that evaluate propofol versus traditional sedative agents (e.g., midazolam) as well as studies that evaluate propofol combined with an analgesic or sedative agent versus other combinations of analgesic and sedative agents. In the latter set of studies, it is difficult to determine whether the outcomes reflect the effect of propofol, the adjunct agents, or the combination of these agents.

Within the scope and limitations outlined above, CHBRP's review of evidence from meta-analyses and randomized controlled trials suggests that:

- There is ambiguous/mixed evidence with regard to physiological and cognitive outcomes (e.g., vital signs, oxygen saturation, and cognitive function) for comparisons between propofol and traditional sedative or analgesic medications used during colonoscopy. In other words, there is no clear evidence indicating that propofol is associated with better or worse physiological and cognitive outcomes than traditional sedation methods.

- There is a pattern toward favorable results with respect to the use of propofol versus traditional sedation methods for:

    - procedural outcomes, for example, procedure duration or sedation level; and

    - post-procedure outcomes, such as patient satisfaction, recovery time, or side effects.

- Findings are similar for studies in which persons in both the intervention and control groups received propofol (alone or in combination with a traditional sedative and/or analgesic)

- While there are concerns and risks associated with the use of anesthesia, the safety outcomes associated with the use of propofol appear to be comparable to those associated with the use of other sedative and analgesic agents. However, many of the studies have sample sizes that may not be large enough to adequately assess the prevalence of complications among persons who receive propofol.

II. Utilization, Cost, and Coverage Impacts

Approximately 20,144,000 individuals under age 65 years in California are enrolled in plans subject to SB 1508. The utilization, cost, and coverage impact analyses indicate:

- CHBRP survey of the largest health plans in California indicates all enrollees have coverage for propofol during colonoscopies when determined to be medically necessary. SB 1508 does not forbid the use of a "medically necessary" determination by health plans.

- The annual colonoscopy utilization rate is estimated to be 17.2 per 1,000 members (or 0.017%) in commercial plans for those under age 65 years. About 14% of people receiving colonoscopies in insured plans have a separate charge for anesthesia professional services.

- The cost of the propofol itself is estimated to be $27 ± $14. These costs are comparable to those costs associated with other commonly used anesthetics. The main cost associated with propofol use is the cost of the anesthesiology professional service, which is approximately $450. Although SB 1508 does not mandate that propofol use for colonoscopy be accompanied by professional anesthesiology service, this analysis assumes that such professional services would be necessary to be compliant with current federal requirements. Specifically, the U.S. Food and Drug Administration (FDA) currently requires that propofol be administered by a professional trained in the use of general anesthesia.

- The utilization of colonoscopies is not expected to increase due to this mandate. However, the utilization rate for propofol with anesthetic service for colonoscopy is estimated to increase by two percentage points (from the current rate of 14% to 16%), for an additional 6,248 members ages 50 to 65 years who would receive propofol for colonoscopies per year. This two–percentage point increase of propofol would result in

the decrease in the use of moderate sedation for the purpose of colonoscopy by 2% (from 86% to 84%).

- The mandate is estimated to increase total annual net expenditures by $3.378 million or 0.01% (Table 1). This estimate of increase should be viewed as an upper bound since it reflects the cost of professional anesthesiology services to administer the drug. If the FDA removes propofol's warning label to allow trained non-anesthesiologists to administer the medication, we would expect little or no increase in expenditures. Health insurance premiums are estimated to increase *on average* by 0.005% or $0.0131 per member per month (PMPM) when professional anesthesiology services are used for administering propofol.

- Increases in PMPM premium expenditures are estimated to range from $0.0008 to $0.017 across different segments of the insurance market. The greatest impact would be on the individual health maintenance organization market. In the large-group market, the resulting premium impact would range from 0.004% to 0.006%. In terms of PMPM, the increase in premiums for the large-group market is estimated to range from $0.0134 to $0.0146.

Table 1. Summary of Coverage, Utilization, and Cost Effects of SB 1508

	Before Mandate	After Mandate	Increase/ Decrease	% Change After Mandate
Coverage				
Percentage of insured individuals with coverage for propofol	100%	100%	0%	0.0%
Number of insured individuals with coverage for the benefit	20,144,000	20,144,000	—	0.0%
Utilization				
Percent of insured receiving colonoscopies				
With propofol	14.0%	15.8%	1.8%	12.8%
With other anesthetic	86.0%	84.2%	–1.8%	–2.1%
Total	100.0%	100.0%	0.0%	0.0%
Number of insured receiving colonoscopies				
With propofol	48,628	54,876	6,248	12.8%
With other anesthetic	298,716	292,468	–6,248	–2.1%
Total	347,345	347,345	—	0.0%
Average cost per service for colonoscopy anesthesia				
Average per-patient marginal cost of propofol versus other anesthetics	$450	$450	$0	0.0%
Expenditures				
Premium expenditures by private employers for group insurance	35,792,975,000	35,794,814,000	1,839,000	0.01%
Premium expenditures for individually purchased insurance	4,744,086,000	4,744,458,000	372,000	0.01%
CalPERS employer expenditures	2,330,367,000	2,330,484,000	117,000	0.01%
Medi-Cal state expenditures	4,334,532,000	4,334,780,000	248,000	0.01%
Healthy Families state expenditures	644,314,000	644,320,000	6,000	0.00%
Premium expenditures by employees with group insurance or CalPERS, and by individuals with Healthy Families	11,378,584,000	11,379,174,000	590,000	0.01%
Member copayments	3,837,497,000	3,837,703,000	206,000	0.01%
Expenditures for non-covered services	—	—	—	N/A
Total annual expenditures	63,062,355,000	63,065,733,000	3,378,000	0.01%

Source: California Health Benefits Review Program, 2006.
Note: The population includes individuals and dependents in California who have private insurance (group and individual) or are enrolled in Knox-Keene licensed health plans obtained through CalPERS, Medi-Cal, or Healthy Families. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-based coverage. Employees and their dependents who receive their coverage from self-insured firms are excluded. *Key:* CalPERS = California Public Employees' Retirement System; HMO = health maintenance organization and point of service plans; PPO = preferred provider organization and fee-for-service plans.

III. Public Health Impacts

- In California, approximately 49.6% of adults ages 50 years or older in health plans affected by SB 1508 receive colorectal cancer screening at the recommended intervals whereas almost one-third report never being screened for colorectal cancer. Colonoscopy is one screening method used to detect colorectal cancer or precursors to colorectal cancer such as adenomatous polyps. It is estimated that the rate of propofol use during colonoscopies in the population affected by the mandate is 14%. In California in 2006, 14,345 cases of colorectal cancer are expected. The 5-year survival rate for those diagnosed with colorectal cancer is 62%, and 4,425 deaths are expected in 2006 due to colon cancer.

- This mandate is not estimated to increase utilization of colonoscopies and there would be no impact on health outcomes such as number of colon cancer cases or mortality rates due to colon cancer. The rate of propofol use during colonoscopies is estimated to increase from 14% to 16%, resulting in 6,248 more colonoscopies conducted with propofol annually. The use of propofol is estimated to result in an average reduction of procedure time of 17 minutes and an average reduction in recovery time of 15 minutes. Therefore, we calculate that this mandate would result in annual savings of 1,770 hours of procedure time and 1,562 hours of recovery time associated with colonoscopy.

- Although there are gender and racial disparities in terms of utilization of colon cancer screening, incidence rates of colon cancer, and colon cancer mortality rates, this mandate is not estimated to change the utilization of colonoscopies or other colon cancer screening methods. Therefore, we conclude that this mandate would have no impact on gender and racial disparities in colon cancer screening and related health outcomes.

- Although approximately 4,425 people are expected to die from colon cancer in California in 2006, this mandate is not expected to increase the number of colonoscopies performed each year only the number of persons electing to use propofol as an analgesic during these procedures. Therefore we conclude that there would be no reduction in premature death or associated economic loss from reduced productivity as a result of SB 1508.

INTRODUCTION

Senate Bill 1508 (SB 1508) would mandate that health care service plans licensed under the Knox-Keene Act[1] and health insurance policies regulated by under California Insurance Code provide coverage for propofol for the purpose of colonoscopies.
Colonoscopy is a procedure that allows complete examination of the large intestine. Colonoscopies are considered an important screening procedure for colorectal cancer. In California, colorectal cancer is the third most common cancer and the third most common cause of cancer-related death (CCR, 2005).

Although colonoscopies are most often used to diagnose or rule out colon cancer, they are also frequently used to evaluate symptoms, such as abdominal pain, rectal bleeding, and weight loss, to diagnose other diseases. Colonoscopies can also be used for treatment, for example, when the procedure is used to excise polyps.[2] A fiber optic camera provides a visual diagnosis and grants the opportunity for biopsy of suspected lesions.

Since 1999, California has mandated insurance coverage for all generally accepted medical cancer screening tests.[3] In addition to colonoscopy, other medically accepted screening tests for colorectal cancer include barium enema, stool (fecal occult) blood test (FOBT), and flexible sigmoidoscopy. Typically, if results from these alternative screening tests are positive, patients are referred for a comprehensive colon examination by colonoscopy.

In the United States, most colonoscopies are performed with the patient under moderate (conscious) sedation. That is, the patient is given pain medication and a moderate sedative to keep from feeling discomfort during an exam that lasts 30–60 minutes. The typical drugs given for moderate sedation are midazolam (Versed) or meperidine (Pethidine or Demerol). Colonoscopies with patients under moderate sedation are typically performed by a gastroenterologist with a nurse assisting.

A minority of colonoscopies are performed under "deep" sedation in which an anesthetic agent is used for sedation. Propofol (tradename: Diprivan ®) is the most recently developed intravenous anesthetic that can be used for deep sedation and is rapidly replacing other anesthetics commonly used for deep sedation. Health plans and insurers do not explicitly exclude coverage. However, the prevailing practice is to use anesthesia (propofol) only when it is determined to be medically necessary by the physician. Clinical guidelines recommend anesthesia for patients undergoing prolonged therapeutic procedures, those with anticipated intolerance of standard sedatives, and those at increased risk for sedation-related complications (Waring, 2004).

[1] The Knox-Keene Health Care Service Plan Act of 1975 regulates all California health maintenance organizations (HMOs) as well as Blue Cross and Blue Shield Preferred Provider Organizations (PPOs).
[2] Polyps are tissue growths that may occur within the colon or other parts of the body. They may vary in size and appearance.
[3] Health and Safety Code Section 1367.665 for Knox-Keene licensed plans except specialized health care service plan contracts. Ca Insurance Code Section 10123.21 for CDI regulated plans.

