California Health Benefits Review Program

Analysis of California Assembly Bill 1520
Prostate Cancer: Screening

A Report to the 2021–2022 California State Legislature

April 20, 2021

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings

Analysis of California Assembly Bill 1520
Prostate Cancer: Screening

Summary to the 2021–2022 California State Legislature, April 20, 2021

SUMMARY

The version of California Assembly Bill (AB) 1520 analyzed by CHBRP would prohibit cost sharing on coverage for prostate cancer screening for enrollees with a prostate who are either aged 55 years or older, or aged 40 years or older and considered high risk. Under AB 1520, the high-risk population includes but is not limited to Black individuals with a prostate, individuals with genetic predisposition or family history of prostate cancer, and veterans.

In 2022, AB 1520 would apply to the benefit coverage of 64% of the 21.9 million Californians enrolled in state-regulated health insurance.

Benefit Coverage: At baseline, CHBRP estimates approximately 97% of enrollees with health insurance subject to AB 1520 have no cost sharing for prostate cancer screening. AB 1520 appears not to exceed the definition of essential health benefits (EHBs) in California.

Medical Effectiveness: CHBRP found *insufficient evidence* on the impacts of cost sharing for prostate cancer screening on health outcomes and utilization of other health services. CHBRP also found *insufficient evidence* that digital rectal exams (DREs) affect health outcomes and subsequent utilization of health services, and *inconclusive evidence* that prostate-specific antigen (PSA) tests are effective at improving health outcomes. There is a *preponderance of evidence* that PSA tests contribute to utilization of other health services, and *limited evidence* of such impacts on Black men. There is *clear and convincing evidence* that PSA tests contribute to false positives and overdiagnosis.

Cost and Health Impacts: At baseline, there are 447,690 prostate cancer screenings annually. Among enrollees with cost sharing at baseline, there are 14,302 prostate cancer screenings annually (3.19% of total). Postmandate, AB 1520 would eliminate cost sharing for 3.19% of prostate cancer screenings, with no change in expected utilization. CHBRP estimates no measurable public health impact on access to, or subsequent rates of, prostate cancer screening.

CONTEXT

Prostate cancer occurs in the prostate, a small gland that is part of the male reproductive system. It is about the shape and size of a walnut, and rests below the bladder and in front of the rectum, surrounding part of the urethra. Prostate cancer is the second most prevalent type of organ cancer among all Californians (25,880 cases diagnosed in 2020).[1] The leading known risk factors for prostate cancer include increasing age, genetic mutations in DNA repair genes, having first-degree relative with prostate cancer, and race (Black men experience higher rates of prostate cancer compared with men of other races).

Prostate cancer screening is conducted on asymptomatic men to detect cancer at its earliest stage with the goal of reducing prostate cancer mortality. The most common method for prostate cancer screening is the prostate-specific antigen (PSA) test, which is typically combined with a digital rectal exam (DRE). DREs are more often included in a regular annual physical and are not usually performed specifically as a prostate cancer screening.

In 2018, the United States Preventive Service Task Force (USPSTF) updated their recommendation for PSA tests to be a C rating for men aged 55 to 69 years and D rating for men aged 70 years or older. For services with a C rating the USPSTF "recommends selectively offering or providing [the] service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small." For services with a D rating the USPSTF "recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits."

BILL SUMMARY

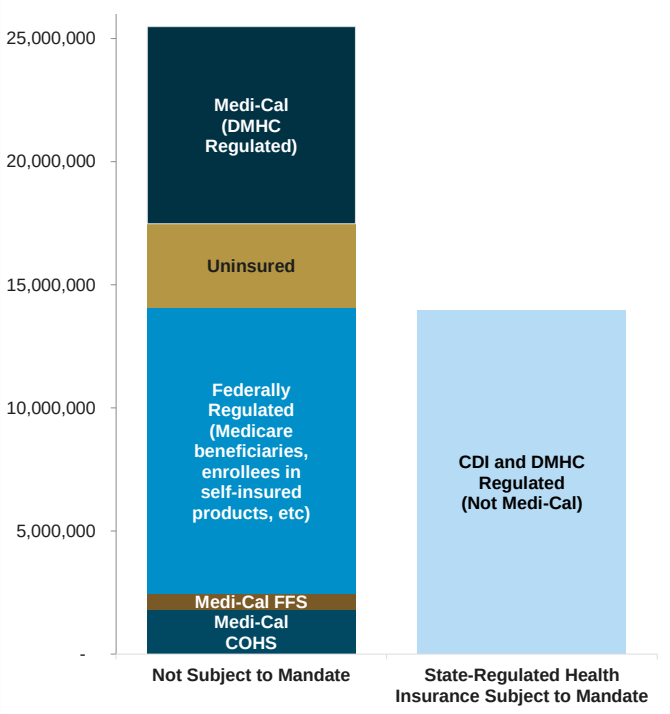
AB 1520 would prohibit cost sharing for prostate cancer screening, including but not limited to screening with PSA testing and DREs for enrollees aged 55 years or older or high-risk enrollees aged 40 years or older. Under AB 1520, the high-risk population includes but is not limited to persons with a prostate who are Black,

[1] Refer to CHBRP's full report for full citations and references.

have a family history of prostate cancer, have a genetic predisposition to prostate cancer, or are veterans.

As noted in Figure A, AB 1520 would apply to the benefit coverage of commercial and California Public Employees' Retirement System (CalPERS) enrollees in group and individual health plans[2] and health insurance policies regulated by the California Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI).

Figure A. Health Insurance in CA and AB 1520



Source: California Health Benefits Review Program, 2021.

IMPACTS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

At baseline, CHBRP estimates that approximately 97% of enrollees with health insurance subject to AB 1520 have coverage for prostate cancer screening with no cost sharing.

Utilization

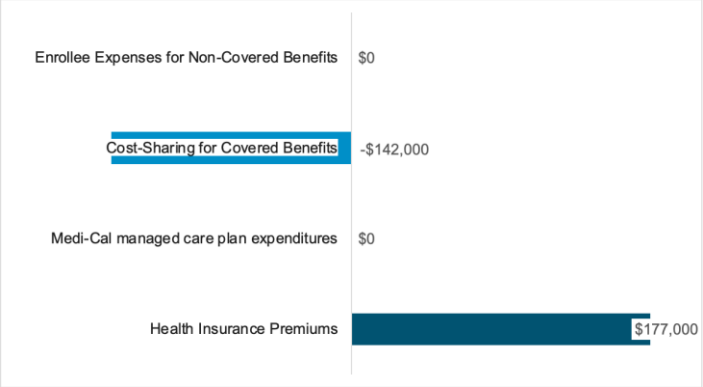
Among enrollees with no cost sharing at baseline, there are 447,690 prostate cancer screenings annually (444,721 PSA tests and 2,969 DREs). Among enrollees with cost sharing at baseline, there are 14,302 prostate cancer screenings annually (14,207 PSA tests and 95 DREs; 3.19% of the total number of screenings).

Postmandate, all enrollees would no cost sharing for coverage of prostate cancer screenings, for a total of 461,992 PSA tests and DREs annually performed with no cost sharing. Because of a lack of evidence in the research literature of cost sharing being a barrier to obtaining a PSA test or DRE, and with confirmatory input from the content expert, CHBRP projects no change in utilization postmandate.

Expenditures

AB 1520 would increase total annual expenditures of $35,000 (<0.0001%). This is due to a $177,000 estimated increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by an estimated decrease in enrollee expenses for covered benefits of $142,000 (Figure B).

Figure B. Expenditure Impacts of AB 1520



Source: California Health Benefits Review Program, 2021.

Medi-Cal

Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to AB 1520 because the bill specifies that it is applicable to group and individual plans and policies. Medi-Cal beneficiaries are enrolled in neither.

[2] Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to AB 1520 because the bill specifies that it is applicable to group and individual plans and policies. Medi-Cal beneficiaries are enrolled in neither.

CalPERS

AB 1520 would not impact CalPERS enrollees' benefit coverage, since these plans already include coverage for prostate cancer screening with no cost sharing.

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 1520.

Medical Effectiveness

CHBRP found *insufficient evidence*[3] on the impacts of cost sharing for PSA tests or DREs on health outcomes, access to care, and the subsequent utilization of additional health services.

The primary outcomes of interest for prostate cancer screening are the utilization of other health services, such as biopsy, and the associated health outcomes including prostate cancer incidence, cumulative incidence of metastatic disease, prostate cancer–specific mortality, and all-cause mortality. Harms were measured by frequency of false-positive PSA screening and overdiagnosis.

There is *insufficient evidence* that DREs affects health outcomes and subsequent utilization of other health services.

With regard to outcomes related to PSA tests, CHBRP found:

- There is *inconclusive evidence*[4] that PSA tests are effective at improving health outcomes, including mortality rates.
- There is a *preponderance of evidence*[5] that PSA tests for prostate cancer screening contribute to the utilization of other health services following a positive PSA test, such as biopsy; there is *limited evidence*[6] of such impacts on Black men.
- There is *clear and convincing evidence*[7] that PSA tests contribute to false positives and over diagnosis which contributes to unnecessary additional testing and treatments that can be associated with substantial harms.

Public Health

CHBRP estimates that, postmandate, AB 1520 would not change utilization, but it would eliminate the average $10 cost sharing amount affecting 14,302 of the 461,992 prostate cancer screening services that would have been charged to enrollees at baseline. CHBRP found insufficient evidence to determine the impacts of cost sharing on health outcomes, access to care, and utilization of services. Therefore, CHBRP estimates no measurable short-term public health impact on access to, or subsequent rates of, prostate cancer screening.

