

California Health Benefits Review Program

Analysis of California Assembly Bill (AB) 1763 Colorectal Cancer Screening

A Report to the 2015-2016 California State Legislature

April 7, 2016



Key Findings:

Analysis of California Assembly Bill AB 1763 Colorectal Cancer Screening

Summary to the 2015-2016 California State Legislature, April 2016



AT A GLANCE

Assembly Bill (AB) 1763 would require plans or policies to provide coverage for colorectal cancer (CRC) screenings and tests.

- **Enrollees covered.** CHBRP estimates that in 2016, 25.2 million Californians have state-regulated coverage that would be subject to Assembly Bill AB 1763.
- **Impact on expenditures** AB 1763 would increase total net annual expenditures by \$5.63 million or 0.004% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a 25.92 million increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, partially offset by a decrease in enrollee expenditures for previously noncovered benefits (\$20.29 million).
- **EHBs.** AB 1763 impacts the terms and conditions of coverage for CRC screenings and tests, but does not change coverage itself. AB 1763 does not exceed EHBs.
- **Medical effectiveness.** There is a preponderance of evidence that USPSTF-recommended CRC screening modalities are medically effective for the detection and prevention of CRC among average- and high-risk individuals.
- **Benefit coverage.** CHBRP estimates the percent of enrollees with coverage for CRC screening exams and lab tests assigned a grade of A or B by the USPSTF and additional screening and tests recommended by a physician will remain to be 100%. However, AB 1763 would eliminate cost sharing on CRC screenings and lab tests for enrollees aged 50 and older including colonoscopies with the removal of polyps if the enrollee has a positive result on any fecal test. CHBRP estimates 5% of their enrollees aged 50 and older in high-deductible plans would be exempted from waving cost sharing. Accordingly, CHBRP estimates that the percent of enrollees aged 50 and older with coverage for CRC screening services listed in AB 1763 without cost sharing would increase from 78% to 95%.
- **Utilization.** CHBRP assumes that the overall utilization of CRC screening and lab tests is going to increase by 0.3% (1,764 users), which is mainly due to the increase in use among enrollees aged 50 and older after the removal of cost-sharing requirements for CRC screening and lab tests.
- **Public Health.** CHBRP projects no measurable public health impact on the diagnosis or prevention of colorectal cancer at the population level due to the small number (1,764) of additional enrollees who would avail themselves of CRC screening. At the individual level, AB 1763 would likely yield health and quality of life improvements, such as reduced screening-related financial burden and identification of CRC at earlier, and therefore more treatable, stages.
- **Long-term impacts.** To the extent that AB 1763 would eliminate cost sharing for medically necessary additional colorectal cancer screenings and all events along the stepwise "continuum of screening", including follow-up colonoscopies to positive fecal tests and polyp removal during colonoscopies, it would be reasonable to assume that this reduction in financial burden would promote greater adherence to physician-recommended screenings beyond those projected for the first 12 months following implementation of the mandate.

BILL SUMMARY

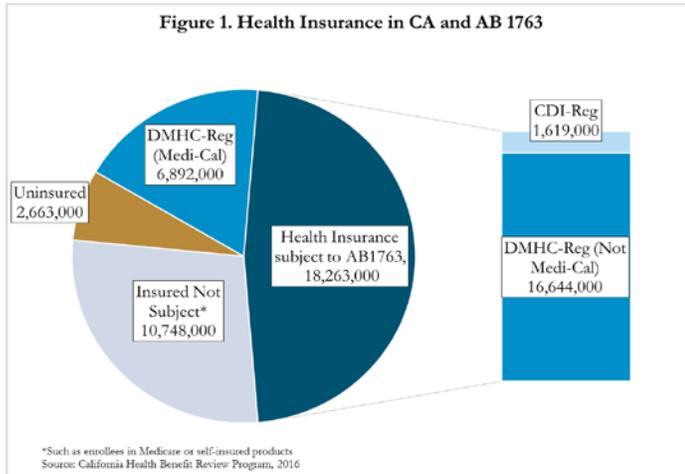
Assembly Bill 1763 (introduced February 2016) would require health care plans and insurance policies to provide coverage for colorectal cancer screenings and tests with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF), provide coverage for additional screenings and tests for high-risk individuals, and remove cost-sharing for enrollees aged 50 and over.

INCREMENTAL IMPACT OF ASSEMBLY BILL AB 1763

Benefit Coverage, Utilization, and Cost

Coverage Impacts

If AB 1763 were enacted, CHBRP estimates the percent of enrollees with coverage for colorectal cancer screening exams and lab tests assigned a grade of A or B by the USPSTF and additional screening and tests recommended by a physician would remain to be 100%. However, AB 1763 would eliminate cost sharing on CRC screenings and lab tests for enrollees aged 50 and older including colonoscopies with the removal of polyps if the enrollee has a positive result on any fecal test. As AB 1763 does not apply to high-deductible plans, CHBRP estimates 5% of enrollees aged 50 and older would be exempted from waving cost sharing. Accordingly, CHBRP estimates that the percent of enrollees aged 50 and older with coverage for CRC screening services listed in AB 1763 without cost sharing would increase from 78% to 95%.

Figure 1. Health Insurance in CA and AB 1763

Utilization Impacts

CHBRP assumes that the overall utilization of CRC screening and lab tests is going to increase by 0.3% (1,764 users), which is mainly due to the increase in use among enrollees aged 50 and older after the removal of cost-sharing requirements. The improved access will be beneficial to those enrollees at average risk who were discouraged from seeking CRC screening services due to the cost-sharing requirements.

Cost Impacts

CHBRP estimates that AB 1763 would increase total net annual expenditures by \$5.63 million or 0.004% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a \$25.92 million increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, partially offset by a decrease in enrollee expenditures for previously noncovered benefits (\$20.29 million).

Public Health

Colorectal Cancer (CRC) Rates

Measurable health outcomes relevant to AB 1763 include reduced incidence of colorectal cancer and CRC-associated morbidity and mortality, improved quality of life, and reduction in financial barriers to screening. However, CHBRP projects no measurable public health impact on the diagnosis or prevention of colorectal cancer at the population level due to the small number (2,358) of

additional enrollees who would avail themselves of CRC screening.

CHBRP estimates that AB 1763 would modify coverage and reduce the net financial burden by \$3.2 million in the first year, postmandate, for covered enrollees aged 50 and older utilizing the 2,358 additional screenings beyond USPSTF recommendations, on the basis of high-risk status.

Medical Effectiveness

There is a moderate preponderance of evidence that USPSTF-recommended screenings are effective for persons with a family history of CRC, persons with prior CRC, persons with a precursor neoplastic polyp, and persons with inflammatory bowel disease.

Evidence of the impact of expanded insurance coverage on screening utilization is limited to observational studies. The impact of insurance coverage for CRC screening and utilization among high-risk populations has not been assessed by these studies.

For average-risk individuals, evidence exists suggesting a small but positive impact of insurance coverage for CRC screening and utilization (Cokkinides, 2011), and that low socioeconomic status individuals may benefit from the elimination of barriers to screening utilization (Fedewa, 2015a).

Long-Term Impacts

Adherence to Recommended Screenings

To the extent that AB 1763 would eliminate cost sharing for medically necessary additional colorectal cancer screenings and all events along the stepwise "continuum of screening," including follow-up colonoscopies to positive fecal tests and polyp removal during colonoscopies, it would be reasonable to assume that this reduction in financial burden would promote greater adherence to physician-recommended screenings beyond those projected for the first 12 months following implementation of the mandate.

CONTEXT FOR BILL CONSIDERATION

Therefore, AB 1763 does not exceed EHBs, and therefore would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs) in Covered California.

Essential Health Benefits and the Affordable Care Act

SB 1763's requirements regarding coverage of CRC screenings and tests given a grade of A or B by the USPSTF and coverage for tests recommended by treating physicians for high-risk individuals is consistent with ACA requirements that health plans that started on or after September 23, 2010, to cover CRC screening tests.

A Report to the California State Legislature

Analysis of California Assembly Bill AB 1763 Colorectal Cancer Screening

April 7, 2016

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ABOUT CHBRP

The California Health Benefits Review Program (CHBRP) was established in 2002 to provide the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates and repeals, per its authorizing statute. The state funds CHBRP through an annual assessment on health plans and insurers in California.



An analytic staff in the University of California's Office of the President supports a task force of faculty and research staff from several campuses of the University of California to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact, and content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, as well as all CHBRP reports and publications are available at www.chbrp.org.

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AB 1763 IMPACTS ON BENEFIT COVERAGE, UTILIZATION, AND COST, 2018

Table 1. AB 1763 Impacts on Benefit Coverage, Utilization, and Cost, 2018

	Premandate	Postmandate	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates ^(a)	25,155,000	25,155,000	0	0.0%
Total enrollees with health insurance subject to AB 1763	13,803,000	13,803,000	0	0.0%
Percentage of enrollees with coverage for the mandated benefit	13,803,000	13,803,000	0	0.0%
Number of enrollees with coverage for the mandated benefit	100%	100%	0%	0.0%
Number of enrollees aged 50 and older with health insurance subject to AB 1763				
With no cost sharing	2,423,111	2,930,412	507,301	20.9%
With cost sharing	678,144	170,843	-507,301	-74.8%
Percent of enrollees aged 50 and older with health insurance subject to AB 1763				
With no cost sharing	78.1%	94.5%	16.4%	20.9%
With cost sharing	21.9%	5.5%	-16.4%	-74.8%
Utilization and cost				
Number of enrollees using benefit	660,600	662,364	1,764	0.3%
Total users aged 50 and older	507,881	509,645	1,764	0.3%
With no cost sharing	396,824	481,667	84,843	21.4%
With cost sharing	111,057	27,978	-83,079	-74.8%
For Users Over 50 years of age:				
Total Number of Procedures	718,897	720,661	1,764	0.2%
Average Cost per Procedure	\$761	\$761	0	0.0%
Average Cost Share per Procedure	\$46	\$18	-\$28	-60.8%
Expenditures				
<u>Premium expenditures by payer</u>				
Private employers	\$69,145,570,000	\$69,157,875,000	\$12,305,000	0.018%

for group insurance				
CalPERS HMO employer expenditures ^(c)	\$5,065,074,000	\$5,065,074,000	\$0	0.000%
Medi-Cal Managed Care Plan expenditures	\$16,670,700,000	\$16,670,700,000	\$0	0.000%
Enrollees for individually purchased insurance	\$23,175,998,000	\$23,185,747,000	\$9,749,000	0.042%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care ^(b)	\$21,856,738,000	\$21,860,607,000	\$3,869,000	0.018%
Enrollee expenses				
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$17,229,732,000	\$17,209,437,000	-\$20,295,000	-0.118%
Enrollee expenses for noncovered benefits ^(d)	\$0	\$0	\$0	0.000%
Total expenditures	\$153,143,812,000	\$153,149,440,000	\$5,628,000	0.004%

Source: California Health Benefits Review Program, 2016.

Notes: (a) This population includes persons with privately funded (including Covered California) and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employer-sponsored health insurance.

(b) Of the CalPERS employer expenditures, about 56.7% would be state expenditures for CalPERS members who are state employees, state retirees, or their dependents. This percentage reflects the share of enrollees in CalPERS HMOs as of September 30, 2015. However, AB 1763 does not apply to enrollees of CalPERS HMO members.

(c) Enrollee premium expenditures include contributions to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(d) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)¹ conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 1763, Colorectal Cancer Screening.

If enacted, AB 1763 would affect the health insurance of approximately 13.8 million enrollees (35% of all Californians). This represents 54% percent of the 25.2 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies.

Bill-Specific Analysis of AB 1763, Colorectal Cancer Screening

AB 1763 addresses insurance coverage for screenings and tests intended to detect colorectal cancer. The U.S. Preventive Services Task Force (USPSTF) makes certain recommendations for screenings for colorectal cancer (CRC) among persons at average risk for the disease (USPSTF, 2008). The USPSTF recommends that all adults aged 50 and over receive CRC screening until age 75. Recommended screening methods include fecal occult blood testing, sigmoidoscopy, or colonoscopy procedures.

Some individuals are designated as high risk for CRC. AB 1763 defines high-risk individuals as those with a family history of CRC, previous occurrences of cancer or neoplastic polyps, certain chronic diseases, and other predisposing factors. Treating physicians may recommend additional testing for high-risk individuals.

Screening colonoscopies, which evaluate asymptomatic people for previously undiagnosed polyps and colon cancer, differ from diagnostic colonoscopies, which are used to evaluate specific problems such as abdominal pain or intestinal bleeding².

Bill Language

The full text of AB 1763 can be found in Appendix A.

AB 1763 addresses coverage for CRC screening procedures for enrollees in DMHC-regulated plans and CDI-regulated policies. AB 1763 specifically directs a health care service plan contract or a health insurance policy — except as specified — that is issued, amended, or renewed on or after January 1, 2018, to:

- Provide coverage for CRC screening exams and lab tests that are assigned a grade of A or B by the USPSTF for persons who are at average risk of contracting colorectal cancer.
- Provide coverage for additional screening and tests recommended by a physician if the person is high risk as defined in the bill.
- Prohibit cost sharing for CRC screening tests for enrollees aged 50 years and older.

High-deductible plans are excluded from the requirement to cover colonoscopies.

AB 1763 defines an individual as high risk if any of the following apply:

¹ CHBRP's authorizing statute is available at www.chbrp.org/docs/authorizing_statute.pdf.

² <http://www.dol.gov/ebsa/faqs/faq-aca12.html>

- A family medical history of colorectal cancer;
- A prior occurrence of colon cancer or precursor neoplastic polyps;
- A prior occurrence of a chronic digestive disease condition including but not limited to inflammatory bowel disease, Crohn's disease, or ulcerative colitis; or
- Other predisposing factors.

The USPSTF recommends one of the follow tests for CRC screening of adults at average risk:

- Annual high-sensitivity fecal occult blood testing;
- Sigmoidoscopy every 5 years combined with high-sensitivity fecal occult blood testing every 3 years; and
- Screening colonoscopy at intervals of 10 years.

