REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

MANDATED COVERAGE FOR HUMAN PAPILLOMAVIRUS (HPV) VACCINATIONS
House Bill 2877

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2008

January 4, 2008

To: The Honorable Timothy M. Kaine
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to § 2.2-2504 and § 2.2-2505 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of House Bill 2877 regarding coverage for human papillomavirus (HPV) vaccinations.

Respectfully submitted,

R. Lee Ware
Chairman
Special Advisory Commission on
Mandated Health Insurance Benefits

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INTRODUCTION

During the 2007 Session of the General Assembly, the House Committee on Commerce and Labor referred House Bill 2877 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission). House Bill 2877 was introduced by Delegate A. Donald McEachin.

The Advisory Commission held a hearing on September 20, 2007 in Richmond to receive public comments on House Bill 2877. Written comments included the signatures of 21 supporters of the bill. The Virginia Association of Health Plans (VAHP) addressed the Advisory Commission and submitted written comments in opposition to House Bill 2877.

The Joint Legislative Audit and Review Commission (JLARC) staff of the Virginia General Assembly prepared a "Review of House Bill 2877, Mandated Coverage of Human Papillomavirus (HPV) Vaccine" pursuant to §§ 2.2-2503 and 30-58.1 of the Code of Virginia. A copy of the evaluation is available on the JLARC website at http://jlarc.state.va.us.

SUMMARY OF PROPOSED LEGISLATION

House Bill 2877 would amend and reenact § 38.2-4319 of the Code of Virginia and add § 38.2-3418.15, which would mandate coverage for the cost of the HPV vaccinations. Insurers proposing to issue individual or group accident and sickness policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporations providing individual or group subscription contracts; and health maintenance organizations (HMOs) providing health care plans are required to provide coverage for the cost of human papillomavirus (HPV) vaccinations for women in accordance with recommendations of the Center of Disease Control's Advisory Committee on Immunization Practices. The bill prohibits insurers, corporations, or HMOs from imposing any copayment, fee, policy year or calendar year, or other durational limit or maximum for benefits or services that is not equally imposed on all individuals in the same benefit category. The bill applies to policies, contracts or plans delivered, issued for delivery, reissued, or extended on or after January 1, 2008, or at any time thereafter when any term of the policy, contract or plan is changed or premium adjustments are made. The bill does not apply to short-tem travel, accident only, limited or specified disease, or individual conversion policies or contracts, or policies or contracts designed for issuance to persons eligible for Medicare, or similar coverage under government plans.

CURRENT LEGISLATION

House Bill 2035 will become effective October 1, 2008. The bill amends and reenacts § 32.1-46 of the Code of Virginia to add human papillomavirus (HPV) vaccine to the required vaccines for school-aged children. The vaccine requires three doses of properly spaced HPV injections for females. The first dose shall be administered before

the child enters the sixth grade. A parent or guardian, at the parent or guardian's sole discretion, may elect for their child not to receive the HPV vaccine, after having reviewed materials describing the link between the HPV and cervical cancer approved by the Board of Health.

HUMAN PAPILLOMAVIRUS (HPV)

A report to the Joint Commission on Health Care (JCHC) on September 19, 2007, by Dr. Jennifer L. Young, MD, Fellow Gynecologic Oncology, University of Virginia showed that HPV is the most common sexually transmitted disease affecting 6.2 million Americans per year. The prevalence rate is 20 million cases in the United States. The lifetime risk of women acquiring the disease is 80% by age 50. The prevalence for sexually active teenagers is 61-82%. **[1]**

HPV is a group of Deoxyribonucleic acid (DNA) viruses that cause a variety of epithelial neoplasia. Approximately 80 viruses have been fully identified. Another 30 types have been detected but not fully described. Twenty-three types infect almost exclusively the skin of the lower genital tract. The remaining types infect skin on other areas of the body, including hands, feet, etc. **[2]**

Genital HPV infections affect approximately 75% of men and women in the US between the ages of 15 and 50. In 2005, the National Toxicology Program declared HPV an official carcinogen, indicating that it was as dangerous as asbestos. **[3]**

The virus is most strongly associated with cervical cancer, with HPV DNA found in up to 99.7 percent of these cancers. HPV types have been divided into high and low risk, based on their association with cervical carcinoma and precursor lesions. The most common low-risk types include 53, 61, 62, and 71. Low-risk types 6 and 11 are associated with external genital warts. Types 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68, 73, and 82 are considered high-risk types, because they have been associated with cervical cancer or squamous intraepithelial lesions. Highest risk is associated with types 16 and 18, which some data indicate causes approximately 75 percent of cervical cancers. The HPV virus is also associated with other carcinomas, such as vulvar, vaginal, anal, penile, and oropharyngeal cancers. [3] Other sources indicate HPV type 16 accounts for approximately 50% of all cervical cancers and HPV types 18, 31, 33, and 44 together account for approximately 20%. **[4]**

A Pap test effectively detects not only cervical cancer, but also changes in cervical cells that suggest cancer may develop in the future. Limited access to Pap tests result in higher rates of cervical cancer. Data shows that in 2002, more than 50 million Pap tests were administered and additional colposcopic follow-up and treatment was required. **[5]** One study concluded that 50-70% of women diagnosed with cervical cancer had not had a pap test within the preceding 5 years.