Although disparities related to prostate cancer screening exist among Black and Hispanic men, AB 1520 does not address the barriers that prevent these men from obtaining prostate cancer screening (i.e., medical mistrust, lack of health insurance and access to care, and fear of cancer diagnosis or manipulation of the prostate). Given these findings, CHBRP estimates no measurable public health impact from AB 1520 on disparities related to prostate cancer screening rates in California.

Long-Term Impacts

The impacts of AB 1520 are unlikely to be different in subsequent years, assuming the same prostate cancer screening tools are available. Thus, CHBRP expects no change in utilization in the long term. Similarly, the potential expenditure increases as a result of removal of cost sharing for prostate cancer screening are likely to be similar in subsequent years.

Due to insufficient evidence on the impacts of cost sharing for prostate cancer screening on health outcomes, access to care, and subsequent utilization of additional health services, and no change in utilization

[3] *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.
[4] *Inconclusive 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.
[5] *Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.
[6] *Limited evidence* indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.
[7] *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.

rates in the long term, CHBRP projects AB 1520 would have no measurable long-term public health impact on access to or subsequent rates of prostate cancer screening.

Essential Health Benefits and the Affordable Care Act

AB 1520 would not require coverage for a new state benefit mandate and instead modifies cost-sharing terms and conditions of an already covered benefit. Therefore, AB 1520 appears not to exceed the definition of EHBs in California.

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

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses 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. 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, authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

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Table 1. AB 1520 Impacts on Benefit Coverage, Utilization, and Cost, 2022

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,945,000	21,945,000	0	0.00%
Total enrollees with health insurance subject to AB 1520	13,940,000	13,940,000	0	0.00%
Total percentage of enrollees with health insurance subject to AB 1520	64%	64%	0%	0.00%
Utilization and unit cost				
Number of prostate cancer screening services				
Total number of prostate cancer screenings with cost sharing	14,302	0	-14,302	-100.00%
Digital rectal exam	95	0	-95	-100.00%
Prostate-specific antigen test (b)	14,207	0	-14,207	-100.00%
Total number of prostate cancer screenings without cost sharing	447,690	461,992	14,302	3.19%
Digital rectal exam	2,969	3,064	95	3.20%
Prostate-specific antigen test (b)	444,721	458,928	14,207	3.19%
Average total cost per service				
Digital rectal exam	$8	$8	$0	0.0000%
Prostate-specific antigen test (b)	$41	$41	$0	0.0000%
Average cost share per service for enrollees with cost sharing				
Digital rectal exam	$1	$0	-$1	-100.00%
Prostate-specific antigen test (b)	$10	$0	-$10	-100.00%
Expenditures				
Total premium expenditures for all payers	$121,549,302,000	$121,549,479,000	$177,000	0.0001%
Enrollee out-of-pocket expenditures	$13,168,032,000	$13,167,890,000	-$142,000	-0.0011%
Total expenditures	$134,717,334,000	$134,717,369,000	$35,000	<0.0001%

Source: California Health Benefits Review Program, 2021.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.[8]

(b) Prostate-specific antigen test costs includes both professional testing services and the assay test.

Key: CDI = California Department of Insurance; DMHC = Department of Managed Health Care.

[8] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2021*, a resource available at http://chbrp.org/other_publications/index.php.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[9] conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 1520, Prostate Cancer: Screening.

Bill-Specific Analysis of AB 1520, Prostate Cancer: Screening

Bill Language

For plans and policies that provide coverage for prostate cancer screening, AB 1520 would prohibit deductibles, copayments, or coinsurance from being charged to enrollees with a prostate who are either 55 years of age or older, or 40 years of age and older and at high risk for prostate cancer, as determined by the attending or treating health care provider.

Under AB 1520, the high-risk population includes but is not limited to persons with a prostate who are Black, have a family history of prostate cancer, have a genetic predisposition to prostate cancer, or are veterans.

The full text of AB 1520 can be found in Appendix A.

Relevant Populations

If enacted, AB 1520 would apply to the benefit coverage of the 13.9 million commercial and CalPERS enrollees in group and individual health plans and health insurance policies regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) (see Figure A in the Summary section. Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to AB 1520 because the bill specifies that it is applicable to group and individual plans and policies and Medi-Cal beneficiaries are enrolled in neither. Therefore, AB 1520 would apply to the benefit coverage of 64% of Californians in plans or policies regulated by DMHC or CDI.

Analytic Approach and Key Assumptions

CHBRP uses the following terms throughout the report:

- "Men." CHBRP uses the term "men," but recognizes that some individuals who identify as female or nonbinary may have male reproductive organs. CHBRP also recognizes that some individuals who identify as men do not have a prostate; AB 1520 does not apply to this population.

- "Cost sharing." CHBRP uses the term "cost sharing" in reference to deductibles, copayments, and coinsurance. See the section below on Cost Sharing for more information.

Although AB 1520 states the definition of high risk is not limited to the four groups listed in the bill text (i.e., persons with a prostate who are Black, have a family history of prostate cancer, have a genetic predisposition to prostate cancer, or are veterans), CHBRP is unable to predict what additional individuals will be considered high risk by their health care providers. Therefore, the analysis of high-risk populations focuses on the four categories explicitly outlined in the bill text.

CHBRP analyzed the impacts of the removal of cost sharing, as proposed under AB 1520, for all currently covered prostate screening tests. To date, the main screening tools available for prostate cancer are the

[9] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.

prostate-specific antigen (PSA) test and digital rectal examination (DRE).[10] See the *Background on Prostate Cancer Screening* section for more information on these tests. CHBRP analyzed the impacts of AB 1520 based on only these two benefits. If additional screening tests for prostate cancer become available as a covered benefit, this may affect the impact of AB 1520.

Interaction With Existing State and Federal Requirements

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

California Policy Landscape

California law and regulations

Existing law requires all individual and group health plans and policies to provide coverage for prostate cancer screening and diagnosis, including PSA testing and DREs, when medically necessary and consistent with good professional practice.[11]

In 1998, California established the Prostate Cancer Screening Program under the Department of Health Care Services (DHCS) to assist uninsured men in obtaining screening services for prostate cancer. Men who are uninsured and aged 50 years or older, or 40 years or older and are high risk, at the advice of a physician or request of the patient, are eligible for the program.[12]

DHCS also manages the state Prostate Cancer Treatment Program known as IMPACT: IMProving Access, Counseling & Treatment for Californians with Prostate Cancer. IMPACT provides up to 12 months of prostate cancer treatment and prostate cancer–related services, in collaboration with community providers and local health departments, to underinsured and uninsured men.[13]

Similar requirements in other states

Two states, New York[14] and Maryland,[15] currently prohibit cost sharing for covered prostate cancer screening services as of 2019.

Three states introduced similar legislation to AB 1520 in the 2021–22 legislative session Texas[16] and Rhode Island[17] would eliminate cost sharing for covered prostate cancer screenings. New York's proposal[18] would expand its current coverage to include comprehensive genetic testing for prostate cancer, and would prohibit all costs associated with the additional coverage from being subject to annual deductibles and coinsurance and borne solely by the health plan.

[10] Personal communication with content expert, Mark Litwin, M.D., March 18, 2021; CDC, 2021.
[11] HSC 1367.64; INS 10123.835.
[12] HSC 104315.
[13] HSC 104322.
[14] New York Senate Bill S6882A of 2018.
[15] Maryland Senate Bill 661 of 2021.
[16] Texas Senate Bill 1539 and House Bill 3951 of 2021.
[17] S383 and H5432 of 2021.
[18] S105 and A425 of 2021.

Federal Policy Landscape

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 1520 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[19,20]

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

Essential Health Benefits

AB 1520 would not require coverage for a new state benefit mandate and instead modifies cost-sharing terms of an already covered service. Therefore, AB 1520 appears not to exceed the definition of EHBs in California.

Federally Selected 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 from specified entities, including the United States Preventive Services Task Force (USPSTF) A and B recommendations.[21] In 2018, the USPSTF updated their recommendation for PSA tests to be a C rating[22] for men aged 55 to 69 years and D rating[23] for men aged 70 years or older (USPSTF, 2018). Thus, AB 1520 would not interact with federally selected preventive services if enacted. More information on the USPSTF recommendations can be found in the *Background* section.

Pending federal legislation

In February 2021, federal legislation was introduced that would prohibit cost sharing for all covered prostate cancer screening services.[24]

[19] 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. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.
[20] Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.
[21] More information is available on CHBRP's website under "Resources": www.chbrp.org/other_publications/index.php.
[22] For Grade C, the USPSTF "recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small."
[23] For Grade D, the USPSTF "recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits."
[24] H.R. 1176 of 2021.

BACKGROUND ON PROSTATE CANCER SCREENING

As discussed in the *Policy Context* section, AB 1520 would prohibit cost sharing for prostate cancer screening, including but not limited to screening with prostate-specific antigen (PSA) testing and digital rectal exam (DRE) for enrollees aged 55 years or older or high-risk enrollees aged 40 years or older. Under AB 1520, the high-risk population includes but is not limited to persons with a prostate who are Black, have a family history of prostate cancer, have a genetic predisposition to prostate cancer, or are veterans. This section provides contextual information about prostate cancer risk factors and incidence; description of prostate screening tests, rates, and guidelines; and known disparities.

Prostate Cancer

Prostate cancer occurs in the prostate, a small gland that is part of the male reproductive system. It is about the shape and size of a walnut and rests below the bladder and in front of the rectum, surrounding part of the urethra. Prostate cancer is the second most prevalent type of cancer among all Californians (25,880 cases diagnosed in 2020) (ACS, 2021a).