Analytic Approach and Key Assumptions

It is important to note that CHBRP's analyses address the incremental effects of proposed legislation.

For this analysis, because identification of high risk is not easily obtained in available data, CHBRP assumes that enrollees receiving screening colonoscopies under the age of 50 are designated as high risk.

High-deductible plans are exempt.

Interaction with Existing Requirements

Proposed legislation can interact with state and federal requirements. When possible, CHBRP indicates possible overlaps or interactions.

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

State Requirements

California Law and Regulations

California law requires DMHC-regulated plans and CDI-regulated³ policies to cover medically accepted cancer screening tests. Although this benefit mandate requires coverage for CRC screening, it does not address additional, doctor-recommended tests for high-risk individuals, nor does it address cost-sharing requirements. AB 1763 mandates coverage for tests recommended by the treating physician for high-risk

³ California Health & Safety Code (1367.665) and California Insurance Code (10123.20)

individuals, and eliminates cost-sharing for persons aged 50 and over for USPSTF-recommended tests with an A or B rating.

Similar requirements in other states

CHBRP is aware of only one other state that addresses the same three components as AB 1763: coverage for screening colonoscopies, expanded coverage for high-risk individuals, and a prohibition on cost-sharing for individuals aged 50 and over. On January 1, 2016, Oregon Revised Statute 743A.124 took effect, requiring health benefit plans to cover CRC screenings and tests rated an A or B by the USPSTF. Additionally, benefit plans are required to exempt persons aged 50 and over from cost sharing for CRC screenings. Persons designated as high risk are entitled to coverage of screening exams and laboratory tests as recommended by the treating physician.

Federal Requirements

Affordable Care Act

The Affordable Care Act (ACA) has impacted health insurance in California, expanding the Medi-Cal program (Medicaid in California)⁴ and making subsidized and unsubsidized health insurance available through Covered California, the state's health insurance marketplace.⁵

A number of ACA provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 1763 may interact with requirements of the ACA, including the requirement for certain health insurance to cover essential health benefits (EHBs).⁶

The Affordable Care Act requires health plans that started on or after September 23, 2010, to cover CRC screening tests.

Under the Affordable Care Act, health insurance plans and policies started after September 23, 2010 must cover preventive screenings with an A or B rating from the USPSTF, including those for colorectal cancer. The Centers for Medicaid and Medicare Services provides further guidance clarifying coverage for screening colonoscopies.⁷ Among the CMS clarifications on ACA coverage is the prohibition of cost sharing imposed on enrollees for the removal of a polyp during a screening colonoscopy.

Essential Health Benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. Health insurance offered in Covered California is required to at least meet the minimum standard of benefits as defined by the ACA

⁴ The Medi-Cal expansion is to 133% of the federal poverty level (FPL) – 138% with a 5% income disregard.

⁵ The ACA requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces.

⁶ The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other_publications/index.php.

⁷ Centers for Medicaid and Medicare Services, 2016. Available at: <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/index.html#Affordable%20Care%20Act>

as essential health benefits (EHBs), and available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{8,9}

States may require such QHPs to offer benefits that exceed EHBs.¹⁰ However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.^{11,12} On the other hand, "state rules related to provider types, cost-sharing, or reimbursement methods" would *not meet* the definition of state benefit mandates that could exceed EHBs.¹³

AB 1763 and EHBs

AB 1763 requires coverage for preventive screening tests for colorectal cancer given a grade of A or B by the USPSTF and coverage for tests recommended by treating physicians for high-risk individuals. Additionally, the bill eliminates cost sharing for persons aged 50 and older. Therefore, AB 1763 does not exceed EHBs, and therefore would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs)¹⁴ in Covered California.

Preventive Services

The ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost sharing when delivered by in-network providers and as soon as 12 months after a recommendation appears in the USPSTF A and B recommendations and other sources.

AB 1763 specifically directs a health care service plan contract or a health insurance policy — except as specified — that is issued, amended, or renewed on or after January 1, 2018, to provide coverage for CRC screening exams and lab tests that are assigned a grade of A or B by the USPSTF for persons who are at average risk of contracting colorectal cancer.

⁸ The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.

⁹ H&SC Section 1367.005; IC Section 10112.27.

¹⁰ ACA Section 1311(d)(3).

¹¹ State benefit mandates enacted on or before December 31, 2011 may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/vfdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

¹² However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in a state's EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

¹³ Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

¹⁴ In California, QHPs are nongrandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state's health insurance marketplace.

BACKGROUND ON COLORECTAL CANCER SCREENING

This *Background* section provides context for CHBRP's analysis of AB 1763 by discussing the incidence of colorectal cancer, relevant risk factors, screening guidelines and patterns of use, as well as the social determinants of health that may influence screening behaviors in California. Note that the following discussion broadly applies to the general population and includes persons with insurance subject to AB 1763 as well as the uninsured and those with health insurance not subject to state-regulated mandates, unless otherwise stated.

Colorectal Cancer

Colorectal cancer (CRC) is cancer that occurs in either the colon or rectum. Most colorectal cancers arise from abnormal growth (adenomatous polyps) in the linings of the large bowel that take 10 to 15 years on average to progress to cancerous tissues (Doubeni, 2016a). In California, CRC is the third most common cancer (after breast and prostate) among men and women and the second most common cause of all deaths attributable to cancer (CCR, 2016).

Nationally, the lifetime incidence of CRC is about 5%, with incidence being 25% greater among men than women and about 20% higher in African Americans than whites (Macrae et al., 2016). Patients with predisposing heritable conditions also demonstrate higher CRC incidence (Macrae et al., 2016). Since 1988, CRC incidence rates in California have declined steadily for the general population and among all major racial/ethnic groups, with the greatest decreases (39%) observed for non-Hispanic whites (CCR, 2015).

With early detection, the 5-year probability of survival from CRC is 94%. In some cases, CRC may be prevented entirely with removal of precancerous polyps during a screening colonoscopy (C4, 2014; CCR, 2016; Doubeni, 2016a). Yet, CRC is known as a "silent killer" since afflicted individuals tend to remain asymptomatic during early stages (i.e., before the cancer has spread beyond the intestinal wall), resulting in a larger proportion of late-stage diagnoses; survival declines to 71% and 13% for patients diagnosed with regional and distant metastases respectively (C4, 2014). In 2012, the most recent year for which data are available, late-stage cancers accounted for 57% of the 14,682 newly diagnosed cases of colon and rectum cancer and the majority of CRC-related deaths in California (CCR, 2016).

Risk Factors and Screening Recommendations

The risk of developing colorectal cancer is most strongly associated with aging. Although CRC is sometimes observed in younger adults, an individual's risk for large bowel cancers increases rapidly after age 50 (Macrae et al., 2016). In the United States, colorectal cancer is infrequent before the age of 40, with 90% of CRCs occurring among individuals aged 50 years and older (Doubeni, 2016a). Accordingly, the United States Preventive Services Task Force (USPSTF) recommends routine screening for all adults who have no other known risk factors (i.e., the average risk population) beginning at age 50, with one of several approved modalities outlined in Table 2.

Table 2. Colorectal Cancer Screening Modalities by Function and Recommended Screening Interval for Average-Risk Individuals

Screening Tests (by suggested interval)	Detects Cancer	Detects Polyps and Cancer
Every Year		
Fecal occult blood test (FOBT)* (a)	X	
Fecal immunochemical test (FIT)* (b)	X	
Every 5 Years		
Flexible sigmoidoscopy* (a)		X
Every 10 Years		
Colonoscopy (a)		X

Source: United States Preventive Services Task Force, 2008.

Note: * Colonoscopy should be performed if test results are positive. (a) Test has received an ‘A’ or ‘B’ recommendation from the United States Preventive Services Task Force, and is therefore a covered service. (b) Recommended in the 2016 USPSTF draft updated guidelines.

Although the USPSTF identifies age as the primary determinant of colorectal cancer risk, several environmental and genetic factors can increase an individual’s likelihood of developing CRC to the extent that additional screening may be recommended.¹⁵ Beyond the USPSTF guidelines for average risk individuals, AB 1763 would mandate coverage for additional screening procedures and labs, as recommended by a physician, for individuals determined to be at high risk for developing colorectal cancer. Specifically, the bill language characterizes high-risk individuals as persons with at least one of the following (a) a family medical history of CRC; (b) a prior occurrence of cancer or neoplastic polyps; (c) a prior occurrence of a chronic digestive condition, including but not limited to inflammatory bowel disease (IBD, Crohn’s disease, or ulcerative colitis); or (d) other predisposing factors.

- Family Medical History:** After age, a family medical history of colorectal cancer, defined as having a single first-degree relative (FDR) — a parent or sibling — with a diagnosis of CRC before the age of 60, or two or more FDRs with CRC diagnosis at any age, confers the greatest increase in risk (Ramsey et al., 2016). A systematic review of 30 major population studies determined that risk of developing CRC was twice as great for people who had a FDR diagnosed with CRC at any age and three times as great for individuals who had a FDR diagnosed before the age of 60; heritable cancer susceptibility syndromes (such as Lynch and familial adenomatous polyposis) were associated with an almost 20-fold increase in relative risk (Henrikson et al., 2015). According to the 2005 California Health Interview Survey, an estimated 4.2% of Californians have a family history of colorectal cancer, with 1.1% meeting the criteria for strong familial risk (Scheuner et al., 2010).
- Prior Occurrence of Cancer or Polyps:** Among patients with a history of treatment for colorectal cancer, 1.5% to 3% develops a second primary CRC in the first five years following resection. Patients with a personal history of large adenomatous polyps are 3 to 6 times more likely to develop colorectal cancer as compared with average-risk counterparts; multiple co-occurring polyps are associated with the greatest increase in risk (Macrae et al., 2016) Nationally, 6.3% of patients present with clinically significant polyps during colonoscopies (Lieberman et al., 2008).

¹⁵ Personal Communication, F. May, March 8, 2016

- **Inflammatory Bowel Disease (IBD):** IBD is a collection of functional disorders in which the gastrointestinal tract is inflamed over long periods of time, the most common of which are Crohn's disease and Ulcerative Colitis (Kappelman et al., 2007). Prolonged exposure to bowel inflammation causes IBD patients to develop pancolitis, which confers a 5- to 15-fold increase in relative risk, reaching as high as 30% among patients with four decades of exposure (Macrae, 2016). IBD affects an estimated 0.4% of the population. It should be noted that, although AB 1763 refers generally to "chronic digestive conditions," only the conditions that comprise IBD are associated with increased risk for CRC (ACS, 2016).
- **Other Predisposing Factors:** AB 1763 makes allowances for "other predisposing factors" that may increase an individuals' risk for CRC, and therefore their likelihood of receiving screenings beyond those recommended for average risk patients. In the 2016 draft update to CRC screening recommendations, the USPSTF recognizes that male gender and African American race are associated with increased CRC risk, with CRC mortality 25% higher among men than women and 20% higher among African Americans than whites. However, the evidence is ambiguous regarding the causes of these noted disparities (Macrae, 2016; USPSTF, 2016). Additional sources of increased risk for CRC that are clinically recognized include abdominal radiation associated with the treatment of other cancers, immunosuppression resulting from renal transplantation, and acromegaly (overproduction of human growth hormone).¹⁶

In addition to the high-risk factors described previously, CRC is closely linked with a large number of clinical considerations and modifiable behavioral choices for which the causal relationship is too small or uncertain to recommend additional screening, including:

- Obesity;
- Tobacco, alcohol, and red meat consumption;
- Diabetes Mellitus;
- Androgen deprivation therapy for the treatment of prostate cancer; and
- Gallbladder removal (ACS, 2014; Macrae, 2016).

It is important to note that the cumulative impact of several factors may increase an individual's risk of developing colorectal cancer beyond the risk conferred by each individual factor (Doubeni, 2015a).

Although the USPSTF does not currently make allowances for risk factors other than age and family history with respect to screening, several professional societies (e.g., the American College of Gastroenterology, the American Cancer Association) suggest amendments to screening intervals and modality use on the basis of risk factor. Please see the *Medical Effectiveness* section for a more detailed discussion of alternate guidelines for high-risk patients.

Colorectal Cancer Screening Prevalence in California

The CDC considers a person over the age of 50 to be up to date with screening guidelines for colorectal cancer if they have been screened with one of the modalities recommended by the USPSTF (Table 1) within the suggested screening interval. By that definition, the California Behavioral Risk Factor Surveillance System (BRFSS) estimates that 36% of Californians aged 50 and over in 2013 were not up to date with screening guidelines, and approximately 25% had never participated in any screening procedure for CRC (Darsie, 2015). The rates observed in California fall short of the national target for CRC, adopted by the California Colon Cancer Control Program (C4P), which promotes 80% adherence to screening guidelines by 2018.

¹⁶ Personal Communication, content expert F. May, March 15, 2016

In the context of colorectal cancer it should be noted that, *screening occurs among asymptomatic individuals, however a complete CRC screening event may include several cascading steps over a “continuum of screening”* (Pollitz, 2012). In the instance that an individual initially chooses to utilize FOBT or flexible sigmoidoscopy and receives a positive result, the USPSTF notes that a follow-up colonoscopy is required for confirmation of the results, thus concluding one discrete screening cycle. Additionally, the USPSTF and American Cancer Society recognize the removal of polyps identified during a screening colonoscopy as an inherent (and preventive) component of the test (Pollitz, 2012). By contrast, *tests that determine the grade and type of cancer are diagnostic.*

Patterns of Screening

In California, the prevalence of screening for CRC differs between demographic groups. According to the 2014 California Behavioral Risk Factor Survey, the most recent year for which data are available, older adults, women, and African Americans were more likely to be in compliance with USPSTF screening recommendations (Table 3). Specifically, women screen at higher rates than men (68% vs. 63%) and screening rates are observed by age group show that 54.3% of adults aged 50 to 59 report compliance to guidelines as compared with 57% among adults aged 70 to 75. Additionally, a smaller proportion of adults aged 50 to 59 (67%) reported never having a screening procedure than adults aged 60 to 79 (86%) (CHIS, 2009). The likelihood of adherence to guidelines is highest among African Americans (77%). By contrast, Hispanics are estimated to have the lowest screening participation with only 48% reporting compliance with guidelines (BRFSS, 2014) and 65% reporting any lifetime CRC screening (CHIS, 2009). As described in Table 3, CRC screening is inversely correlated with income and educational attainment with persons making less than \$15,000 and who have not graduated high school reporting adherence to guidelines below 50%.