HPV infections are thought to be either cleared by the immune system or forced into a clinically latent state. It is inconclusive how long latency can last. Eighty percent

of HPV infections disappear from the body spontaneously. Additionally, studies show that 91 percent of new HPV infections will clear from the body's system within two years. The median duration of HPV infection was 8 months. **[6]** Within 24 months of initially acquiring HPV, the infection persisted in 9% resulting in genital warts, cervical dysplasia or cervical cancer. **[7]**

Cervical dysplasia resulting from HPV infection is also more likely to not advance or persist unchanged than to progress to invasive cancer. But, once HPV infection is present, there is no medical treatment to rid the body of the virus. Current treatments are directed at addressing the precancerous conditions or genital warts resulting from HPV infection. **[8]**

BACKGROUND INFORMATION ON VACCINE

The Centers for Disease Prevention and Control (CDC) states the following on its website:

> In 2006, the Food and Drug Administration (FDA) approved and licensed the first vaccine developed to prevent cervical cancer and other diseases in females caused by certain types of HPV. The quadrivalent vaccine, Gardasil®, protects against four HPV types (6, 11, 16, 18), which are responsible for 70% of cervical cancers and 90% of genital warts. Also in June, 2006, the Advisory Committee on Immunization Practices (ACIP) voted to recommend use of this vaccine in females, ages 9-26 years. This prophylactic vaccine, made from non-infectious HPV-like particles (VLP), is promoted as a prevention of HPV and associated conditions. The vaccine will not replace other prevention strategies since it will not work for all genital HPV types.
>
> **Provisional HPV Vaccine Recommendations**
> The HPV vaccine is recommended for 11- to 12-year-old girls, but can be administered to girls as young as 9 years of age. The vaccine also is recommended for 13- to 26-year-old females who have not yet received or completed the vaccine series. Ideally, the vaccine should be administered before onset of sexual activity. However, females who are sexually active also may benefit from vaccination. Females who have not been infected with any vaccine HPV type would receive the full benefit of vaccination. Females who already have been infected with one or more HPV types would still get protection from the vaccine types they have not acquired. Few young women are infected with all four HPV types in the vaccine. Currently, there is no test available for clinical use to determine whether a female has had any or all of the four HPV types in the vaccine.
>
> **HPV Vaccine Delivery (Provisional Recommendations)**
> The vaccine should be delivered through a series of three intra-muscular injections over a six-month period. The second and third doses should be given two and six months after the first dose. The vaccine may be

administered at the same visit as other age-appropriate vaccines, such as Tdap, Td, MCV4, and hepatitis B vaccines.

The HPV vaccine may be given to females who have an equivocal or abnormal Pap test, a positive Hybrid Capture II® high risk test, or genital warts. However, women should be advised that data does not indicate that the vaccine will have any therapeutic effect on existing Pap test abnormalities, HPV infection or genital warts. Lactating women can receive the HPV vaccine. Immunocompromised females, either from disease or medication, can receive this vaccine; however, the immune response to vaccination and vaccine efficacy might be less than in immunocompetent females.

The HPV vaccine is not recommended for use in pregnancy. The vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events to the developing fetus. However, data on vaccination in pregnancy is limited. The HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to yeast or to any vaccine component. The HPV vaccine can be administered to people with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections, with or without fever). Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves.

Cervical cancer screening recommendations have not changed for females who receive the HPV vaccine. Vaccine providers should notify vaccinated women that: (i) they should continue to receive regular cervical cancer screening because the vaccine will NOT provide protection against all types of HPV that cause cervical cancer; (ii) women may not receive the full benefits of the vaccine if they do not complete the vaccine series; and (iii) women may not receive the full benefits of the vaccine if they receive the vaccine after they have already acquired a vaccine HPV type.

Vaccine providers should notify vaccinated women that they should continue to practice protective sexual behaviors (e.g., abstinence, monogamy, limiting the number of sex partners, and using condoms, which may have a protective effect on HPV acquisition, reduce the risk for HPV-associated diseases, and mitigate the adverse consequences of infection with HPV), since the vaccine will *not* prevent all cases of genital warts—nor will it prevent other sexually transmitted infections (STIs). **[9]**

MEDICAL EFFICACY

The HPV vaccine works to guard against viral types 6, 11, 16, 18 by creating antibodies to protect the body and prevent the HPV virus from infecting cells and developing the cervical cell changes seen on pap tests that can lead to cancer.

Although the vaccine can prevent HPV infection, it is not known if it can eliminate existing cervical cell changes due to HPVs. **[10]**

MERCK FUTURE II studies show Gardisil to be 95% effective in preventing HPV infection and 98.5% effective in preventing persistent disease necessary for cervical cancer. Studies show that the vaccine is most effective when given prior to the onset of sexual activity. **[11]**

The Centers for Disease Control (CDC) states the following on its website regarding the efficacy of the HPV vaccine:

> **HPV Vaccine Efficacy**
> The efficacy of this vaccine has mainly been studied in young women (16-26 years of age) who previously had not been exposed to any of the four HPV types in the vaccine. These clinical trials have demonstrated 100% efficacy in preventing cervical precancers caused by the targeted HPV types, and nearly 100% efficacy in preventing vulvar and vaginal precancers and genital warts caused by the targeted HPV types.
>
> The vaccine has no therapeutic effect on HPV-related disease. If a girl or woman is already infected with one of the HPV types in the vaccine, the vaccine will not prevent disease from that type. The ACIP recommendation for vaccine use in girls as young as 9 years of age is based on 'bridging' immunogenicity and safety studies, which were conducted in about 1,100 females, 9- to 15 years of age. These studies demonstrated that over 99% of study participants developed antibodies after vaccination. Concentration of antibodies was higher for young girls than for older females participating in the efficacy trials.
>
> While it is possible that vaccination of males with the quadrivalent vaccine may offer direct health benefits to males and indirect health benefits to females, there are currently no efficacy data available to support use of HPV vaccine in males. Efficacy studies in males are ongoing.
>
> **Duration of Vaccine Protection**
> The duration of vaccine protection is unclear. Current studies (with five-year follow-up) indicate that the vaccine is effective for at least five years. There is no evidence of waning immunity during that time period. This information will be updated as additional data regarding duration of immunity become available. It is inconclusive if boosters of HPV vaccine may be needed. **[12]**