Currently, the U.S. Food and Drug Administration (FDA), which determined propofol was safe and effective for use, restricts the personnel who can administer propofol to those "trained in the administration of general anesthesia and not involved in the surgical/diagnostic procedure." [4] These personnel requirements are being contested by the American College of Gastroenterology (ACG). In a petition filed with the FDA, they are asking for the removal of the specifications requiring individuals to be trained in the administration of general anesthesia.[5] In response, the American Society of Anesthesiologists and American Association of Nurse Anesthetists issued a joint statement against the use of propofol by non-anesthesiologists (AANA-ASA, 2004). At the time this report was submitted, the FDA was "still reviewing the petition."[6] For the purpose of this analysis, CHBRP incorporates the existing restrictions of the FDA labeling requirement in its review of the medical effectiveness, cost, and public health impact of this mandate.

Based on discussions with the author's staff, the intent of this bill is to ensure physicians have the option to use deep sedation with propofol for those patients whose anxiety interferes with their willingness to undergo a colonoscopy or return for a subsequent screening exam. The bill does not propose to dictate "best practices" or eliminate medical necessity criteria in the utilization review process.

The population affected by this mandate includes privately insured individuals who are enrolled in health service plans regulated by the California Department of Managed Care (DMHC) or the California Department of Insurance. This mandate also affects individuals who are enrolled in health service plans purchased by CalPERS and state-administered programs (e.g., Medi-Cal, Healthy Families).

No other state has enacted legislation requiring coverage of a specific anesthetic agent to be used for sedation during colonoscopies.

This report describes the medical evidence, cost, and public health impact of a mandate to provide coverage of propofol under those circumstances when a physician would authorize anesthesia for patients reluctant to be moderately sedated.

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[4] FDA-approved package insert states: "For general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN ®Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure. Patients should be continuously monitored, and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available."

[5] ACG petition filed 6/28/2005 states that "substantial clinical evidence establishes that propofol can be administered safely, effectively, and cost-effectively by gastroenterologists and by registered nurses working under their supervision. The requested label change will promote efficiency and reduce costs to payors by eliminating the need for an anesthesiologist or nurse anesthetist to be present to administer propofol during an endoscopic procedure, The requested label change also will eliminate a restriction on the practice of gastoenterologists that, in light of the clinical evidence, is unwarranted." Available at: http://www.fda.gov/ohrms/dockets/dockets/05p0267/05p0267.htm. Accessed 3/2/2006

[6] Personal communication with Quinn Nguyen, re: U.S. FDA Docket No. 2005P-0267, on March 24, 2006.

MEDICAL EFFECTIVENESS

Results from the Literature Review

The results of the review of the scientific literature on the medical effectiveness of propofol use during colonoscopy are organized into the following major categories of outcomes:

- Physiological and cognitive outcomes, for example, vital signs, oxygen saturation, and cognitive function;
- Procedural outcomes, for example, procedure duration and sedation level; and
- Post-procedure outcomes, such as patient satisfaction, recovery time, complications, and side effects.

Studies on the effectiveness of propofol use during colonoscopy were identified from the PubMed and Cochrane databases for the period from January 1985 through March 2006, yielding 321 references. The types of publications included in the literature search were randomized controlled trials, clinical trials, meta-analyses, review articles, practice guidelines, observational studies, and case reports. The present analysis, however, relied largely on 19 well-done randomized controlled trials and one meta-analysis to determine the impact of propofol use during colonoscopy on the outcomes assessed.

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

A Note on the Interpretation of the Medical Effectiveness Literature

In assessing the literature on the medical effectiveness of propofol use during colonoscopy, it is important to note that there is currently an FDA package insert for propofol that recommends the presence of a health professional "trained in the administration of general anesthesia and not involved in the surgical/diagnostic procedure" (see footnote #7 in the Introduction to this report). However, this literature review includes studies in which a health professional specifically trained in anesthesia was not present to administer propofol and monitor the patients' airways. Of the 19 studies included in the medical effectiveness review, propofol was administered by anesthesiologists (two studies), gastroenterologists (one study), endoscopists (three studies), registered nurses (three studies), critical care physicians (one study), and by patients themselves through the use of patient-controlled sedation devices (five studies). Four studies did not specify what type of provider administered the propofol.

These studies are included in the medical effectiveness review because the focus of SB 1508 is on the agent, propofol, and not the health professional who administers the agent. However, it should be noted that the two studies that used anesthesiologists (Gasparovic et al., 2003; Paspatis et al., 2002) reported results that were consistent with the outcomes of studies that utilized providers not trained in anesthesia.

In addition, five studies reviewed the effectiveness of propofol using patient-controlled sedation devices. Although patient-controlled sedation is not a standard of care for the administration of propofol during colonoscopies, these studies are included because they provide data on the safety and effectiveness of this agent.

Finally, the literature may not be adequate to assess the safety of propofol. All anesthesia carries potential risks that do not accompany conscious sedation. Patients can become so deeply sedated that they may be unable to react if their airways become obstructed and may need to be intubated. In the case of propofol, the effects of propofol cannot be reversed by other agents. Large samples are required to detect the prevalence of such complications because they rarely occur. Many of the studies reviewed have sample sizes that are probably too small to obtain accurate estimates of the rates at which these complications occur among persons who receive propofol in conjunction with a colonoscopy.

Physiological and Cognitive Outcomes

In the literature on propofol use during colonoscopy, 13 studies presented evidence on physiological and cognitive outcomes including measurements of blood pressure, pulse, oxygen saturation or desaturation, swallow reflex, pain or discomfort, cognitive function, psychomotor function, and complications (Bright et al., 2003; D'Honneur et al., 1994; Gasparovic et al., 2003; Koshy et al., 2000; Kostash et al., 1994; Lee et al., 2002; Moerman et al., 2003; Paspatis et al., 2002; Qadeer et al., 2005; Reimann et al., 2000; Roseveare et al., 1998; Sipe et al., 2002; Ulmer et al., 2003). Six of these studies compared the effects of propofol use during colonoscopy to the use of a traditional sedative or analgesic agent, such as midazolam, meperidine, diazepam, remifentanil, and fentanyl, or combination of agents. The remaining seven studies compared the combination of propofol and a traditional sedative or analgesic agent to use of one or more traditional sedative or analgesic agents.

Of the 12 studies that include measurements of blood pressure/hypotension, pulse, and oxygen saturation or desaturation, five studies reported significantly better outcomes for subjects receiving propofol (or a propofol combination) than those receiving a traditional sedative or analgesic agent (Gasparovic et al., 2003; Lee et al., 2002; Roseveare et al., 1998; Sipe et al., 2002; Ulmer et al., 2003), whereas five studies reported no significant differences between the groups (Bright et al., 2003; Koshy et al., 2000; Moerman et al., 2003; Paspatis et al., 2002; Reimann et al., 2000). One study (Kostash et al., 1994) reported a significantly unfavorable outcome with regard to oxygen desaturation (oxygen saturation value below 85%). The one meta-analysis (Qadeer et al., 2005) included in this literature review reported significantly fewer complications (hypoxia or hypotension) associated with the use of propofol than with traditional sedative or analgesic agents.

Six studies presented information on measurements of pain or discomfort. One of these studies reported significantly less pain or discomfort associated with the use of propofol (Koshy et al., 2000), whereas four studies reported no significant difference between the groups (Bright et al., 2003; Kostash et al., 1994; Paspatis et al., 2002; Roseveare et al., 1998). One study reported significantly more pain associated with the use of propofol during colonoscopy (Lee et al., 2002).

One study reported on cognitive function and presented results that reflected significantly less cognitive function for subjects receiving propofol than for subjects receiving traditional sedative or analgesic agents (Moerman et al., 2003). However, this finding may simply reflect a higher degree of sedation in subjects receiving propofol.

One study presented information on latency time of the swallow reflex (D'Honneur et al., 1994). A shorter latency time suggests a decreased risk of aspiration. This study reported that the latency time of the swallow reflex is significantly shorter in subjects receiving propofol than in subjects receiving traditional sedative or analgesic agents.

Overall, the evidence from studies that compare the effects of propofol and traditional sedative or analgesic medications used during colonoscopy on physiological and cognitive outcomes is ambiguous.

Procedural Outcomes

Eleven publications reported data on the effect of propofol use on outcomes that occur during the colonoscopy procedure (Bright et al., 2003; Hansen et al., 2004; Koshy et al., 2000; Kostash et al., 1994; Lee et al., 2002; Ng et al., 2001; Paspatis et al., 2002; Reimann et al., 2000; Roseveare et al., 1998; Sipe et al., 2002; Ulmer et al., 2003).). Four of these studies compared the effects of propofol to a traditional sedative or analgesic agent or combination of agents such as midazolam, meperidine, diazepam, remifentanil, and fentanyl. The remaining seven studies compared the combination of propofol and a traditional sedative or analgesic agent to use of one or more traditional sedative or analgesic agents.

Seven publications presented information on the procedure duration. Six of these studies (Bright et al., 2003; Kostash et al., 1994; Lee et al., 2002; Ng et al., 2001; Reimann et al., 2000; Roseveare et al., 1998) reported no statistically significant difference in procedure duration associated with the use of propofol or another sedative or analgesic agent, although in two of these studies the propofol group had a shorter estimated procedural duration. The remaining study reported that the use of propofol significantly reduced colonoscopy procedure time (Sipe et al., 2002). Of the three studies that recorded the average time it took to reach the cecum (the pouch at the end of the colon that connects to the small intestine) during the colonoscopy procedure, none reported significant results (Hansen et al., 2004; Sipe et al., 2002; Ulmer et al., 2003).

Eight studies reported data on the sedation level of subjects during the colonoscopy procedure. Five studies indicated that subjects sedated with propofol experienced significantly more appropriate levels of sedation during the procedure than subjects in the control groups (Koshy et al., 2000; Ng et al., 2001; Roseveare et al., 1998; Sipe et al., 2002; Ulmer et al., 2003). Of the remaining publications, two reported no significant difference in sedation between the two groups (Paspatis et al., 2002; Reimann et al., 2000), and one reported a significantly lower degree of sedation among subjects receiving propofol (Bright et al., 2003).

Three publications provided information on the use of abdominal pressure and position change during colonoscopy. These tactics are used when the scope is not moving easily through the

colon, a situation that can lead to cramping and potential risk for perforation of the colon. All three studies reported significantly less need to reposition subjects during procedures where subjects received propofol (Hansen et al., 2004; Sipe et al., 2002; Ulmer et al., 2003). One study reported a significantly decreased need for the use of abdominal pressure in subjects receiving propofol (Sipe et al., 2002), and two studies reported no significant difference in the use of abdominal pressure among the groups (Hansen et al., 2004; Ulmer et al., 2003).

Thus, overall, the evidence suggests a pattern toward favorable effects for comparisons between propofol and traditional sedative or analgesic medications used during colonoscopy on procedural outcomes.

