CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

EXECUTIVE SUMMARY
Analysis of Senate Bill 158: Human Papillomavirus Vaccination

A Report to the 2009-2010 California Legislature
April 13, 2009

CHBRP 09-05

The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. In 2002, CHBRP was established to implement the provisions of Assembly Bill 1996 (California Health and Safety Code, Section 127660, et seq.) and was reauthorized by Senate Bill 1704 in 2006 (Chapter 684, Statutes of 2006). The statute defines a health insurance benefit mandate as a requirement that a health insurer or managed care health plan (1) permit covered individuals to obtain health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 158: Human Papillomavirus Vaccination

The California Legislature has asked the California Health Benefits Review Program (CHBRP) to conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 158. In response to a request from the California Senate Health Committee on February 13, 2009, CHBRP undertook this analysis pursuant to the provisions of SB 1704 (Statutes of 2006, Chapter 684) as chaptered in Section 127600, et seq., of the California Health and Safety Code.

SB 158 would amend Section 1367.66 of the Health and Safety Code and Section 10123.18 of the Insurance Code. These sections of the Health and Safety Code and Insurance Code currently mandate coverage for cervical cancer screening tests. SB 158 would amend current law to require health plans and insurance policies that include coverage for treatment of or surgery for cervical cancer to provide coverage for a human papillomavirus (HPV) vaccination upon referral. SB 158 is intended to prevent cervical cancer and other conditions caused by HPV by requiring health insurance to cover HPV vaccinations approved by the U.S. Food and Drug Administration (FDA).

HPV is the most common sexually transmitted infection in the United States. It is estimated that more than 80% of sexually active women will be infected with HPV at some point in their lifetime. HPV infection has been identified as a necessary condition for cervical cancer. This means that only in rare cases is cervical cancer diagnosed in women not infected with HPV. However, cervical cancer is a relatively rare cancer in the United States, making up approximately 1% of all new cancers cases each year.

There is currently one quadrivalent vaccine—meaning that it is designed to protect against four strains of HPV—approved by the FDA. The vaccine, Gardasil by Merck, protects girls and young women from the two HPV strains that cause 70% of cervical cancers and the two HPV strains that cause 90% of genital warts. Materials in support of another HPV vaccine, Cervarix by GlaxoSmithKline, have been submitted to the FDA for approval. This bivalent vaccine is designed to protect against the two HPV strains that cause 70% of cervical cancers.

Medical Effectiveness

- The *Medical Effectiveness* section summarizes the published literature on the quadrivalent HPV vaccine (Gardasil) that has been approved by the FDA and the bivalent vaccine (Cervarix) that is under review by the FDA.

- A full course of the quadrivalent HPV vaccine requires the injection of three doses of the vaccine over a six-month period.

- All clinical trials of the quadrivalent and bivalent HPV vaccines published to date were sponsored by their manufacturers.

- While the quadrivalent HPV vaccine is recommended for females aged 11 to 26 years, the three major clinical trials on the vaccine limited enrollment to females aged 15 to 26 years.

- The only trial to enroll girls younger than 15 has only published results on the vaccine's efficacy one year following vaccination. Long-term efficacy in this population is unknown.

- Interim results from the largest clinical trial of the quadrivalent vaccine published to date indicate that **among females who complete all three doses of the vaccine and were not previously exposed to HPV 16 or 18**, the vaccine provides for reductions in precancerous cervical lesions of 98% for lesions caused by the HPV types 16 and 18. However, the efficacy of the vaccine against precancerous lesions associated with all types of HPV has not been reported for this population.

- Interim results of the largest clinical trial of the quadrivalent vaccine published to date indicate that the vaccine is less effective among females who have not completed all three doses of the vaccine and/or were exposed to HPV prior to vaccination. Analyses that included all women who received at least one dose of the vaccine regardless of prior exposure to HPV report that the vaccine provides for the following reductions in precancerous cervical lesions:

    - 44% reduction in precancerous lesions caused by the HPV types **targeted** by the vaccine, and
    - 17% reduction in precancerous lesions regardless of associated HPV type, **including those not targeted** by the vaccine. Of note, the overall effect of vaccination on what many experts consider to be the most proximal cervical cancer precursor lesion (carcinoma *in situ*, or cervical intraepithelial neoplasia grade 3) was not statistically significant.