MERCK FUTURE II studies conclude the younger in age a recipient is when vaccinated, the more pronounced the immune response. **[13]** The ACIP recommendation to immunize young girls capitalizes on the low likelihood of prior sexual activity in early-adolescent girls and facilitates the delivery of two other recommended vaccines (i.e., tetravalent meningococcal conjugate vaccine [MCV4;

Menactra] and tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis booster [Tdap; Boostrix, Adacel]). These three vaccines provide the opportunity for important anticipatory guidance during early adolescence. **[14]**

The American Cancer Society (ACS) does not find sufficient evidence to recommend for or against universal vaccination of women aged 19 to 26 years in the general population. The ACS recommends routine vaccinations for all girls aged 11 to 12. The ACS supports the vaccine being administered to girls as young as age 9 and finds benefit in immunizing girls between the ages of 13 and 18 if they were not vaccinated earlier. **[15]**

The impact of vaccination accessibility on mortality rates would probably not be reflected until the current pediatric population reaches age 40, the peak age of cervical cancer incidence. Cervical cancer mortality is directly related to stage at diagnosis with more than 95% survival for Stage IA and less than 50% five-year survival for Stage III or higher. Stage at diagnosis is directly related to access to health care and preventive services. **[16]**

In the Gardasil clinical trials, there was no clear evidence of protection from disease caused by HPV types for females with a current or prior HPV16 or HPV18 infection that could be detected. Because HPV is highly prevalent in the sexually active population, and the median number of lifetime sexual partners for women aged 19 to 26 years is 3 to 4, the likelihood of prior HPV exposure to at least one of the high-risk vaccine types is substantial. The potential population benefit of universal prophylactic HPV vaccination in women aged 19 to 26 years, therefore, is diminished. A woman in this age group who has been sexually active may choose whether to receive the vaccine based upon her personal sexual history; an understanding of the likely diminished benefit with increasing likelihood of previous HPV exposure; and her values, preferences, and competing health care needs. **[17]**

The CDC reported most common reactions in adolescents have been reaction at the local injection site and some cases of fainting after the injection. Since the vaccine has been licensed, there have been 13 reports of Guillain-Barre Syndrome (a disorder in which the body's immune system attacks part of the peripheral nervous system). Of the 13 reports, 6 received the individual HPV vaccination; the remaining 7 received it in conjunction with other another vaccine. **[18]**

SOCIAL IMPACT

Research suggests a significant link between HPV and cervical cancer. An editorial in the American Academy of Family Physicians states that HPV acquisition occurs rapidly after the initiation of sexual activity. Fifty-four percent of females have been shown to have HPV infection within four years of first sexual intercourse. Research indicates 29.3 percent of ninth-grade girls in the United States report prior sexual activity. The percentage increases to 62.4 percent by 12th grade.**[19]** In the

United States in 2004, there were 10,500 newly diagnosed cervical cancer cases and 3,900 cervical cancer-related deaths. **[20]**

Virginia recorded 1,492 cases of cervical cancer from 1998-2002. The incidence of cervical cancer in Virginia is 7.6 per 100,000. The percentage of Stage I disease is lower than the national average (47.2% vs. 52% nationally) indicating that in Virginia more women suffer with advanced cervical cancer. **[21]**

It is difficult to determine HPV occurrence in Virginia due to the complex nature of reporting very mild symptoms and limited data relating to sexually transmitted diseases. The incidence of HPV infection appears to be lowest in women who never had sexual intercourse and begins to decrease after age 25. Women younger than 25 with an early onset of first sexual intercourse and multiple sex partners are at increased risk for HPV infection.

Existing data is not sufficiently clear to determine the number of middle school and high school aged girls in public or private school in Virginia who may be afffected by the HPV mandate. Although the information currently available does not substantiate its reliability, it can be assumed that the number of children offered the HPV vaccination would approximate the utilization rate of other childhood vaccinations recommended for this age range adjusted by the percentage of females in the state. Another factor determining the number of Virginians impacted by the mandate would be the parental refusal rate, which is projected to be as high as 25%. **[22]**

Based on the U.S. Census Bureau 2005 American Community Survey report, 725,055 females were counted in Virginia. Ten- to 14-year-old females represented 6.6% of the total (248,031.63); 15 to 19 year old females represented 6.2% of the total (232,999.41); and 20- to 24-year-old females represented 6.2% of the total (232,999.41). **[23]** Based on this data, of the approximately 712,631 total females between ages 10 and 24 in Virginia, 534,473 young girls and women could be impacted by House Bill 2877 (712,631 X 75% projected acceptance rate).