Post-Procedure Outcomes

Eleven publications reported data on the effect of propofol use in the post-procedure or recovery period (up to 24 hours post-procedure) and included measurements of patient satisfaction, complications, side effects, recovery from sedation, learning and memory, pain and comfort, activity, time to discharge, sleep, visual-motor coordination, and subsequent hospital admission (Bright et al., 2003; Lee et al., 2002; Moerman et al., 2003; Ng et al., 2001; Paspatis et al., 2002; Koshy et al., 2000; Kostash et al., 1994; Reimann et al., 2000; Roseveare et al., 1998; Sipe et al., 2002; Ulmer et al., 2003). Four of these studies compared the effects of propofol to a traditional sedative or analgesic agent or combination of agents such as midazolam, meperidine, diazepam, remifentanil, and fentanyl. The remaining seven studies compared the combination of propofol and a traditional sedative or analgesic agent to use of one or more traditional sedative or analgesic agents.

Six studies provide information on patient satisfaction, with three studies reporting significantly better patient satisfaction among subjects who received propofol (Moerman et al., 2003; Ng et al., 2001; Sipe et al., 2002). The remaining three studies indicated no significant difference in patient satisfaction rates among the groups (Bright et al., 2003; Lee et al., 2002; Ulmer et al., 2003).

Eight publications reported information on recovery from sedation. Six of these studies indicated that subjects receiving propofol had significantly faster recovery times than comparison groups (Bright et al., 2003; Paspatis et al., 2002; Reimann et al., 2000; Roseveare et al., 1998; Sipe et al., 2002; Ulmer et al., 2003). Two studies reported no significant difference between the groups (Koshy et al., 2000; Kostash et al., 1994). Three additional studies provided data on the time to discharge (Ng et al., 2001; Reimann et al., 2000; Ulmer et al., 2003). These studies reported significantly shorter discharge times for subjects receiving propofol than for subjects receiving traditional sedative or analgesic agents.

Three studies reported data on post-procedure pain or comfort levels. One study reported significantly more pain associated with propofol (Roseveare et al., 1998), one study reported no significant difference among the groups (Ng et al., 2001), and one study reported a significantly increased post-procedural comfort level associated with the use of propofol (Bright et al., 2003).

Three publications recorded measurements of verbal learning, memory, and/or amnesia. Two

studies reported significantly favorable results for these outcomes among subjects receiving propofol (Sipe et al., 2002; Ulmer et al., 2003). The remaining study reported mixed results among subjects receiving propofol, with significantly favorable results on measures of memory impairment and significantly unfavorable results on measures of complete amnesia (Reimann et al., 2000).

Two studies measured the number of delayed side effects such as pain or drowsiness associated with propofol and other traditional sedative or analgesic agents, measured at 24 hours post-procedure (Lee et al., 2002; Roseveare et al., 1998). Both publications reported fewer delayed side effects in the propofol groups. One additional study looked at the impact of propofol versus traditional sedative or analgesic agents on activity in the post-procedure period and found no difference between the groups (Bright et al., 2003).

Finally, one study observed the number of post-procedure hospital admissions and found no difference between the propofol and control groups (Lee et al., 2002).

Overall, the evidence suggests a pattern toward favorable for comparisons between propofol and traditional sedative or analgesic medications used during colonoscopy on post-procedure outcomes.

Additional Publications

Three publications report data on the use of propofol plus other sedative or analgesic agents in both the control and intervention groups (Heuss et al., 2004; Moerman et al., 2004; Rudner et al., 2003). The measurements reported in these studies include vital signs (respiratory rate, blood pressure, mean arterial pressure, pulse), oxygen saturation, pain, sedation level, recovery, amnesia, and patient satisfaction. None of these studies reported significant unfavorable outcomes for the measurements listed above.

Overall, the evidence suggests a pattern toward favorable for interventions and control groups that utilize propofol during colonoscopy on physiological and cognitive outcomes, procedural outcomes, and post-procedure outcomes. However, the use of propofol in both the intervention and control groups makes it difficult to separate the effects of propofol from the effects of other agents.

Conclusions

A review of the evidence of the medical effectiveness of propofol use during colonoscopy reveals a pattern toward a favorable effect on procedural and post-procedural outcomes. There is ambiguous or mixed evidence that propofol use during colonoscopy improves physiological or cognitive outcomes when compared with traditional sedative or analgesic agents.

In terms of overall safety, the outcomes associated with the use of propofol appear to be comparable to those associated with the use of other sedative and analgesic agents reviewed. However, many of the studies have sample sizes that may not be large enough to adequately assess the prevalence of complications among persons who receive propofol.

II. UTILIZATION, COST, AND COVERAGE IMPACTS

Present Baseline Cost and Coverage

Current coverage of the mandated benefit

SB 1508 will require all Knox-Keene licensed health plans and insurance policies regulated by the California Department of Insurance to cover propofol for the purpose of colonoscopies. This includes enrollees in managed care plans offered by Healthy Families, MediCal, and the California Public Employees' Retirement System (CalPERS). Currently, there are 20,144,000 individuals under age 65 years in plans affected by the mandate.

Coverage for propofol was determined by CHBRP's survey of the seven major health insurance plans in the state. Responses received from six of the seven plans (accounting for approximately 94% of the privately insured population in CA) show that none explicitly exclude coverage for propofol. Instead, all responding plans cover the use of propofol for "deep" sedation during colonoscopies when determined to be medically necessary by a plan physician. Although the definition of medical necessity varies by health plan, most consider factors such as pregnancy, extreme age, a history of drug or alcohol abuse, and any neck, jaw, or other anatomic variation that can lead to airway obstruction considered to be "high risk" and therefore acceptable for the use of propofol; in some cases, plans also consider whether the patient is uncooperative or acutely agitated, and has a history of or anticipated intolerance to standard sedative as criteria for medically necessary. Once the use of propofol is determined to be a medical necessity, the cost of having professional anesthesiology services is covered. SB 1508 would not explicitly preclude a health plan or insurer from determining medical necessity, or conducting utilization review. Therefore, we determine that most plans are currently in compliance with the mandate.

Current utilization levels and costs of the mandated benefit

In this section we discuss the utilization levels for colonoscopies, the percentage of colonoscopies performed using propofol, and the per-unit cost of general anesthesia using propofol.

Colonoscopy Utilization

Using Milliman 2004 data, the annual colonoscopy utilization rate was 17.2 per 1,000 members (or 0.017%) in commercial plans for those under 65 years. However, colonoscopy annual utilization rates vary greatly by age. For children 18 years and under, annual colonoscopy rates fall between 0.2 and 1.2 per 1,000 members. The rate steadily increases with age such that for 19- to 39-year-olds, it ranges from 4.3 to 14.7 per 1,000 members; for 40- to 49-year-olds, the rate is 23.6 to 34.3 per 1,000 members; and for those between 50 and 64 years, it is 86.1 to 103.1 per 1,000 members.

Higher utilization of colonoscopies with increasing age is associated with diagnosis for and treatment of colorectal cancer. Current colon cancer screening rates for adults aged 50 and over in the United States is reported to be 43.4%, including fecal occult blood testing (FOBT),

sigmoidoscopy/colonoscopy, or both FOBT and sigmoidoscopy/colonoscopy (Ioannou et al., 2003). According to the 2003 California Health Interview Survey (CHIS 2003), 68.8% of California adults with employment-based insurance ages 50–65 years reported a colorectal cancer screening test in the past 5 years. Of these, 56.7% reported having had a colonoscopy in the past 5 years.

Though current medical guidelines recommend that all adults 50 years and over should receive a colorectal screening exam, there are barriers that exist to limit the utilization of screening colonoscopy. One study by Harewood, Wiersema, and Melton (2002) found that the four most common reasons given for not getting a colonoscopy were:

- Not wanting to take the bowel preparation,
- Afraid of discomfort during procedure,
- Not having had the procedure recommended by [a] doctor, and
- Embarrassed by the procedure (Harewood et al., 2002).

These findings are in agreement with CHIS 2001 in which it was reported that 8.8% of adults ages 50 to 65 years with employment-based insurance did not have a colorectal cancer exam in the past 10 years because it was painful or embarrassing, and 26.2% of adults said they did not receive one because their doctor did not tell them it was needed.

Use of Propofol for Colonoscopies

No reliable data are available on actual propofol rates during colonoscopies. Milliman claims data, which include over 4 million commercial claims nationally, indicate that 14% of enrollees receiving colonoscopies in insured plans have a separate charge for anesthesia professional services. Because in general, only the use of propofol during colonoscopy requires involvement of an anesthesia professional, 14% was used as a proxy for current propofol use in this analysis. The rate is consistent with the experience reported by one of the largest carriers in California. It is possible that 14% is a low estimate for actual propofol use since gastroenterologists who perform colonoscopies or an assisting registered nurse sometimes administer propofol without an anesthesia professional involved.

There are some controversies over who should administer propofol during colonoscopies. In 2004, the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), and the American Society of Gastrointestinal Endoscopy (ASGE) issued a joint statement that "there are data to support the use of propofol by adequately trained non-anesthesiologists" and that propofol can be administered safely by an "adequately trained physician-supervised nurse" (AGA, 2004). However, a joint statement released by the American Society of Anesthesiologists (ASA) and the American Association of Nurse Anesthetists (AANA) in 2004 reads, "whenever propofol is used for sedation/anesthesia, it should be administered only by persons trained in the administration of general anesthesia, who are not simultaneously involved in these surgical or diagnostic procedures" (AANA-ASA, 2004). In 2005, the ACG filed a petition with the Food and Drug Administration (FDA) asking for the removal of the specifications requiring that propofol should be administered only by individuals trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedures. Due to the fact that the participation of anesthesiology

professionals is currently required and the FDA has not yet removed this specification, CHBRP assumed that the utilization of propofol with anesthesiology professional services (14%) during colonoscopy is a reasonable assumption for this analysis.

Per-Unit Cost

The differential cost between propofol and other commonly used anesthetics is negligible, with one study reporting the cost of propofol to be $27 ± $14 and meperidine/midazolam, $29 ± $22, another commonly used anesthetic for "conscious" sedation (Vargo et al., 2002). The main cost associated with propofol use is the cost of the anesthesiology professional service. Previous studies indicate that the extra cost for anesthesiology professionals is from $250 to $400 (Aisenberg et al., 2005; Vargo et al., 2002). Milliman claims data showed cost differences between colonoscopies with and without anesthesia professionals were approximately $385 in 2004, which is adjusted to $450 for 2006 because of an 8% increase in the service charge per year. Although the charge did not specify the anesthetic agent, CHBRP estimates $450 as the marginal or additional cost for using propofol versus other anesthetics.

Extent to which costs resulting from lack of coverage are shifted to other payers, including both public and private entities

All health plans, including public plans, currently cover propofol use during colonoscopies when medically necessary. CHBRP estimates no cost shifting among payers due to SB 1508. If the mandate were to be enacted, these costs would continue to be borne by the same plan with the same distribution between the private and public market.

Public demand for coverage

As a way to determine whether public demand exists for the proposed mandate, CHBRP is to report on the extent to which collective bargaining entities negotiate for and the extent to which self-insured plans currently have coverage for the benefits specified under the proposed mandate. Currently, the largest public self-insured plans are CalPERS' PERS Care and PERS Choice preferred provider organization (PPO) plans. These plans include coverage for colonoscopies. Based on conversations with the largest collective bargaining agents in California, no evidence exists that unions currently include a provision for propofol for colonoscopies during the negotiations of their health insurance policies. In order to determine whether any local unions engage in negotiations at such detail, they would need to be surveyed.

