Key Findings

Analysis of California Assembly Bill 2516
Health Care Coverage: Human Papillomavirus

Summary to the 2021–2022 California State Legislature, April 15, 2022

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

SUMMARY

The version of California Assembly Bill (AB) 2516 analyzed by CHBRP would require DMHC-regulated plans and CDI-regulated policies to provide coverage for the human papillomavirus (HPV) vaccine for enrollees for whom it is approved by the FDA. Plans and policies would be prohibited from charging cost sharing for the HPV vaccine. The bill would also expand comprehensive clinical family planning services under the Family Planning, Access, Care, and Treatment (Family PACT) program to include the HPV vaccine for enrollees for whom the vaccine is approved by the FDA.

In 2023, of the 22.8 million Californians enrolled in state-regulated health insurance, all of them would have insurance subject to AB 2516.

Benefit Coverage: At baseline, 99.6% of enrollees have coverage that is fully compliant with AB 2516. The 0.41% of enrollees without coverage are enrolled in grandfathered health plans and policies. Postmandate, 100% of enrollees would have coverage for the HPV vaccine with no cost sharing. AB 2516 does not exceed the definition of essential health benefits (EHBs) in California.

Medical Effectiveness: For females vaccinated at age 26 or younger, CHBRP found *clear and convincing evidence* that the HPV vaccine is effective against high-grade cervical intraepithelial neoplasia (CIN), adenocarcinoma in situ (AIS), and cervical cancer. For females vaccinated after age 26, there is *limited evidence* that the HPV vaccine is effective against cervical lesions. There is *insufficient evidence* that HPV vaccines reduce the overall incidence of oral or oropharyngeal cancers after vaccination at any age. CHBRP found a *preponderance of evidence* that the HPV vaccine is effective at providing protection against HPV-related anogenital disease for males vaccinated at any age, and *clear and convincing evidence* the vaccine protects against genital warts in females and males vaccinated at age 26 or younger.

Cost and Health Impacts[1]: In 2023, AB 2516 would increase total net annual expenditures by $3,834,000 or 0.0026% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $3,975,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a decrease of $141,000 in enrollee cost-sharing for covered benefits.

Due to minimal changes in utilization of the HPV vaccine, CHBRP concludes that passage of AB 2516 would have no measurable short-term public health impact. The long-term public health impacts are mostly isolated to enrollees aged 9 to 26 years in grandfathered plans or policies who later received the vaccine due to the elimination of cost sharing. The larger population may benefit from reduced transmission of the disease in the larger community.

CONTEXT

Human papillomavirus (HPV) is a group of more than 200 viruses, 14 of which have been identified as high-risk and are associated with several types of cancers, including nearly all cervical cancers, and most anal, vaginal, penile, vulvar, head, and neck cancers. Depending on the type of HPV and the immune system of the individual, infection can cause no symptoms at all and completely resolve, lead to the development of genital warts, or persist and potentially develop into precancerous cell changes or cancer in later life.[2]

HPV is usually spread through sexual activity with an infected partner. It is the most common sexually transmitted infection in the United States, with an estimated 13 million new cases each year and will infect approximately 85% of the population at some point in their lifetime. Most individuals have been infected with HPV by age 27, and for this reason the HPV vaccine is recommended primarily for those aged 11 to 12 years, as the vaccine is most effective for individuals who have not yet been exposed to the virus (often occurring soon after initiating sexual activity).

[1] Similar cost and health impacts could be expected for the following year, though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.

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

The FDA has approved three HPV vaccines for use in the United States. Gardasil® has been approved for use in females and males aged 9 to 26 years, Gardasil® 9 has been approved for use in females and males aged 9 to 45 years, and Cervarix™ has been approved for use in females aged 9 to 25 years. However, only Gardasil® 9 is available on the market. Since FDA approval of the HPV vaccine in 2006, HPV infections associated with genital warts and most HPV-related cancers have dropped 88% among adolescent females and 81% among adult females, and cervical precancerous changes have decreased 40% among adult females.