Studies consistently demonstrate that the following five barriers specific to HPV vaccines challenge widespread implementation:

1. lack of knowledge among the US population about HPV transmission and its relation to cervical cancer and other anogenital diseases;
2. parental concerns about vaccines in general and about vaccinating minors against sexually transmitted diseases;
3. challenges related to adolescents' healthcare-seeking behavior and health insurance coverage;
4. barriers related to the dynamics of HPV infection (e.g., protection against only certain types HPV, duration of immunity, immunization schedules); and
5. financing by the government and private insurers for newly recommended vaccines. [24]

Wide utilization of the HPV vaccine could reduce HPV-associated illnesses within the general population according to medical experts. Consumers may access the vaccine through private healthcare providers who accept private insurance, or access is available through the federal Vaccine for Children (VFC) program for children 18 and under who are Medicaid eligible, uninsured, underinsured, or who receive immunizations through a Federally Qualified Health Center or Rural Health Clinic, or are Native American or Alaska Native. **[25]** The ACIP recommendation for the HPV vaccination extends to women between the ages of 19 and 26 who are not affected by the school mandate. This target group would have limited access to the vaccine because they are a part of the population most likely to be without private insurance or who would be underinsured. Currently, there is no public purchase program for non-elderly adults' recommended vaccinations. **[26]**

Data from Merck reflects 160,575 doses of Gardasil were ordered in the Commonwealth of Virginia in the public sector in 2006. Through May 2007, local health departments in Virginia had ordered 2,610 doses of Gardasil of which 1,398 had been administered. The VFC program had distributed 4,900 doses Gardisil to Community and Rural Health Centers and 24,280 doses to participating physicians.

The third-party administrator for the Commonwealth of Virginia employee health care coverage reported that 29,645 girls aged 9 to 26 (as of 12/31/2006) had begun the series of 3 doses or had completed the full regimen of HPV vaccine in 2006. In 2007, for girls who either turned age 9 or became a new member of the insurance plan in 2007, records indicate 2,646 girls had either received partial or full dosage of the HPV vaccine. The top five geographical areas dispensing the vaccine are the cities of Richmond, Blacksburg and Virginia Beach, and Chesapeake and Harrisonburg tie for fourth place. **[27]**

In a May 2007 survey of obstetricians-gynecologists and family practitioners in Virginia conducted by the University of Virginia regarding implementation and usage of the HPV vaccine, 72% of providers responding to the survey indicated they currently offer the vaccine in their practices. The providers indicated that 12% of patients declined the vaccination. The 12% patient rejection rate is less than the projected rate of refusal (20-25%) from previous surveys of adolescents and their parents. **[28]**

Eighty-three percent of obstetricians and gynecologists and eighty-two percent of family practitioners in the Commonwealth of Virginia who participated in the 2007 survey support mandatory insurance coverage of the HPV vaccine. Their position is that mandating insurance coverage of the HPV vaccine would improve availability to the patient. [29]

FINANCIAL IMPACT

Universal HPV vaccination of women prior to onset of sexual activity is projected to decrease the incidence of HPV 6, 11, 16, and 18. In turn, the need for more frequent Pap test screening would be decreased. The cost-effectiveness would be evidenced by

a decrease in false positive results, additional evaluations, or treatment of non-cancer-forming HPV lesions. HPV 6, 11, 16, and 18 account for almost 50% of all abnormal Pap results and 70% of high-grade lesions, which require follow-up visits and other invasive procedures. HPV infection accounts for expenditures of more than $3.6 billion per year in the United States for follow-up and treatment of abnormal Pap tests. **[30]**

In addition to reducing the health care costs associated with abnormal Pap and HPV tests, HPV vaccines could reduce the burden associated with the anxiety of invasive procedures and false-positive outcomes. **[31]** In an epidemiologic study of 103,476 female enrollees of a northwestern US health care insurer from 1997 to 2002, annual cervical HPV-related prevention and treatment costs were estimated to be $26,415 per 1,000 enrollees. **[32]**

A Pap test at the University of Virginia costs approximately $37. The reimbursement Medicare rate ranges from $14 to $24. Additional fees can include professional costs that may range from $30 to $60 per visit or per test for pathology or for the physician performing the tests. Nationally, the cost of pap tests screening and treatment of HPV-related illness is more than $6 billion. However, the actual treatment of cervical cancer is less than 10% of the national costs. **[33]**

The retail price of the Gardisil vaccine is $120 per dose and $360 for the full 3-dose series. The vaccine will be the most expensive series recommended by the ACIP. Individuals with no insurance coverage and those who are underinsured may have limited access to the HPV vaccine due to the cost. [34] A survey of Virginia obstetricians and gynecologists also indicate that cost of the HPV vaccine would be the most significant barrier to a child being immunized. **[35]**

Health care providers in Virginia report additional costs associated with the HPV vaccination which average approximately $25-50 for administering the vaccine. Other reports indicate an additional $15 per injection or administration cost. Most providers who do not offer the vaccine cited costs of administering the vaccine or reimbursement issues as the main reasons why they do not offer the HPV vaccine to their patients. **[36]**

The Virginia Department of Health (VDH) will receive $1.4 million from the General Fund to support the provision of cervical cancer vaccination to females who are not eligible to receive the vaccine at no cost. The Non-General Fund (NGF) impact covers administration costs only; the vaccine itself is a direct assistance grant item (in lieu of cash) from the federal Centers for Disease Control (CDC) **[37]**

The expenditure impact is based on the 35% referral rate of expected sixth grade females eligible to receive the vaccine. Thirty-six percent of sixth-grade females will not be eligible for the Federal Vaccine for Children (VFC), and 64% will receive the VFC vaccine. The estimated federal contract price per dose (3 required) of the vaccine beginning in FY 2008-2009 is $97.92. The cost of the vaccine is expected to increase by 2% each year. The cost to administer the vaccine is approximately $11.00 per dose and is expected to remain constant. The Virginia Department of Health (VDH)

anticipates 25% of parents or guardians will not elect to have their child receive the HPV vaccine). **[38]**

The health insurance administrator for the Commonwealth of Virginia employees reported that in 2006, 2,174 claims for the HPV vaccine were submitted. The total claim payments for 2006 were $271,529.82; the average payment required of the insured was $124.89. As of June 13, 2007, 26 claims had been submitted for total claim payments of $3,345.83. The average payment required of the insured is $128.86. **[39]**

INSURANCE COVERAGE

The State Corporation Commission Bureau of Insurance (BOI) recently surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission this year. Forty companies responded by July 23, 2007. Nine companies indicated little or no applicable health insurance business in force in Virginia, and therefore, could not provide the information requested.