Although CHBRP found limited literature regarding differential screening rates between risk groups, results from a New Jersey study of over 700 patients in primary care settings suggest that screening prevalence differs by known level of risk for developing CRC (Felsen, 2011). When surveyed, patients who identified as high risk (on the basis of family medical history and diagnosis with IBD) demonstrated the highest rates of screening guideline adherence (63%) as compared to 41% of average-risk patients. Additionally, high-risk patients had more than three times the odds of being up to date with guidelines and seven times the odds of adhering to a physician recommendation for CRC screening than average-risk controls (Felsen et al., 2011).

Social Determinants of Health¹⁷ and Disparities¹⁸ in Colorectal Cancer Screening

Per statute, CHBRP now includes discussion of disparities under the broader umbrella of social determinants of health (SDoH). SDoH include factors outside of the traditional medical care system that influence health status and health outcomes. CHBRP will consider the full range of SDoH and related disparities (e.g., income, education, and social construct around age, race/ethnicity, gender, and gender identity/sexual orientation) that are relevant to this bill and where evidence is available. In the case of AB

¹⁷ CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from APHA, 2014; Healthy People 2020, 2015). [See SDoH white paper for further information.](#)

¹⁸ Several competing definitions of “health disparities” exist. CHBRP relies on the following definition: “Health disparities are potentially avoidable differences in health (or health risks that policy can influence) between groups of people who are more or less advantaged socially; these differences systematically place socially disadvantaged groups” at risk for worse health outcomes (Braveman, 2006)

1763, evidence shows that colorectal cancer-related mortality occurs disproportionately among older adults, African Americans, and men. A review of the literature also indicates that educational attainment and socioeconomic status are inversely correlated with death from CRC (Jemal et al., 2014).

Although CRC mortality rates are highest among adults aged 70 to 75 years (46.9 per 100,000 persons) and African Americans (18.6 per 100,000 persons), these populations have the most robust screening rates (82% and 77% respectively) as compared with all other groups (Table 3). This pattern may be reflective of the magnitude of increased risk that these groups experience, particularly among older adults; however, the literature is inconclusive on the reasons that African Americans experience high CRC mortality. In a qualitative survey of CRC screening behaviors among African Americans, 33% of subjects reported avoiding screening due to cultural stigma and 35% of those who completed colonoscopies did so because of a history of other comorbidities and previous cancers; these results indicate that this community may be slow to seek screening although their risk factors are high (Wong et al., 2013). By contrast, researchers evaluating the geographic distribution of gastroenterologists relative to populations of insured individuals found that African Americans are more likely to live near a GI specialist (Stimpson et al., 2012).

The California Cancer Registry does not collect incidence and mortality by income or educational attainment; however, researchers comparing vital statistics and demographics at the state level observed that CRC mortality was inversely related to educational attainment (used in this study as a proxy for income). In California, non-Hispanic blacks with less than 12 years of schooling were found to have the highest mortality rates (18.3 per 100,000 persons) and highly-educated (greater than 16 years of schooling) Hispanics had the lowest mortality rates (3.9 per 100,000 persons) (Jemal et al., 2014).

Table 3. Percent Distribution Of Colorectal Cancer Screening Use and CRC Incidence Among Californians Aged 50-75, By Age, Gender, Race/Ethnicity, Income, and Educational Attainment, California, 2014

Demographic	Meets USPSTF Colorectal Cancer Screening Recommendations (%) ^(a)	California CRC mortality rate, per 100,000 persons, per year, 2012 ^(b)
ALL	66.0	10.8
Age Group		
50-59 years	54.3	11.5
60-69 years	75.4	25.8
70-75 years	82.0	46.9
Gender		
Male	63.9	12.4
Female	67.9	9.5
Race/Ethnicity		
Non-Hispanic White	71.9	10.7
African American	77.7	18.6
Hispanic	48.1	9.9
Asian/PI	67.2	9.5

Demographic	Meets USPSTF Colorectal Cancer Screening Recommendations (%) ^(a)	California CRC mortality rate, per 100,000 persons, per year, 2012 ^(b)
Income		
Less than \$15,000	49.2	*
\$15,000-\$24,999	47.0	*
\$25,000-\$34,999	61.0	*
\$35,000-\$49,999	73.6	*
\$50,000+	74.6	*
Educational Attainment		
Less than high school	45.2	*
High school diploma or GED	63.4	*
Some college or vocational school	70.6	*
Bachelor's degree or higher	74.3	*

Source: Behavioral Risk Factor Surveillance System, 2014; CCR, 2015.

Note: (a) Numbers collected from the 2014 Behavioral Risk Factor Survey in California. (b) Mortality data collected from the California Cancer Registry. 2012 is the most recent year for which incidence and mortality data are available.

*California mortality data not available

Key: CRC=colorectal cancer; GED=Graduate Equivalency Diploma

MEDICAL EFFECTIVENESS

CHBRP's medical effectiveness analysis for AB 1763 focuses on the impact of insurance coverage for USPSTF-recommended CRC screening modalities for average-risk individuals, and for coverage for additional procedures and labs, as recommended by a physician, for individuals determined to be at high risk for developing CRC, and for the elimination of cost sharing for enrollees over the age of 50. CHBRP chose this focus because AB 1763 would not increase the number of Californians who have health insurance coverage for colon cancer screening in general. Instead, AB 1763 would affect the terms and conditions of insurance coverage for specific types of CRC screening for certain patients, though the provisions shall not apply to a high-deductible health plan.

Research Approach and Methods

Studies were identified through searches of PubMed, Embase, the Trip Database, the Cochrane Library, EconLit, and Web of Science. The search was limited to abstracts of studies published in English.

Timeframe

For the impact of screening on health outcomes for average-risk persons, abstracts published from 2015 (the cutoff date for the USPSTF's latest systematic review) to the present were included. For the impact of screening on health outcomes for high-risk persons, abstracts published from 2006 to the current date were included (with the intent to capture any study published in the past 10 years on the various "high-risk groups" identified in the bill). For the impact of insurance coverage on use of CRC screening by average-risk and/or high-risk persons, abstracts published from 2006 to the current date were included.

Age

For persons of average risk, literature review was limited to adults aged 50 to 75 years (as the USPSTF recommends screening for individuals in that age range). As the bill language expands coverage for high-risk individuals beyond USPSTF recommendations, the literature review included studies reporting findings for all ages for individuals at increased risk for CRC.

Of the 480 articles found in the literature review, a total of 23 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on the effect of insurance coverage or cost sharing on CRC screening; did not focus on the effectiveness of CRC screening for average-risk or high-risk individuals; were of poor quality as defined by the CHBRP protocol for evaluating the research literature; or did not report findings from clinical research studies.

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 is presented in Appendix B.

Health Outcomes Assessed in Included Studies

As per the bill language of AB 1763, coverage for CRC screening examinations and laboratory tests for average-risk adults aged 50 to 75 years is limited to tests assigned either a grade A or B by the USPSTF. Thus, CHBRP will highlight the evidence of the effectiveness of various approved screening tests to reduce the incidence and mortality of disease, as well as associated adverse effects reported by the USPSTF.

Average-Risk Individuals

CHBRP's analysis of the evidence for expansion of coverage for CRC screening for average-risk individuals relies substantially on the screening recommendations of the USPSTF (Lin et al., 2015). The USPSTF has developed recommendations for average-risk individuals based on a revised systematic review addressing the effectiveness of screening programs in reducing incidence of and mortality from CRC, the test performance characteristics of the different screening tests for detecting CRC, and the potential harms of the different screening tests. The USPSTF is currently updating recommendations on CRC screening¹⁹.

The primary harms of CRC screening are due to the use of invasive procedures (colonoscopy or flexible sigmoidoscopy) initially or in the evaluation sequence. Harms may also arise from the preparation the patient undergoes to have the procedure, the sedation used during the procedure, and the procedure itself. Potential harms associated with invasive CRC screening procedures include perforation, major bleeding, diverticulitis, severe abdominal pain, and cardiovascular events. Few harms are associated with non-invasive screening tests directly, though potential harms arise from additional diagnostic testing and procedures resulting from false-positive tests or for lesions found incidentally, which may have no clinical significance. Additional testing also has the potential to burden the patient and adversely impact the health system. CT colonography also presents a small risk of radiation exposure.

Recommended Screening Tests and Their Impact on Incidence and Mortality

For average-risk individuals aged 50 to 75 years, the USPSTF concludes that there is high certainty that the net benefit for screening by the following three modalities designated grade A is substantial: (1) fecal occult blood testing, (2) flexible sigmoidoscopy, and (3) colonoscopy. For all screening modalities, USPSTF notes that starting screening at age 50 resulted in a balance between life-years gained and colonoscopy risks that was more favorable than commencing screening earlier. Despite the increasing incidence of colorectal adenomas with age, for individuals previously screened, the gain in life-years associated with extending screening from age 75 years to 85 years is small in comparison to the risks of screening people in this decade. For adults age 76 to 85 years, there is moderate certainty that the net benefits of screening are small, as the lead time between the detection and treatment of colorectal neoplasia and potential mortality is substantial, and competing causes of mortality make it progressively less likely that this benefit will be realized with advancing age. There are currently no tests with a grade B assignment. In the 2016 draft USPSTF recommendation statement, an additional screening modality, the fecal immunochemical test (FIT), is included as an endorsed screening modality. The USPSTF concludes that there is insufficient evidence to assess the benefits and harms to recommend CT colonography or fecal DNA testing.

Stool-based tests

FOBT and FIT are stool-based tests to detect blood in the stool, which can be an early sign of cancer. A positive result must be followed by colonoscopy for the screening tests to be effective. As detailed in the USPSTF recommendation statement, multiple RCTs have shown that FOBT screening reduces colorectal

¹⁹ In its October 5, 2015, draft recommendation regarding CRC screening, the USPSTF assigned an "A" grade to CRC screening starting at age 50 and continuing until age 75. In addition to the option of screening colonoscopy every 10 years, the USPSTF recommended 3 screening options: (1) annual FIT alone, (2) annual FIT in combination with flexible sigmoidoscopy every ten years, and (3) annual high-sensitivity fecal occult blood test (hsFOBT) (Berger et al., 2016, Lin et al., 2015).

cancer deaths in adults aged 50 to 75 years. Because of the harms of colonoscopy described later in the *Medical Effectiveness* section, the chief benefit of less invasive screening tests is that they may reduce the number of colonoscopies required and their attendant risks; additionally, more people may be willing participate in screening because of the less invasive nature of stool-based tests.

Endoscopic tests

Flexible sigmoidoscopy and colonoscopy are endoscopic tests. A flexible sigmoidoscopy enables the examination of the lower part of the colon and rectum. Multiple meta-analyses of RCTs and RCTs demonstrate screening by flexible sigmoidoscopy is effective at reducing colorectal cancer incidence and deaths (Atkin et al., 2010; Brenner et al., 2014; Elmunzer et al., 2012; Holme et al., 2013; Holme et al., 2014; Segnan et al., 2011). Colonoscopy differs from a sigmoidoscopy in that it allows for the visual inspection of the entire colon, with tissue biopsies of abnormal appearing areas and polyp removal throughout the colorectum in a single session. Evidence from meta-analyses of observational studies suggests a substantial added value of screening colonoscopy for average-risk individuals, especially in the prevention of deaths (Brenner et al., 2014). Despite a lack of evidence from RCTs evaluating the impact of screening colonoscopy on colorectal cancer morbidity (or prevalence) and mortality, the aforementioned features suggest that colonoscopy is an ideal test for both early detection and prevention (Brenner et al., 2014; Garborg et al., 2013).

Screening for colorectal cancer reduces mortality through detection and treatment of early-stage cancer and detection and removal of adenomatous polyps (polyps that may develop into cancer over time). Consequently, it is likely that the largest reduction in colorectal cancer mortality during the 10 years after initial screening comes from the detection and removal of early-stage cancer. USPSTF notes colonoscopy is a necessary step in any screening program that reduces mortality from colorectal cancer. This reduction in mortality does come at the expense of an increased morbidity associated with identifying new cases of disease, and the USPSTF notes that evidence to date does not allow a differential estimate of colonoscopy-related morbidity for different age groups or for examinations done with or without biopsy.

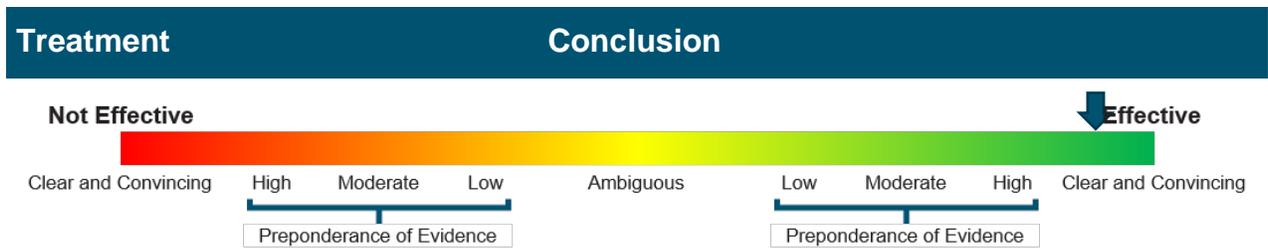
Testing frequency

Modeling evidence suggests that population screening programs between the ages of 50 and 75 years using any of the three USPSTF-endorsed modalities will be approximately equally effective in life-years gained, assuming 100% adherence to the recommended frequency and regimen as follows: (1) annual high-sensitivity fecal occult blood testing, (2) sigmoidoscopy every 5 years combined with high-sensitivity fecal occult blood testing every 3 years, and (3) screening colonoscopy at intervals of 10 years. It is important to note that testing frequencies are standard when prior screening is negative; a prior positive screen may indicate more frequent testing.