Risk Factors for Prostate Cancer

The leading known risk factors for prostate cancer include:

- Increasing age;
- Genetic mutations in DNA repair genes (i.e., breast cancer susceptibility gene 2 [BRCA2], ataxia telangiectasia mutated [ATM], which are associated with aggressive forms of prostate cancer, especially among men younger than 50 years);
- First-degree relative with prostate cancer diagnosed before age 65 (indicative of genetic predisposition); and
- Race (Black men experience higher rates of prostate cancer compared with men of other races; see Disparities and Social Determinants of Health in Prostate Cancer Screening section below).

There is less conclusive evidence regarding the role of smoking, diet, hormone levels, and obesity. Risk factor calculators are available for clinicians to help estimate patient risk when considering prostate cancer screening and biopsies (Sartor, 2021).

Highest risk populations for prostate cancer: Men who are Black, from African descent; have a first-degree relative with prostate cancer diagnosed before age 65; and veterans[25] exposed to Agent Orange during the Vietnam War.

Prostate Cancer Incidence

In California, prostate cancer is the most common organ cancer among men and the second leading cause of all-cancer mortality among men (estimated deaths: 4,140 in 2021) (CCR, 2021a; CCR, 2021b). See Table 2 for age-adjusted incidence and mortality rates for prostate cancer in California. The National Cancer Institute (NCI) estimates that 12% of men in the United States will be diagnosed with prostate cancer at some point during their lifetime with the majority of cancer diagnoses occurring in men older than age 60 (NCI, 2021a). Nationally, the majority of men diagnosed with prostate cancer fall into the

[25] AB 1520 specifically exempts veterans who are aged 40 years or older from prostate cancer screening cost sharing (for those enrolled in state-regulated plans and policies). In the Veterans Health Administration, 15,000 men are diagnosed with prostate cancer every year, which makes prostate cancer the most frequent cancer diagnosed among veterans (PCF, 2020). There is no evidence of increased risk of prostate cancer associated with veteran status, with the exception of those who were exposed to Agent Orange during the Vietnam War (1965–1971) (Sartor, 2021).

localized[26] category (74.5%). Just under 6% of men are categorized as distant, 12% as regional, and 7.4% are at an unknown stage (NCI, 2021a).

In the United States, the relative 5-year survival rate for men with prostate cancer is 97.8% (2010–2016). The 5-year survival rate for local or regional prostate cancer is approximately 100%, but for men diagnosed with prostate cancer that has spread throughout the body, the 5-year survival rate drops to 30% (ACS, 2021b).

Table 2. Age-Adjusted Incidence and Mortality Rate of Prostate Cancer Among Men in California, 2017

Demographic	Incidence Rate (per 100k population)	Mortality Rate (per 100k population) [b]
All Cases in California[a]	93.79	19.22
Age Group		
40–44	3.11	*
45–49	18.45	*
50–54	81.81	2.60
55–59	198.16	7.58
60–64	353.20	19.40
65–69	556.45	39.69
70–74	555.04	72.04
75–79	535.87	134.21
80–84	425.26	203.35
85+	321.11	450.21
Race/Ethnicity		
Asian/Pacific Islander	51.55	9.17
Black	138.78	43.44
Hispanic	78.02	17.55
White	93.26	20.34

Source: California Health Benefits Review Program, 2021; CCR, 2021a; CCR, 2021b.

Notes: *This indicates fewer than 15 cases.

(a) Rates are age-adjusted to the 2000 U.S. Standard Population.

(b) Based on 1988–2017 death master files.

Prostate Cancer Screening Methods, Rates, and Guidelines

Prostate cancer screening is conducted on asymptomatic men to detect cancer at its earliest stage with the goal of reducing prostate cancer mortality. Advanced prostate cancer may be detected through

[26] Localized cancer is when the cancer remains in the organ of origin and does not spread throughout the body; distant cancer is when the cancer or tumor has spread to areas of the body including extension outside of the primary organ, “travel in lymph channels beyond the first drainage area,” invasion of the blood vessels, and “spread through fluids in the body cavity;” regionalized cancer is when the tumor extends outside of the organ of origin and “there is potential for spread by more than one lymphatic or vascular supply route;” unknown cancer is when there is not enough evidence to stage the cancer properly (NCI, 2021b).

screening (for asymptomatic men) or through diagnostic testing if symptoms are present (e.g., problems urinating, blood in urine or semen, erectile dysfunction, pain in the hips, back, chest, or other areas where cancer may have spread, weakness or numbness in legs or feet, and loss of bladder or bowel control) (ACS, 2019).

Prostate Cancer Screening Methods

The most common method for prostate cancer screening is the PSA test, which is typically combined with a DRE. Both screening methods are controversial due to weak or mixed evidence of effectiveness in diagnosing malignant prostate cancer (see Inconsistent Prostate Screening Guidelines section).

Prostate-specific antigen (PSA) test

This blood test measures the level of PSA in the blood. PSA is a substance made by the prostate. Many factors, such as age, race, comorbidities, and individual antigen levels can affect PSA levels (CDC, 2020a). The PSA test is not a prostate cancer–specific biomarker; rather it indicates the potential for some sort of prostate problem because elevated PSA levels are associated with conditions such as prostatitis, benign prostatic hyperplasia, urinary tract infections, certain medical procedures, and medications in addition to prostate cancer (PCF, 2018; CDC, 2020a; Bernal-Soriano et al., 2019).

Although there is no specific PSA level to determine whether a man has prostate cancer, some doctors use a PSA level of 4 nanograms per milliliter (ng/mL) to decide whether a man requires diagnostic testing (ACS, 2021c). According to the American Cancer Society, a PSA level between 4 and 10 ng/mL is considered the “borderline range” and men in this range have a 1 in 4 chance of having prostate cancer; men with a PSA greater than 10 have a 50% chance of having prostate cancer (ACS, 2021c). However, some experts use age-specific ranges for PSA test levels instead of using the 4 ng/mL cutoff because PSA levels tend to increase with age (Hoffman, 2021). The PSA test is effective at detecting prostate cancer among asymptomatic men. However, the PSA test does not differentiate between low-risk cancer that may not be life threatening and malignant, fast-growing cancer, which may have already spread to other parts of the body before detection (NCI, 2021c).

Digital rectal examination (DRE)

A DRE is a physical exam by a clinician who inserts a gloved, lubricated finger into the patient’s rectum to feel the prostate for anything abnormal, such as cancer. In 2018, the USPSTF stated that it does not recommend DRE as a screening test because of lack of evidence on the benefits (Fenton et al., 2018; Sartor, 2021).

Rates of Prostate Cancer Screening

In the United States, rates of prostate cancer screening via PSA tests are similar by race/ethnicity but differ by education and income; those adults earning less than 200% of the federal poverty level (27.1%) or having less than a high school education (27.8%) are two-thirds as likely to undergo prostate cancer screening as the average screening rate for all adults (39%) (NIH, 2020) (Table 3). The difference in prostate cancer screening by age cohort is attributable to level of risk and national screening guidelines.

Table 3. PSA Test Rates by Race/Ethnicity, Poverty Income Level, and Educational Level Among Men in the United States

	Demographic	Percent of Men Who Had PSA Test in Past Year
By Race/Ethnicity*		
	All races	39.0%
	Non-Hispanic White	40.4%

	Non-Hispanic Black	37.0%
	Hispanic	33.2%
By Poverty Income Level*	<200% of the federal poverty level	27.1%
	≥200% of the federal poverty level	42.2%
By Education Level*	Less than high school	27.8%
	High school	34.5%
	Greater than high school	42.7%
By Age	40–54 years	13.4%
	55–69 years	39.0%
	70+ years	44.6%

Source: California Health Benefits Review Program, 2021; NIH, 2020.

Notes: *For men aged 55 to 69 years.

Inconsistent Prostate Cancer Screening Guidelines

Research shows that, if prostate cancer were not detected through screening, most men would be unaware they had the cancer and death would occur from other causes (Hoffman, 2021). This is because prostate cancer occurs primarily in older men and typically grows slowly such that other comorbidities cause death. National organizations examined the benefits and harms of screening and found that prostate cancer screening leads to overdiagnosis and overtreatment (Carter et al., 2013; Fenton et al., 2018; USPSTF, 2018; Wolf et al., 2010). The guidelines from three national organizations generally agree that the decision to screen periodically for prostate cancer should be based on individual patient preferences and values and shared decision-making between the patient and physician, accounting for life expectancy, age, ethnicity, and genetic predispositions. None of the guidelines recommend routine screening in all men aged 55 to 69 years old. The prostate cancer screening guidelines differ in their recommended age to start screening and frequency of screening, but all recommend shared decision-making between the patient and the physician (Table 4).

Table 4. Summary of PSA Screening Guidelines by Three National Organizations

	USPSTF	American Cancer Society	American Urological Association
Age	• 55–69 years old • Not recommended for men aged 70 years or older	• Aged 40 years for highest risk men with more than one first-degree relative with prostate cancer at early age • Aged 45 years for high-risk men who are Black or with first-degree relative with prostate cancer at early age • Aged 50 years and greater for average-risk men • Not recommended for men who have less than 10-year life expectancy	• Not recommended for men under age 40 years • Not recommended for men aged 40–54 years at average risk • Aged 40–54 years at high risk • Aged 55–69 years • Not recommended for men aged 70 or older
Decision-Making	• Shared decision-making between patient and physician • Individualized	• Shared decision-making between patient and physician • Discussion of uncertainties, risks and potential benefits	• Shared decision-making between patient and physician

	• Discuss harms and benefits with physician, patient preferences and values	• If patient is unable to decide, the physician can decide whether to screen, taking account of patient preferences and values	• Discussions of benefits and harms of screening, patient preferences and values
High-Risk Groups	• Black men, men with family history • Specific recommendations for each high-risk group	• Men who are Black, from African descent; or have a first-degree relative diagnosed with prostate cancer before 65	• Black men; a family history of metastatic or lethal adenocarcinomas spanning multiple generations, affecting multiple first-degree relatives, and that developed at younger ages
Additional Screening Tests		• DRE may be performed	• Urinary and serum biomarkers, imaging, and risk calculations to make decision about biopsy
Screening Frequency		• PSA less than 2.5 ng/mL rescreened every 2 years • PSA greater than 2.5 ng/mL or higher rescreened every year	• May be individualized by a baseline PSA level • Every 2 years for men who decide to screen with shared decision-making • Longer interval (i.e., 4 years) for men aged 60 years or older with PSA level below 1 ng/mL

Source: California Health Benefits Review Program, 2021 (USPSTF, 2018; Wolf et al., 2010; Carter et al., 2013).
Key: DRE = digital rectal exam; PSA = prostate-specific antigen.