Of the 31 respondents completing the BOI survey, 24 reported they provide coverage for the HPV vaccine in Virginia as a standard benefit. Twenty-four insurers reported currently covering the HPV vaccine under an immunization provision. However one of the companies reported its intent to reduce coverage for the benefit. Seven insurers did not provide coverage for the HPV vaccine in Virginia as a standard benefit. Of the seven insurers not covering the HPV vaccine as a standard benefit, five companies indicated they provide the coverage on an optional basis. One company reported it will begin covering the vaccine in January 2008.

Eleven companies provided cost estimates ranging from $.15 to $10.83 per month to provide the coverage required by House Bill 2877 in individual standard contracts. Three companies estimated the cost of providing the coverage on an individual optional basis. The responses ranged from $.68 to $5.00. A fourth response was not applicable.

Fourteen companies provided responses for standard group coverage that ranged from $.13 per month to $65 per year ($5.41 per month). Three companies provided estimates of $.61 per month to $2.68 per condition to provide the coverage on an optional basis for group contracts. Two companies did not respond to the question of cost on an optional basis for group contracts. One company provided the monthly premium for a standard contract and did not provide premium attributable to the individual bills.

The survey asked if the vaccine was covered under a “Preventive” benefit or a “Wellness” provision. Twelve companies reported covering the vaccine under both preventive and wellness benefits; six companies cover the vaccine under the preventive benefit only; six insurers cover the benefit under a wellness provision only; seven companies responded that the vaccine was not covered under either of these provisions.

The survey asked about co-payment responsibility for the HPV vaccine and if the co-payment amount was different from other immunization co-payment amounts. Twenty-two companies indicated there was a required co-payment for the HPV vaccine, and that it was the same amount required for other immunizations. Of the 22 companies indicating a required co-payment amount, 5 indicated the co-payment amount was determined by the specific benefit plan design. One company covered the vaccine for females under age 18 under "well-baby" provisions and covered adult females under the "adult routine visit" provision. One company responded that the "employer" would decide the co-payment amount. Nine companies either did not respond to the question or indicated co-payments would not be applicable.

In response to a question regarding co-insurance responsibility for the HPV vaccine, 19 companies indicated there was required co-insurance. Twelve companies responded either there was no required co-insurance or did not answer the question. Of the 19 affirmative responses, one company specified the co-insurance was based on a dollar amount; four companies showed that co-insurance was based on the plan design; and fourteen companies indicated a range of co-insurance amounts based on percentage or dollar calculations. Twelve companies responded the co-insurance amount was the same as for other immunizations.

In response to the question regarding any age provisions for the course of treatment, 22 companies follow the ACIP recommendations and/or a variety of sources which specify providing the vaccine from ages 9 to 26. Four companies indicated no age restriction. One company specified its age from 11 to 26. Four companies either did not respond or indicated a response was not applicable.

LEGISLATION IN OTHER STATES

Information was reviewed from the National Association of Insurance Commissioners (NAIC) to determine whether other states have requirements similar to House Bill 2877. Information was also obtained from the National Council of State Legislatures (NCSL) website. The NCSL reports three states require varying degrees for provider/insurance company coverage for the HPV vaccine. Rhode Island requires providers to cover the cost of the HPV vaccine. Nevada requires insurance companies to cover the cost of the HPV vaccine for policyholders and their dependents without prior authorization. New Mexico requires insurance plans in the state to cover the FDA-approved vaccine for girls aged 9 to 14. **[40]**

Legislation requiring, funding, or educating the public about the HPV vaccine has been introduced in 41 states. Seventeen states have passed legislation, including Virginia. Legislation varies among the 17 states: Utah has an awareness campaign on the causes, prevention and risks of cervical cancer; North Dakota provides funding for distribution of education material, including information on HPV and the HPV vaccine; North Carolina requires the department of health to distribute information on HPV and the HPV vaccine through schools to all parents of children in grades five through twelve;

and Indiana requires parents of sixth-grade girls to sign a statement notifying the school of their decision to vaccinate or not vaccinate their daughter after receiving information about the link between HPV and cervical cancer and the availability of the HPV vaccine. New Hampshire will provide the vaccine at no cost to girls under age 18. South Dakota will combine $7.5 million in federal vaccine funds and $1.7 million from the state's general fund to provide the vaccine at no cost to girls under age 18. Washington state approved spending $10 million to voluntarily vaccinate 94,000 girls in the next two years. **[41]**

In 2007, twenty-four states and the District of Columbia introduced legislation to specifically require the HPV vaccine for schools-aged girls. Virginia is currently the only state with a school requirement for the vaccine. Texas enacted a mandate by executive order from the Governor requiring all females entering sixth grade receive the HPV vaccine, with some exceptions. However, the mandate failed. Current Texas legislation requires schools to distribute medically accurate, scientific, unbiased, and peer reviewed information about the vaccine to parents or legal guardians at the appropriate time in the immunization schedule. **[42]**

REVIEW CRITERIA

SOCIAL IMPACT

a. The extent to which the treatment or service is generally utilized by a significant portion of the population.