There is clear and convincing evidence that these screening modalities are effective for average-risk individuals aged 50 to 75.

Figure 2. Screening for Persons at Average Risk Aged 50-75 for Colorectal Cancer Summary

Treatment	Conclusion
Evidence about CRC screening for persons of average risk and over the age of 50	Clear and convincing evidence that screening is effective



CHBRP concludes that there is clear and convincing evidence for the average-risk population that adherence to the USPSTF recommended screening modalities and intervals are medically effective to reduce incidence and mortality of colorectal cancer.

High-Risk Individuals

The bill defines high-risk individuals as those with any of the following: (a) Family medical history of colorectal cancer; (b) prior occurrence of cancer or precursor neoplastic polyps; (c) prior occurrence of a chronic digestive disease condition, including but not limited to inflammatory bowel disease (IBD), Crohn’s disease, or ulcerative colitis; or (d) other predisposing factors. The USPSTF guidelines for CRC screening are limited to average-risk individuals. For high-risk populations, various clinical practice guidelines, such as those developed by the American College of Gastroenterology or the National Comprehensive Cancer Network, must be utilized depending on the type of risk under consideration. In general, screening guidelines for persons with an elevated risk for colorectal cancer follow a more aggressive screening strategy. Screening by endoscopic tests is the primary recommendation across high-risk categories, and there are no randomized, controlled clinical trials evaluating the efficacy of one screening tool in favor of another tool for these populations.

Family History of Colorectal Cancer

First-degree relatives with CRC diagnosis

A category for high-risk colorectal cancer for which screening recommendations differ from the recommendations for average-risk individuals include patients with a first-degree relative with a diagnosis of CRC before the age of 60, or two or more first-degree relatives with a colorectal cancer diagnosis at any age (Levin et al., 2008; Ramsey et al., 2016)

Recommended testing and frequency. As there are no RCTs of screening in people with a family history of colorectal cancer, screening recommendations are based upon extrapolation from evidence of effectiveness in average-risk individuals, and modified by knowledge of how the biology of disease differs when family history is present (Ramsey et al., 2016).

In contrast to individuals at average risk, a colonoscopy is the singular recommended screening test. Colonoscopy screening is generally recommended to begin at age 40, or 10 years younger than the age at diagnosis of the youngest affected relative in people with a family history of early onset cancer, since their risk at age 40 is generally comparable to an average-risk individual’s risk at age 50. In individuals with a family history, repeat colonoscopy is recommended every 5 years. (Ramsey, 2016). Evidence from a large, 22-year longitudinal observational study found that screening colonoscopy resulted in a decreased risk of colorectal cancer over 10 years for average-risk patients, but for patients with a first-degree relative with colorectal cancer, risk returned to baseline at five years (Nishihara et al., 2013). The

cohort under study with positive family history supports screening patients with higher than average risk every five years (Nishihara et al., 2013).

The diagnostic accuracy of FIT screening method to detect cancer, currently a screening test under consideration by the USPSTF (Lin et al., 2015), has been studied in one RCT and one prospective observational study for persons with a positive family history. The RCT evaluated the equivalency of repeated FITs and colonoscopy in detecting CRC in FDRs of patients with CRCs. Asymptomatic FDRs were randomly assigned to screening either by 3 FITs (1 per year for three years) or one colonoscopy (Quintero et al., 2014). Repeated FIT screening detected all CRCs and proved equivalent to colonoscopy in detecting CRC in FDRs of patients with CRC. Another cohort study also determined that FIT accuracy for cancer detection is equivalent in average and familial-risk CRC screening cohorts (Cubiella et al., 2014).

Other tests outside of USPSTF recommendation. CHBRP found no recent studies examining of the effectiveness of other screening tests outside of USPSTF recommended tests.

Hereditary Syndromes

Hereditary familial genetic syndromes that are associated with an elevated risk and early development of CRC most commonly include Lynch syndrome, familial adenomatous polyposis (FAP), attenuated familial adenomatous polyposis (AFAP), and MUTYH-associated polyposis (MAP) (Syngal et al., 2015). Other less frequent hereditary syndromes with increased risk for CRC include Peutz-Jeghers syndrome, juvenile polyposis syndrome, Cowden syndrome, and serrated (hyperplastic) polyposis syndrome (Ramsey et al., 2016). While such hereditary syndromes confer an extremely high risk of CRC, they are rare and account for a minority of all CRC cases (Henrikson et al., 2015).

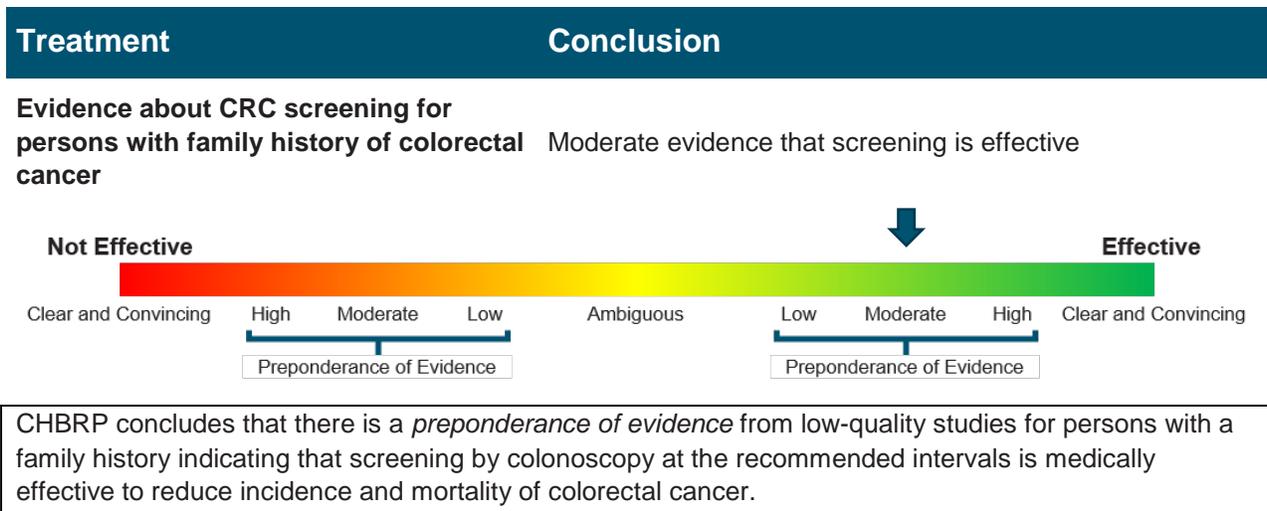
Recommended testing and frequency. Guidelines for cancer screening in patients diagnosed with Lynch syndrome have been proposed by several groups and are based on expert opinion and limited observational data suggesting that CRC screening decreases mortality in individuals with Lynch syndrome (Bonis et al., 2016). A screening colonoscopy every one to two years beginning at age 20 to 25 years, or two to five years prior to the earliest age of CRC diagnosis in the family (whichever comes first) is recommended by the U.S. Multi-Society Task Force on Colorectal Cancer (Lieberman et al., 2012) and the American College of Gastroenterology (Syngal et al., 2015). It is important to note that optimal interval for colonoscopic surveillance in individuals with Lynch syndrome mutations has not been established in randomized trials; however, data from observational studies suggest that annual surveillance is appropriate, given the time interval between normal colonoscopy and subsequent detection of CRC (Bonis et al., 2015). For FAP, AFAP, and MAP, gastroenterology guidelines recommend screening by annual colonoscopy or flexible sigmoidoscopy beginning at puberty (Syngal et al., 2015). Rationale for screening tests and intervals for these populations are based on a moderate quality of evidence of prospective observational studies.

There is a *preponderance of evidence* from low-quality studies that endoscopic screening is effective for persons with a family history of colorectal cancer.

Figure 3. Screening of Persons with Family History of Colorectal Cancer Summary

Treatment

Conclusion



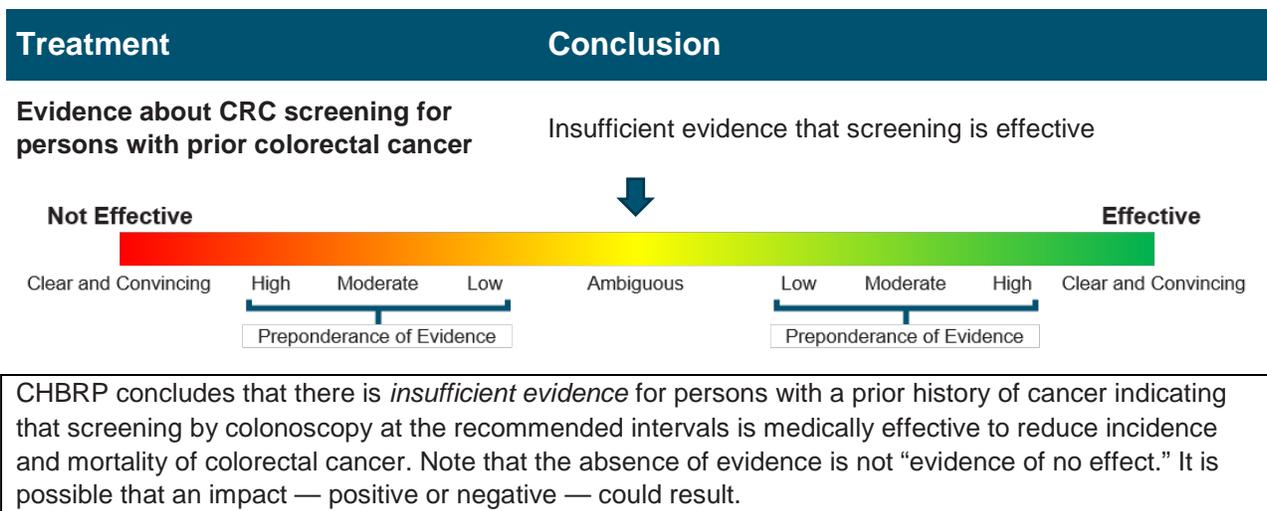
Prior occurrence of cancer

Recommended testing and frequency

For persons with prior occurrence of CRC that has been removed by surgery with a normal colonoscopy after one year, the American Cancer Society (ACS) and the U.S. Multi-Society Task Force on Colorectal Cancer guidelines recommend a repeat colonoscopic screening in three years, and every five years thereafter, provided cancer was not detected at the three-year mark (Levin et al., 2008). Time between tests may be shorter if polyps are found or there’s reason to suspect Lynch syndrome. The ACS and U.S. Multi-Society Task Force recommendations are not based on recent review of literature on screening for this population, but rather on expert consensus and rationale that incidence of colorectal cancer is increased after the first occurrence (Levin et al., 2008).

There is *insufficient evidence* that endoscopic screening is effective for persons with a prior occurrence of colorectal cancer.

Figure 4. Screening of Persons with Prior Colorectal Cancer Summary



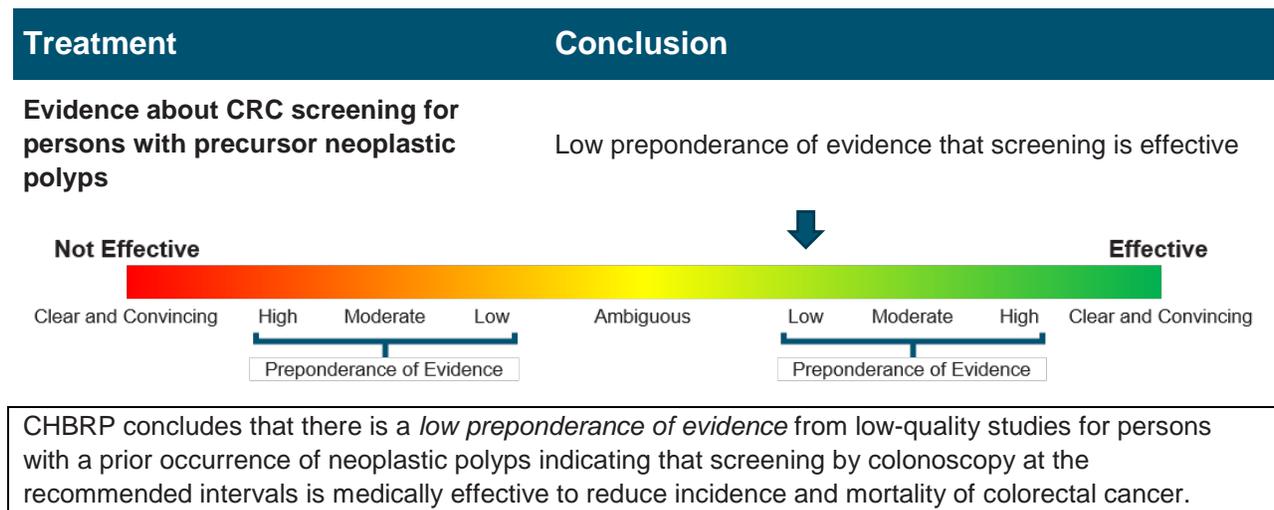
Prior occurrence of precursor neoplastic polyps

Recommended testing and frequency

For individuals with a baseline colonoscopy that has detected precursor neoplastic polyps, the U.S. Multi-Society Task Force on Colorectal Cancer recommends colonoscopy surveillance at varying intervals depending on the size and number of polyps (Lieberman et al., 2012). The basis of this recommendation is grounded in retrospective or prospective observational, cohort, population-based, or case-control studies, as there are no high-quality randomized controlled trials of polyp surveillance (Lieberman et al., 2012).

There is a *low preponderance of evidence* from low-quality studies that endoscopic screening is effective for persons with neoplastic polyps.

Figure 5. Screening for Persons with Precursor Neoplastic Polyps Summary



Prior occurrence of IBD: Crohn’s disease or ulcerative colitis

Inflammatory bowel disease (IBD) is comprised of the two disorders Crohn’s disease (CD) and ulcerative colitis (UC).