Harms of PSA Screening, Diagnostic Procedures, and Prostate Cancer Treatment

There are known benefits of the PSA test, which include screening for men who prefer to know if they have an elevated PSA level, earlier detection of prostate cancer that may be at high risk of spreading, and reduced mortality for some men (CDC, 2020b; Hugosson et al., 2019). See *the Medical Effectiveness* section for further discussion of reduced mortality related to the PSA test. However, inconsistencies between prostate cancer screening guidelines exist because of variation in interpretation of the results of randomized trials of screening. Emphasis on shared decision-making is consistent due to the documented harms associated with the PSA test (Carter et al., 2013; Fenton et al., 2018; Illic et al., 2018; USPSTF, 2018; Wolf et al., 2010). The harms associated with prostate cancer screening include false-positive testing, diagnostic biopsies, the physical and psychological harms of screening and diagnostic follow-up, and overdiagnosis and overtreatment (CDC, 2020b; Fenton et al., 2018). While the PSA test may reduce mortality from prostate cancer, testing is also associated with a high rate of overdiagnosis and overtreatment. Many older men may harbor prostate cancers that never cause symptoms. Screening may result in unnecessary diagnostic procedures and prostate cancer treatment with no improvement in life expectancy or quality of life (Fenton et al., 2018). In addition to the harms associated with prostate

cancer screening, there are potential harms associated with diagnostic tests and procedures and the treatment of prostate cancer.

Following an elevated PSA test, a prostate biopsy is the main tool for diagnosing prostate cancer. A biopsy removes one or more small pieces of the prostate tissue using a hollow needle inserted into the prostate (ACS, 2021c); physicians may use transrectal ultrasound (TRUS) or magnetic resonance imaging (MRI) to guide the biopsy and to ensure the biopsy is taken from right location. If the biopsy is positive, the prostate cancer will be assigned a grade and the Gleason score[27] will be determined (ACS, 2021c).

There are harms related to diagnostic procedures including complications of the prostate biopsy (pain, blood in semen, infection) with approximately 1% of biopsies requiring hospitalization for these complications (Fenton et al., 2018). Additional imaging tests and follow up visits may be required to assess for cancer in the prostate, to see the prostate during procedures such as biopsy or for types of prostate cancer treatment, and to assess for spread of cancer to other areas in the body. These imaging tests or procedures include trans rectal ultrasound scan (TRUS), magnetic resonance imaging (MRI), bone scan, positron emission tomography (PET) scan, computed tomography (CT) scan, or lymph node biopsy (ACS, 2021c).

According to the CDC, the most common treatments for prostate cancer are radiation therapy and prostatectomy (removal of the prostate) (CDC, 2020b). The harms related to prostate cancer treatment include erectile dysfunction (impotence), urinary incontinence, and burdensome bowel symptoms. These complications are often long term and pervasive (Fenton et al., 2018). Urinary incontinence is accidental leakage of urine, and 1 out of 5 men who undergo a prostatectomy experience loss of bladder control. Erectile dysfunction affects 2 out of 3 men who undergo a prostatectomy and about 50% of men who receive radiation therapy. Burdensome bowel symptoms include fecal incontinence (leakage of stool) and urgency (sudden and uncontrollable sensation to have a bowel movement), and about 1 out of 6 men who received radiation therapy experiences bowel problems (CDC, 2020b).

Disparities[28] and Social Determinants of Health[29] in Prostate Cancer Screening

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to cost sharing associated with prostate cancer screening. Disparities are noticeable and preventable differences between groups of people.

Disparities and Cost Sharing for Prostate Cancer Screening

CHBRP found no literature identifying disparities by race and ethnicity related to cost sharing for prostate cancer screening. Racial/ethnic disparities do exist for rates of prostate cancer screening, incidence, and mortality.

[27] The Gleason score is used to describe cancer cells from the tissue sample obtained from the prostate biopsy and how likely the cells are to grow and spread (NCI, 2021d). Most prostate cancers are made of cells from different grades, and the Gleason score is a combination of two different grades of cells from the largest areas biopsied. The Gleason score ranges from 2 to 10, and the lower the score, the more likely the cancer cells appear like normal calls and will grow more slowly (NCI, 2021d).

[28] Several competing definitions of “health disparities” exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population. (Wyatt et al., 2016).

[29] 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: CDC, 2014; Healthy People 2020, 2019). See CHBRP’s SDoH white paper for further information: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

Disparities in Rates of Screening and Disease

Race or ethnicity

Although risk of prostate cancer increases with age, Black men and men of African descent and men with family history are at increased risk of developing prostate cancer and dying from prostate cancer (Fenton et al., 2018; CDC, 2021a). Black men experience higher rates of prostate cancer, higher mortality, and more aggressive disease than all other racial groups (ACS, 2021b; Chornokur et al., 2011; Powell et al., 2010). In a review of the literature on prostate cancer disparities, Smith et al. (2017) reported that the risk of developing prostate cancer is 1.6 times higher for Black men than for White men, and Black men are also more likely to have prostate cancer at an earlier age, be diagnosed at a late stage of the disease, and have poorer outcomes (Smith et al., 2017). Table 2 shows that the incidence rate for Black men (138.78 per 100,000) is higher than the incidence rate for White men (93.26 per 100,000) in California (CCR, 2021a). In 2017, the prostate cancer mortality rate for Black men (44.44 per 100,000) was more than double the mortality rate for White men (20.34 per 100,000) and more than double the overall age-adjusted mortality rate of prostate cancer in California (19.22 per 100,000) (CCR, 2021b). See Table 2 for incidence and mortality rates for prostate cancer by all races/ethnicities.

Black and Hispanic men are less likely to obtain PSA tests compared to White men (Hosain et al., 2011; Johnson et al., 2021; Roberts et al., 2018). Research from a large cohort study showed declining PSA screening rates for all men between 2014 and 2018. However, PSA screening rates for Black men were consistently similar or lower than rates for White men (Kearns et al., 2020). In the United States from 2005 to 2018, 37% of Black men aged 55 to 69 years reported obtaining PSA tests compared to 40.4% of White men aged 55 to 69 years (NIH, 2020) (Table 3). PSA screening rates among Latino men are lower than rates for Black (Hosain et el, 2011; Johnson et al., 2021) or non-Hispanic White men (Haque et al., 2009; Stern, 2019; Zhou et al., 2011). In the United States, 33.2% of Hispanic men aged 55 to 69 years reported having a PSA test (NIH, 2020).

CHBRP found evidence in the literature related to barriers to prostate cancer screening for Black men but found no studies that directly assessed barriers to prostate cancer screening for Hispanic men, the racial/ethnic group with the second highest prostate cancer incidence and mortality rate. Black and Hispanic men are more likely to receive PSA tests when they have annual check-ups with a physician compared to when they do not have annual check-ups (Hosain et al., 2011). Barriers reported by Black men to having PSA tests are related to:

- An overall mistrust of the medical system and providers (Davis et al., 2010; Stepanikova et al., 2006);
- Less access to health care (Hargraves and Hadley, 2003; Jones et al., 2008; Talcott et al., 2007); and
- Fear that manipulation of the prostate may affect fertility (Parchment, 2004; Plowden, 1999; Shelton et al., 1999).

Additionally, a small focus group study of 31 men of African or Caribbean descent reported attitudes related to prostate cancer screening that included:

- A link between the lack of doctor visits and being unaware of prostate cancer screening;
- Lack of health insurance or the lack of access to health care; and
- A fear of cancer diagnosis (Cobran et al., 2018).

CHBRP found no evidence that cost sharing is a barrier to obtaining prostate cancer screening for Black and Hispanic men.

Social Determinants of Health (SDoH)

SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography, etc.). CHBRP found no literature associated with cost sharing for prostate cancer screening related to SDoH but found evidence that prostate cancer screening rates are impacted by income and education.

Income and education

PSA screening rates are positively associated with an individual's income and educational level (Moses et al., 2017). Men with higher education are more knowledgeable about PSA tests and understand the role of cancer prevention and early detection (Eisen et al., 1999; Fowke et al., 2005; Steenland et al, 2004). As presented in Table 3, 42.7% of men aged 55 to 69 years with education greater than high school reported having PSA tests compared to 27.8% of men with less than high school education and 34.5% of men with high school education (NIH, 2020). Additionally, men aged 55 to 69 years who report income less than 200% of the federal poverty level (27.1%) are about two-thirds as likely to obtain PSA tests compared to men who report income greater than 200% of the federal poverty level (42.2%) (NIH, 2020).

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 1520 would prohibit cost sharing on prostate cancer screening for men aged 55 years or older, or aged 40 years or older if considered high risk. Under AB 1520, the high-risk population includes but is not limited to persons with a prostate who are Black, have a family history of prostate cancer, have a genetic predisposition to prostate cancer, or are veterans. Additional information on prostate cancer and prostate cancer screening is included in the *Background on Prostate Cancer* section.