Consumers may access the vaccine through pediatric or gynecologic health care providers who accept private insurance, or access is available through the Virginia Department of Health (VDH), as well as the federal Vaccine for Children (VFC) program for children 18 and under who are Medicaid eligible, uninsured, underinsured, or who receive immunizations through a Federally Qualified Health Center or Rural Health Clinic, or are Native American or Alaska Native.

Data from Merck reflects 160,575 doses of Gardasil were ordered in the Commonwealth of Virginia in the public sector in 2006. Through May 2007, local health departments in Virginia had ordered 2,610 doses of Gardasil of which 1,398 had been administered. The VFC program had distributed 4,900 doses Gardisil to Community and Rural Health Centers and 24,280 doses to participating physicians.

The third-party administrator for the Commonwealth of Virginia employee health care coverage reported that as of December 31, 2006, 29,645 girls aged 9 to 26 had begun the series of 3 doses or had completed the full regimen of HPV vaccine in 2006. In 2007, for girls who either turned age 9 or became a new member of the insurance plan in 2007, records indicate 2,646 girls had either received partial or full dosage of the HPV vaccine. The top five geographical areas dispensing the vaccine are the cities of

Richmond, Blacksburg and Virginia Beach, and Chesapeake and Harrisonburg tied for fourth place. **[43]**

Existing data is not sufficiently clear to determine the number of middle- and high-school-aged girls in public or private school in Virginia who may be afffected by the HPV mandate. Although the information currently available does not substantiate its reliability, it can be assumed that the number of children offered the HPV vaccination would approximate the utilization rate of other childhood vaccinations recommended for this age range adjusted by the percentage of females in the state. Another factor determining the number of Virginians impacted by the mandate would be the parental refusal rate, which is projected to be as high as 25%. **[44]**

Based on the U.S. Census Bureau 2005 American Community Survey report, 725,055 females were counted in Virginia. Ten- 14-year-old females represented 6.6% (248,031.63); 15- to 19-year-old females represented 6.2% of the total (232,999.41); and 20- to 24-year- old females represented 6.2% of the total (232,999.41). **[45]** Based on this data, of the approximate 712,631 total females between ages 10 and 24 in Virginia, 534,473 young girls and women could be impacted by House Bill 2877 (712,631 X 75% projected acceptance rate).

b. The extent to which insurance coverage for the treatment or service is already available.

The State Corporation Commission Bureau of Insurance (BOI) recently surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission this year. Forty companies responded by July 23, 2007. Nine companies indicated they have little or no applicable health insurance business in force in Virginia, and therefore could not provide the information requested.

Of the 31 respondents completing the BOI survey, 24 reported they provide coverage for the HPV vaccine in Virginia as a standard benefit. Twenty-four insurers reported currently covering the HPV vaccine under an immunization provision. However one of the companies reported its intent to reduce coverage for the benefit. Seven insurers did not provide coverage for the HPV vaccine in Virginia as a standard benefit. Of the seven insurers not covering the HPV vaccine as a standard benefit, five companies indicated they provide the coverage on an optional basis. One company reported it will begin covering the vaccine in January 2008.

Insurer responses to the BOI survey indicate varying coverage restrictions, some based on age. ACIP recommendations do not require HPV vaccinations beyond age 26.

The vaccine is generally available through private physicians and local health departments. In response to a May 2007 survey conducted by the University of Virginia Health System, 72% of gynecologists, obstetricians and family practitioners in Virginia

offer the HPV vaccine. An additional 16% indicated they plan to offer the vaccine in the near future. **[46]**

Some consumers may have limited access to the vaccine due to variations in plan design or an inability to afford vaccine cost. In the University of Virginia Health System survey, 35.7% of providers in Virginia identified inadequate reimbursement as a barrier to offering the HPV vaccine to patients. **[47]**

c. If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.

According to the University of Virginia Health System, women between the ages of 16 and 26, who are not affected by the school mandate but are included in the largest percentage of Virginia's uninsured population, may have limited access to the HPV vaccination. Mandating coverage for the HPV vaccine would ensure those populations at highest risk of contracting HPV would have access to the vaccine. Currently, there is no public purchase program for non-elderly adults' recommended vaccinations. **[48]**

Current studies do not project future availability of vaccine necessary to meet mandate requirements to immunize all girls entering the sixth grade. Studies consistently demonstrate that the following five barriers are specific to the HPV vaccine and challenge widespread implementation:

1. lack of knowledge among the U.S. population about HPV transmission and its relation to cervical cancer and other anogenital diseases;
2. parental concerns about vaccines in general and about vaccinating minors against sexually transmitted diseases;
3. challenges related to adolescents' healthcare-seeking behavior and health insurance coverage;
4. barriers related to the dynamics of HPV infection (e.g., protection against only certain types HPV, duration of immunity, immunization schedules); and
5. financing by the government and private insurers for newly recommended vaccines. **[49]**

The Code of Virginia currently requires insurers to provide coverage for annual Pap tests, including coverage, on and after July 1, 1999, for annual testing performed by any FDA-approved gynecologic cytology screening technologies. Correlating requirements for coverage for state employees is located in Section 2.2-2818.

A Pap test effectively detects not only cervical cancer, but also changes in cervical cells that suggest cancer may develop in the future. Limited access to Pap tests result in higher rates of cervical cancer. Data shows that in 2002, more than 50 million Pap tests were administered and additional colposcopic follow-up and treatment was required. **[50]** One study concluded that 50-70% of women diagnosed with cervical cancer had not had a pap test within the preceding 5 years.

d. If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.