The Affordable Care Act (ACA) requires nongrandfathered group and individual health plans and policies to provide coverage without cost sharing for certain preventive services, including those recommended by the Advisory Committee on Immunization Practices (ACIP). ACIP currently recommends HPV vaccination at age 11 or 12, although vaccination may begin at age 9. Catch-up HPV vaccination is also recommended for all individuals through age 26. For adults aged 27 to 45 years, ACIP recommends shared clinical decision-making for potential HPV vaccination.

BILL SUMMARY

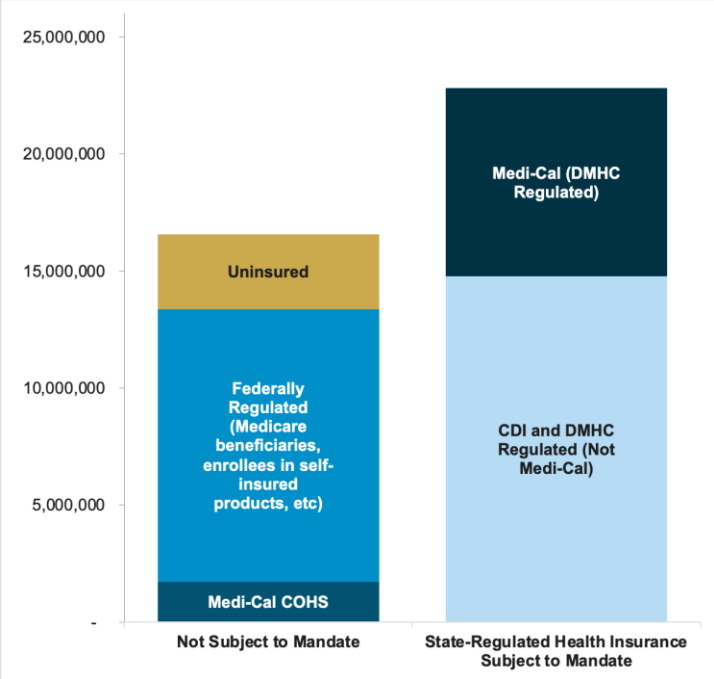
AB 2516 would require DMHC-regulated plans and CDI-regulated policies to provide coverage for the human papillomavirus (HPV) vaccine for enrollees for whom it is approved by the FDA. Plans and policies would be prohibited from charging cost sharing for the HPV vaccine. AB 2516 would also expand comprehensive clinical family planning services under the Family PACT program to include the HPV vaccine for enrollees for whom the vaccine is approved by the FDA.

Figure A notes how many Californians have health insurance that would be subject to AB 2516 (approximately 57.3% of Californians).

Family PACT

Family PACT is a limited benefit program that provides Californians with incomes below 200% of the federal poverty level (FPL) and no other coverage for family planning services access to free family planning services, sexually transmitted infection testing and treatment, cervical cancer screening, and limited fertility services. In 2019, Family PACT provided services to 695,245 individuals.

Figure A. Health Insurance in CA and AB 2516



Source: California Health Benefits Review Program, 2022.

IMPACTS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

CHBRP estimates that, at baseline, 99.6% of enrollees in DMHC-regulated plans and CDI-regulated policies have coverage of the HPV vaccine without cost sharing. Enrollees without coverage or coverage with cost sharing for the HPV vaccine have DMHC-regulated plans or CDI-regulated policies that are "grandfathered" under the provisions of the ACA, and so are able to retain cost sharing for vaccinations. Postmandate, 100% of enrollees would have coverage for HPV vaccines with no cost sharing.

Utilization

At baseline, there are 120.9 HPV vaccine shots per 1,000 female enrollees aged 9 to 26 years, and there are 113 HPV vaccines per 1,000 male enrollees aged 9 to 26 years. Among those aged 27 to 45 years, there are 6.1 HPV vaccines per 1,000 female enrollees and 4.4 HPV vaccines per 1,000 male enrollees.