- Interim results from the largest clinical trial of the quadrivalent vaccine suggest that the vaccine prevents precancerous vaginal and vulvar lesions. As with cervical cancer lesions, the vaccine is less effective among females who do not receive all three doses of the vaccine or are exposed to HPV prior to vaccination.

- The quadrivalent vaccine provides protection against anogenital warts, but findings from the clinical trials do not indicate what proportion of females enrolled in the trials were concerned about their anogenital warts.

- The approved quadrivalent vaccine appears safe at 5 years postvaccination with minimal side effects such as transient injection-site discomfort common to many vaccines.

- Duration of protection is unknown beyond five years. Ongoing Phase 3 trials are monitoring durability to assess the need for a future booster vaccination.

- Because the vaccine does not provide complete protection against all types of HPV associated with cervical cancer, Papanicolaou (Pap) tests remain recommended to ensure that precancerous cervical lesions are detected and treated early.

Utilization, Cost, and Coverage Impacts

Coverage

- About 21,340,000 enrollees are in health plans or policies subject to SB 158. This includes approximately 3,348,000 females aged 11 to 26 years.

- An estimated 99.5% of enrollees currently have coverage for HPV vaccination. If the mandate were to become law, an additional 17,000 or 0.5% would gain coverage.

Utilization

- An HPV vaccine has been available since June 2006. Utilization rates for new vaccines are dynamic within the first few years of availability, and are likely to be higher at onset and to diminish over time as pent-up demand decreases and equilibrium is achieved.

- CHBRP estimates that by 2010, and before SB 158 would go into effect, approximately 33.0% of insured females aged 11 to 26 years would have been vaccinated for HPV. CHBRP estimates that among the newly covered population of insured females, 19.0% of those aged 11 to 18 years and 13% of those aged 19 to 26 years would be vaccinated in 2010 and after the implementation of SB 158.

- An additional 2,500 or 1.4% of insured females aged 11 to 26 years are estimated to receive the HPV vaccine in 2010 after SB 158 is implemented.

Costs

- The expenditures presented in this report are projected for the year following the implementation of the mandate and are likely to diminish over time as more older females are vaccinated. Over time (assuming that vaccination guidelines remain the same) primarily girls aged 11 to 12 years would obtain the vaccine on an ongoing basis. However, some girls older than 12 may receive HPV vaccination in their later teens due to various considerations preventing early vaccination.

- The unit cost of vaccination using Gardasil, the only HPV vaccine currently approved by the FDA, is estimated at $468 for those covered by private insurance, which includes the cost of the three-dose vaccine and the cost of administration of the vaccine.

- The increase in expenditures is limited to health policies regulated by the California Department of Insurance (CDI) in the individual and the large group market segments. This is because these are the market segments that currently have gaps in coverage for female enrollees aged 11 to 26 years.

- The overall increase in expenditures due to SB 158 is estimated at $1,625,000, or 0.0019%, in total California health care expenditures in the year following the mandate.

- The increase in premium expenditures is $1,357,000, or 0.0228%, in the individual market and $84,000, or 0.0002%, in the large group market.

- Employee share of premiums is expected to increase by $24,000, or 0.0002%.

- Out-of-pocket costs in the form of copayments and deductibles are expected to increase by $345,000, or 0.0054%.

- Because plans regulated by the Department of Managed Health Care (DMHC), CalPERS, and other public managed care programs currently have coverage for the vaccine, no cost increases are expected for these plans due to SB 158.

- Existing studies indicate that HPV vaccination, primarily of females aged 12 years, is cost-effective. Estimated cost-effectiveness ratio of vaccination ranges from $2,964 to $43,600 per quality-adjusted life year gained for 12-year-old girls. This means $2,964 to $43,600 in vaccinations would have to be spent to save a quality-adjusted life-year.

Public Health Impacts

- HPV is the most common sexually transmitted infection in the United States, with over 80% of sexually active women infected at some point in their lifetime. It is estimated that 3.4% of females aged 14 to 59 years are infected with one of the four strains of HPV that the current FDA-approved vaccine targets.

- Models predict that vaccinating a cohort of 12-year-old girls would result in a reduction in cervical cancer cases by 36% to 62% over the course of the lifetime of the cohort. Catch-up vaccination of older females is predicted to have a lower efficacy rate due to higher rates of prior exposure in this group. Thus, assuming 2,500 additional females get vaccinated in the first year after passage of the mandate, between 8 and 13 cases of cervical cancer could be prevented.