The vaccine and coverage for the vaccine is generally available.

A consumer who is without insurance coverage or who is underinsured may pay (whole or in part) for the vaccine out of pocket. The cost of a complete three-dose regimen may be as expensive as $540 per female. The cost could become considerable for families with more than one eligible female. The HPV vaccine is the most expensive of the childhood vaccines recommended by the ACIP. These consumers may be referred to the local health department for HPV vaccination.

e. The level of public demand for the treatment or service.

The occurrence of HPV is not routinely reported in the United States. HPV is a common infection that is customarily underreported because of its mild symptoms, and limited information is required to be collected on the prevalence of some sexually transmittable diseases. The University of Virginia Health Systems survey of 385 obstetrician-gynecologists and family practitioners confirmed that 36% of their patients aged 16 to 26 have been vaccinated. **[51]**

f. The level of public demand and the level of demand from providers for individual and group insurance coverage of the treatment or service.

Staff received a letter containing 21 faxed signatures of registered voters in support of HB 2877.

In a survey of the top fifty writers of insurance in Virginia conducted by the State Corporation Commission, Bureau of Insurance, 31 respondents completed the survey; of those 31, 24 indicated that they currently provide the coverage in their standard benefit package that would be required by House Bill 2877.

Twenty-four insurers reported currently covering the HPV vaccine under an immunization provision. One company reported its intent to reduce coverage for the benefit. Seven insurers did not provide coverage for the HPV vaccine in Virginia as a standard benefit. Of the seven insurers not covering the HPV vaccine as a standard benefit, five companies indicated they provide the coverage on an optional basis. One company reported it will begin covering the vaccine in January 2008.

The vaccine is available through private physicians and local health departments. According to JLARC's assessment, an HPV health insurance mandate in Virginia would impact insurers' decisions to provide coverage under a basic benefits package.

The VAHP commented at the September 20, 2007 public hearing that health insurance plans, including employer plans, do provide coverage for the HPV vaccine,

and that the General Assembly passed legislation to add it to the immunization schedule. VAHP noted that the parental exemption provision incorporated in the school mandate (HB 2035, effective 2008) is indicative of a new approach to some vaccines on the immunization schedule. Conversely, employers may want the opportunity to opt out of making full payments for the vaccination. **[52]**

g. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts is unknown.

h. Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.

In accordance with Executive Directive 5 (2005) The Virginia Department of Health (VDH) evaluated information related to HPV transmission and vaccinations in order to identify cervical cancer incidence, mortality and epidemiology in Virginia. In July 2007, at a presentation to the Association of State and Territorial Health Officials (ASTHO) concerning the HPV school mandate, VDH indicated that new vaccines usually encounter shortages in the first year, which could lead to waivers. VDH found the HPV vaccine to be very costly. VDH noted the expense to private physicians of stocking the vaccine, indicating that private physicians may not be willing to invest in expensive inventories. **[53]**

Access to the vaccine is available through local departments of health and participating private physicians. Access is also available through the federal Vaccine for Children (VFC) program for children 18 and under who are Medicaid eligible, uninsured, underinsured, or who receive immunizations through a Federally Qualified Health Center or Rural Health Clinic, or are Native American or Alaska Native. **[54]**

FINANCIAL IMPACT

a. The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.

The HPV vaccine recommended by the ACIP and approved by the FDA is generally covered by most insurance providers. The proposed mandate does not appear to impact the cost of treatment over the next five years. Future proposed HPV vaccines may decrease costs because of market competition.

b. The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.

The expectation is that the mandate would increase the appropriate use of the HPV vaccination for those young girls and women prior to sexual activity, and would be projected to decrease the incidence of HPV 6, 11, 16, and 18. In turn, the need for more frequent Pap test screening would be decreased. The cost-effectiveness would be evidenced by a decrease in false positive results, additional evaluations, or treatment of non-cancer-forming HPV lesions. **[55]**

The impact of vaccination on mortality rates would probably not be reflected until the current pediatric population reaches age 40, the peak age of cervical cancer incidence. Cervical cancer mortality is directly related to stage at diagnosis with more than 95% survival for Stage IA and less than 50% five-year survivor for Stage III or higher. Stage at diagnosis is directly related to access to health care and preventive services. **[56]**

c. The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.

The virus is most strongly associated with cervical cancer, with HPV DNA found in up to 99.7 percent of these cancers. The efficacy of the vaccine has mainly been studied in young women (16-26 years of age) who previously had not been exposed to any of the four HPV types in the vaccine. The clinical trials have demonstrated 100% efficacy in preventing cervical precancers caused by the targeted HPV types, and nearly 100% efficacy in preventing vulvar and vaginal precancers and genital warts caused by the targeted HPV types. **[57]**

HPV infection accounts for expenditures of more than $3.6 billion per year in the United States on follow-up and treatment of abnormal Pap tests. **[58]** In addition to reducing the health care costs associated with abnormal Pap and HPV tests, HPV vaccines could reduce the burden and associated with the anxiety of invasive procedures and false-positive outcomes. **[59]** In an epidemiologic study of 103,476 female enrollees of a northwestern US health care insurer from 1997 to 2002, annual cervical HPV-related prevention and treatment costs were estimated to be $26,415 per 1,000 enrollees. **[60]**

A Pap test at the University of Virginia costs approximately $37. The reimbursement Medicare rate ranges from $14 to $24. Additional fees can include professional costs that may range from $30 to $60 per visit or per test for pathology or for the physician performing the tests. Nationally, the cost of pap tests screening and treatment of HPV-related illness is more than $6 billion. However, the actual treatment of cervical cancer is less than 10% of the national costs. **[61]** Studies encourage abstinence as the most effective means of preventing the spread of HPV.