Postmandate, utilization for females and males aged 9 to 26 years would increase slightly, as the utilization rate

for the 0.4% of enrollees in DMHC-regulated plans or CDI-regulated policies who previously had cost sharing would increase to match those who did not have cost sharing at baseline. CHBRP estimates that the resulting new average utilization would increase by 1.5 per 1,000 enrollees from 120.9 to 122.3 for females aged 9 to 26 years and by 1.3 from 113 to 114.4 for males aged 9 to 26 years. CHBRP estimates that the change in benefit coverage and reduction in cost sharing for those aged 27 to 45 years would result in no measurable in utilization since the medical guidelines for shared clinical decision-making will keep utilization down to those who are both medically eligible and want to obtain the series of HPV vaccination shots. Postmandate, the average utilization rate for the HPV vaccine for both males and females aged 27 to 45 years will have no measurable change.

Among enrollees with coverage at baseline, cost sharing was present for 0.7 vaccine injections per 1,000 females aged 9 to 26 years, 1.1 vaccines per 1,000 males aged 9 to 26 years, 0.1 vaccines per 1,000 females aged 27 to 45 years, and 0.2 vaccines per 1,000 males aged 27 to 45 years. Postmandate, no enrollees would have cost sharing for HPV vaccine shots. This equates to approximately 9,400 vaccine shots that had cost sharing for HPV vaccines at baseline.

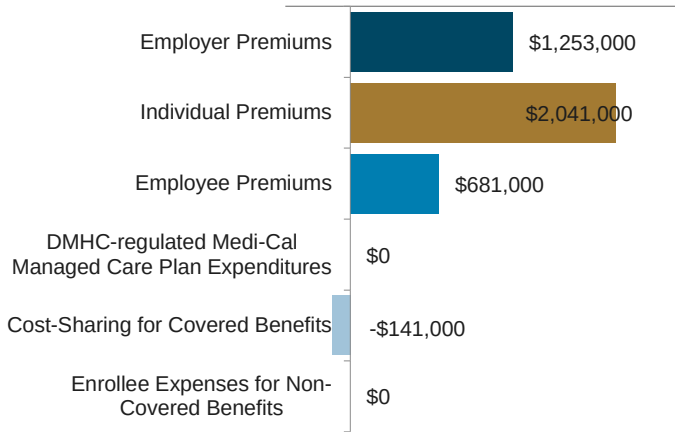
Expenditures

AB 2516 would increase total net annual expenditures by $3,834,000 or 0.0026% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $3,975,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a decrease of $141,000 in enrollee expenses for covered and/or noncovered benefits.

Changes in expenditures are due to (1) a shift of cost sharing for enrollees with cost sharing at baseline to no cost sharing postmandate and (2) new utilization of the HPV vaccine.

For enrollees with cost sharing at baseline, average annual out-of-pocket expense reductions range between $102 and $262. Cost sharing amounts are dependent upon an enrollee's plan or policy design. For the enrollees with cost sharing, on average, 81% is due to deductible, 17% is due to coinsurance, and 2% is due to copayments.

Figure B. Expenditure Impacts of AB 2516



Source: California Health Benefits Review Program, 2022.

Medi-Cal

Medi-Cal provides coverage without cost sharing for the HPV vaccine at baseline. As such, no impact on this population by AB 2516 is projected.

CalPERS

CalPERS provides coverage without cost sharing for the HPV vaccine at baseline. As such, no impact on this population by AB 2516 is projected.

Covered California – Individually Purchased

Individually purchased Covered California plans or policies provide coverage for the HPV vaccine at baseline. As such, no impact on this population by AB 2516 is projected.

Family PACT

CHBRP is unable to estimate how many Family PACT enrollees are vaccinated with the HPV vaccine at baseline, and how many future enrollees would receive this service should AB 2516 pass.

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 2516.

Medical Effectiveness

CHBRP examined literature on the clinical effectiveness of the HPV vaccine for preventing HPV-related cancers and HPV-related genital warts in both females and males.

CHBRP found there is:

- *Clear and convincing evidence*[3] that the HPV vaccine is effective at preventing high-grade cervical intraepithelial neoplasia (CIN), adenocarcinoma in situ (AIS), and cervical cancer for females vaccinated at age 26 or younger, and at preventing HPV-related anogenital warts for both females and males vaccinated at age 26 or younger.
- *Preponderance of evidence*[4] that the HPV vaccine is effective at preventing HPV-related anogenital disease for males vaccinated at age 26 or younger.
- *Limited evidence*[5] that the HPV vaccine is effective at preventing cervical lesions for females vaccinated at age 27 or older.
- *Insufficient evidence*[6] that the HPV vaccine is effective at preventing oral or oropharyngeal HPV infections for females and males vaccinated at any age, as well as for preventing genital warts for females males vaccinated at age 27 or older.