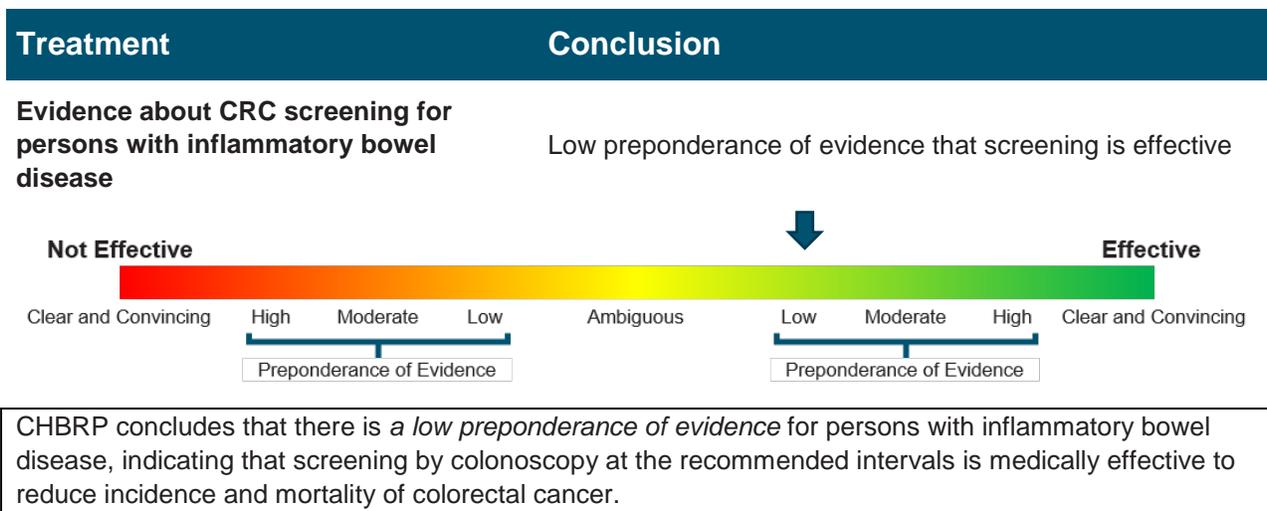
Recommended testing and frequency

Screening and surveillance recommendations are similar for persons with UC who have at least left-sided colitis and for patients with Crohn’s colitis involving more than one segment or at least one third of the colon, and in regard to recommended screening modality there is consensus for endoscopic surveillance (Itzkowitz and Present, 2005; Sengupta et al., 2016). In a recent retrospective cohort study, having a recent colonoscopy was found to be associated with a reduced incidence of CRC in patients with IBD, as well as lower mortality rates in those patients diagnosed with CRC (Ananthakrishnan et al., 2015; Sengupta et al., 2016).

In regard to timing of initial screening colonoscopy and timing of surveillance intervals, recommendations of societies vary. Most guidelines recommend performing an initial screening with colonoscopy with staging biopsies eight to ten years after onset of symptoms to rule out colonic neoplasia (dysplasia or cancer), evaluate the extent of disease, and determine the need for ongoing surveillance (Itzkowitz and Present, 2005; Sengupta et al., 2016). However, some guidelines suggest initiating screening six years after symptom onset, depending on the presence of other risk factors (Sengupta et al., 2016). Several European societies recommend a risk-stratified approach to determine the timing intervals of endoscopic surveillance ranging from one to five years, while U.S. societies (including American Gastroenterological Association, American College of Gastroenterology, and American Society of Gastrointestinal Endoscopy) do not explicitly recommend surveillance intervals greater than three years (Sengupta et al., 2016). However, from the basis of expert consensus, the 2014 American Society of Gastrointestinal Endoscopy guidelines suggest the potential to lengthen intervals for people with UC and CD who have normal results on at least two sequential surveillance colonoscopies until UC or IBD has been present for 20 years (Shergill et al., 2015). At that time, consideration should be given to performing surveillance every one to two years, on the basis that CRC risk increases with longer duration of colitis (Itzkowitz and Present, 2005).

There is a *low preponderance of evidence* that endoscopic screening is effective for persons with inflammatory bowel disease.

Figure 6. Screening for Persons with Irritable Bowel Disease Summary



Other predisposing factors

Acromegaly

Persons with a diagnosis of acromegaly — a hormonal disorder that results from too much growth hormone and resulting in over-growth of bone and cartilage (NIDDK, 2012) — are at increased risk of CRC. Given the rarity of acromegaly, there are currently no published guidelines for colonoscopic screening or surveillance, but one expert²⁰ has suggested starting screening colonoscopy at age 40 years (Konda and Duffy, 2008). Moreover, colonoscopy may be more difficult in patients who have acromegaly because of inadequate bowel preparation resulting from slowed colonic transit and difficulty reaching the cecum because of an elongated, tortuous colon (Konda and Duffy, 2008).

²⁰ This came from a study that performed CRC screening at five different hospitals in Italy.

Abdominal radiation

Adult survivors of childhood malignancy who received abdominal radiation treatment are at increased risk of CRC, with evidence of its occurrence in ages younger than 50. Guidelines from the Children's Oncology Group recommend colonoscopy every five years for survivors of childhood cancer who received 30 Gy or more of abdominal radiation, with screening beginning at age 35 years or 10 years after radiation, whichever is later (Nathan, 2010).²¹ CHBRP found no other screening guidelines for other persons who have undergone abdominal radiation.

Diabetes

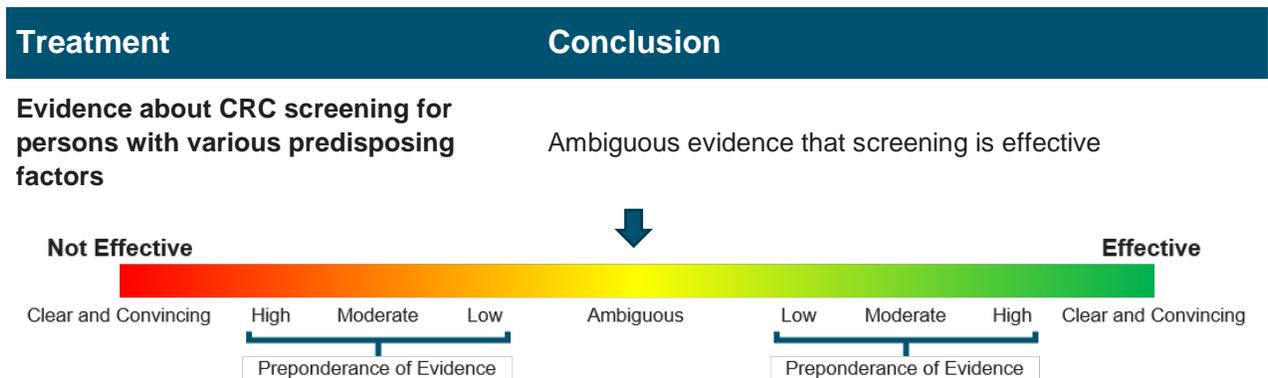
Although there is evidence of increased risk of CRC for persons with diabetes, CHBRP found no screening guidelines for modality and frequency.

Renal transplant

Renal transplantation, in association with long-term immunosuppression, has been linked with increased risk for CRC (Webster et al., 2007). Currently there is no consensus for screening approach as the matter is complicated by shortened life expectancy (Kiberd, 2013).

There is *ambiguous/conflicting evidence* that screening for colorectal cancer is effective for persons with various predisposing factors.

Figure 7. Screening for Persons with Various Predisposing Factors Summary



CHBRP concludes that, for the diseases and conditions that predispose individuals to colorectal cancer, there is *insufficient evidence* that screening is medically effective to reduce incidence and mortality of colorectal cancer. Note that the absence of evidence is not “evidence of no effect.” It is possible that an impact — positive or negative — could result.

Increased Insurance Coverage and Screening Utilization

Evidence of the impact of expanded insurance coverage on screening utilization is limited to observational studies. The impact of insurance coverage for CRC screening and utilization among high-risk populations with has not been assessed by these studies.

²¹ The evidence base for this screening modality and frequency is not noted in the guidelines.

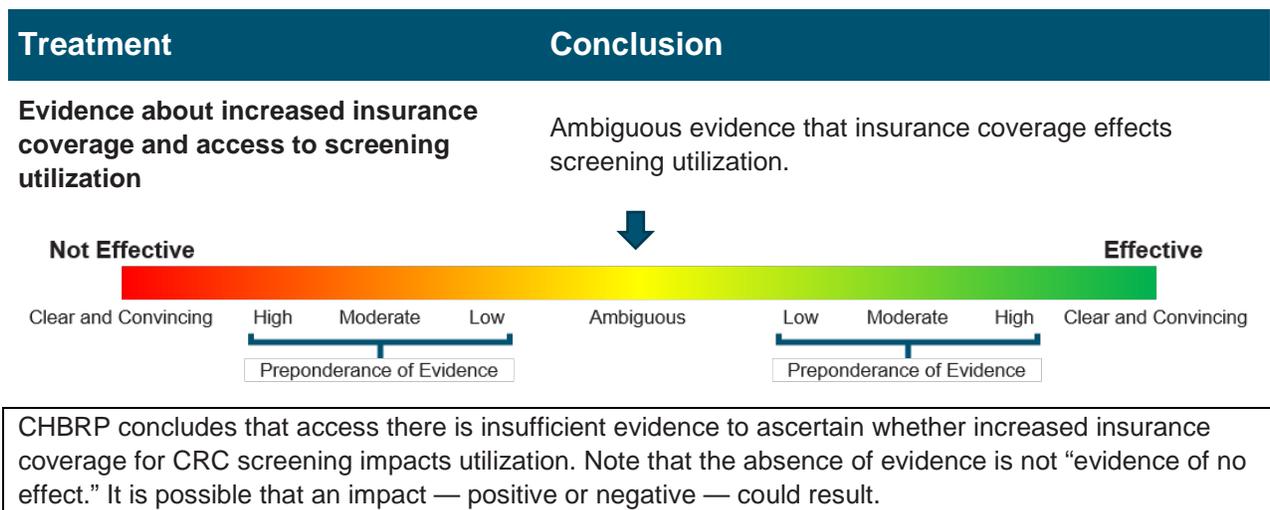
For average-risk individuals, evidence exists suggesting a small but positive impact of insurance coverage for CRC screening and utilization ((Khatami, Xuan et al. 2012) Cokkinides, 2011), and that low socioeconomic status individuals may benefit from the elimination of barriers to screening utilization (Fedewa, 2015a).

An observational study comparing rates of compliance with the USPSTF screening recommendations in individuals with private insurance plans living in states with state-mandated insurance coverage of CRC screening procedures found no statistically significant increase utilization among any of the specified populations, except in endoscopic screening utilization rates among lower income individuals (Hamman, 2015).

As discussed elsewhere in this report, there are nonfinancial barriers to screening that may impact utilization.

There is *insufficient evidence* to assess whether increased insurance coverage impacts screening utilization.

Figure 8. Increased Insurance Coverage and Screening Utilization Summary



BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 1763 would require nongrandfathered DMHC-regulated health plans and CDI-regulated policies to provide coverage for CRC screening exams and lab tests that are assigned a grade of A or B by the USPSTF; as well as coverage for additional screening and tests recommended by a physician if the individual is high risk. The bill also requires that for an enrollee aged 50 and older, the plan shall not impose cost sharing on the required coverage of colonoscopies, including the removal of polyps during a screening process, or if the enrollee has a positive result on any fecal test assigned either a grade of A or B by the USPSTF. However, AB 1763 would exempt high-deductible plans from waiving cost sharing on colonoscopies for enrollees aged 50 and older.

This section reports the potential incremental impact of AB 1763 on estimated baseline benefit coverage, utilization, and overall cost. For further details on the underlying data sources and methods, please see Appendix C.

Benefit Coverage

Premandate (Baseline) Benefit Coverage

Currently, CHBRP estimates 100% of the 13.8 million enrollees subject to AB 1763 have coverage for CRC screening exams and lab tests that are assigned a grade of A or B by the USPSTF, and have coverage for additional screening and tests recommended by a physician if the person is high risk. Using MarketScan data, CHBRP estimates that 21% of enrollees aged 50 and older have cost sharing for CRC screenings and lab tests including colonoscopies with the removal of polyps, or after the enrollee has a positive result on any fecal test. Since AB 1763 would exempt high-deductible plans from waiving cost sharing on colonoscopies for enrollees aged 50 and older, CHBRP excludes 5.5% enrollees in high-deductible plans in the estimates. Also, since the bill language is silent on the cost sharing for CRC screening procedures performed for high-risk enrollees younger than 50 or for diagnostic purpose, CHBRP assumes that the cost sharing of these procedures will remain after the enactment of AB 1763.

Current coverage of the proposed mandate was determined by a survey of the seven largest providers of health insurance in California. Responses to this survey represent:

- 77% of enrollees in the privately funded market subject to state mandates, including.
 - 81% of enrollees in the privately funded, DMHC-regulated market; and
 - 51% of enrollees in the CDI-regulated market.

Postmandate Benefit Coverage

If AB 1763 were enacted, CHBRP estimates the percent of enrollees with coverage for CRC screening exams and lab tests assigned a grade of A or B by the USPSTF and additional screening and tests recommended by a physician will remain to be 100%. However, AB 1763 will eliminate cost sharing on CRC screenings and lab tests for enrollees aged 50 and older, including colonoscopies with the removal of polyps, or after the enrollee has a positive result on any fecal test. As AB 1763 does not apply to high-deductible plans, CHBRP estimates 4% of their enrollees aged 50 and older will be exempted from waving cost sharing. Accordingly, CHBRP estimates that the percent of enrollees aged 50 and older with coverage for CRC screening services listed in AB 1763 without cost sharing would increase from 75% to 96%.

Utilization

Premandate (Baseline) Utilization

CHBRP estimates that there are 660,600 users of CRC screenings and lab tests among the enrollees subject to AB 1763 (including both high-risk and average-risk individuals), of which approximately 75% are aged 50 and older. These users undergo approximately 718,897 CRC screening procedures annually, the majority of which are colonoscopies or FOBT/FIT tests.