Research Approach and Methods

Studies of digital rectal exams (DREs) and prostate-specific antigen (PSA) tests for prostate cancer screening were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English. The search was limited to studies about DRE and PSA tests for prostate cancer screening methods published from 2018 to present. CHBRP relied on a systematic review published in 2018 for findings of studies published prior to 2018. Of the 147 articles found in the literature review, 17 were reviewed for potential inclusion in this report on AB 1520, and a total of 11 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on prostate cancer screening, were of poor quality, weak research design, 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.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[30] Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

This literature review focuses on key questions regarding the impact of cost sharing on access to and use of prostate cancer screening, the effectiveness of prostate cancer screening on health outcomes (morbidity and mortality), and access to and utilization of health services subsequent to positive screening results. Because AB 1520 does not include prostate cancer treatment, this review does not review evidence of effectiveness of prostate cancer treatments.

Key Questions

1. What is the evidence regarding the impact of cost sharing on health outcomes, access to, and uptake of prostate cancer screening?

2. What is the evidence of effectiveness of prostate cancer screening on health outcomes, including morbidity and mortality, specifically in the high-risk populations defined by AB 1520 (i.e., Black men, men with a genetic predisposition of prostate cancer, men with a family history of prostate cancer, and veterans)?

[30] Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

3. What is the evidence of the impact of DREs and PSA tests on access to care and utilization of subsequent health services based on a positive screening, specifically in the high-risk populations defined by AB 1520, on access to care and utilization of health services?

4. What are the harms associated with DREs and PSA tests?

Most of the research on prostate cancer screening is summarized in a large meta-analysis and systematic review of three large, randomized control trials (RCTs) (Fenton et al., 2018). These studies include:

- *European Randomized study of Screening for Prostate Cancer* (ERSPC): The ERSPC, conducted in multiple European countries, was initiated in 1993 (median follow-up of 16 years) with the primary aim to investigate the effect of regular PSA screening on prostate cancer mortality (Hugosson et al., 2019; Schroder et al., 2009; Schroder et al., 2012; Schroder et al., 2014). A total of 162,387 men aged 55 to 69 years at enrollment were assigned to the screening group (72,952) or to the control group (usual care) (89,435). For the intervention group, the screening interval was 4 years at all sites except in Sweden, which used a 2-year interval. It is unknown what percentage of the usual care group received screening and how often. During this study, 126,462 PSA tests were performed, with an average of 2.1 per subject who underwent screening. This study used a PSA cutoff value of 3.0 to 4.0 ng/mL as an indication for biopsy, depending on the country where the screening was performed.
- *Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial (PLCO)*: The PLCO was a large, randomized trial designed and sponsored by the NCI to determine the effects of screening on cancer-related mortality and secondary endpoints in men and women aged 55 to 74 years. The PLCO trial (Andriole et al., 2005; Andriole et al., 2012; Pinksky et al., 2019), initiated in 1993 (median follow-up of 14.8 years for the screening group and 14.7 years for the control group), included 76.683 men aged 55 to 74 years; 38,340 men were randomized to the intervention arm and 38,343 men were randomized to the control arm (38,343) throughout 10 centers across the United States. Men in the intervention arm underwent a PSA test and DRE at the baseline, a DRE annually for 3 more years, and PSA tests annually for 5 more years. Approximately 46% of subjects in the control group received routine screening PSA tests from community physicians during each year, compared with approximately 85% of subjects in the intervention group. DRE results were considered abnormal if there was nodularity or induration of the prostate or if the examiner judged other criteria to be suspicious for cancer, including asymmetry. PSA results were classified as abnormal if they were greater than 4 ng/mL,
- *Cluster Randomized Trial of PSA Testing for Prostate Cancer (CAP):* The CAP study was conducted from 2001 to 2009 and included 419,582 men aged 50 to 69 years who were seen at 573 primary care practices across the United Kingdom (Martin et al., 2018). Subjects were randomized to a single PSA test (n=189,386) or usual care, which was no screening (n=219,439).

CHBRP found literature that directly examined the effect of DRE and PSA tests for prostate cancer screening on Black men, but not on any other groups identified as high risk by AB 1520 (i.e., with a family history of prostate cancer, with a genetic predisposition to prostate cancer, or veterans).

Outcomes Assessed

The primary outcomes of interest for the effect of prostate cancer screening are the utilization of other health services, such as biopsy, and the associated health outcomes including prostate cancer incidence, cumulative incidence of metastatic disease, prostate cancer–specific mortality, and all-cause mortality. Harms were measured by frequency of false-positive PSA tests and overdiagnosis. Studies of PSA tests include metastatic disease incidence rate and mortality rates from prostate cancer, defined as deaths from prostate cancer during the follow-up period divided by the person-years of follow-up.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of DRE and PSA tests for prostate cancer screening by AB 1520. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in the box below, and more information is in Appendix B.

The following terms are used to characterize the body of evidence regarding an outcome:

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.

Preponderance of evidence indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

Limited evidence indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

Inconclusive 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.

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.

More information is available in Appendix B.

Findings on the Impact of Cost Sharing for DREs and PSA Tests on Health Outcomes

CHBRP did not find any literature that directly examines the impact of cost sharing for DRE or PSA tests for prostate cancer screening on health outcomes or access to care or utilization of other health services.

Summary of findings regarding the impact of cost sharing for DREs and PSA tests for prostate cancer screening on health outcomes and access to care and utilization of other health services: There is *insufficient evidence* that cost sharing for DRE or PSA tests for prostate cancer screening affects health outcomes, access to care, or utilization of additional health services.

Figure 1. Impact of Cost Sharing for DREs and PSA Tests on Health Outcomes

Findings on the Impact of DREs on Health Outcomes

CHBRP did not find any literature that examined the effect of DREs for prostate cancer screening on health outcomes or utilization of other health services.

Summary of findings regarding the impact of DREs on health outcomes and utilization of other health services: There is *insufficient evidence* that DREs affect health outcomes and subsequent utilization of other health services.

Figure 2. Impact of DRE on Health Outcomes and Utilization of Other Health Services

Findings on the Impact of PSA Tests on Subsequent Utilization of Health Services

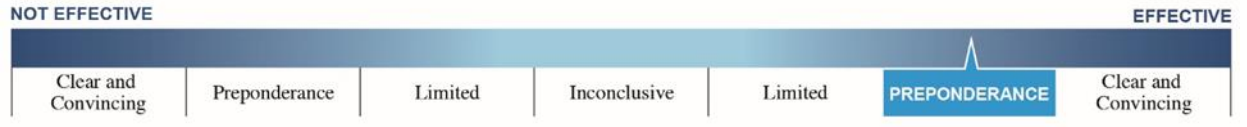
The ESPRC trial reported that, for all men undergoing PSA tests for prostate cancer screening, 16.2% of all tests were positive (11.1% to 22.3%) across the study sites, on average. Of these men, 85.8% (17,543) went on to have additional tests such as biopsy (Schroder et al., 2009). In the PLCO trial, 12.6% of men randomized to screening underwent one or more biopsies, resulting in a total of 6,295 biopsies (16.4 biopsies per 100 men randomized to screening). The CAP trial reported that, of 64,436 subjects with a valid PSA test result, 11% (6,857) had a PSA level considered elevated and 85% (5,850) with an elevated PSA underwent prostate biopsy (Martin et al., 2018).

High-risk populations

One study (Miller et al., 2018; 68,548 subjects) examined differences in PSA tests and DREs for prostate cancer screening by race. The study found that, among all men who were screened, Black men were significantly more likely to undergo a biopsy than White men (16.5% vs 13.8%, respectively [P = 0.003]), but there was no significant difference when limited to those with a positive PSA test (versus a positive DRE exam).

Summary of findings regarding the impact of PSA tests for prostate cancer screening on utilization of other health services: There is a *preponderance of evidence* that PSA tests for prostate cancer screening contribute to the utilization of other health services following a positive PSA test, such as biopsy. There is *limited evidence* in studies that specifically examine Black men that screening PSA tests contribute to the utilization of other health services such as biopsy.

Figure 3. Findings on the Impact of PSA Tests on Subsequent Utilization of Health Services



Findings on the Impact of PSA Screening Tests on Health Outcomes

As discussed in the Research Approach and Methods section, three large RCTs examined the difference in prostate cancer mortality between men in the screening and control groups. The results of these studies are conflicting.

Cumulative incidence of metastatic disease

An analysis from the ERSPC trial reported the cumulative incidence of metastatic cancer at 12-year follow-up was significantly lower among men randomized to screening compared with usual care (rate

ratio [RR] 0.70; 95% CI, 0.60–0.82). Randomization to screening was associated with an absolute reduction in long-term risk of metastatic prostate cancer of 3.1 cases per 1,000 men (Schroder et al., 2012).[31]

In the 16-year follow-up analysis from the PLCO study (Pinsky et al., 2019), rates of total metastatic disease and metastatic progression were similar among men in the screening group and the usual care group. The rates of total metastatic disease were 4.72 and 4.83 per 10,000 person years in the screening group and usual care groups, respectively (RR 0.98; 95% CI, 0.81–1.18), and the rates of metastatic progression among men (with clinical stage I/II prostate cancer) were 43.7 and 50.5 per 10,000 person years in the screening versus usual care groups, respectively (P =0.30).