Table A provides a visual summary of CHBRP's evidence findings by age at vaccination and infection/disease type.

Table A. Summary of Effectiveness of the HPV Vaccine in Preventing HPV Infection and Related Cancers, by Age at Vaccination

	Vaccinated at age 26 or younger	Vaccinated at age 27 or older
Cervical cancer (females)	Clear and convincing evidence, effective	Limited evidence, effective
CIN (females)	Clear and convincing evidence, effective	Limited evidence, effective
AIS (females)	Clear and convincing evidence, effective	Limited evidence, effective
Oral or oropharyngeal infections (females/males)	Insufficient evidence	Insufficient evidence
Anogenital disease (males)	Preponderance of evidence, effective	Preponderance of evidence, effective
Anogenital warts (females/males)	Clear and convincing evidence, effective	Insufficient evidence

Source: California Health Benefits Review Program, 2022.
Notes: Anogenital diseases include anal intraepithelial neoplasia (AIN) and anal cancer. Anogenital warts are the same as genital warts.

Key: AIS= adenocarcinoma in situ; CIN= high-grade cervical intraepithelial neoplasia.

Public Health

In the first year postmandate, CHBRP projects AB 2516 will have no measurable impact on public health. Postmandate, approximately 4,078 additional vaccinations would occur among male enrollees and 4,367 additional vaccinations would occur among female enrollees aged 9 to 26 years because of increased coverage and reduced cost sharing. Although the HPV vaccine is found to be medically effective, CHBRP concludes that passage of AB 2516 would have no measurable short-term public health impact due to

[3] *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.
[4] *Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.
[5] *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.
[6] *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.

minimal change in overall utilization and lack of manifest of vaccine effects in the short term. For this reason, CHBRP also concludes that AB 2516 would have no measurable impact on disparities in vaccination status or health outcomes (by sex, race/ethnicity, or sexual orientation/gender identity). It also would have no measurable impact on premature death and societal economic losses.

At the person level, one potentially detectable vaccine impact in the first year following vaccination would be a potential reduction in genital warts.

While elimination of cost sharing eliminates a barrier for a small group of enrollees who currently are subject to cost sharing, other barriers to HPV vaccination may continue to persist postmandate. These may include prior authorization requirements, transportation issues to complete the entire vaccine series, parental disagreement about whether or not a minor enrollee should receive the vaccine, or individual decisions not to receive the vaccine.

Long-Term Impacts

CHBRP estimates that increases in utilization of the HPV vaccine among enrollees in grandfathered plans or policies and who had cost sharing at baseline will lead to future decreases in cervical cancer, as well as other HPV-related genital diseases. The decreases in HPV-related disease and cancer would lead to decreases in tests, treatments, and services related to these conditions over time. Reductions in the incidence of HPV-related diseases will be associated with decreases in costs of tests, treatments, and services related to those conditions.

Due to minimal changes in utilization of the HPV vaccine, CHBRP concludes that passage of AB 2516 would have no measurable long-term public health impact. The long-term public health impacts are mostly isolated to enrollees aged 9 to 26 years in grandfathered plans or policies who later received the vaccine due to the elimination of cost sharing. The larger population may benefit from reduced transmission of HPV infections in the larger community.

One provision of AB 2516 that could not be quantified by CHBRP was the expansion of services covered in Family PACT. Because Family PACT primarily serves low-income persons of color in California regardless of immigration status, there is the potential to increase vaccination rates among this population. However, the extent to which vaccination rates would increase and the resulting impact on disparities and social determinants of health is unknown.

Essential Health Benefits and the Affordable Care Act

The HPV vaccine is currently covered by California's EHB benchmark plan and is recommended by ACIP. Therefore, AB 2516 appears not to exceed the definition of EHBs in California.