- In subsequent years, after catch-up vaccinations are complete, the number of additional females getting vaccinated as a result of the mandate would decrease to approximately 350, preventing one to two cases of cervical cancer over the lifetime of these females.

- It is possible that a reduction in cases of anal, vulvar, vaginal, penile, or oral cavity and pharynx cancer due to HPV vaccination would occur as a result of this mandate, as well.

- Blacks and Hispanics have higher mortality rates from cervical cancer compared to other racial/ethnic groups. Over time, as researchers are able to assess differences in the vaccination rates across racial and ethnic groups, the potential for the HPV vaccine to reduce disparities in health outcomes related to HPV infection will be clearer. Therefore, the extent to which this mandate would reduce these disparities is unknown.

- CHBRP estimates that, as a result of this mandate, three to five deaths could be prevented over the lifetime of women vaccinated in the first year, yielding a total savings of 80 to 140 person years, valued at an amount between $1.3 and $2.2 million.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of SB 158

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Total population in plans subject to state regulation (a)	21,340,000	21,340,000	0	0%
Total population in plans subject to SB 158	21,340,000	21,340,000	0	0%
Number of females aged 11 to 26 in plans subject to SB 158				
Covered	3,331,000	3,348,000	17,000	0.5%
No coverage	17,000	-	-17,000	-100%
Percentage of females aged 11 to 26 in plans subject to SB 158				
Covered	99.5%	100.0%	0.5%	0.5%
No coverage	0.5%	0.0%	-0.5%	-100%
Utilization and cost				
Number of females aged 11 to 26 vaccinated annually	181,100	183,600	2,500	1.4%
Average per unit cost (commercial plans)	$468	$468	-	0%
Expenditures				
Premium expenditures by private employers for group insurance	$50,546,207,000	$50,546,291,000	$84,000	0.0002%
Premium expenditures for individually purchased insurance	$5,944,229,000	$5,945,586,000	$1,357,000	0.0228%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM or MRMIP (b)	$13,475,994,000	$13,476,018,000	$24,000	0.0002%
CalPERS employer expenditures (c)	$3,161,160,000	$3,161,160,000	$0	0.0000%
Medi-Cal state expenditures	$4,112,865,000	$4,112,865,000	$0	0.0000%
Healthy Families state expenditures	$643,247,000	$643,247,000	$0	0.0000%
Individual out-of-pocket expenditures for HPV vaccine such as deductibles and copayments	$6,384,077,000	$6,384,422,000	$345,000	0.0054%
HPV vaccination expenditures paid by individuals not covered for HPV vaccine	$185,000	$0	-$185,000	-100%
Total annual expenditures	$84,267,964,000	$84,269,589,000	$1,625,000	0.0019%

Source: California Health Benefits Review Program, 2009.
Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) individuals enrolled in health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment sponsored insurance.
(b) Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public insurance.
(c) Of the CalPERS employer expenditures, about 59% would be state expenditures for CalPERS members who are state employees, however CHBRP estimates no impact of the mandate on CalPERS employer expenditures.
Key: CalPERS = California Public Employees' Retirement System.

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Edward Yelin, PhD, Janet Coffman, MPP, PhD and Mi-Kyung (Miki) Hong, MPH, of the University of California, San Francisco, prepared the medical effectiveness analysis. Min-Lin Fang, MLIS, of the University of California, San Francisco, conducted the literature search. Sara McMenamin, MPH, PhD, and Helen Halpin, ScM, PhD, of the University of California, Berkeley, prepared the public health impact analysis. Gerald Kominski, PhD, and Nadereh Pourat, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Robert Cosway, FSA, MAAA of Milliman, provided actuarial analysis. George Sawaya, MD, of the University of California, San Francisco, provided technical assistance with the literature review and expert input on the analytic approach. Susan Philip, MPP, and Angela Killilea of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Sarah Ordódy, provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and members of the CHBRP Faculty Task Force, Theodore Ganiats, MD, of the University of California, San Diego, and Richard Kravitz of the University of California, Davis, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

CHBRP gratefully acknowledges all of these contributions but assumes full responsibility for all of the report and its contents. Please direct any questions concerning this report to:

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California Health Benefits Review Program Committees and Staff

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

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

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

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