Impacts of Mandated Coverage

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

No effect on per-unit cost of the propofol or the service provided by anesthesiology professionals is expected. This legislation does not propose an increase in the number of people who have health insurance coverage, but rather it mandates coverage of a benefit already available to those

with coverage. Any increased advertising efforts by manufacturers to consumers and physicians as a direct consequence of this mandate is expected to be small with little perceptible change in increased utilization or unit costs of the drug since propofol itself is not an expensive medication (around $30 per use).

How would utilization change as a result of the mandate?

The utilization of colonoscopies is not expected to increase due to this mandate. The overall rates of colonoscopies are not expected to increase due to higher patient or physician demand for this diagnostic procedure as a result of increased awareness of coverage for propofol.

However, the utilization rate of propofol with an anesthesiology professional for the purpose of colonoscopies is estimated to increase two percentage points—from 14% to 16%, resulting in an additional 6,248 members aged 50 to 65 years who would receive propofol for colonoscopies. Health plans frequently define their medical necessity requirements for patients undergoing deep sedation, or "monitored anesthesia care," based on the type of procedure being performed and any co-existing conditions. Monitored anesthesia care, such as deep sedation using propofol, is often not considered medical necessary for colonoscopies unless certain conditions coexist. These conditions can be defined by health plans in several ways, including International Classification of Diseases, 9th Revision (ICD-9) codes. Using the diagnostic codes that support the medical appropriateness of monitored anesthesia care, CHBRP found that 5% of members who had a colonoscopy without a separate charge for anesthesia professional services had a coded diagnosis on the day of their colonoscopy that met the medical necessity criteria.[7] Increased awareness of propofol after the mandate —among physicians and patients—may result in an increase in the use of propofol for colonoscopies among those who met medical necessity criteria, especially among those who indicate pain is a barrier to receiving colonoscopies. However, it is not likely that *all* enrollees who meet medical necessity criteria for monitored anesthesia care would choose deep sedation over moderate sedation or undergo the procedure with professional anesthesiologist services. For these reasons CHBRP estimates the postmandate utilization rate to be an approximate mid-point between 0 and 5% or 2-percentage points. This 2-percentage point increase in propofol will result in the decreased utilization of alternative sedation for the purpose of colonoscopy from 86% to 84%.

For members younger than 50 years of age, CHBRP estimates a negligible increase in utilization rates for propofol with anesthesiology services for the purpose of colonoscopies. For these members, overall utilization is low, and the procedure is performed for diagnostic or therapeutic reasons rather than for routine screening. Therefore, any additional perceived access to propofol would not increase their utilization of propofol. CHBRP estimates no effects on those members aged 65 years and over, because almost all of them are covered under Medicare, SB 1508 would not impact coverage for enrollees with Medicare as a primary payor.

[7] The ICD-9 codes that support monitored anesthesia care was taken from one major health plan, which may be representative but not all inclusive of medical necessity criteria used by all plans.

To what extent does the mandate affect administrative and other expenses?

CHBRP's model of costs assumes that if premiums increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost *proportion of premiums* is unchanged. All health plans and insurers include a component for administration and profit in their premiums. If premiums do not increase, then overall administrative costs are the same.

Impact of the mandate on total health care costs

The mandate is estimated to increase total annual net expenditures by $3.378 million or 0.01% (Table 1). This estimate should be viewed as an upper bound since the cost of professional anesthesiology service is factored into each procedure. If the FDA removes propofol's warning label to allow trained non-anesthesiologists to administer the medication, we expect little or no increase in costs. Actuarial analysis for SB 1508 shows that the total expenditures for covering propofol for the purpose of colonoscopies with professional anesthetic services in California (including total premiums and out-of-pocket spending for co-payments and non-covered benefits) would increase by between 0.001% and 0.01% for those markets affected by the mandate (Table 3). For those markets, health insurance premiums are estimated to increase *on average* by 0.005% or $0.0131 per member per month (PMPM).

Costs or savings for each category of insurer resulting from the benefit mandate

SB 1058 would lead to estimated increases in total annual expenditures by 0.01% for each major category of payer. However, the amounts vary as follows:

- Private employer premiums: $1.839 million;
- Individually purchased insurance premiums: $372,000;
- CalPERS employer expenditures: $117,000;
- Medi-Cal: $248,000;
- Premium expenditures by employees with group insurance or CalPERS: $590,000.

Increases as measured by PMPM payments are estimated to range from $0.0008 to $0.017 (Table 3). The greatest impact would be on the individual HMO market. In the large-group market, the resulting premium impact would range from 0.004% to 0.006%. In terms of PMPM, the increase in premiums for the large-group market is estimated to range from $0.0134 to $0.0146. These costs represent the short-term (one-year) increases and do not account for potential long-term impact of this mandate on costs.

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

All health plans, including public plans, currently cover propofol use during colonoscopies when medically necessary. CHBRP estimates no cost shifting among payers due to SB 1508. If the mandate was to be enacted, these costs would continue to be borne by the same plan with the same distribution between the private and public market.

Impact on access and health service availability

The mandate would not change access to propofol for the purpose of colonoscopy in general. However, the increased awareness of propofol after the mandate may improve the access to propofol among those who meet the medically necessity requirements. The mandate would have minimal impact on the availability or supply of gastroenterologists, anesthesiologists, or nurse anesthetists.

III. PUBLIC HEALTH IMPACTS

Present Baseline Health Outcomes

Colorectal cancer screening

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all men and women 50 years of age or older for colorectal cancer (USPSTF, 2002). The USPSTF found good evidence that periodic fecal occult blood testing (FOBT) reduces mortality from colorectal cancer and fair evidence that flexible sigmoidoscopy alone or in combination with FOBT reduces mortality. The USPSTF did not find direct evidence that screening colonoscopy is effective in reducing colorectal cancer mortality rates; efficacy of colonoscopy is supported by its integral role in trials of FOBT, extrapolation from sigmoidoscopy studies, limited case-control evidence, and the ability of colonoscopy to inspect the proximal colon. Typically, if results from alternative screening tests are positive, patients will be referred for a total colon examination by colonoscopy.

In the population of men and women in California ages 50 years or older in health insurance plans affected by SB 1508, rates of screening for colorectal cancer were low, with less than half (49.6%) reporting receiving either a FOBT in the past year and/or a colonoscopy/sigmoidoscopy in the past 5 years, 17.7% reporting receiving either a FOBT more than 1 year ago and/or a colonoscopy/sigmoidoscopy more than 5 years ago, and almost one-third (32.7%) reporting never having had a colorectal cancer screening (CHIS, 2003).[8] Of those adults 50 years or older, 55.9% reported their most recent exam was a colonoscopy, 34.9% reported a flexible sigmoidoscopy, 3.0% reported a proctoscopy, and 6.1% reporting something else (CHIS, 2003)[9]. This translates into 27.8% of the population ages 50 years and older affected by this mandate reporting received a colonoscopy in the past 5 years. The main reasons given by these adults for receiving the colonoscopy were: routine exam/screening test (55.1%), specific problem (22.7%), family history (12.7%), and follow-up to a previous problem (9.5%) (CHIS, 2003). In California, the main reasons reported by adults 50 years and older for not having a colorectal exam within the past 10 years (or never) included: doctor did not tell patient it was needed (25.7%), haven't had any problems (17.2%), painful or embarrassing (8.0%), and did not know that it was needed (7.6%) (CHIS, 2001).

Use of propofol

A literature review was conducted to determine the public health impact of the use of propofol in colonoscopies among Californians. There have been no studies to date that estimate the use of propofol in California. National data suggest that the use of propofol in colonoscopies throughout the United States is steadily growing. In a recent national Web study, 22% of gastroenterologists stated they routinely use propofol for colonoscopies, and 43% said they planned to start using it within the year (Faulx et al., 2005). Another study found that the number

[8] Throughout this section, data taken from CHIS was restricted to the following population: ages 50+ years with the following health insurance coverage: employer sponsored, privately purchased, Medicaid.

[9] Sigmoidoscopy isa visual examination of the sigmoid colon and rectum with a flexible or rigid tube, called a sigmoidoscope; protoscopy is a visual examination of the rectum and the end of the colon by means of a proctoscope

of colonoscopies in Medicare beneficiaries during which anesthesiologists provided sedation more than doubled between 2001 and 2003 (Aisenberg et al., 2005). As reported in the Utilization, Cost, and Coverage Impacts section, based on claims data, it is estimated that 14% of colonoscopies performed in California use propofol. This translates into approximately 48,628 colonoscopies performed using propofol per year in California among the population of persons enrolled in health plans affected by this mandate.

Colorectal cancer incidence and prevalence

Rates of colorectal cancer, the main outcome associated with colonoscopy screening, are documented in the California Cancer Registry (CCR). In California, colorectal cancer is the third most common cancer and the third most common cause of cancer-related death, representing approximately 10% of all cancer cases and 10% of all cancer deaths (CCR, 2005). In 2006, the expected new cases of colorectal cancer in California are 14,345 (CCR, 2005). In 2002, the age-adjusted colorectal cancer incidence rate in California was 46.3 per 100,000 (USCSWG, 2005).

Stage at diagnosis and colorectal cancer mortality

The aim of colon cancer screening is to detect the presence of cancer at an early stage when the survival rates are the highest or to detect an adenomatous polyp (which can become a cancer), allowing its removal, thus preventing the cancer. For colon and rectum cancer diagnosed in California, the 5-year survival rates are 89% for localized cancer (the tumor has not spread outside the colon and/or rectum), 65% for regional cancer (the tumor has spread to the lymph nodes or adjacent tissue), and 8% for distant cancer (the tumor has spread to other parts of the body) (CCR, 2005). It is estimated that 38% of cases are diagnosed early (i.e., in situ or localized), and across all stages, the 5-year survival rate is 62%. In 2006, an estimated 4,425 people will die from colon cancer in California (CCR, 2005). The age-adjusted death rate from colorectal cancer in California in 2002 was 17.0 deaths per 100,000 (USCSWG, 2005).

Impact of the Proposed Mandate on Public Health

Impact on community health

As presented in the Utilization, Cost, and Coverage Impacts section, it is estimated that the use of propofol during colonoscopy is currently covered for 100% of the people enrolled in health plans that are affected by this mandate. It is estimated that 14% of colonoscopies currently use propofol and that post-mandate this would increase to 16%. This would translate into approximately 6,248 more colonoscopies performed using propofol. (see Section II, page16 for more detail).