Prostate cancer mortality

In 2012, an analysis from the ERSPC trial reported that prostate cancer mortality rate ratio was significantly reduced in the screening group compared to usual care (RR 0.79; 95% CI, 0.69–0.90). In 2019, an additional analysis from the ERSPC trial reported a continued reduction in prostate cancer mortality in the screening group (compared to the usual care group) at 16 years follow-up (RR 0.80; 95% CI, 0.72–0.89, p<0.001) (Hugosson et al., 2019). The 16-year follow-up analysis also reported that the findings were stable over time and the benefit may have increased slightly. At 16-year follow-up, the number of men needed to be invited for screening to prevent one prostate cancer death was 570.[32] The number needed to diagnose one prostate cancer was 18 at 16-year follow-up.[33]

However, two studies reported that prostate cancer screening was not associated with a statistically significant reduction in prostate cancer mortality for the screening group compared to the usual care groups (Martin et al., 2018; Pinksy et al., 2019). The CAP trial (Martin et al., 2018) reported that subjects randomized to a single PSA screening intervention compared to standard practice (without screening) showed no significant difference in prostate cancer mortality after a median follow-up of 10 years. The PLCO study reported that, at 13-year follow-up, the prostate cancer mortality rate was not significantly different between groups (Andriole et al., 2012). Extended follow-up of the PLCO trial at 16 years continued to show no significant reduction in prostate cancer mortality for the intervention group compared to the control group (Pinksy et al., 2019).

All-cause mortality

A systematic review by Fenton et al. (2018) identified studies reporting that after median follow-up periods ranging from 10 to 14.8 years, the CAP, PLCO, and ERSOC trials reported that PSA screening, compared to usual care, was not associated with a statistically significant reduction in all-cause mortality in any of the three trials.

Health outcomes in high-risk populations

Miller et al. (2018; 68,548 subjects) reported that prostate cancer–specific mortality rates were more than two times greater in Black men than White men. The overall mortality rate in Black men was 105.9 per 100,000 compared to 45.8 per 100,000 in White men. When control and intervention groups were combined to examine outcomes by race, prostate cancer–specific survival was significantly better among White men compared to Black men (89.8% vs 80.4%; HR = 1.64). However, after controlling for cancer severity (Gleason score), the difference in survival rate was no longer significant. The 19-year survival rates found in this study in both Black and White men (80.4% and 89.8%) to the national cancer database Surveillance, Epidemiology, and End Results (SEER) Program data rates (84.0% and 88.9%).

[31] The relative risk of prostate cancer for the intervention arm to the control arm was computed as the ratio of the rates in the two arms.
[32] The number needed to invite, to avert one prostate cancer death was calculated as the inverse of the absolute risk difference in prostate cancer deaths between groups.
[33] The number needed to detect was defined as the number needed to invite multiplied by the excess incidence of prostate cancer in the screening group.

Summary of findings on the impact of screening PSA tests on health outcomes: Due to conflicting results of three large RCTs, there is *inconclusive evidence* that screening PSA tests are effective at improving health outcomes. Two of the RCTs found no evidence that screening PSA tests reduced prostate cancer mortality and one found evidence that testing did reduce prostate cancer mortality. All the RCTs found no evidence that PSA tests reduced all-cause mortality. There is *insufficient evidence* that screening through PSA tests impacts health outcomes of Black men.

Figure 4. Findings on the Impact of screening PSA Tests on Health Outcomes

Findings on the Harms of PSA Tests for Prostate Cancer Screening

Cancer overdiagnosis can be defined as the detection of cancer that would otherwise not become clinically significant over a patient's lifetime or not result in cancer-related death. This is a phenomenon that has been observed in several cancers including lung, breast, and prostate cancer (Sandhu et al., 2012). The introduction of population-based screening must consider overdiagnosis, overtreatment, quality of life, cost, and cost-effectiveness and the ratio of benefits to risks that are involved. Overdiagnosis can lead to adverse consequence of prostate cancer screening, including a high risk of overtreatment with unavoidable adverse effects. It can also have adverse effects on quality-of-life outcomes for men undergoing prostate cancer screening (Bulliard et al., 2015; Fenton et al., 2018; Singh et al., 2018).

There is general agreement among guidelines groups that the decision to screen for prostate cancer needs to involve shared decision-making with consideration of potential benefits and harms, but differing interpretation of trial findings has led to some disagreement in the literature about the relative weights of benefits and harms (Shoag et al., 2020; Wittman et al., 2020).

As discussed in the *Background* section, following an elevated PSA test, a biopsy is frequently performed, which can contribute to harms such as pain, bleeding, and infection. However, the most serious harm of prostate cancer screening is overdiagnosis, because overdiagnosis burdens men with the potential harms of diagnosis and treatment without improving life expectancy or quality of life (Fenton et al., 2018).

Autopsy studies have confirmed a high prevalence, increasing with age, of asymptomatic and undiagnosed prostate cancers in men. About half of White men over 80 years likely have slow-growing prostate cancer (Jahn et al., 2015), which highlights the harms of diagnosing certain prostate cancers that are likely to have remained asymptomatic. One study reported that 42% to 66% of diagnosed prostate cancers would have caused no clinical harm had they remained undetected (Draisma et al., 2009).

Fenton et al. (2018) reported on the harms of PSA tests and diagnostic follow-up based on the PLCO, CAP, and ERSPC trials (647,906 subjects), and one cohort study (Walter et al., 2013; 295,645 subjects). These studies included asymptomatic men undergoing PSA tests or prostate biopsy after abnormal screening results and assessed the frequency of false-positive PSA tests, harms of screening, or overdiagnosis. Of biopsies performed in the three large trials, 67.7%, 75.8%, and 60.6% did not result in a prostate cancer diagnosis in the PLCO, ERSPC, and CAP trials, respectively (Fenton et al., 2018).

Among men who underwent at least one PSA test during the initial four (of six) PLCO screening rounds (32,576 subjects), 10.4% received at least one false-positive PSA test result. Across all PLCO screening rounds, 12.6% of men randomized to screening underwent one or more biopsies, resulting in a total of 6,295 biopsies (16.4 biopsies per 100 men randomized to screening). Within the ERSPC trial, of men who

were screened at least once (61,604 subjects), 17.8% received one or more false-positive PSA test results. The rate of biopsies among men randomized to screening was higher in the ERSPC trial than the PLCO trial (27.7 biopsies per 100 men randomized to screening) (Fenton et al., 2018). An additional cohort study reported that among men undergoing a single round of PSA test within the Veterans Affairs health system (295,645 subjects), 8.5% had an elevated PSA level (4 ng/mL or greater). Of these, 32.9% had a subsequent prostate biopsy. Of biopsies performed, 37.2% did not result in a prostate cancer diagnosis (Walter et al., 2013).

Fenton et al. (2018) estimated overdiagnosis as a percentage of all prostate cancers diagnosed, at 16.4% of prostate cancers in the PLCO trial, 33.2% in the ERSPC trial, and 40.7% in the CAP trial. When estimated as a percentage of cancers detected by screening during the two trials reporting such data, 20.7% of cancers were overdiagnosed in the PLCO trial and 50.4% in the ERSPC trial.

At 17-year follow-up, the PLCO trial reported that, while there was a significant reduction in the incidence of high-risk prostate cancer in the screening arm, there was also significantly increased incidence of low-risk prostate cancer in the screening arm, indicating overdiagnosis (Pinskey et al., 2019).

Findings on the Harms of Screening PSA tests and DREs in High-Risk Populations

Black population

Although the PLCO study population only included 4% Black participants (3,370), a follow-up analysis (Miller et al., 2018; 68,548 subjects) examined differences in PSA tests for prostate cancer screening and DRE screening overdiagnosis and false positives by race. The study reported that Black men were more likely to have a false-positive from a PSA test compared to White men (14.5% vs 12.4%; $P = 0.02$) but were less likely to have a false-positive DRE test (10.9% vs 14.2%, respectively; $P < 0.001$). The estimated overdiagnosis rate (as a percent of PSA tests and DRE-based screen detected cases) was higher but not statistically significant between groups.

Summary of findings regarding the harms associated with PSA tests for prostate cancer screening: There is *clear and convincing evidence* that PSA testing for prostate cancer screening contributes to false positives and overdiagnosis based on three large RCTs and one cohort study. This leads to unnecessary additional testing and treatments that can be associated with substantial harms.

Figure 5. Harms Associated with PSA Tests for Prostate Cancer Screening

Summary of Findings

- There is *insufficient evidence* on the impacts of cost sharing for PSA tests or DREs on health outcomes, access to care, and the subsequent utilization of additional health services.
- There is *insufficient evidence* that DREs affect health outcomes and subsequent utilization of other health services.
- There is *inconclusive evidence* that PSA tests are effective at improving health outcomes, including mortality rates.
- There is a *preponderance of evidence* that PSA tests for prostate cancer screening contribute to the utilization of other health services, including biopsy, following a positive PSA test.

- There is *limited evidence* that PSA tests for prostate cancer screening contribute to the utilization of other health services, including biopsy, in studies that specifically examine Black men.
- There is *clear and convincing evidence* that PSA tests contribute to false positives and overdiagnosis, which contributes to unnecessary additional testing and treatments that can be associated with substantial harms.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 1520 would eliminate cost sharing for enrollees in DMHC-regulated plans and CDI-regulated policies relating to prostate cancer screening. This includes eliminating deductibles, copayments, or coinsurance for prostate-specific antigen (PSA) tests, which are the most commonly used screening tests for prostate cancer. Less commonly, digital rectal exams (DREs) may also be used for prostate cancer screening, but these tests are more often included in a regular annual physical and are not usually performed specifically as a prostate cancer screening.

In addition to commercial enrollees, more than 50% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS) and more than 70% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.[34] As noted in the *Policy Context* section, Medi-Cal beneficiaries are not subject to AB 1520 and therefore have been excluded from the analysis.

This section reports the potential incremental impacts of AB 1520 on estimated baseline benefit coverage, utilization, and overall cost. Based on CHBRP's survey of the major health insurance carriers in California with responses representing 77% of enrollees, CHBRP found that approximately 97% of enrollees in DMHC-regulated plans and CDI-regulated policies had no cost sharing at baseline for prostate cancer screening. The small percentage of enrollees with cost sharing for prostate cancer screening all had coverage under "grandfathered" plans or policies.[35] CHBRP estimates these enrollees accounted for 3.19% of all screening claims for prostate cancer (Table 1). Additionally, according to Milliman's medical claims data, PSA tests and DREs have total costs of $41 and $8, respectively, leading to cost sharing, if applicable, of $10 and $1, respectively (Table 1).[36] Based on these cost sharing estimates and baseline coverage of approximately 97%, CHBRP finds there is <0.0001% impact on overall health care costs (Table 1).