Postmandate Utilization

CHBRP assumes that the overall utilization of CRC screening and lab tests is going to increase by 0.3% (1,764 users), which is mainly due to the increase in use among enrollees aged 50 and older after the removal of cost-sharing requirements for CRC screening and lab tests. Details of CHBRP's calculation are included in Appendix C. The estimates are based on the findings of a previous study showing that the elimination of copayment results in a modest increase (1.5%) in use of CRC screening (Khatami, Xuan et al. 2012) CHBRP applied this 1.5% increase to the users with cost sharing aged 50 and older and averaged it among all the users of CRC screening users (1,764/660,600 (premandate users)=0.3 %). The impact is also dampened due to the exemption of high-deductible plans from the waiver of cost-sharing requirements. This is an upper-bound estimate, as some studies show persons may be less price sensitive to CRC screenings and lab tests (Fedewa, 2015).

Impact on access and health treatment/service availability

CHBRP assumes that the mandate will increase access to CRC screening exams and lab tests, especially for those enrollees aged 50 and older currently having required coverage with cost sharing. The improved access will be beneficial to those enrollees who were discouraged from seeking CRC screening services due to the cost-sharing requirements. Though there are no existing data to verify the sufficiency of CRC screening providers in California, CHBRP does not anticipate any impacts on the service availability after the mandate because the number of persons with increased use of CRC screening annually is limited (1,764 persons) and because facilities that provides CRC screening exist, CHBRP expects that persons with new benefit coverage would find a facility providing CRC screening.

Per-Unit Cost

Premandate (Baseline) and Postmandate Per-Unit Cost

CHBRP estimates premandate (baseline) per-unit cost based on the analysis of 2014 California MarketScan claim data. The per-unit cost estimates (\$761 per procedure) are based on the average of most commonly used procedures for CRC screenings and lab tests (i.e., FOBT, FIT, sigmoidoscopy, or colonoscopy). These costs include those for pathology tests and other related services provided on the same date of service, but exclude certain facility costs, which could not be accurately allocated between these procedures and other procedures performed on the same day. The per-unit cost was trended forward to 2018 using a 2.1% annual trend based on the 2015 consumer price index for professional medical services. CHBRP estimates that the per-unit cost for CRC screenings and lab tests will not change in the first 12 months postmandate due to the limited number of enrollees whose utilization will increase. CHBRP's estimates for the per-unit cost and cost share per procedure are also summarized in Table 7 in Appendix C.

Premiums and Expenditures

Premandate (Baseline) Premiums and Expenditures

Table 4 presents per member per month (PMPM) premandate estimates for premiums and expenditures by market segment for DMHC-regulated plans and CDI-regulated policies.

PMPM by market segment is as follows for DMHC-regulated plans and CDI-regulated policies, respectively:

- Large group: \$590.46 and \$706.38.
- Small group: \$501.91 and \$624.17.
- Individual market: \$445.13 and \$383.47.

Total current annual expenditures for all DMHC-regulated plans and CDI-regulated policies is \$153.14 billion.

Postmandate Expenditures

Changes in total expenditures

AB 1763 would increase total net annual expenditures by \$5.63 million or 0.004% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a 25.92 million increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, partially offset by a decrease in enrollee expenditures for previously noncovered benefits (\$20.29 million).

Postmandate premium expenditures and PMPM amounts per category of payer

Increases in insurance premiums as a result of AB 1763 would vary by market segment. Note that the total population in Table Y reflects the full 13.8 million enrollees in DMHC-regulated plans and CDI-regulated policies subject to AB 1763.

The increase in expenditures is primarily related to the assumed 1.5% increase in utilization of CRC screening and lab services among the enrollees aged 50 and older (1,764 enrollees) after the removal of premandate cost sharing. The impact is dampened due to the assumed exemption of high-deductible plans from the waiver of cost-sharing requirements. The increase in total annual health insurance premiums paid by employers and enrollees is due to the assumed utilization increase and the shift of cost-sharing amounts previously paid by enrollees into premiums.

Among publicly funded DMHC-regulated health plans, there is no expected impact since AB 1763 does not apply to Medi-Cal Managed Care and CalPERS HMOs.

Potential cost offsets or savings in the first 12 months after enactment

CHBRP estimates that there will be no cost offsets or savings in the first 12 months after enactment. However, some model-based studies have found that CRC screening can become cost-saving in the long run, mainly because of the rising cost of cancer care at the end of life (Lansdorp-Vogelaar, 2009).

Postmandate administrative expenses and other expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. CHBRP assumes that if health care costs 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 portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Related Considerations for Policymakers

Cost of exceeding essential health benefits

As explained in the *Policy Context* section, coverage for CRC screening and lab tests would not be expected to exceed the Affordable Care Act's essential health benefits (EHBs).

Postmandate Changes in Uninsured and Public Program Enrollment

Changes in the number of uninsured persons²²

CHBRP estimates premium increases of less than 1% for each market segment; this premium increase would not have a measurable impact on the number of persons who are uninsured. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer contribution rates, changes in take-up of health insurance by employees, or purchase of individual market policies, due to the small size of the increase in premiums after the mandate.

Changes in public program enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs or on utilization of covered benefits in the publicly funded insurance market.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

AB 1763 would not result in a shift in payment or service delivery to public payers. CHBRP assumes that enrollees who do not have full benefit coverage pay for CRC screenings directly (e.g., self-pay).

²² See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php

Table 4. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2016

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) ^(a)			Publicly Funded Plans			Privately Funded Plans (by Market) ^(a)			
	Large Group	Small Group	Individual	CalPERS HMOs ^(b)	MCMC (Under 65) ^(c)	MCMC (65+) ^(c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates ^(d)	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000
Total enrollees in plans/policies subject to AB 1763	6,776,000	2,365,000	3,516,000	0	0	0	282,000	722,000	142,000	13,803,000
Premium Costs										
Average portion of premium paid by employer	\$473.92	\$330.32	\$0.00	\$490.23	\$180.00	\$445.00	\$558.51	\$454.55	\$0.00	\$90,881,344,000
Average portion of premium paid by employee	\$116.53	\$171.59	\$445.13	\$122.56	\$0.00	\$0.00	\$147.87	\$169.63	\$383.47	\$45,032,736,000
Total premium	\$590.46	\$501.91	\$445.13	\$612.79	\$180.00	\$445.00	\$706.38	\$624.17	\$383.47	\$135,914,080,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$47.39	\$99.76	\$117.97	\$33.47	\$0.00	\$0.00	\$119.11	\$188.90	\$114.42	\$17,229,732,000
Enrollee expenses for benefits not covered ^(e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$637.84	\$601.68	\$563.10	\$646.26	\$180.00	\$445.00	\$825.49	\$813.07	\$497.89	\$153,143,811,000

Source: California Health Benefits Review Program, 2016.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the health insurance marketplace.

(b) As of September 30, 2015, 57%, or 462,580 CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2017.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care.

Table 5. Postmandate Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2018

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) ^(a)			Publicly Funded Plans			Privately Funded Plans (by Market) ^(a)			
	Large Group	Small Group	Individual	CalPERS HMOs ^(b)	MCMC (Under 65) ^(c)	MCMC (65+) ^(c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates ^(d)	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000
Total enrollees in plans/policies subject to AB 1763	6,776,000	2,365,000	3,516,000	0	0	0	282,000	722,000	142,000	13,803,000
Premium Costs										
Average portion of premium paid by employer	\$0.0810	\$0.0852	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0305	\$0.0506	\$0.0000	\$12,305,000
Average portion of premium paid by employee	\$0.0199	\$0.0443	\$0.2112	\$0.0000	\$0.0000	\$0.0000	\$0.0081	\$0.0189	\$0.0028	\$13,619,000
Total premium	\$0.1009	\$0.1295	\$0.2112	\$0.0000	\$0.0000	\$0.0000	\$0.0386	\$0.0694	\$0.0028	\$25,924,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	-\$0.0831	-\$0.0979	-\$0.1600	\$0.0000	\$0.0000	\$0.0000	-\$0.0253	-\$0.0474	\$0.0000	-\$20,294,000
Enrollee expenses for benefits not covered ^(e)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total expenditures	\$0.0177	\$0.0316	\$0.0512	\$0.0000	\$0.0000	\$0.0000	\$0.0133	\$0.0221	\$0.0028	\$5,629,000
Postmandate Percent Change										
Insured premiums	0.0171%	0.0258%	0.0474%	0.0000%	0.0000%	0.0000%	0.0055%	0.0111%	0.0007%	0.0191%
Total expenditures	0.0028%	0.0053%	0.0091%	0.0000%	0.0000%	0.0000%	0.0016%	0.0027%	0.0006%	0.0037%

Source: California Health Benefits Review Program, 2016.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, inside and outside the exchange.

(b) As of September 30, 2013, 57.5%, or 462,580 CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2018.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, AB 1763 would require insurers to cover, without cost-sharing, all USPSTF-recommended ('A' or 'B' grade) CRC screening procedures. This benefit includes services that are recognized by the USPSTF and ACS/MSTF²³ joint guidelines as part of the stepwise "continuum of screening" (i.e., colonoscopy following a positive fecal test) (Pollitz et al., 2012). Specifically, for *average-risk enrollees aged 50 years and older*, AB 1763 would eliminate cost sharing for any additional screening procedures as recommended by a physician including follow-up colonoscopies to confirm positive fecal or sigmoidoscopy tests, and polyp removal during a screening colonoscopy. Although AB 1763 mandates coverage for any additional screening and laboratory tests required for persons of any age at high risk for developing colorectal cancer, *high-risk enrollees under the age of 50* would still be subject to cost sharing for screening procedures received beyond USPSTF recommendations for average-risk individuals. As discussed in the *Background on Colorectal Cancer Screening* section, individuals are considered to be at high-risk if they have any of the following: (a) a family medical history of CRC, (b) a prior occurrence of cancer or adenomatous polyps, (c) a history of chronic digestive conditions, and (d) other predisposing conditions.

Estimated Public Health Outcomes

Measurable health outcomes relevant to AB 1763 include reduced incidence of colorectal cancer and CRC-associated morbidity and mortality, improved quality of life, and reduction in financial barriers to screening.

As presented in the *Medical Effectiveness* section, there is a preponderance of evidence that screening is effective in reducing net mortality from colorectal cancers among persons at average risk for developing CRC across all USPSTF-rated screening modalities. Furthermore, the acquired benefits of reduced CRC incidence, morbidity, and mortality from CRC screening outweigh the harms for average-risk individuals aged 50 to 75. Although literature suggests that high-risk individuals benefit from screening with colonoscopy, CHBRP found ambiguous evidence from observational studies confirming the optimal screening frequency recommended by various medical societies for the risk groups identified by AB 1763.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, 100% of the 13.8 million enrollees in DMHC-regulated plans and CDI-regulated policies currently have coverage for USPSTF-recommended CRC screening. However, 22% of average-risk enrollees aged 50 years and older have experienced cost-sharing associated with screening procedures — commonly for follow-up colonoscopies and/or polyp removal during colonoscopies. Postmandate, cost sharing on these services would be eliminated for 95% of enrollees aged 50 and older, due to exemptions for high-deductible plans. All high-risk enrollees younger than 50 currently have coverage, with cost sharing, for medically necessary additional CRC screenings; however, AB 1763 would attempt to define the "continuum of screening" in order to prevent diagnostic billing on screening procedures. CHBRP estimates no change in unit cost of CRC screening procedures while out-of-pocket expenses for enrollees aged 50 and older would decrease/shift toward the carriers. As a result, 1,764 enrollees would newly utilize CRC screening, an increase of up to 0.3% primarily concentrated among enrollees aged 50 and older for whom cost sharing would be eliminated.

To the extent that the elimination of cost sharing for additional screenings among enrollees aged 50 years and older, as well as extended coverage for extra screenings for high risk under 50 years could increase

²³ 2008 Joint Guidelines issued by the American Cancer Society (ACS), United States Multisociety Task Force on Colorectal Cancer (MSTF), and American College of Radiology.

utilization of CRC screenings across all modalities by 0.3%, CHBRP estimates that polyp removal and early stage CRC diagnoses would increase, with an attending decrease in incidence of CRC and late-stage (i.e., less survivable) diagnoses. However, as discussed in the *Background on Colorectal Cancer Screening* section, high-risk enrollees — who have the greatest incidence of CRC and would be subject to the highest cost-sharing burden prior to the mandate — already demonstrate higher rates of compliance with screening recommendations relative to their average risk counterparts, and therefore may be less price-sensitive (Felsen et al., 2011).

Although studies evaluating the effect of increased coverage and cost-sharing removal for CRC screening (Cokkinides et al., 2011; Fedewa et al., 2015a; Hamman et al., 2015) observed that persons of low socioeconomic status (SES) accounted for the greatest increases in screening uptake, when surveyed low SES patients in California were more likely to be out of date with screening recommendations due to lack of physician prompting or low community awareness as compared with expense (Darsie, 2015). Accordingly, Stimpson et al. (2012) found that racial/ethnic disparities in CRC screening persisted following expanded health insurance coverage and increased access to gastroenterologists, indicating that cultural factors, such as health beliefs, may have a greater impact on screening behaviors than coverage. Finally, since all DMHC plans and CDI-regulated policies are compliant with the ACA preventive care benefit, CHBRP estimates that the magnitude of the public health impact will not be measurable at the population level.

As described in the *Medical Effectiveness* section, there is a preponderance of evidence that USPSTF-recommended CRC screening modalities are medically effective for the detection and prevention of CRC among average and high-risk patients. Furthermore, CHBRP projects that AB 1763 would increase utilization of CRC screening up to 0.3% (see *Benefit Coverage, Utilization, and Cost Impacts* section). However, CHBRP projects no measurable public health impact on the diagnosis or prevention of colorectal cancer at the population level due to the small number (1,764) of additional enrollees who would avail themselves of CRC screening. At the individual level, AB 1763 would likely yield health and quality of life improvements, such as reduced screening-related financial burden and identification of CRC at earlier, and therefore more treatable, stages.