The literature presented in the Medical Effectiveness section summarizes the effect of propofol compared to other anesthetics during the colonoscopy procedure on three major categories of outcomes: physiologic and cognitive, intra-procedural, and recovery/post-procedure outcomes. There are no standardized and/or consistent measures with which to provide a quantitative estimate within the category of physiologic and cognitive outcomes. Within the second set, intra-procedural outcomes, seven studies measure the duration of the procedure when done with

propofol versus a comparator, with a reduction in procedure length that averages 17 minutes across the seven studies. No other outcomes within the second set are measured consistently across studies and/or are from well-done studies. Within the third set, recovery and post-procedure outcomes, four studies measure the duration from completion of the procedure to recovery with propofol versus a comparator, with a reduction in the time between procedure and recovery that averages 15 minutes. No other outcomes within the third set are measured consistently across studies and/or are from well-done studies.

Combining the utilization data with the medical effectiveness data, we are able to calculate the total annual reduction in procedure length and recovery time associated with the use of propofol during colonoscopy postmandate. Specifically, for the 6,248 additional colonoscopies conducted with propofol postmandate, this would translate into 1,770 fewer hours of procedure time and 1,562 fewer hours of recovery time per year.

Impact on community health where gender and racial disparities exist

A literature review was conducted to determine whether there are gender or racial disparities associated with the colonoscopy rates, use of propofol in colonoscopies, and the prevalence of colorectal cancer documented in the academic literature.

Colorectal Cancer Screening by Gender and Race/Ethnicity
Although overall rates of screening for colorectal cancer or specific rates of colonoscopy screening did not vary significantly by gender, of those who did receive colonoscopies in the past 5 years, the main reason for the exam was different for men and women. Men were more likely to report that they had a colonoscopy as part of routine screening (61% vs. 50%), whereas women were more likely to report that they had a colonoscopy in response to a specific problem (27% vs. 18%) (CHIS, 2003). Race or ethnicity has been proven to be an important barrier to colon cancer screening (Wee et al., 2005). In the population of adults in California ages 50 years or older in health insurance plans affected by SB 1508, rates of screening for colorectal cancer varied across race and ethnicity, with Latinos and Asians reporting the highest rates of never having a colorectal cancer screening (44% and 45% respectively) compared to blacks (32%), and whites (28%) (CHIS, 2003).

Use of Propofol by Gender and Race/Ethnicity
A literature review was conducted to determine whether gender or racial disparities existed in the use of propofol during colonoscopies. There have been no studies to date that estimate these differences. The utilization data presented in the Utilization, Cost, and Coverage Impacts section showed that the rates of propofol use during colonoscopies was the same in women and men.

Colorectal Cancer Incidence and Mortality by Gender and Race/Ethnicity
Incidence and mortality of colorectal cancer in California varies significantly by gender. Incidence rates of colorectal cancer are higher in men (54.5 per 100,000) compared to women (39.8 per 100,000) (USCSWG, 2005). Corresponding with incidence, mortality rates from colorectal cancer among men are also higher than those among women (19.9 per 100,000 vs. 14.7 per 100,000) (USCSWG, 2005). Incidence and mortality of colorectal cancer in California also varies significantly by race/ethnicity. Blacks have the highest rates of colorectal cancer

(53.2 per 100,000) followed by whites (46.1 per 100,000) and Hispanics (36.2 per 100,000) (USCSWG, 2005). Blacks have the lowest percentage (39% for men and 36% for women) of colon and rectum cancer diagnosed at an early stage (in situ or localized), followed by Asian and Pacific Islanders (39% for men and women), Hispanics (40% for men and women), and whites (43% for men and 41% for women) (CCR, 2005). In California, the age-adjusted death rate for blacks in 2002 was significantly higher (25.2 per 100,000) than for whites (17.0 per 100,000) and Hispanics (11.7 per 100,000) (USCSWG, 2005).

Although there clearly are disparities in terms of utilization of colorectal cancer screening, incidence rates of colorectal cancer, and colorectal cancer mortality rates, this mandate would not result in a change in utilization of colonoscopies or other colorectal cancer screening methods. Therefore, we conclude that this mandate would have no impact on gender and racial disparities in colorectal cancer screening and related health outcomes.

Reduction of premature death and the economic loss associated with disease

A literature review was conducted to determine the extent that propofol use in colonoscopies results in premature death and economic loss to California and whether SB 1508 might have an impact on these outcomes. In order to quantify the reduction of premature death due to a health insurance benefit mandate, the following must be true: Mortality must be a relevant health outcome, the impact of the mandated benefit must be established in the medical effectiveness literature, and the mandate must increase the number of utilizers (through either increased coverage or increased utilization). Although approximately 4,425 people are expected to die from colon cancer in California in 2006, this mandate is not expected to increase the number of colonoscopies performed each year, only the number of persons electing to use propofol during these procedures. We could find no evidence that use of propofol affects the effectiveness of screening and, ultimately, mortality. Therefore we conclude that there will be no reduction in premature death or associated economic loss from reduced productivity as a result of SB 1508.

TABLES

Table 2. Baseline (Premandate) Per-Member Per-Month Premium and Expenditures in California by Insurance Type, 2006

	Large Group		Small Group		Individual		CalPERS	MediCal		Healthy Families	
	HMO	**PPO**	**HMO**	**PPO**	**HMO**	**PPO**	**HMO**	**HMO 65 yrs and Over**	**HMO Under 65 yrs**	**HMO**	**Total Annual**
Population currently covered	8,237,000	1,827,000	2,593,000	1,215,000	984,000	1,030,000	782,000	339,000	2,423,000	714,000	20,144,000
Average portion of premium paid by employer	$202.76	$292.75	$189.45	$235.81	$0.00	$0.00	$248.33	$265.00	$112.00	$75.20	$43,102,188,000
Average portion of premium paid by employee	$62.47	$77.87	$74.62	$49.58	$257.58	$137.75	$43.82	$0.00	$0.00	$4.80	$16,122,670,000
Total premium	$265.23	$370.62	$264.07	$285.39	$257.58	$137.75	$292.16	$265.00	$112.00	$80.00	$59,224,858,000
Covered benefits paid by member (deductibles, copays, etc.)	$9.39	$50.08	$15.90	$42.40	$15.68	$32.14	$10.35	$0.00	$0.00	$2.18	$3,837,497,000
Benefits not covered	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total expenditures	$274.62	$420.70	$279.97	$327.79	$273.26	$169.89	$302.51	$265.00	$112.00	$82.18	$63,062,355,000

Source: California Health Benefits Review Program, 2006.
Note: The population includes individuals and dependents in California who have private insurance (group and individual) or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-based coverage.
Employees and their dependents who receive their coverage from self-insured firms are excluded because these plans are not subject to mandates.
Key: CalPERS = California Public Employees' Retirement System; HMO = health maintenance organization and point of service plans;
PPO = preferred provider organization and fee-for-service plans.

Table 3. Postmandate Impacts on Per Member Per Month and Total Expenditures In California by Insurance Type, 2006

	Large Group		Small Group		Individual		CalPERS	Medi-Cal		Healthy Families		
	HMO	PPO	HMO	PPO	HMO	PPO	HMO	HMO 65 yrs and Over	HMO Under 65 yrs	HMO	All Plans	Total Annual
Population currently covered	8,237,000	1,827,000	2,593,000	1,215,000	984,000	1,030,000	782,000	339,000	2,423,000	714,000	20,144,000	20,144,000
Average portion of premium paid by employer	$0.0112	$0.0106	$0.0108	$0.0115	$0.0000	$0.0000	$0.0124	$0.0000	$0.0085	$0.0008	$0.0091	$2,210,000
Average portion of premium paid by employee	$0.0034	$0.0028	$0.0042	$0.0024	$0.0170	$0.0139	$0.0022	$0.0000	$0.0000	$0.0000	$0.0040	$962,000
Total premium	$0.0146	$0.0134	$0.0150	$0.0139	$0.0170	$0.0139	$0.0146	$0.0000	$0.0085	$0.0008	$0.0131	$3,173,000
Covered benefits paid by member (deductibles, copays, etc.)	$0.0005	$0.0018	$0.0009	$0.0021	$0.0010	$0.0032	$0.0005	$0.0000	$0.0000	$0.0000	$0.0009	$206,000
Benefits not covered	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0
Total expenditures	$0.0151	$0.0152	$0.0159	$0.0160	$0.0180	$0.0171	$0.0151	$0.0000	$0.0085	$0.0008	$0.0140	$3,379,000
Percentage impact of mandate												
Insured premiums	0.006%	0.004%	0.006%	0.005%	0.007%	0.010%	0.005%	0.000%	0.008%	0.001%	0.005%	0.005%
Total expenditures	0.006%	0.004%	0.006%	0.005%	0.007%	0.010%	0.005%	0.000%	0.008%	0.001%	0.005%	0.005%

Source: California Health Benefits Review Program, 2006.
Note: The population includes individuals and dependents in California who have private insurance (group and individual) or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-based coverage.
Employees and their dependents who receive their coverage from self-insured firms are excluded because these plans are not subject to mandates.
Key: CalPERS = California Public Employees' Retirement System; HMO = health maintenance organization and point of service plans;
PPO = preferred provider organization and fee-for-service plans.

Table 4: California Colorectal Cancer Screening, Incidence and Mortality.

Race	Screening Rate, 2003 (% of Adults 50 yrs and Over Who Received a Colorectal Exam in the Past 5 Years)	Age-Adjusted Incidence Rate, 2002 (per 100,000)	Age-Adjusted Death Rate, 2002 (per 100,000)
All races	49.6	46.3	17.0
White	52.0	46.1	17.0
Black	56.4	53.2	25.2
Hispanic	41.1	36.2	11.7
Asian/Pacific Islander	40.8	NA	NA

Source: Screening rates come from the California Health Interview Survey, 2003.
Age-adjusted incidence and mortality rates come from the U.S. Cancer Statistics Working Group, 2005.

APPENDICES

Appendix A: Literature Review Methods

Senate Bill 1508 (SB 1508) would require health care service plans regulated and licensed by the California Department of Managed Care (DMHC), as provided in the Knox-Keene Health Care Services Plan Act of 1975, and health insurance policies and plans regulated by the California Department of Insurance to provide coverage for propofol for the purpose of colonoscopies.

Appendix A describes the methods used in the medical effectiveness literature review for SB 1508. This literature review included meta-analyses, systematic reviews, randomized controlled trials, clinical trials, cohort studies, pilot studies, practice guidelines, and observational studies. The PubMed, UpToDate, National Guideline Clearinghouse, and Cochrane databases, including the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials (CENTRAL), were searched.

The scope of the literature search included effects of propofol use during colonoscopy on patient comfort, physiological measurements, procedural efficiency, and recovery outcomes. The search was limited to abstracts published in English and to studies of both pediatric and adult patients. However, no trials in the pediatric population fit the criteria for inclusion in this review (see exclusion criteria below).

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.

A total of 321 articles were obtained and reviewed in the literature review for SB 1508. There were 302 articles that were not included in the analysis of SB 1508 for the following reasons:

- Topic or research question not relevant to the use of propofol or not inclusive of the use of propofol.
- Lack of an adequate control group.
- Dosages used in the study were non-standard.
- Results not clearly stated or reported by intervention group.
- Comparison group did not include a current standard of care.