CHBRP does not make additional assumptions to adjust for changes in utilization due to COVID-19 because recent 2020 claims data indicates utilization in aggregate has mostly returned to prepandemic levels. CHBRP assumes utilization of health care services in 2022 would be roughly equivalent to utilization in 2019[37], with adjustments made to account for changes in enrollment and population. However, CHBRP acknowledges utilization has not rebounded for some services and for some groups of enrollees (e.g., visits for younger children had not returned to prepandemic baseline as of October 2020) (Mehrota et al., 2020). Additionally, there are other unknown factors that may impact utilization as a result of COVID-19, such as the potential impacts of deferred care and long-term impacts from COVID-19 infections.

For further details on the underlying data sources and methods used in this analysis, see Appendix C.

Baseline and Postmandate Utilization, Per-Unit Costs, and Expenditures

At baseline, CHBRP estimates that approximately 97% of enrollees with coverage subject to AB 1520 have coverage for prostate cancer screening with no cost sharing. Among enrollees with no cost sharing at baseline, there are 447,690 prostate cancer screenings annually (444,721 PSA tests and 2,969 DREs; see Table 1). Among enrollees with cost sharing at baseline, there are 14,302 prostate cancer screenings

[34] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2021*, a resource available at http://chbrp.org/other_publications/index.php.
[35] The term "grandfathered" refers to plans or policies that were in existence when the Patient Protection and Affordable Care Act of 2010 was enacted, and have not significantly changed their benefit or cost-sharing structures since. These plans and policies are allowed to continue operation with their existing benefit coverage and cost-sharing provisions.
[36] Total per-unit average costs are derived from the amount paid to providers according to the Milliman claims data. For more detail, see Appendix C.
[37] CHBRP uses Milliman's 2019 Consolidated Health Cost Guidelines Sources Database (CHSD) to estimate utilization in 2022.

annually (14,207 PSA tests and 95 DREs; 3.19% of the total number of screenings). Postmandate, all enrollees would have prostate cancer screenings with no cost sharing, for a total of 461,992 PSA tests and DREs annually performed with no cost sharing (Table 1). Because of a lack of evidence in the research literature of cost sharing being a barrier to obtaining a PSA test or DRE, and with confirmatory input from the content expert, CHBRP projects no change in utilization postmandate in its analysis of the impact of AB 1520.[38]

On average, per-unit costs for PSA tests are $41 total, which includes $10 per enrollee for those that have cost sharing at baseline. Per-unit costs for DREs are an average of $8 total, which includes $1 per enrollee for those that have cost sharing at baseline (Table 1). The total per-unit costs are expected to remain the same postmandate as there is no change in utilization to affect total costs, and the cost sharing would be reduced to $0 for all enrollees.

AB 1520 would have an estimated overall change to annual expenditures of $35,000 (<0.0001%; Table 1). This is due to a $177,000 estimated increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by an estimated decrease in enrollee expenses for covered benefits of $142,000.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost related considerations for policymakers are discussed below.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% (see Table 1), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 1520.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 1520.

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

CHBRP is unaware of any cost shifts to other payers that are occurring due to the existence of cost sharing for enrollees who have cost sharing in their grandfathered DMHC-regulated plans or CDI-regulated policies.

[38] Personal communication with Dr. Mark Litwin, Chair of the Department of Urology at the University of California, Los Angeles, on March 18, 2021.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, AB 1520 would prohibit DMHC-regulated plans and CDI-regulated policies that provide coverage for prostate cancer screening from requiring cost sharing by enrollees with a prostate who are either aged 55 years or older, or aged 40 years or older and at high risk of prostate cancer, as defined by AB 1520.

Estimated Public Health Outcomes

The *Medical Effectiveness* section concludes that the evidence is *inconclusive* regarding the effectiveness of prostate cancer screening in preventing morbidity and mortality, and that there is *insufficient evidence* to determine whether cost sharing is a barrier to obtaining prostate cancer screening. As discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, at baseline, approximately 97% of enrollees have coverage with no cost sharing for prostate cancer screening; for the ~3% of screening tests that require cost sharing, CHBRP estimates an average $10 payment per prostate-specific antigen (PSA) test.

AB 1520 would eliminate an average $10 cost-share responsibility for the enrollees who used ~14,300 (of the ~444,700) PSA tests, postmandate. Based on best available evidence, CHBRP projects no change in utilization (Table 1). CHBRP found insufficient evidence to determine the impacts of cost sharing on health outcomes, access to care, and utilization of services. Therefore, in the first year postmandate, **CHBRP projects no measurable public health impact on access to or subsequent rates of prostate cancer screening.**

Although disparities related to prostate cancer screening exist among Black and Hispanic men, AB 1520 does not address the barriers that prevent these men from obtaining prostate cancer screening (i.e., medical mistrust, lack of health insurance and access to care, and fear of cancer diagnosis or manipulation of the prostate). Given these findings, in the first year postmandate, **CHBRP estimates no measurable public health impact from AB 1520 on disparities related to prostate cancer screening rates in California**.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 1520, which CHBRP defines as impacts occurring beyond the first 12 months after 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.

Long-Term Utilization and Cost Impacts

Utilization and Cost Impacts

The impacts of AB 1520 are unlikely to be different in subsequent years, assuming the same prostate cancer screening tools are available. Thus, CHBRP expects no change in utilization in the long term. Similarly, the potential expenditure increases as a result of removal of cost sharing for prostate cancer screening are likely to be similar in subsequent years.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12 months postmandate) to the public's health that would be attributable to the mandate, including impacts on social determinants of health, premature death, and economic loss.

In the case of AB 1520, CHBRP found insufficient evidence on the impacts of cost sharing for prostate cancer screening on health outcomes, access to care, and subsequent utilization of additional health services. In addition, CHBRP estimates there would be no change in the utilization in the long term. As such, CHBRP projects AB 1520 would have no measurable long-term public health impact on access to or subsequent rates of prostate cancer screening.

APPENDIX A TEXT OF BILL ANALYZED

On February 25, 2021, the California Assembly Committee on Health requested that CHBRP analyze AB 1520. On April 14, 2021, AB 1520 was amended, and the California Assembly Committee on Health requested that CHBRP analyze the version of AB 1520 amended on that date.

AMENDED IN ASSEMBLY APRIL 14, 2021

CALIFORNIA LEGISLATURE— 2021–2022 REGULAR SESSION

ASSEMBLY BILL **NO. 1520**

Introduced by Assembly Member Levine
(Principal coauthor: Senator Allen)
(Coauthor: Assembly Member Gipson)

February 19, 2021

An act to amend Section 1367.64 of the Health and Safety Code, and to amend Section 10123.83 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 1520, as amended, Levine. Health care coverage: prostate cancer: screening.

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 the screening and diagnosis of prostate cancer, when medically necessary and consistent with good professional practice. Existing law specifies that it does not prevent the application of deductible or copayment provisions for those services. Existing law requires an individual or small group health care service plan contract or health insurance policy 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 prohibit a health care service plan *contract* or a health insurance policy issued, amended, renewed, or delivered on or after January 1, 2022, from applying a deductible, ~~copayment,~~ *copayment,* or coinsurance to coverage for ~~preventive care~~ *specified* screening services for prostate cancer for an ~~enrolled~~ *enrollee* or insured who is 55 years of age or older or is 40 years of age or older and is high risk, as ~~defined.~~ *determined by their health care provider.*

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.

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

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As Amends the Law Today

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

SECTION 1. Section 1367.64 of the Health and Safety Code is amended to read:

1367.64. (a) Every individual or group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, or renewed on or after January 1, 1999, shall be deemed to provide coverage for the screening and diagnosis of prostate cancer, including, but not limited to, prostate-specific antigen testing and digital rectal examinations, when medically necessary and consistent with good professional practice.

(b) ~~Nothing in this section shall be construed to~~ *This section does not* establish a new mandated benefit or ~~to~~ prevent application of deductible or copayment provisions in a policy or plan, nor ~~shall this section be construed to~~ *does this section* require that a policy or plan be extended to cover any other procedures under ~~an individual or a group~~ *a* health care service plan contract. ~~Nothing in this section shall be construed to~~ *This section does not* authorize an enrollee to receive the services required to be covered by this section if those services are furnished by a nonparticipating provider, unless the enrollee is referred to that provider by a participating physician or nurse practitioner providing care.

(c) (1) Notwithstanding subdivision (b), a health care service plan contract, except a specialized health care service plan contract, that is issued, amended, or renewed on or after January 1, 2022, shall not apply a deductible, copayment, or coinsurance to coverage for ~~preventive care~~ screening services for prostate cancer *described in subdivision (a)* for an enrollee who meets either of the criteria in paragraph (2).

(2) This subdivision applies to both of the following:

(A) A person with a prostate who is 55 years of age or older.

(B) (i) A person with a prostate who is 40 years of age or older and who is high ~~risk.~~ *risk, as determined by the attending or treating health care provider.*

(ii) "High risk" ~~includes~~ *includes, but is not limited to,* a person with a prostate who is ~~AfricanAmerican,~~ *Black,* has a family history of prostate cancer, *has* a genetic predisposition to prostate cancer, or is a veteran.

(3) For high deductible plans, this subdivision is subject to federal guidance on the preventive care safe harbor for the absence of a preventive care deductible provided for under 26 ~~U.S.C.~~ *U.S.C. Sec.* 223(c)(2)(C).