Estimated Impact on Financial Burden

When possible, CHBRP estimates the marginal impact of mandates on financial burden, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and co-insurance). AB 1763 would decrease the financial burden for those enrollees aged 50 years and older requiring screenings in addition to USPSTF recommendations, for whom cost-sharing would be eliminated under this mandate. The *Benefit Coverage, Utilization, and Cost Impacts* section estimates a net decrease of \$3.2 million in out-of-pocket expenses postmandate. Therefore, the enrollees with uncovered expenses premandate would receive a \$3.2 million net reduction in their financial burden associated with the 1,764 additional screening procedures that would be performed as a result of this mandate. CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

CHBRP estimates that AB 1763 would modify coverage and reduce the net financial burden by \$3.2 million in the first year, postmandate, for covered enrollees aged 50 and older utilizing the 1,764 additional screenings beyond USPSTF recommendations, on the basis of high-risk status.

LONG-TERM IMPACT OF AB 1763 COLORECTAL CANCER SCREENING

In this section, CHBRP estimates the long-term impact²⁴ of AB 1763, defined as impacts occurring beyond the first 12 months of implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

In the long term, the number of Californians enrolled in DMHC-regulated plans or CDI-regulated policies subject to AB 1763 would remain constant.

Long-Term Utilization and Cost Impacts

Utilization Impacts

In the 12 months following enactment, CHBRP estimates that the overall utilization of CRC screening and lab tests is going to increase by 0.3%, which is mainly due to the increase in use among the enrollees at high risk or enrollees aged 50 years and older after the removal of cost-sharing requirements for colonoscopies CRC screening and lab tests. In later years, similar patterns of increases are expected because AB 1763 would remove cost-sharing for individuals who are due for CRC screenings.

Cost Impacts

Studies show that the various tests for CRC screening are cost effective. Their degree of cost effectiveness is more similar than differences in initial upfront costs would suggest, largely because all positive screening tests lead to colonoscopy (including repeated colonoscopies, if polyps are found). Also, negative colonoscopy results in completed screening for 10 years, whereas other tests are repeated more frequently and may or may not be completed in the next recommended interval. A model that was used as a basis for the United States Preventive Services Task Force recommendations showed that, as compared with no screening and high adherence, several strategies resulted in similar life-years gained: colonoscopy every 10 years, annual Hemoccult SENSAs or FIT testing, and sigmoidoscopy every five years with mid-interval FIT testing (Zauber, 2010, Doubeni 2016). One analysis showed that the cost per year of life saved was <\$15,000 for all recommended tests, compared with no screening (Zauber, 2010). Some models have found that CRC screening has become cost-saving, mainly because of the rising cost of cancer care at the end of life (Lansdorp-Vogelaar, 2009).

Long-Term Public Health Impacts

To the extent that AB 1763 would eliminate cost sharing for medically necessary additional CRC screenings and all events along the stepwise “continuum of screening”, including follow-up colonoscopies to positive fecal tests and polyp removal during colonoscopies, it would be reasonable to assume that this reduction in financial burden would promote greater adherence to physician-recommended screenings beyond those projected for the first 12 months following implementation of the mandate. As discussed in the *Background on Colorectal Cancer Screening* and *Medical Effectiveness* sections, adherence to screening guidelines may reduce the number of lethal and costly advanced CRC diagnoses, which

²⁴ See also CHBRP’s *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php

account for the majority (57%) of all CRC diagnoses in California. In addition, any increase in clinically significant polyp removal during colonoscopies beyond the 6.3% national rate could result in a long-term reduction in colorectal cancer incidence (Lieberman et al., 2008). Although CRC screening may increase among the 10.8% of Californians for whom expense was the primary reason for nonadherence guidelines, as discussed previously, low-income individuals are more likely to forego screening due to lack of awareness and physician prompting (Darsie, 2015). Similarly, racial/ethnic disparities in CRC screening were found to persist following the removal of financial and insurance barriers; therefore, the disparities observed in CRC screening among low-income enrollees and between racial/ethnic groups in California would likely remain in the long term.

APPENDIX A TEXT OF BILL ANALYZED

On February 8, 2016, the California Assembly Committee on Health requested that CHBRP analyze AB 1763.

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

ASSEMBLY BILL

No. 1763

Introduced by Assembly Member Gipson

February 03, 2016

An act to add Section 1367.667 to Health and Safety Code, and to add Section 10123.205 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 1763, as introduced, Gipson. Health care coverage: colorectal cancer: screening and testing. Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires individual and group health care service plan contracts and health insurance policies to provide coverage for all generally medically accepted cancer screening tests and requires those contracts and policies to also provide coverage for the treatment of breast cancer. Existing law requires an individual or small group health care service plan contract or insurance policy issued, amended, or renewed on or after January 1, 2014, to, at a minimum, include coverage for essential health benefits, which include preventive services, pursuant to the federal Patient Protection and Affordable Care Act.

This bill would require a health care service plan contract or a health insurance policy, except as specified, that is issued, amended, or renewed on or after January 1, 2018, to provide coverage for colorectal cancer screening examinations and laboratory tests, as specified. The bill would require the coverage to include additional colorectal cancer screening examinations and laboratory tests recommended by the treating physician if the individual is at high risk for colorectal cancer. The bill would prohibit a health care service plan contract or a health insurance policy from imposing cost sharing on this coverage for an individual who is 50 years of age or older. Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

DIGEST KEY

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

BILL TEXT

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1.

Section 1367.667 is added to the Health and Safety Code, to read:
1367.667.

(a) Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, or renewed on or after January 1, 2018, shall provide coverage for all colorectal cancer screening examinations and laboratory tests assigned either a grade of A or a grade of B by the United States Preventive Services Task Force for individuals at average risk. The coverage shall include, at a minimum, all of the following:

- (1) High sensitivity fecal occult blood tests (FOBT).
- (2) Flexible sigmoidoscopy with high sensitivity FOBT.
- (3) Colonoscopies, including the removal of polyps during a screening procedure.

(b) (1) If an enrollee is at high risk for colorectal cancer, the coverage required by subdivision (a) shall include additional colorectal cancer screening examinations and laboratory tests as recommended by the treating physician.

(2) For purposes of this subdivision, an individual is at high risk for colorectal cancer if the individual has any of the following:

- (A) A family medical history of colorectal cancer.
- (B) A prior occurrence of cancer or precursor neoplastic polyps.
- (C) A prior occurrence of a chronic digestive disease condition, including, but not limited to, inflammatory bowel disease, Crohn's disease, or ulcerative colitis.

(D) Other predisposing factors.

(c) For an enrollee who is 50 years of age or older, a health care service plan contract shall not impose cost sharing on either of the following:

(1) The coverage required by this section.

(2) Colonoscopies, including the removal of polyps during a screening procedure, if the enrollee has a positive result on any fecal test assigned either a grade of A or a grade of B by the United States Preventive Services Task Force.

(d) Paragraph (3) of subdivision (a) shall not apply to a high deductible health plan, as described in Section 223 of Title 26 of the United States Code.

SEC. 2.

Section 10123.205 is added to the Insurance Code, to read:
10123.205.

(a) Every health insurance policy, except a specialized health insurance policy, that is issued, amended, or renewed on or after January 1, 2018, shall provide coverage for all colorectal cancer screening examinations and laboratory tests assigned either a grade of A or a grade of B by the United States Preventive Services Task Force for individuals at average risk. The coverage shall include, at a minimum, all of the following:

(1) High sensitivity fecal occult blood tests (FOBT).

(2) Flexible sigmoidoscopy with high sensitivity FOBT.

(3) Colonoscopies, including the removal of polyps during a screening procedure.

(b) (1) If an insured is at high risk for colorectal cancer, the coverage required by subdivision (a) shall include additional colorectal cancer screening examinations and laboratory tests as recommended by the treating physician.

(2) For purposes of this subdivision, an individual is at high risk for colorectal cancer if the individual has any of the following:

(A) A family medical history of colorectal cancer.

(B) A prior occurrence of cancer or precursor neoplastic polyps.

(C) A prior occurrence of a chronic digestive disease condition, including, but not limited to, inflammatory bowel disease, Crohn's disease, or ulcerative colitis.

(D) Other predisposing factors.

(c) For an insured who is 50 years of age or older, a health insurance policy shall not impose cost sharing on either of the following:

(1) The coverage required by this section.

(2) Colonoscopies, including the removal of polyps during a screening procedure, if the insured has a positive result on any fecal test assigned either a grade of A or a grade of B by the United States Preventive Services Task Force.

(d) Paragraph (3) of subdivision (a) shall not apply to a high deductible health plan, as described in Section 223 of Title 26 of the United States Code.

SEC. 3.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

Appendix B describes methods used in the medical effectiveness literature review for AB 1763, a bill that would require insurance coverage for CRC screenings and tests graded as an A or B by the USPSTF, coverage for additional tests for high-risk individuals, and coverage without cost-sharing for enrollees aged 50 and over. AB 1763 would not increase the number of Californians who have health insurance coverage for CRC screening in general.

The medical effectiveness review focuses on the impact of insurance coverage for USPSTF-recommended CRC screening modalities for average risk individuals, and for coverage for additional procedures and labs, as recommended by a physician, for individuals determined to be at high risk for developing CRC, and for the elimination of cost sharing for enrollees aged 50 and older. CHBRP chose this focus in line with specific bill language.

Studies of CRC were identified through searches of MEDLINE (PubMed), PubMed, Embase, the Trip Database, the Cochrane Library, EconLit, and Web of Science. For the impact of screening on health outcomes for average-risk individuals, abstracts published from 2015 to the present were included. For the impact of screening on health outcomes for high-risk individuals, abstracts published from 2006 to the current date were included. For the impact of insurance coverage on use of CRC screening by average risk and/or high-risk individuals, abstracts published from 2006 to the current date were included. For average-risk individuals, the review was limited to adults aged 50 to 75 years. As the bill language expands coverage for high-risk individuals beyond USPSTF recommendations, the literature review included studies reporting findings for all ages for individuals at increased risk for CRC. Of the 480 articles reviewed for potential inclusion in this report on AB 1763, 23 studies were included in the medical effectiveness review for this report.

Evidence Grading System

In making a “call” for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP’s *Medical Effectiveness Analysis Research Approach*.²⁵ To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention’s effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- Clear and convincing evidence;

²⁵ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

- Preponderance of evidence;
- Ambiguous/conflicting evidence; and
- Insufficient evidence.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective. This can be further subdivided into preponderance of evidence from high-quality studies and preponderance of evidence from low-quality studies.

A grade of *ambiguous/conflicting evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Search Terms

The search terms used to locate studies relevant to AB 1763 were as follows:

Major MeSH terms used to search PubMed

- Acromegaly
- Adenomatous Polyposis Coli
- African Americans
- Age Distribution
- Age Factors
- Alcohol Drinking/adverse effects/epidemiology
- Colonography, Computed Tomographi
- Colonic Polyps
- Colonoscopy/utilization
- Colorectal Neoplasms/diagnosis/economics/mortality/prevention and control
- Colorectal Neoplasms, Hereditary Nonpolyposis
- Cost-Benefit Analysis
- Cost Sharing
- Crohn's disease
- Diet
- Dietary Fiber/deficiency
- Diabetes Mellitus
- Early Detection of Cancer
- Immunochemistry
- Healthcare Disparities/ethnology
- Genetic Predisposition to Disease
- Incidence
- Income
- Inflammatory Bowel Diseases
- Insurance Coverage
- Life Style
- Lynch Syndrome II
- Mass Screening
- Mortality
- Occult Blood
- Organ Transplantation

- Overweight/epidemiology
- Outcome Assessment (Health Care)
- Prevalence
- Risk Factors
- Sex Factor
- Sigmoidoscopy/utilization
- Smoking/adverse effects
- Social Class
- Socioeconomics Factors
- Ulcerative colitis

Keywords used to search PubMed, Business Source Complete, Cochrane Library, TRIP database, and Web of Science

- Acromegaly
- “Abdominal radiation”
- “African Americans”
- “Alcohol consumption”
- “Alcohol drinking”
- “Age factors”
- Barriers
- Blacks
- “Colorectal cancer screening”
- “Cost effective”
- “CRC screening”
- “Crohn’s disease”
- “CT colonography”
- Diet
- “Dietary fiber”
- Diabetes
- Disparities
- Ethnic
- “Fecal Immunochemical test”
- “Familial colorectal cancer”
- “Familial adenomatous polyposis “
- FOBT
- Frequency
- “Health beliefs”
- “Heavy weight”
- “Hereditary nonpolyposis colorectal cancer”
- “High risk”
- Hispanics
- Incidence
- Income
- “Inflammatory bowel diseases”
- “Insurance mandate”
- Interval
- “Family history”
- “Hispanic Americans”
- Lifestyle
- “Lower education”

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

This appendix describes data sources, estimation methodology, as well as general and mandate-specific 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 website at: www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as contracted actuarial firms, Milliman, Inc, and Pricewaterhouse Coopers (PwC).²⁶

Data Sources

This subsection discusses the variety of data sources CHBRP uses. Key sources and data items are listed below, in Table 6.

Table 6. Data for 2017 Projections

Data Source	Items
California Department of Health Care Services (DHCS) administrative data for the Medi-Cal program, data available as of end of December 2014	Distribution of enrollees by managed care or FFS distribution by age: 0–17; 18–64; 65+ Medi-Cal Managed Care premiums
California Department of Managed Health Care (DMHC) data from the interactive website “Health Plan Financial Summary Report,” August–October, 2015	Distribution of DMHC-regulated plans by market segment*
California Department of Insurance (CDI) Statistical Analysis Division data; data as of December 31, 2015	Distribution of CDI-regulated policies by market segment

²⁶ CHBRP’s authorizing statute, available at www.chbrp.org/docs/authorizing_statute.pdf, requires that CHBRP use a certified actuary or “other person with relevant knowledge and expertise” to determine financial impact.