The potential of the HPV vaccine is that it can prevent high-risk HPV infection. It does not cure existing infection. Female consumers, especially those older than the ACIP recommended cut-off age of 26, may become compelled to screen for HPV in addition to their scheduled Pap test. **[62]**

d. The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.

The number and types of providers is not expected to be affected by the proposed mandate. Seventy-two percent of obstetricians-gynecologists and family practitioners in Virginia indicated that they currently offer the vaccine in their practices. The providers indicated that 12% of patients declined the vaccination. The 12% patient rejection rate is less than the projected rate of refusal (20-25%) from previous surveys of adolescents and their parents. **[63]**

Eighty-three percent of obstetricians and gynecologists and eighty-two percent of family practitioners in the Commonwealth of Virginia support mandatory insurance coverage of the HPV vaccine. Their position is that mandating insurance coverage of the HPV vaccine would improve availability to the patient. **[64]**

e. The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.

The administrative cost of most insurance companies is not expected to increase as most carriers already provide coverage for the vaccine. There should be minimal increase in premiums as a result of the mandate.

f. The impact of coverage on the total cost of health care.

The impact on the total cost of health care is difficult to determine due to limited information related to the cost of HPV infection and cervical cancer in Virginia. The vaccine is a new addition to the immunization chart, and is the most expensive vaccine recommended by the ACIP. Also, most insurers already provide coverage for the vaccination.

The JLARC assessment notes the potential to reduce long-term epidemiologic consequences and overall health care costs for the treatment of cervical cancer and related oncological diseases.

<u>MEDICAL EFFICACY</u>

a. The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.

The HPV vaccine would benefit the population by decreasing HPV infection, cervical and other anogenital cancers, and genital warts in the United States. Several research studies establish and validate the vaccines' safety and efficacy. However,

studies are ongoing relating to long-term effects and other associated indicators of cervical cancers. There were few physical complications as a result of the injections. **[65]**

The Centers for Disease Control (CDC) indicates that the efficacy of the vaccine has mainly been studied in young women (16-26 years of age) who previously had not been exposed to any of the four HPV types in the vaccine. These clinical trials have demonstrated 100% efficacy in preventing cervical precancers caused by the targeted HPV types, and nearly 100% efficacy in preventing vulvar and vaginal precancers and genital warts caused by the targeted HPV types. **[65]**

The vaccine has no therapeutic effect on HPV-related disease. If a girl or woman is already infected with one of the HPV types in the vaccine, the vaccine will not prevent disease from that type. The ACIP recommendation for vaccine use in girls as young as 9 years of age is based on 'bridging' immunogenicity and safety studies, which were conducted in about 1,100 females, 9 to 15 years of age. These studies demonstrated that over 99% of study participants developed antibodies after vaccination; concentration of antibodies was higher for young girls than for older females participating in the efficacy trials. **[66]**

The limitations of the vaccine include its incomplete protection. The vaccine guards against high-risk HPV infection. There are several other types of HPV virus that have been shown to cause cervical cancer. The vaccine does not fully protect those women already infected with HPV.

Research suggests that a comprehensive approach to eliminating the HPV virus would include identifying the need for a "booster" shot to ensure continued protection, and young girls and women adhering to recommended screening timetables and guidelines.

b. If the legislation seeks to mandate coverage of an additional class of practitioners:

The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.

Not applicable.

The methods of the appropriate professional organization that assure clinical proficiency.

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

a. The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.

The benefit is consistent with the role of health insurance and addresses a medical need. Both public providers and private carriers make the vaccine available and cover some, if not all, of the costs. Although the cost of the HPV vaccines is one of the most expensive vaccines recommended by the ACIP, the cost of prevention is less than the cost of treatment for cervical cancer.

The JLARC assessment cited the broad availability of existing insurance coverage as a basis for not mandating the HPV vaccine at this time. Research studies are inconclusive regarding the vaccine's duration. This factor and other variables may determine future utilization or may impact coverage levels.

b. The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.

The HPV vaccine could reduce the health care costs associated with abnormal Pap tests, the burden associated with the anxiety of invasive procedures and false-positive outcomes, and the need for other specific HPV tests. **[67]** In an epidemiologic study of 103,476 female enrollees of a northwestern US health care insurer from 1997 to 2002, annual cervical HPV-related prevention and treatment costs were estimated to be $26,415 per 1,000 enrollees. **[68]**

Because the vaccine is widely available in public health departments and consumers have coverage via private carriers or employer groups, the need for a mandate at this time may be minimized. The JLARC assessment indicates it is prudent to consider monitoring future utilization trends and modifying the language to ensure coverage of all FDA-approved HPV vaccines.

c. The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.

A mandated offer would allow individual consumers without coverage to purchase the benefit, particularly those females beyond the ACIP recommended cut-off age of 26 who may want the vaccine. For consumers covered by group contracts, the decision would be made by the group policyholder.

RECOMMENDATION

The Advisory Commission voted unimously on November 29, 2007 to recommend against enacting House Bill 2877 (Yes- 0 , No- 10).

CONCLUSION

The members of the Advisory Commission believe that based on information reviewed, there already exists a wide availabilty of coverage through private and public providers, as well as a wide level coverage from insurers.

NOTE: A bivalent HPV vaccine, Ceravix (GlaxoSmithKline) is currently pending FDA approval. For the purpose of this analysis, reference to an HPV vaccine refers to FDA-approved Gardisil, manufactured by MERCK.

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