SEC. 2. Section 10123.835 of the Insurance Code is amended to read:

10123.835. (a) ~~Every individual or group policy of disability insurance that covers hospital, medical, or surgical benefits~~ *A health insurance policy* that is issued, amended, or renewed on or after January 1, 1999, shall be deemed to provide coverage for the screening and diagnosis of prostate cancer, including, but not limited to, prostate-specific antigen testing and digital rectal examinations, when medically necessary and consistent with good professional practice.
(b) ~~Nothing in this section shall be construed to~~ *This section does not* require ~~an individual or group~~ *a health insurance* policy to cover the surgical and other procedures known as radical prostatectomy, external beam radiation therapy, radiation seed implants, and combined hormonal therapy, or to prevent application of deductible or copayment provisions contained in the policy, nor ~~shall this section be construed to~~ *does this section* require that coverage under ~~an individual or group~~ *a health insurance* policy *to* be extended to any other procedures.
~~(c)This section shall not apply to specified accident, specified disease, hospital indemnity, Medicare supplement, or long-term care health insurance policies.~~
~~(d)(1)Notwithstanding subdivision (b), an individual or group policy of disability insurance that covers hospital, medical, or surgical benefits~~
(c) (1) Notwithstanding subdivision (b), a health insurance policy that is issued, amended, or renewed on or after January 1, 2022, shall not apply a deductible, copayment, or coinsurance to coverage for ~~preventive care~~ screening services for prostate cancer *described in subdivision (a)* for an insured who meets either of the criteria in paragraph (2).
(2) This subdivision applies to both of the following:
(A) A person with a prostate who is 55 years of age or older.
(B) (i) A person with a prostate who is 40 years of age or older and who is high ~~risk.~~ *risk, as determined by the attending or treating health care provider.*
(ii) "High risk" ~~includes~~ *includes, but is not limited to,* a person with a prostate who is ~~AfricanAmerican,~~ *Black,* has a family history of prostate cancer, *has* a genetic predisposition to prostate cancer, or is a veteran.
(3) For high deductible plans, this subdivision is subject to federal guidance on the preventive care safe harbor for the absence of a preventive care deductible provided for under 26 ~~U.S.C.~~ *U.S.C. Sec.* 223(c)(2)(C).
(d) This section does not apply to specified accident, specified disease, hospital indemnity, Medicare supplement, or long-term care health insurance policies.

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

This appendix describes methods used in the literature review conducted for this report. A discussion of CHBRP's system for medical effectiveness grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of digital rectal exams (DREs) and prostate-specific antigen (PSA) tests for prostate cancer screening were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English. The search was limited to studies about digital rectal exams (DREs) and prostate-specific antigen (PSA) tests for prostate cancer screening methods published from 2018 to present. CHBRP relied on a systematic review published in 2018 for findings of studies published prior to 2018. Of the 147 articles found in the literature review, 17 were reviewed for potential inclusion in this report on AB 1520, and a total of 11 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on prostate cancer screening, were of poor quality, weak research design, or did not report findings from clinical research studies.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

Medical Effectiveness Review

The medical effectiveness literature review returned abstracts for 147 articles, of which 17 were reviewed for inclusion in this report. A total of 11 studies were included in the medical effectiveness review for AB 1520.

Medical Effectiveness 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*.[39] 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:

[39] Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence;*
- *Inconclusive 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.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive 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

African Americans
Blacks
Cancer Screening
Coinsurance
Comorbidity
Copayments (Insurance)
Cost Sharing
Death/Fatality Rate
Disparities
Early Detection of Cancer
Economic Aspects of Illness
Economics
Ethnic
False-Negative
False-Positive
Genetic Predisposition to Disease
Health Impact Assessment
Health Insurance Costs
Health and Life Quality
Health Outcomes
Hereditary Diseases
Insurance, Health, Reimbursement
Military Veterans
Minorities
Premature Death/Mortality
Prostate-Specific Antigen
Prostate cancer detection/diagnosis/screening/testing
Prostate Health Index
Prostatic Neoplasms
Prostatic Neoplasms/Diagnosis/Prevention & Control
PSA
Psychological Well-Being
Psychotherapeutic Outcomes
Radical Prostatectomy
Sexual Dysfunction, Male
United States Department of Veterans Affairs
Veterans

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

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[40] Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.[41]

This appendix describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

Analysis-Specific Data Sources

Current coverage of cost sharing for prostate cancer screening services for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 77% of commercial enrollees with health insurance that may be subject to state benefit mandates.

Analysis-Specific Caveats and Assumptions

Identification of Prostate-Specific Antigen Tests and Digital Rectal Exams

CHBRP examined Milliman's proprietary 2019 Consolidated Health Cost Guidelines™ Sources Database (CHSD) for enrollees with prostate exam procedure codes in California's commercial markets. The databases contain annual enrollment and paid medical and pharmacy claims for over 72 million commercially insured individuals covered by the benefit plans of large employers, health plans, and governmental and public organizations nationwide. The analysis of California's 2019 CHSD claims data for prostate exams required categorizing claims to estimate annual utilization rates and costs per service. Prostate exams were classified as either a PSA test or a DRE based on Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes. Prostate-specific laboratory services rendered on the same day as a PSA test were included in the cost of the PSA test.

CHBRP completed the following steps to identify male enrollees who received prostate exams:

- First, enrollees receiving prostate screening were identified. Claims were subset to only include members with the following HCPCS codes:
    - DRE: G0102
    - PSA test: G0103, 84152, 84153, 84154.
- Enrollees were identified as being high risk by having an increased risk due to personal, genetic, or family history, or due to being a veteran. These "high risk" statuses were identified by searching through each enrollee's 2019 claims for the following ICD-10 diagnosis codes in all diagnosis fields:
    - Personal history: Z8546

[40] CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[41] See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2021 Cost Analyses: Data Sources, Caveats, and Assumptions*.

  - Genetic history: Z1503
  - Family history: Z8042
  - Veteran: Z9182, Y991, Z5682
- Enrollees were further split into 40 to 54, 55 to 64, and 65+ age buckets. Enrollees aged 40 to 54 years were subset to only include those identified above as being high risk.

Baseline utilization — Prostate Exams

CHBRP conducted a survey of the largest DMHC- and CDI-regulated commercial plans and policies to determine the percent of enrollees with cost sharing for prostate exams. For enrollees in other market segments, CHBRP assumed that CalPERS enrollees were covered similarly to DMHC-regulated, large-group, nongrandfathered plans at 100% without cost sharing.

The proportion of enrollees using services is assumed to be similar to the proportion of commercial members in California identified in the 2019 CHSD database found to have received a prostate exam by type and age category.

Utilization data from the 2019 CHSD was trended forward three years to reflect the 2022 baseline. The utilization trend was based on data from the Milliman Health Cost Guidelines (HCG) professional trend. All prostate exams were trended by 1.5% per year.

Postmandate utilization — Prostate Exams

If passed, AB 1520 would eliminate all cost sharing for all plans that cover prostate exams. CHBRP assumed no cost sharing in the postmandate period. For enrollees currently subject to cost sharing, CHBRP assumed no increase in utilization postmandate.

Baseline cost — Prostate Exams

Using the methodology outlined in the Identification of Prostate-Specific Antigen Tests and Digital Rectal Exams section, the California average cost per identified user was calculated for commercial enrollees using trended 2019 CHSD cost data. Cost data from the 2019 CHSD was trended forward three years to reflect the 2022 baseline. The cost trend was based on data from the Milliman HCG professional trend. All prostate exams were trended by 4.5% per year.

Postmandate cost — Prostate Exams

Postmandate costs of prostate exams were assumed to be the same as in the baseline scenario.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Determining Public Demand for the Proposed Mandate

CHBRP does not expect demand to change due to the proposed mandate.

Determining Public Demand for the Proposed Mandate

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.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that in general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Second-Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 1520 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed; the utilization of any indirectly affected utilization; or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts of AB 1520 and determined they would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

APPENDIX D INFORMATION SUBMITTED BY OUTSIDE PARTIES

In accordance with the California Health Benefits Review Program (CHBRP) policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

The following information was submitted by Assemblymember Levine's office and ZERO – The End of Prostate Cancer in March 2021.

American Urological Association. *How Prostate Cancer Affects Your Constituents.* 2019.

Ansbaugh N, Shannon J, Mori M, Farris PE, Garzotto M. Agent Orange as a risk factor for high-grade prostate cancer. *Cancer*. 2013 Jul 1;119(13):2399-404.

Benjamins MR, Hunt BR, Raleigh SM, Hirschtick JL, Hughes MM. Racial Disparities in Prostate Cancer Mortality in the 50 Largest US Cities. *Cancer Epidemiology*. 2016 Oct;44:125-131.

Bloom JR, Stewart SL, Oakley Girvan I, Banks PJ, Chang S. Family history, perceived risk, and prostate cancer screening among African American men. *Cancer Epidemiol Biomarkers Prev*. 2006 Nov;15(11):2167-73.

Chamie K, DeVere White RW, Lee D, Ok JH, Ellison LM. Agent Orange exposure, Vietnam War veterans, and the risk of prostate cancer. *Cancer*. 2008 Nov 1;113(9):2464-70.

Department of Legislative Services, Maryland General Assembly. *Fiscal and Policy Note on Senate Bill 661*. 2020.

Dovey ZS, Nair SS, Chakravarty D, Tewari AK. Racial disparity in prostate cancer in the African American population with actionable ideas and novel immunotherapies. *Cancer Rep (Hoboken)*. 2021 Feb 17:e1341.

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Submitted information is available upon request. For information on the processes for submitting information to CHBRP for review and consideration please visit: www.chbrp.org/requests.html.

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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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