The results of the trials fell into three major categories: physiological and cognitive outcomes, procedural outcomes, and post-procedure outcomes. Physiological and cognitive measurements were obtained during the procedure and included vital signs (pulse, blood pressure, mean arterial pressure, respiratory rate), oxygen saturation levels, pain, and psychomotor and cognitive function. Procedural outcomes were also obtained during the colonoscopy procedure and included measurements of procedure duration, mean time to reach the cecum (the pouch at the end of the colon that connects to the small intestine), need for repositioning or abdominal pressure, and sedation. Post-procedure data reflected recovery times, sedation level, pain, patient satisfaction, and outcomes up to 24 hours after completion of the procedure.

The intervention groups in these studies received propofol alone or propofol in combination with another sedative or analgesic agent (e.g., midazolam, fentanyl, alfentanil). Control groups received either a single agent or a combination of sedative and analgesic agents (e.g., meperidine, midazolam, alfentanil, fentanyl, remifentanil). In studies in which both the control and intervention groups received propofol or a combination of propofol and another sedative or analgesic agent, the following agents were used: propofol, remifentanil, midazolam, and fentanyl.

To "grade" the evidence for all outcome measures, the CHBRP effectiveness team uses a system[10] with the following categories:

1. Favorable (statistically significant effect): Findings are uniformly favorable, and many or all are statistically significant.
2. Pattern[11] toward favorable (but not statistically significant): Findings are generally favorable, but there may be none that are statistically significant.
3. Ambiguous/mixed evidence: Some findings are significantly favorable, and some findings with sufficient statistical power show no effect.
4. Pattern toward no effect/weak evidence: Studies generally find no effect, but this may be due to a lack of statistical power.
5. No effect: There is statistical evidence of no clinical effect in the literature with sufficient statistical power to make this assessment.
6. Unfavorable: No findings show a statistically significant benefit, and some show significant harms.
7. Insufficient evidence to make a "call": There are very few relevant findings, so that it is difficult to discern a pattern.

The search terms used to locate studies relevant to the AB 1508 were as follows:

PubMed

Medical Subject Headings (MeSH), pharmacological actions, and registry numbers used for searching PubMed:

"propofol"[MeSH Terms]*
2078-54-8[rn]
"benzodiazepines"[MeSH Terms]

"conscious sedation"[MeSH Terms]
"anti-anxiety agents"[MeSH Terms]
"anti-anxiety agents"[Pharmacological Action]
"anesthesia"[MeSH Terms]

[10] The foregoing system was adapted from the system used by the U.S. Preventive Services Task Force, available at http://www.ahcpr.gov/clinic/3rduspstf/ratings.htm. The medical effectiveness team also considered guidelines from the Centers for Medicare & Medicaid Services (available at http://www.cms.hhs.gov//FACA/Downloads/recommendations.pdf and guidelines from the Blue Cross and Blue Shield Association (available at http://www.bcbs.com/tec/teccriteria.html).

[11] In this report, the word "trend" may be used synonymously with "pattern."

“anesthetics”[MeSH Terms]
“anesthetics”[Pharmacological Action]
“anesthesiology”[MeSH Terms]
“analgesia”[MeSH Terms]
“analgesia, Patient-Controlled”[MeSH]

“colonoscopy”[MeSH Terms]*
“colonoscopy/utilization”[MeSH Terms]
“colonoscopy/economics”[Mesh Terms]

“utilization”[Subheading]
“drug utilization”[MeSH Terms]
“economics”[MeSH Terms]
“economics”[Subheading]
“economics, medical”[MeSH Terms]
“costs and cost analysis”[MeSH Terms]
“medicare”[MeSH Terms]
“insurance”[MeSH Terms]

“nurse anesthetists”[MeSH Terms]
“patient care team”[MeSH Terms]
“nurse clinicians”[MeSH Terms]

“treatment outcome”[MeSH Terms]
“anesthesia recovery period”[MeSH Terms]
“recovery room”[MeSH Terms]
“recovery of function”[MeSH Terms]
“postanesthesia nursing”[MeSH Terms]
“prognosis”[MeSH Terms]
“prevention and control”[Subheading]
“cognition”[MeSH Terms]
“psychomotor performance”[MeSH Terms]

“colonoscopy/adverse effects”[MeSH Terms]
“colonoscopy/mortality”[MeSH Terms]
“heart arrest”[MeSH Terms]
“arrhythmia”[MeSH Terms]
“heart rate”[MeSH Terms]
“anoxia”[MeSH Terms]
“hypoxia-ischemia, brain”[MeSH Terms]
“oxygen/blood”[MeSH Terms]
“hypotension”[MeSH Terms]
“syncope, vasovagal”[MeSH Terms]
“apnea”[MeSH Terms]
“airway obstruction”[MeSH Terms]
“intestinal perforation”[MeSH Terms]

"colonic neoplasms"[MeSH Terms]

"patient acceptance of health care"[MeSH Terms]

Publication types:

Meta-analysis
Randomized controlled trial
Clinical trial
Clinical trial, phase III
Practice guidelines
Multicenter study
Review
Evaluation studies
Comment
Editorial
Letter
Legal cases
Validation studies
Case reports
Journal article

Keywords:

Below is a list terms entered as non-specific keywords in the search to retrieve recently published articles that have not been indexed with MeSH terms. Some map directly to MeSH terms, and some are searched as is.

Propofol
Diprivan
Benzodiazepines

Colonoscopy
Benzodiazepines
Anesthesia
Anesthesia
Anesthetics
Analgesia
Anxiolysis

Conscious sedation
"moderate sedation"
"deep sedation"

Nurse anesthetists
Nurse clinicians

Anesthetists
Anesthesiologist
Patient care team

Treatment outcome
Anesthesia recovery period
Recovery room
Recovery of function
Postanesthesia nursing
Recovery time
Cognitive function

Heart arrest
Arrhythmia
Anoxia
Brain hypoxia-ischemia
Hypoxia
Hypotension
Apnea
Airway obstruction
Intestinal perforation
Prognosis
Prognos*
Mortality
Drug utilization
Drug utilization
Medical economics
Economics
Medicare
Insurance
Costs and cost analysis
Colonic neoplasms
Prevention

Searches were not limited to a specific age group. Cost analysis searches were limited to the year 2003 and later. Main clinical search was limited to the year 1989 and later. All searches in PubMed were limited to the English Language articles.
* = truncation
“” = exact phrase searching

Cochrane Library

Terms used to search: Propofol, Diprivan, colonoscopy in all fields

Publication types:

Systematic Reviews
Meta-analyses

UpToDate

Terms used to search: Propofol, Diprivan, colonoscopy, sedation, anesthesia, analgesia

Publication types:

Evidence-Based/Expert Opinion Reviews

National Guideline Clearinghouse (http://www.guideline.gov**)**

Terms used to search: Propofol, Diprivan

Publication types:

Practice Guidelines

Appendix B: Summary of Medical Effectiveness Findings on the Use of Propofol for Colonoscopy

Appendix B presents detailed information on medical effectiveness findings on the use of propofol for colonoscopy.

Table B-1 is a summary of the published studies on the use of propofol for colonoscopy. The table includes study citations, descriptions of the types of studies, intervention and control groups, length of studies, populations studied, and the locations in which the studies were conducted.

Table B-2 is a summary of the evidence of medical effectiveness of the studies in Table B-1. Table B-2 includes study citations, results, and categorization of results.

Table B-2 Part 1 presents evidence by outcome of studies comparing the use of propofol and traditional sedative or analgesic medications for colonoscopy. Part 2 presents evidence by outcome of studies comparing the use of propofol for colonoscopy in both intervention and control groups.

These tables include studies obtained from the literature review.

Full bibliographic information can be found in the list of references at the end of this report.

Table B-1. Summary of Published Studies on the Use of Propofol for Colonoscopy

Citation	Type of Study	Intervention vs. Control Group	Length of Study	Population Studied	Location
Qadeer et al., 2005	Meta-analysis of six RCTs	Propofol vs. midazolam or midazolam/fentanyl	Peri-procedural	Adults (>18 years)	United States (Three studies), Singapore, Croatia, Belgium
D'Honneur et al., 1994	RCT	Midazolam (75 µg/kg bolus)/propofol (0.1 mg/kg/min infusion) vs. propofol (1.5 mg/kg bolus, 0.1 mg/kg/min infusion)	Peri-procedural	Adults	France
Gasparovic et al., 2003	RCT	Propofol (1–1.5 mg/kg bolus) vs. midazolam (5–10 mg bolus) vs. no sedation	Peri-procedural	Adults, outpatient	Croatia
Hansen et al., 2004	RCT	Propofol vs. fentanyl/midazolam (dosage not stated)	Peri-procedural	Adults, outpatient	United States
Kostash et al., 1992	Double-blind RCT	Diazepam (0.12 mg/kg)/meperidine (2 mg/kg) vs. midazolam (0.07 mg/kg)/fentanyl (2.2 µg/kg) vs. propofol (1.3 mg/kg bolus, 76.5 µg/kg/min infusion)/fentanyl (2.2 µg/kg)	Peri-procedural	Adults, elective	Canada
Kostash et al., 1994	Double-blind RCT	Diazepam (0.07 mg/kg)/meperidine (1.5 mg/kg) vs. midazolam (0.035 mg/kg)/fentanyl (1.5 µg/kg) vs. propofol (50 µg/kg/min)/fentanyl (1.5 µg/kg)	Peri-procedural, 1.5 hours post-procedure	Adults, elective	Canada

Citation	Type of Study	Intervention vs. Control Group	Length of Study	Population Studied	Location
Lee et al., 2002	RCT	Propofol (4.8 mg)/alfentanil (12 µg) PCS (no lockout) vs. diazepam (0.1 mg/kg)/meperidine (0.5 mg/kg)	Peri-procedural	Adults >65 years	Hong Kong
Moerman et al., 2003	RCT	Propofol (1 mg/kg bolus, 10 mg/kg/hr infusion) vs. remifentanil (0.5 µg/kg bolus, 0.2 µg/kg/min infusion)	Peri-procedural	Adults 18–65 years, outpatient	Belgium
Ng et al., 2001	RCT	PCS propofol (0.3 mg/kg boluses, no lockout) vs. midazolam (0.05 mg/kg, then 1 mg boluses, titrated for comfort)	Peri-procedural	Adults, elective	Singapore
Paspatis et al., 2002	RCT	Midazolam (2–3 mg)/propofol (titrated for sedation with no min/max limit) vs. midazolam (2–3 mg then 0.1 mg/kg if needed)/pethidine (50 mg)	Peri-procedural, 24-h post-procedure	Adults (18–80 years)	Greece
Reimann et al., 2000	RCT	Midazolam (2 mg bolus then 1–3 mg titrated for sedation)/nalbuphine (10–20 mg, if needed) vs. midazolam (2 mg)/propofol (20–50 mg boluses, titrated for sedation)	Peri-procedural, 1-h post-procedure	Adults 18–60 years, elective	Germany