Data Source	Items
California Health Benefits Review Program (CHBRP) Annual Enrollment and Premium Survey of California’s largest (by enrollment) health care service plans and health insurers; data as of September 30, 2015; responders’ data represent approximately 97% of persons not associated with CalPERS or Medi-Cal with health insurance subject to state mandates(full-service (nonspecialty) DMHC-regulated plan enrollees and of full-service (nonspecialty) CDI-regulated policy enrollees).	Enrollment by: <ul style="list-style-type: none"> • Size of firm (2–50 as small group and 51+ as large group) • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered Premiums for individual policies by: <ul style="list-style-type: none"> • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered
California Employer Health Benefits Survey, 2014 (conducted by NORC and funded by CHCF)	Enrollment by HMO/POS, PPO/indemnity self-insured, fully insured, Premiums (not self-insured) by: <ul style="list-style-type: none"> • Size of firm (3–25 as small group and 25+ as large group) • Family vs. single • HMO/POS vs. PPO/indemnity vs. HDHP employer vs. employer premium share
California Health Interview Survey (CHIS)	Uninsured, age: 65+ Medi-Cal (non-Medicare), age: 65+ Other public, age: 65+ Employer-sponsored insurance, age: 65+
California Public Employees’ Retirement System (CalPERS) data, enrollment as of October 1, 2015	CalPERS HMO and PPO enrollment <ul style="list-style-type: none"> • Age: 0–17; 18–64; 65+ • HMO premiums
California Simulation of Insurance Markets (CalSIM) (projections for 2017)	Uninsured, age: 0–17; 18–64 Medi-Cal (non-Medicare) (a), age: 0–17; 18–64 Other public (b), age: 0–64 Individual market, age: 0–17; 18–64 Small group, age: 0–17; 18–64 Large group, age: 0–17; 18–64
Centers for Medicare and Medicaid (CMS) administrative data for the Medicare program, annually (if available) as of end of September	HMO vs. FFS distribution for those 65+ (noninstitutionalized)
PwC estimate	Medical trend influencing annual premium increases

Notes: (*) CHBRP assumes DMHC-regulated PPO group enrollees and POS enrollees are in the large-group segment.

Key: CDI=California Department of Insurance; CHCF=California HealthCare Foundation; CHIS=California Health Interview Survey; CMS=Centers for Medicare & Medicaid Services; DHCS=Department of Health Care Services; DMHC=Department of Managed Health Care; FFS=fee-for-service; HMO=health maintenance organization; NORC=National Opinion Research Center; POS=point of service; PPO=preferred provider organization.

Further discussion of external and internal data follows.

Internal data

- CHBRP's Annual Enrollment and Premium Survey collects data from the six largest providers of health insurance in California (including Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, and Kaiser Foundation Health Plan,) to obtain estimates of enrollment not associated with CalPERS or Medi-Cal by purchaser (i.e., large and small group and individual), state regulator (DMHC or CDI), grandfathered and nongrandfathered status, and average premiums. CalSIM and market trends were applied to project 2017 health insurance enrollment in DMHC-regulated plans and CDI-regulated policies.
- CHBRP's other surveys of the largest plans/insurers collect information on benefit coverage relevant to proposed benefit mandates CHBRP has been asked to analyze. In each report, CHBRP indicates the proportion of enrollees — statewide and by market segment — represented by responses to CHBRP's bill-specific coverage surveys. The proportions are derived from data provided by CDI and DMHC.

External sources

- California Department of Health Care Services (DHCS) data are used to estimate enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans), which may be subject to state benefit mandates, as well as enrollment in Medi-Cal Fee For Service (FFS), which is not. The data are available at: www.dhcs.ca.gov/dataandstats/statistics/Pages/Monthly_Trend_Report.aspx.
- California Employer Health Benefits Survey data are used to make a number of estimates, including: premiums for employment-based enrollment in DMHC-regulated health care service plans (primarily health maintenance organizations [HMOs] and point of service [POS] plans) and premiums for employment-based enrollment in CDI-regulated health insurance policies regulated by the (primarily preferred provider organizations [PPOs]). Premiums for fee-for-service (FFS) policies are no longer available due to scarcity of these policies in California. This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. More information on the CHCF/NORC data is available at: www.chcf.org/publications/2014/01/employer-health-benefits.
- California Health Interview Survey (CHIS) data are used to estimate the number of Californians aged 65 and older, and the number of Californians dually eligible for both Medi-Cal and Medicare coverage. CHIS data are also used to determine the number of Californians with incomes below 400% of the federal poverty level. CHIS is a continuous survey that provides detailed information on demographics, health insurance coverage, health status, and access to care. More information on CHIS is available at: www.chis.ucla.edu.
- California Public Employees Retirement System (CalPERS) data are used to estimate premiums and enrollment in DMHC-regulated plans, which may be subject to state benefit mandates, as well as enrollment in CalPERS' self-insured plans, which is not. CalPERS does not currently offer enrollment in CDI-regulated policies. Data are provided for DMHC-regulated plans enrolling non-Medicare beneficiaries. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at: www.calpers.ca.gov. California Simulation of Insurance Markets (CalSIM) estimates are used to project health insurance status of Californians aged 64 and under. CalSIM is a microsimulation model that projects the effects of

the Affordable Care Act on firms and individuals. More information on CalSIM is available at: <http://healthpolicy.ucla.edu/programs/health-economics/projects/CalSIM/Pages/default.aspx>.

- To estimate the premium impact of certain mandates, PwC's projections may derive from its proprietary comprehensive pricing model, which provides benchmark data and pricing capabilities for commercial health plans. The pricing model factors in health plan features such as deductibles, copays, out-of-pocket maximums, covered services, and degree of healthcare management. The pricing model uses normative data and benefit details to arrive at estimates of allowed and net benefit costs. The normative benchmarking utilization metrics within the pricing model are developed from a database of commercial (under 65) health plan experience representing approximately 20 million annual lives.
- The MarketScan databases, which reflect the health care claims experience of employees and dependents covered by the health benefit programs of large employers, are used to estimate utilization and unit cost. These claims data are collected from insurance companies, Blue Cross Blue Shield plans, and third party administrators. These data represent the medical experience of insured employees and their dependents for active employees, early retirees, individuals with COBRA continuation coverage, and Medicare-eligible retirees with employer-provided Medicare Supplemental plans. No Medicaid or Workers Compensation data are included.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon claims from commercial insurance companies, HMOs, and self-insured health plans.

Projecting 2018

This subsection discusses adjustments made to CHBRP's Cost and Coverage Model to project 2018, the period when mandates proposed in 2016 would, if enacted, generally take effect. It is important to emphasize that CHBRP's analysis of specific mandate bills typically addresses the incremental effects of a mandate — specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, *holding all other factors constant*. CHBRP's estimates of these incremental effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

Baseline premium rate development methodology

The key components of the baseline model for utilization and expenditures are estimates of the per member per month (PMPM) values for each of the following:

- Insurance premiums PMPM;
- Gross claims costs PMPM;
- Member cost sharing PMPM; and
- Health care costs paid by the health plan or insurer.

For each market segment, we first obtained an estimate of the insurance premium PMPM by taking the 2015 reported premium from the abovementioned data sources and trending that value to 2017. CHBRP uses trend rates published in the PwC's "Behind the Numbers" health care trend report to estimate the health care costs for each market segment in 2018.

The large-group market segments for each regulator (CDI and DMHC) are split into grandfathered and nongrandfathered status. For the small-group and individual markets, further splits are made to indicate

association with Covered California, the state's health insurance marketplace. Doing so allows CHBRP to separately calculate the impact of ACA and of specific mandates, both of which may apply differently among these subgroups. The premium rate data received from the CHCF/NORC California Employer Health Benefits survey did not split the premiums based on grandfathered or exchange status. However, CHBRP's Annual Enrollment and Premium (AEP) survey asked California's largest health care service plans and health insurers to provide their average premium rates separately for grandfathered and nongrandfathered plans. The ratios from the CHBRP survey data were then applied to the CHCF/NORC aggregate premium rates for large and small group, to estimate premium rates for grandfathered and nongrandfathered plans that were consistent with the NORC results. For the individual market, the premium rates received from CHBRP's AEP survey were used directly.

The remaining three values were then estimated by the following formulas:

- Health care costs paid by the health plan = insurance premiums PMPM × (1 – profit/administration load);
- Gross claims costs PMPM = health care costs paid by the health plan ÷ percentage paid by health plan; and
- Member cost sharing PMPM = gross claims costs × (1 – percentage paid by health plan).

In the above formulas, the quantity “profit/administration load” is the assumed percentage of a typical premium that is allocated to the health plan/insurer's administration and profit. These values vary by insurance category, and under the ACA, are limited by the minimum medical loss ratio requirement. CHBRP estimated these values based on actuarial expertise at PwC, and their associated expertise in health care.

In the above formulas, the quantity “percentage paid by health plan” is the assumed percentage of gross health care costs that are paid by the health plan, as opposed to the amount paid by member cost sharing (deductibles, copays, etc.). In ACA terminology, this quantity is known as the plan's “actuarial value.” These values vary by insurance category. For each insurance category, estimated the member cost sharing for the average or typical plan in that category is based on the actuarial value of the plan. For “metal tier” plans, the average cost share is calculated as 100% minus the plan actuarial value. For non-“metal tier” plans, Milliman estimated the actuarial value using the Milliman Health Cost Guidelines to estimate the percentage of gross health care costs that are paid by the carrier.

General Caveats and Assumptions

This subsection discusses the general caveats and assumptions relevant to all CHBRP reports. The projected costs are estimates of 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 may be different from CHBRP assumptions.
- Utilization of mandated benefits (and, therefore, the services covered by the benefit) before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.

Additional assumptions that underlie the cost estimates presented in this report are:

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate.

- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of the premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for 1 year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts, please see: www.chbrp.org/analysis_methodology/docs/longterm_impacts08.pdf.

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

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefits: To help offset the premium increase resulting from a mandate, deductibles or copayments may be increased. Such changes would have a direct impact on the distribution of costs between health plans/insurers and enrollees, and may also result in utilization reductions (i.e., high levels of cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.
- Adverse selection: Theoretically, persons or employer groups who had previously foregone health insurance may elect, postmandate, to enroll in a health plan or policy because they perceive that it is now to their economic benefit to do so.
- Medical management: Health plans/insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan/policy types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation exists in existing utilization and costs, and in the impact of the mandate, by geographic area and by delivery system models. Even within the health insurance plan/policy types CHBRP modeled (HMO, including HMO and POS plans, and non-HMO, including PPO and FFS policies), there are likely variations in utilization and costs. Utilization also differs within California due to differences in the health status of the local 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 providers and health plans/insurers. 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, CHBRP has estimated the impact on a statewide level.
- Compliance with the mandate: For estimating the postmandate impacts, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the benefit coverage requirements of the bill. Therefore, the typical postmandate coverage rates for persons enrolled in health insurance plans/policies subject to the mandate are assumed to be 100%.

Analysis Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to specifically to an analysis of AB 1763:

- A list of CPT / HCPC codes related to CRC screening exams were compiled using a variety of sources (CMS guidelines, American Gastroenterological Association website, United HealthCare website, and CHBRP Carrier Survey responses).
- 2014 MarketScan® Commercial Claims and Encounters Database was used to develop baseline cost and utilization information for outpatient and professional services. Baseline cost and utilization rate per 1,000 members were developed separately for five major types of CRC screening exams (colonoscopy with polyps removal, colonoscopy without polyps removal, CRC screening, FOBT/FIT blood tests and sigmoidoscopy), other screenings, which included CT colonography, colorectal cancer screening DNA analysis, screening proctoscopy and CRC screening (double contrast barium enema), and the related pathology services on the same service date. Baseline cost was trended at a 2.1% annual rate of increase from 2014 to 2018 based on the 2015 Medical CPI for medical commodities and professional services trend. Baseline utilization rate was not trended from 2014 to 2018.
- Screening CRC services are generally expected to be without cost sharing, whereas diagnostic CRC procedures are more likely to be subject to cost sharing. PwC attempted to use diagnosis codes and other criteria to analyze cost sharing in the MarketScan data, but the results did not appear to strongly correlate to the level of cost share observed in the data. Therefore, PwC could not accurately determine the amount of screening versus diagnostic procedures that were provided.
- PwC applied the estimated percentage of enrollees using CRC screening exams to the enrollees subject to state-level benefit mandates. Estimated usage rates were calculated by age group and applied to the age distribution by population sub-group resulting in varying average usage rates by population sub-group.
- The percentage of covered enrollees without cost sharing calculated from the MarketScan data was adjusted to reflect the percentage of enrollees without cost sharing in the carrier surveys by population sub-group. Though not perfectly correlated, population sub-groups with higher percentages of enrollees in high deductible plans based on the Annual Enrollment Surveys also had higher percentages of procedures with cost sharing. Please see the details of allowed cost per procedure and cost sharing per procedure in the table below.

Table 7. Unit Cost and Cost Sharing Per Procedure (Enrollees aged 50 and older)

	Allowed Cost	Cost Sharing
Colonoscopy w/o removal of polyp	\$1,197	\$0
Colonoscopy w/removal of polyp	\$1,262	\$0
Colorectal cancer screening	\$711	\$0
Fobt/fit	\$24	\$0
Other	\$432	\$0
Sigmoidoscopy	\$619	\$0

	Allowed Cost	Cost Sharing
Total (Aged 50 and Older with No Cost Sharing)	\$736	\$0
Colonoscopy w/o removal of polyp	\$1,349	\$343
Colonoscopy w/removal of polyp	\$1,269	\$303
Colorectal cancer screening	\$773	\$146
Fobt/fit	\$23	\$9
Other	\$456	\$112
Sigmoidoscopy	\$602	\$130
Total (Aged 50 and Older with Cost Sharing)	\$850	\$212

- The increase in total expenditure calculated is due to administrative fees incurred by the currently enrollees with cost sharing and the increase in utilization.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits (AB) 1763 would mandate. Considering the criteria specified by CHBRP’s authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

CHBRP is unaware if the largest collective bargaining agents in California includes access to colorectal cancer screenings with no cost-sharing for enrollees over the age of 50, or for coverage for additional colorectal cancer screenings and tests for high risk individuals.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. CHBRP assumes that CalPERS is not subject to AB 1763.

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A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC that conduct 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 manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, PricewaterhouseCoopers, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

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 of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP Faculty Task Force comprises rotating representatives from six University of California (UC) campuses. 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.

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.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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