Citation	Type of Study	Intervention vs. Control Group	Length of Study	Population Studied	Location
Roseveare et al., 1998	RTC	PCS propofol (4.8 mg)/alfentanil (12 µg) times four, then boluses per patient (no lockout) vs. pethidine (50 mg)/diazepam (10–20 mg)	Peri-procedural, 24–48 h post-procedure	Adult, outpatient	United Kingdom
Sipe et al., 2002	Blinded RCT	Propofol (40 mg bolus, then 10–20 mg boluses titrated for sedation) vs. meperidine (12.5–25 mg bolus, then titrated for sedation)/midazolam (0.5–1 mg bolus, then titrated for sedation)	Peri-procedural	Adults, outpatient	United States
Ulmer et al., 2003	Blinded RCT	Propofol (40 mg, then 10–20 mg boluses, titrated for sedation) vs. midazolam (0.5–1 mg boluses, titrated for sedation)/fentanyl (12.5–25 µg boluses, titrated for sedation)	Peri-procedural, up to 48h post-procedure	Adult, outpatient	United States
Koshy et al., 2000	RCT	Propofol (20–120 mg)/fentanyl (0.25–1.5 mg) vs. midazolam (2–6 mg)/meperidine (25–75 mg)	Peri-procedural	Adults (including >65 years)	United States

Citation	Type of Study	Intervention vs. Control Group	Length of Study	Population Studied	Location
Bright et al., 2003	RCT	PCS Propofol (4.8 mg)/alfentanil (12 µg) times four, then boluses per patient (no lockout) vs. pethidine (50 mg)/midazolam (2.5 mg plus 2.5 mg boluses, titrated for sedation)	Peri-procedural, 24-h post-procedure	Adults, outpatient	United Kingdom
Heuss et al., 2004	RCT	PCS propofol (20 mg then 10 mg boluses per patient, no lockout) vs. propofol (20 mg then 10–20 mg boluses, titrated for sedation)	Peri-procedural	Adults 22–90 years, elective	United States
Moerman et al., 2004	Double-blind RCT	Propofol (1 mg/kg, then 10 mg boluses, titrated for sedation) vs. propofol (1 mg/kg, then 10 mg boluses, titrated for sedation)/remifentanil (0.1 µg/kg/min)	Peri-procedural	Adults 18-65 years, outpatient	Belgium
Rudner et al., 2003	RT	Remifentanil (0.2–0.25 µg/kg/min)/propofol (titrated for moderate sedation) vs. fentanyl (2 µg/kg), midazolam (0.05 mg/kg), and propofol (titrated for unconsciousness)	Peri-procedural	Adults 18–75 years, elective	Poland

Table B-2. Summary of Evidence of Medical Effectiveness of the Use of Propofol for Colonoscopy by Outcome

Part 1- Studies Comparing Propofol and Traditional Sedative or Analgesic Medications

Physiological and cognitive outcomes—ambiguous/mixed evidence

Citation	Results	Categorization of Results (significance, direction)
D'Honneur et al., 1994	Propofol vs. midazolam Latency time of swallow reflex: 1.6 s (SD[12] 0.6), 1.5 s (SD 0.4)	Sig, favors propofol
Gasparovic et al., 2003[13]	Propofol vs. midazolam or no sedation Systolic BP[14]: 130 (SD 20)	Sig, favors propofol
	Diastolic BP: 80 (SD 10)	Sig, favors propofol
	Pulse: 81 (SD 12)	Sig, favors propofol
	Oxygen saturation: 92% (SD 4)	Sig, favors propofol
Lee et al., 2002	Propofol/alfentanil vs. diazepam/meperidine Hypotension: 4% of subjects	Sig, favors propofol/alfentanil
	Oxygen desaturation: 0% of subjects	Sig, favors propofol/alfentanil
	Pain (10-cm VAS[15]): 4.9 (SD 3.1)	Sig, not fav

[12] SD = standard deviation.
[13] The significance of these values reflects the difference between the subjects' pre-procedural and inter-procedural physiologic measurements.
[14] BP = blood pressure.
[15] Visual Analog Scale.

Citation	Results	Categorization of Results (significance, direction)
Moerman et al., 2003	<u>Propofol vs remifentanil</u> Oxygen saturation: >95% for all subjects	NS, no difference
	Cognitive function (DSST[16]): 10 (at 5 min), 28 (at 15 min), and 32 (at 30 min)	Sig, not fav
	Psychomotor function (TDT[17]): 36 (at 5 min), 25 (at 15 min), 21 (at 30 min)	Sig for 5min and 15min values, not fav; NS, favors propofol for 30min value
Paspatis et al., 2002	<u>Propofol/midazolam vs. midazolam/pethidine</u> Oxygen desaturation: 11% of subjects (SD 17)	NS, not fav
	Drop in BP: 24% of subjects (SD 37.5)	NS, not fav
	Alteration in pulse: 3% of subjects (SD 4.6)	NS, not fav
	Pain (10-cm VAS): 0.9 (SD 1.3)	NS, favors propofol/midazolam
	Level of discomfort: 84.3% reported no discomfort	Sig, favors propofol/midazolam
Sipe et al., 2002	<u>Propofol vs. midazolam/meperidine</u> Mean nadir oxygen saturation: 96% (SD 2.9)	Sig, favors propofol
Koshy et al., 2000	<u>Propofol/fentanyl vs. midazolam/meperidine</u> Oxygen saturation <90%: 7.3% of subjects	NS, not fav
	Drop in BP (>20mmHg from baseline): 24% of subjects	NS, not fav
	Comfort score[18]: 84% of subjects had “excellent” comfort	Sig, favors propofol/fentanyl

[16] Digit Symbol Substitution Test.
[17] Trieger Dot Test.
[18] Comfort rated on a 4-point scale, with 1 = excellent comfort and 4 = poor comfort.

Citation	Results	Categorization of Results (significance, direction)
Bright et al., 2003	<u>Propofol/alfentanil vs. midazolam/pethidine</u> BP, pulse, oxygen saturation: specific measurements not given Nurses' evaluation of pain[19]: 1 (range 0–3)	 NS, no difference NS, no difference
Reimann et al., 2000	<u>Propofol/midazolam vs. midazolam/nalbuphine</u> Oxygen saturation <85%: 40% of subjects Median increase in pulse: 7 (IQR[20] 0–17)	 NS, favors propofol/midazolam NS, favors propofol/midazolam
Roseveare et al., 1998	<u>Propofol/alfentanil vs. pethidine/diazepam</u> Maximum fall in systolic BP: 23 (range 7–36) Minimum oxygen saturation: 98% Nurses' evaluation of pain (median): 1 (range 0–3)	 Sig, favors propofol/alfentanil NS, favors propofol/alfentanil NS, no difference
Ulmer et al., 2003	<u>Propofol vs. midazolam/fentanyl</u> Pulse: 73.4 (SD 12.1) Systolic BP: 111.8 (SD 19.6) Diastolic BP: 65.3 (SD 13.2) Oxygen saturation: 99% (SD 1.5)	 NS, not fav Sig, favors propofol Sig, favors propofol NS, favors propofol

[19] Pain rated on a 0–3 scale, with 0 = no pain and 3 = severe pain.
[20] Interquartile range.

Citation	Results	Categorization of Results (significance, direction)
Qadeer et al., 2005[21]	<u>Propofol vs. traditional sedative agents</u> Complications (hypoxia or hypotension): Pooled OR[22] 0.40 (95% CI[23], 0.20–0.79)	Sig, favors propofol
Kostash et al., 1994	<u>Propofol/fentanyl vs. diazepam/meperidine vs. midazolam/fentanyl</u> Pain, moderate to severe: 40% of patients Oxygen required (oxygen saturation <85%): value not stated	NS, no difference Sig, not fav

[21] Note: Authors state that all studies included in this meta-analysis lacked power to detect significant differences between the intervention and control groups.
[22] OR = odds ratio.
[23] CI = confidence interval.

Procedural outcomes—pattern towards favorable

Citation	Results	Categorization of Results (significance, direction)
Hansen et al., 2004	<u>Propofol vs. midazolam/fentanyl</u> Use of position change: 2% of subjects	Sig, favors propofol
	Use of abdominal pressure: 12% of subjects	NS, favors propofol
	Mean time to cecum: 3.2 min (SD 1.7)	NS, favors propofol
Lee et al., 2002	<u>Propofol/alfentanil vs. diazepam/meperidine</u> Procedure duration: 17.9 min (SD 9.9)	NS, not fav
Paspatis et al., 2002	<u>Propofol/midazolam vs. midazolam/pethidine</u> Mean sedation score[24]: 2.7 (SD 0.5)	NS, favors propofol/midazolam
	Endoscopist's evaluation of sedation: 93.7% had excellent sedation	NS, not fav

[24] Sedation rated on a 5-point scale, with 1 = awake and 5 = not arousable.

Citation	Results	Categorization of Results (significance, direction)
Sipe et al., 2002	<u>Propofol vs. midazolam/meperidine</u> Mean time to cecum: 4.5 min (SD 2.8) Mean time to sedation: 2.1 min (SD 1.2) Procedure duration: 18.7 min (SD 5.5) Nurses' evaluation of sedation: 100% of subjects had adequate sedation Use of abdominal pressure: 20% of subjects Average number of position changes: 0.4 (SD 1.0)	 NS, favors propofol Sig, favors propofol Sig, favors propofol Sig, favors propofol Sig, favors propofol Sig, favors propofol
Koshy et al., 2000	<u>Propofol/fentanyl vs. midazolam/meperidine</u> Sedation score >1: 54.6% of subjects	 Sig, favors propofol/fentanyl
Bright et al., 2003	<u>Propofol/alfentanil vs. midazolam/pethidine</u> Procedure duration: 15 min (range 7–40) Maximum sedation score: 3 (range 0–5)	 NS, not fav Sig, not fav
Reimann et al., 2000	<u>Propofol/midazolam vs. midazolam/nalbuphine</u> Procedure duration: 18 min Endoscopist's evaluation of sedation: good to excellent	 NS, favors propofol/midazolam NS, no difference
Roseveare et al., 1998	<u>Propofol/alfentanil vs. pethidine/diazepam</u> Median procedure duration: 15 min (range 4–29) Minimum sedation score: 3 (range 2–5)	 NS, not fav Sig, favors propofol/alfentanil

Citation	Results	Categorization of Results (significance, direction)
Ulmer et al., 2003	<u>Propofol vs. midazolam/fentanyl</u> Mean time to cecum: 3.2 min (SD 1.7) Mean time to sedation: 2.1 min (SD 0.7) Mean sedation score: 4.9 (SD 0.2) Nurses' evaluation of sedation: adequate in 98% of subjects Use of position change: 1 subject Use of abdominal pressure: 6 subjects	 NS, favors propofol Sig, favors propofol Sig, favors propofol Sig, favors propofol Sig, favors propofol NS, fav
Ng et al., 2001	<u>Propofol vs. midazolam</u> Duration of procedure: 8.7 min (SD 3.9) Median deepest sedation score: 4 (range 2–4)	NS, fav Sig, favors propofol
Kostash et al., 1994	<u>Propofol/fentanyl vs. diazepam/meperidine vs. midazolam/fentanyl</u> Procedure duration: 23.4 min (SD 9.4)	 NS, not fav

Post-procedure outcomes—pattern towards favorable

Citation	Results	Categorization of Results (significance, direction)
Lee at el., 2002	<u>Propofol/alfentanil vs. diazepam/meperidine</u> Patient satisfaction (10-cm VAS): 7.7 (SD 2.4) Post-procedure hospital admission: 6% of subjects Delayed side effects: 4% of subjects	 NS, favors propofol NS, no difference Sig, favors propofol

Citation	Results	Categorization of Results (significance, direction)
Moerman et al., 2003	<u>Propofol vs. remifentanil</u> Patient satisfaction (100-point VAS): 96 (SD 7)	Sig, favors propofol
Paspatis et al., 2002	<u>Propofol/midazolam vs. midazolam/pethidine</u> Recovery from sedation (Aldrete score[25]): 9.5 (SD 0.6) at 5 min, 9.8 (SD 0.3) at 10 min, 9.9 (SD 0.1) at 30 min	Sig, favors propofol
Sipe et al., 2002	<u>Propofol vs. midazolam/meperidine</u> Time from completion of procedure to recovery: 14.4 min (SD 6.5) Patient satisfaction (10-cm VAS): 9.3 (SD 1.1) Verbal learning and memory (HVLT-R form[26]): higher total recall scores at all time points	Sig, favors propofol Sig, favors propofol Sig, favors propofol
Koshy et al., 2000	<u>Propofol/fentanyl vs. midazolam/meperidine</u> Aldrete score = 10: 47.3% of subjects at 5 min and 96.6% of subjects at 10 min	NS, favors propofol/fentanyl

[25] Aldrete score rates sedation on a 0–10 scale, 10 = recovery from sedation.
[26] Hopkins Verbal Lear test of verbal learning and memory.

Citation	Results	Categorization of Results (significance, direction)
Bright et al., 2003	<u>Propofol/alfentanil vs. midazolam/pethidine</u> Pain, post-procedure: 1 (range 0–3)	Sig, favors propofol/alfentanil
	Time from completion of procedure to recovery: 5 min (range 0–25min)	Sig, favors propofol/alfentanil
	Pain, 24-h post-procedure: 1 (range 0–3)	Sig, favors propofol/alfentanil
	Post-recovery amnesia: 3 of 4 events recalled more clearly	Sig, favors propofol/alfentanil
	Impact on activity[27] 24-h post-procedure: 0 (range 0–3)	NS, favors propofol/alfentanil
	Patient satisfaction: 100% satisfied	NS, no difference
Reimann et al., 2000	<u>Propofol/midazolam vs. midazolam/nalbuphine</u> Median time to ambulation: 5 min	Sig, favors propofol/midazolam
	Median time to discharge: 17 min	Sig, favors propofol/midazolam
	Complete amnesia: 28% of subjects	Sig, not fav
	Memory impairment: 40% of subjects	Sig, favors propofol/midazolam
	Comfort level, 1-h post-procedure: 50% of subjects were comfortable	Sig, favors propofol/midazolam

[27] Activity rates on a 4-point scale, with 0 = not affected and 3 = severely affected.

Citation	Results	Categorization of Results (significance, direction)
Roseveare et al., 1998	<u>Propofol/alfentanil vs. pethidine/diazepam</u> Median pain, post-procedure: 1 (range 0–3)	Sig, not fav
	Median recovery time: 10 min (range 10–40)	Sig, favors propofol/alfentanil
	After effects, 24-h post-procedure: 3 subjects	Sig, favors propofol/alfentanil
Ulmer et al., 2003	<u>Propofol vs. midazolam/fentanyl</u> Time to full recovery: 16.5 min (SD 8.6)	Sig, favors propofol
	Time to discharge: 36.5 min (SD 11.6)	Sig, favors propofol
	Patient satisfaction[28]	NS, not fav
	Time sleeping, 24-h post-procedure: 7.6 h (SD 1.4)	Sig, favors propofol
	Verbal learning and memory (HVLT-R form): higher score than control group in Trials 1–3, delayed recall, and discrimination	Sig, favors propofol
	Visual-motor coordination (Trails test): better performance than control group	Sig, favors propofol
Ng et al., 2001	<u>Propofol vs. midazolam</u> Median pain score[29], post-procedure: 1 (interquartile range 1–1)	NS, no difference
	Time to discharge: 43.3 (SD 12.1)	Sig, favors propofol
	Patient satisfaction with sedation: 86% “very” or “mostly” satisfied	Sig, favors propofol

[28] Patient satisfaction measured on a 10-point verbal scale.
[29] Pain based on a 4-point scale, with 1 = no pain and 4 = severe pain.

Citation	Results	Categorization of Results (significance, direction)
Kostash et al., 1994	<u>Propofol/fentanyl vs. diazepam/meperidine vs. midazolam/fentanyl</u> Aldrete score = 10: 13.3 min (SD 15.7)	NS, favors propofol/fentanyl
	Return to level one sedation (recovery): 23.5 min (SD 24.4)	NS, favors propofol/fentanyl

Table B-2. Summary of Evidence of Medical Effectiveness of the Use of Propofol for Colonoscopy by Outcome

Part 2- Studies Comparing Use of Propofol in Both Intervention and Control Groups[30]

Physiological and cognitive outcomes—pattern toward favorable

Citation	Results	Categorization of Results (significance, direction)
Rudner et al., 2003	Propofol/remifentanil vs. Propofol/fentanyl/midazolam	
	Oxygen saturation: 96%–99% (Note: oxygen saturation >95% for all subjects across groups)	Sig, favors propofol/remifentanil
	Decrease in MAP[31]: greater in the propofol/fentanyl/midazolam group	Sig, favors propofol/remifentanil
	Respiratory rate: 15 respirations/min	Sig, favors propofol/remifentanil
Heuss et al., 2004	PCS Propofol vs. nurse-administered propofol	
	Decrease in oxygen saturation: –2.0% (SD 1.9)	NS, favors PCS propofol
	Decrease in MAP: –22.6% (SD 11.7)	NS, favors nurse-administered propofol
	Pain (10-cm VAS): 2.8 (SD 2.5)	NS, favors nurse-administered propofol

[30] The design of these trials does not allow for the separation of the effects of propofol versus other agents.
[31] MAP = mean arterial blood pressure

Citation	Results	Categorization of Results (significance, direction)
Moerman et al., 2004	<u>Propofol vs. propofol/remifentanil</u> Apnea: 4% of subjects	Sig, favors propofol
	Bradypnea (RR[32]<6): 0 subjects	Sig, favors propofol
	Tachycardia (HR[33]>30% above baseline): 16% of subjects	Sig, favors propofol/remifentanil
	Hypertension (MAP>30% above baseline): 4% of subjects	NS, favors propofol/remifentanil NS, favors propofol
	Bradycardia (HR>30% under baseline): 24% of subjects	NS, favors propofol
	Hypotension (MAP>30% under baseline): 20% of subjects	

Procedural outcomes—pattern toward favorable

Citation	Results	Categorization of Results (significance, direction)
Rudner et al., 2003	<u>Propofol/remifentanil vs. Propofol/fentanyl/midazolam</u> Intensity of pain: propofol/remifentanil mean = 0, propofol/fentanyl/midazolam mean = 0.4	Sig, favors propofol/remifentanil

[32] RR = respiratory rate.
[33] HR = heart rate.

Post-procedure outcomes—pattern toward favorable

Citation	Results	Categorization of Results (significance, direction)
Rudner et al., 2003	<u>Propofol/remifentanil vs. Propofol/fentanyl/midazolam</u> Time from last drug administration to recovery (Aldrete score = 10): 12.8 min (SD 4.8) Time from last drug administration to recovery (MPADS[34] score = 10): 31.2 min (SD 9.1)	 Sig, favors propofol/fentanyl/ midazolam Sig favors propofol/fentanyl/ midazolam
Heuss et al., 2004	<u>PCS Propofol vs. nurse-administered propofol</u> Patient satisfaction (10-cm VAS): 1.6 (SD 2.1) Partial or complete amnesia: 43.6%	 NS, favors PCS propofol NS, favors nurse-administered propofol

[34] MPADS = Modified Post Anesthesia Discharge Scoring System

Appendix C: Cost Impact Analysis: Caveats and Assumptions

This appendix describes caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site, http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

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

General Caveats and Assumptions

The expected costs in this report are not predictions of future costs. Instead, they are estimates of the costs that would result if a certain set of assumptions were exactly realized. Actual costs will differ from these estimates for a wide variety of reasons, including:

- Prevalence of mandated benefits before and after the mandate different from our assumptions;
- Utilization of mandated services before and after the mandate different from our assumptions;
- Random fluctuations in the utilization and cost of health care services.

Additional assumptions that underlie the cost estimates presented here are:

- Cost impacts are only shown for people with insurance;
- The projections do not include people covered under self-insurance employer plans because those employee benefit plans are not subject to state-mandated minimum benefit requirements;
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.

There are other variables that may affect costs, but which Milliman did not consider in the cost projections presented in this report. Such variables include, but are not limited to:

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

- Changes in benefit plans. To help offset the premium increase resulting from a mandate, enrollees or insured may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and the insured person, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). Milliman did not include the effects of such potential benefit changes in its analysis.
- Adverse selection. Theoretically, individuals or employer groups who had previously foregone insurance may now elect to enroll in an insurance plan postmandate because they perceive that it is to their economic benefit to do so.
- Health plans may react to the mandate by tightening their medical management of the mandated benefit. This would tend to dampen our cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., fee for service [FFS] and PPO plans).
- Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the plan types we modeled (HMO, point-of-service [POS] and PPO/FFS), there are variations in utilization and costs within California. One source of difference is geographic. Utilization differs within California due to differences in the health status of the local commercial population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between health plans and providers.
- Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, we have estimated the impact on a statewide level.

Mandate-specific assumptions and caveats

- As discussed in the *Utilization, Coverage and Cost Impacts* section, the utilization increase is estimated to be two-percentage points for reasons discussed. The actual change in utilization of propofol as a result of the mandate may be higher or lower than this assumption.

Appendix D: Information Submitted by Outside Parties for Consideration for CHBRP Analysis

CHBRP policy includes analysis of information submitted by outside parties, and places an open call to all parties who want to submit information during the first two weeks of the CHBRP review.

No information was directly submitted by interested parties for this analysis.

For information on the processes for submitting information to CHBRP for review and consideration please visit: http://www.chbrp.org/recent_requests/index.php

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Committees and Staff

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

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

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

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